Addressing violence and HIV cascade of care outcomes among transgender women

Phase II Research Protocol

1R21-MH-121974-01

A *Love Her Collective* Study

Contents

I. Research Team

University of Michigan School of Public Health

Principal Investigator: Kristi Gamarel, Ph.D., M.A.

Co-Investigator/Project Director: Laura Jadwin-Cakmak, M.P.H.

Co-Investigator: Gary W. Harper, Ph.D., M.P.H.

Research Associate: Racquelle Trammell

Data Manager: Wesley M. King, M.Ed.

Trans Sistas of Color Project (Ruth Ellis Center)

Co-Investigator/TSoCP Site PI: Lilianna Reyes, M.S.W.

Peer Health Educators: Latrice Ward, Julisa Abad, and Harmony Harris

II. Acronyms

ART: Anti-retroviral therapy

CAB: Community Advisory Board

Co-I: Co-Investigator

GBV: Gender-based violence

IPV: Intimate partner violence

HIV-CoC: HIV Continuum of Care

IRB: Institutional Review Board

LGBT: Lesbian, gay, bisexual, transgender

NIMH PO: National Institutes of Mental Health Project Officer

PD: Project Director

PHE: Peer Health Educator

PHI: Protected health information

PI: Principal Investigator

PTSD: Post-Traumatic Stress Disorder

RA: Research Associate

RCT: Randomized Controlled Trial

SSP: Seeking Safety Program

STI: Sexually transmitted infection

TasP: Treatment as Prevention

TSoCP SSP: Trans Sistas of Color Project Seeking Safety Program

TSoCP: Trans Sistas of Color Project

TW: Transgender women

TWOC: Transgender women of color

UM-SPH: University of Michigan School of Public Health

VL: Viral Load

III. Study Objectives

This protocol outlines the research procedures for Phase II of "Addressing violence and HIV cascade of care outcomes among transgender women" (1R21-MH-121974-01). Phase I of this study included the systematic adaptation of the Seeking Safety Program (SSP) for transgender women of color (TWOC) living with HIV to improve engagement in the HIV Cascade of Care, using the ADAPT-ITT model. The objectives of Phase II of this study are: (1) to examine the feasibility, acceptability, and preliminary efficacy of the adapted behavioral intervention by conducting a one-arm pilot with 30 transgender women of color (TWOC) living with HIV who have a history of trauma; and (2) to identify strategies for large-scale rigorous implementation of intervention research with transgender women through exit interviews with pilot participants.

IV. Specific Aims

HIV disproportionately affects transgender women (TW; individuals with a feminine and/or female gender identity who were assigned male at birth). Evidence suggests that TW have 49 times higher odds of infection compared to the general adult population,[1] and in the U.S. they have the highest rates of new diagnoses by gender, with TW of color (TWOC) representing a majority of these cases.[2] The HIV Continuum of Care (HIV-CoC) framework emphasizes rapid diagnosis of HIV upon seroconversion, linkage to care, and ultimately, maintaining viral load suppression; however, there is substantial drop-off at each step of the HIV-CoC among TWOC with significant disparities in rapid diagnosis and linkage to and retention in care.[3,4]

TWOC experience frequent discrimination and oppression due to their gender identity and/or expression, often in the form of violence from partners, strangers, law enforcement, and in public accommodations.[5] TWOC experience these gender-related stressors in combination with other social and structural factors affecting communities of color, such as high rates of poverty and incarceration, less access to healthcare and quality education.[6-8] Violence is a significant public health concern for TWOC, and is consistently linked with worse HIV outcomes, post-traumatic stress disorder (PTSD), and substance use, which is also a major issue among some communities of TWOC.[9-11] Epidemics of HIV, violence, and substance use are concurrent and mutually reinforcing, constituting a "syndemic" or synergistic interaction that contributes to documented inequities in HIV-CoC outcomes among TWOC.[12-18] Existing interventions designed for cisgender individuals do not meet the needs of TWOC with regard to violence and HIV.[19] Currently there are few evidence-supported, trauma-informed strategies for meeting the unique needs of TWOC living with HIV. The "Seeking Safety Program" (SSP) is an empirically based, flexible, empowering, and trauma-informed group-level intervention designed to reduce PTSD symptoms and substance use among a variety of populations.[20] Primary acceptability data of an adaptation of this program with TW in San Francisco lends support to the relevance of the intervention with TWOC living with HIV.[21] Guided by our team's expertise working with TWOC and SSP, we respond to RFA-MH-20-2010 (Addressing the Role of Violence on HIV Care and Viral Suppression) by proposing to adapt this intervention (the adapted intervention will be referred to as "Trans Sistas of Color Project Seeking Safety Program (*TSoCP SSP*)." *TSoCP SSP* will include individual and group sessions that will address unique experiences of violence, power, and gender affirmation needs of TWOC living with HIV, with a specific focus on engagement in HIV care and PTSD symptoms.

There are three specific aims of the parent study (1R21-MH-121974-01). Aim 1 was completed in Phase I. Aims 2 and 3 will be completed in Phase II, the current study:

IV-1. Aim 1: To conduct a systematic adaptation of SSP for TWOC living with HIV, with a focus on addressing trauma caused by experiences of violence and intersectional oppression, gender affirmation needs, and engagement in HIV care.

In Phase I of this study, the ADAPT-ITT model[22] was be used to systematically adapt this intervention. To achieve this aim, we conducted interviews with TWOC (n=15-20) and key stakeholders (n=5-10; i.e., organization leaders, healthcare providers) to inform the adaptation. Our community advisory board of TWOC living with HIV will review all adapted materials.

IV-2. Aim 2: To examine the feasibility, acceptability, and preliminary efficacy of the adapted SSP intervention on engagement in care (primary outcome), PTSD symptoms (secondary outcome), viral load (tertiary outcome) and the potential mediating roles of gender affirmation, empowerment, self-efficacy, and collective self-esteem.

To address Aim 2, we will conduct a feasibility and acceptability one-arm pilot of the adapted intervention by enrolling 30 TWOC living with HIV with a history of trauma. We will collect feasibility, acceptability data related to identifying, recruiting, enrolling, intervening with, and retaining participants (i.e. length of recruitment period, screening procedures, feasibility of conducting group sessions, acceptability of the intervention, rates of retention, feasibility of verifying self-reported and medical chart review data on retention in care and viral load) and conduct exit interviews with participants and staff at program conclusion. Preliminary efficacy data will be collected at baseline, end of program, and 1-month post-intervention follow-up.

IV-3. Aim 3: To identify strategies for large-scale rigorous implementation of intervention research with TW.

To address Aim 3, we will gather information from one-arm pilot participants during exit interviews to identify strategies to overcome barriers to implementing rigorous efficacy trials with TW within close-knit communities and limited-resources settings.

The proposed study has the potential for high public health impact by evaluating the feasibility, acceptability, and preliminary efficacy of an adapted, evidence-based program to address violence and HIV CoC outcomes among a highly vulnerable and overlooked population disproportionately impacted by HIV. Our focus on TWOC is in line with the prioritization of sexual and gender minority communities for health disparities research,[23,24] as well as the “treat” and “respond” strategies of the new HHS plan for ending the U.S. HIV epidemic.[25] Study findings will provide the necessary groundwork to examine the efficacy of intervention in a future, large-scale clinical trial. Findings also have the potential to provide a “blueprint” to guide future research efforts with TWOC who are often embedded in close-knit communities with few culturally-responsive services.

V. Background Information

HIV disproportionately affects TW (i.e., individuals with a feminine and/or female gender identity who were assigned male at birth). TW have 49 times higher odds of infection compared to the general adult population.[26,27] Reports of HIV prevalence and incidence rates for TWOC are among the highest of all risk groups.[27] Treatment as Prevention (TasP) involves preventing new infections by treating existing infections through early diagnosis, immediate initiation of antiretroviral therapy (ART) and maintaining viral load (VL) suppression [28-31] and presently represents the most promising HIV prevention strategy.[32] TasP is estimated to be highly beneficial—in both simulation work and population-based data, achieving and maintaining high levels of VL suppression within a community has been shown to lead to substantial reductions in HIV transmission.[29-31,33-35] Though there have been great strides in achieving the UNAIDS 90-90-90 targets, there are notable inequities in timely care engagement, ART adherence, and VL suppression,[36-40] and we have yet to achieve these goals with TWOC in the U.S.[3,41,42] Thus, research is urgently needed to understand to develop interventions that achieve optimal movement along the HIV-CoC among TWOC living with HIV.[3,41,42]

Violence is a significant public health crisis for TW and undermines HIV-CoC outcomes.[43-45] TW living with HIV experience violence in a variety of contexts, including from intimate and sex partners, strangers, law enforcement, and in public accommodations.[5,9] Data suggest extremely high burden of violence among transgender populations, with prevalence estimates of 58-89% in the US.[5,26] Exposure to violence has been linked to substance use, post-traumatic stress disorder symptoms, stress, anxiety, and depression among TW.[12-17,46] Among people living with HIV, violence is linked to avoiding care, suboptimal ART adherence, and a lower odds of viral suppression, via pathways including chronic stress, immune inflammatory response, PTSD, and substance use.[47-51] These epidemics of violence and HIV are concurrent and mutually reinforcing, constituting a “syndemic” that contributes to documented inequities in HIV-CoC outcomes among TW.[8,17] Despite the dual and interconnected associations between violence and HIV-CoC outcomes, there are few public health strategies for meeting the unique needs of TWOC living with HIV.

Gender affirming, trauma-informed, and culturally-responsive HIV interventions are critically needed for TWOC. Gender affirmation refers to “an interpersonal, interactive process whereby a person receives social recognition and support for their gender identity and expression”.[52] For TW, positive gender affirmation is a source for positive identity development, self-esteem, and self-efficacy;[52,53] the lack of gender affirmation can contribute to adverse health outcomes and has been shown to be a barrier to progression through the HIV CoC for TW youth living with HIV.[54] On the contrary, gender-affirming services are essential for recognizing and reinforcing the identities and unique experiences of TWOC, including experiences of violence that affect their psychological health and risk behaviors.[55,56] Trauma-informed care, which recognizes and responds to the prevalence and impact of trauma, are also needed due to the high prevalence of violence and other sources of trauma among TWOC.[57,58] Finally, given the transphobia, racism, and HIV stigma that TWOC face,[59] culturally-responsive interventions must be developed in partnership with and led by TWOC. Health and counseling services that are gender affirming and are responsive to TWOC’s intersectional identities and unique experiences are warranted to reduce internalized transphobia/racism, enhance feelings of self-efficacy, and build collective-self-efficacy and empowerment.[60-62] Thus, to be maximally effective, interventions designed to address HIV-CoC outcomes with TWOC need to incorporate gender affirmation, address the role of violence, and be responsive to the unique needs and experiences of TWOC.

Seeking Safety Program (SSP) is an evidence-based intervention that represents a promising approach to improving HIV-CoC outcomes and PTSD symptoms among TWOC. Our formative qualitative data with 32 TWOC in Detroit highlighted the need for gender affirming group-based interventions that address trauma and mental health concerns TWOC experience as a result of violence and intersectional oppression.[63] They also expressed the need for individual sessions focused on personal needs and referrals to gender affirming healthcare and social services, and emphasized the importance of programs for TWOC being led by TWOC.[63] SSP is a trauma-informed manualized, group-based intervention conceptually grounded in Cognitive Behavioral Therapy,[64] and includes modules focused on: PTSD; Taking Back Your Power; Detaching from Emotional Pain; Taking Good Care of Yourself; Compassion; Commitment; Setting Boundaries in Relationships; Respecting Your Time; Healthy Relationships; and Healing from Anger. This psychoeducational approach helps participants understand the links between trauma (including violence), substance use, and coping skills with a focus on the present and future, discouraging detailed discussions of past trauma.[64] A 2016 meta-analysis concluded SSP had positive effects on co-occurring substance use and PTSD symptoms, including increased treatment retention and attendance, reduced PTSD symptoms, and reduced substance use, among multiple populations.[65] Dr. Dawson-Rose recently successfully adapted SSP to 12 sessions for TW living with HIV in San Francisco, with promising improvements in PTSD symptoms and substance use.[21] We will build on the success of Dr. Dawson-Rose, again conducting the SSP with TW living with HIV, but focusing on co-occurring HIV and PTSD symptoms, shifting the primary outcome of focus from substance abuse to engagement along the HIV-CoC. This adaptation will also be specific to TWOC living with HIV in settings where there are limited resources for TW, like Detroit. Intervention content will be adapted to prioritize HIV-CoC outcomes and enhance the cultural relevance and contextual depth of the program for TWOC living with HIV. We will retain the general SSP structure, but adapt individual sessions (# of sessions to be determined) to assist TWOC to access gender affirming care for HIV, mental health, and substance use, as well as gender-related care and other needed social services. Finally, program facilitation and individual sessions will be provided by TWOC in the community who are trained as Peer Health Educators (PHEs).

This study develops a foundation for rigorous randomized controlled trials (RCT) addressing violence and HIV with TW in limited-resource settings. Consistent with RFA (MH-20-2010), this R21 exploratory/ developmental grant application will provide essential understandings about the community readiness for rigorous efficacy trials addressing the dual issues of violence and HIV treatment outcomes in this highly vulnerable population. RCTs in bio-behavioral research are the “gold standard” in evaluations of interventions; however, the responsible and ethical conduct of RCTs in vulnerable populations requires consideration of the target community’s perspectives about methodological criteria and standards that are valued by the scientific community. For example, community perspectives are needed to inform the selection and delivery of a control condition, which will be essential in larger efficacy trials. Moreover, it has long been noted that cross-contamination, or the interchange of information among participants from different study conditions, may be a source of considerable bias.[66] Although procedures are often adopted to reduce these threats the validity (e.g., blinding to study condition), TWOC have close-knit communities and often live in limited-resource settings such that there is the real potential for differential effects of cross-contamination vis-à-vis sharing intervention content between conditions. Compounding these methodological issues is the deep rooted mistrust of researchers by communities of color – which affects recruitment, retention, and engagement of participants in intervention research.[67,68] As such, the adaptation of promising and urgently needed interventions requires input from community members to identify solutions to implement rigorous research designs.

In summary, violence is a public health priority for TWOC and has been consistently linked with avoiding care, suboptimal ART adherence, and lower odds of viral suppression among TWOC living with HIV. These epidemics are concurrent and mutually reinforcing, constituting a "syndemic" that contributes to documented inequities in HIV-CoC outcomes among TWOC. Despite the dual and interconnected associations between violence and HIV-CoC, there are few evidence-supported and trauma-informed strategies for meeting the unique needs of TWOC living with HIV. SSP is a promising, flexible, empowering, and trauma-informed group-level intervention that has had positive effects on PTSD symptoms and substance use among a variety of populations with a history of violence, including TW. The intervention developed through the proposed research will be based in a gender affirmation framework on engagement in care and PTSD symptoms. Findings will also provide critical insights into solutions to overcome challenges to implementing RCT designs (e.g. mistrust, contamination, control conditions) in geographical locales with limited resources for TWOC.

Table 1. Intervention Selection and Adaptation		
System-Level (Institutional) Screening		
Screening	Intimate Partner Violence Screening assessed by healthcare providers	Self-administered screener to increase comfort that PHE's use for navigation sessions. Information is provided to health care and mental health providers to facilitate "warm hand-offs". There is a need to expand beyond intimate partners to be inclusive of experiences of violence from dates, family, and strangers. Violence also took on psychological forms (e.g., controlling behaviors, partners keeping relationship on the "down low"). The screener would also be most useful if it included gender affirmation needs (i.e., legal and medical) to assist with linkage to appropriate services.
Group-Level (Interpersonal) Seeking Safety Program (SSP)		
SSP	Peer Health Educator deliver 8 two hour group sessions that are approximately 1 week apart focused on teaching effective, concrete cognitive and behavioral skills.	PHE's need to be TWOC and deliver the intervention. The intervention needs to be condensed to 8 sessions maximum for TWOC to complete the entire program. After reviewing the content of all of the SSP sessions, the team decided on the following sessions: 1) Prioritizing Safety, 2) Understanding trauma and PTSD; 3) Getting support from yourself and others; 4) Taking care of your whole self; 5) Knowing your triggers and how to handle them; 6) Setting boundaries in relationships; 7) Healthy relationship beliefs; 8) Review game and Graduation. Sessions will also be adapted to include gender-based violence, and gender affirmation.
Individual-Level Peer Navigation		
HIV Peer Services	One-to-one navigation to help link people to healthcare systems and identify and reduce barriers to care. Navigation services also include working together to create an individualized health behavior change plan.	PHE's who are also TWOC need to deliver the navigation services, which is key to building trust and safety planning based on shared experience. PHE's will need to provide assistance with identifying trans-friendly HIV prevention and care services, as well as gender affirmation services (e.g., name changes, hormones). Individualized health behavior change plans will also identify and work to address barriers to reducing HIV transmission risk (e.g., violence from dates) and engagement in HIV services.

VI. Study Team Experience

This project is led by the *Love Her Collective*, a community-academic partnership between the Trans Sistas of Color Project (TSoCP) in Detroit, MI and researchers at the University of Michigan School of Public Health (UM-SPH). After informally partnering since 2015, Ms. Reyes, Dr. Gamarel, Ms. Jadwin-Cakmak, and Dr. Harper had several meetings to discuss future research and service endeavors as a partnership, gaps in research for TWOC, and how to work together to meet TSoCP's objective to build the organization's research capacity. We applied and received internal funding to formalize the community-academic partnership between TSoCP and the UM-SPH to identify the priorities of TWOC in Detroit and build the research infrastructure of our TSoCP partners. Subsequently, Dr. Gamarel received additional pilot funding to hire TSoCP member, Ms. Trammell as a Research Associate (RA) at UM-SPH. Between January and March 2019, the *Love Her Collective* conducted focus groups with TWOC in Detroit (5 groups, n=32). In this study, 85% of participants reported violence and safety as a priority health area.[63]

Our collective experience leads to this proposal to adapt and pilot the SSP to address violence and engagement in HIV care. **Dr. Gamarel, PhD, EdM** (PI) has over 6 years of HIV-related, empowerment-based research with TW, including serving as PI on a couples-focused HIV prevention intervention for TW (R01MH115765). **Ms. Reyes, MSW** (Community Lead) is a TWOC, who is the Executive Director of TSoCP and brings over 8 years working with TWOC, including implementing HIV-focused programs with TW. **Dr. Harper, PhD, MPH** (Co-I) is a clinical psychologist who brings over 25 years of community-based HIV-focused intervention development, implementation, and evaluation experience with LGBT communities, including TWOC. **Ms. Laura Jadwin-Cakmak, MPH** (Co-Investigator and Project Director) brings significant expertise in community-engaged research with TWOC, including directing intervention development and evaluation with transgender communities. **Ms. Trammel** (RA) is a TWOC with extensive experience working with and for transgender communities in Detroit related to health and advocacy. **Mr. Wesley King, EdM** (Doctoral Student) will assist the team with database development and data management. **Ms. Latrice Ward, Ms. Julisa Abad, and Ms. Harmony Harris** (health educators) are TWOC who each have significant experience facilitating health promotion groups with trans women of color in Detroit. Ms. Abad has experience facilitating TREM for transgender women, a similar group-based program to help transgender women of color health from trauma, at All Well-Being Services, a community-based organization in Detroit. Ms. Harris and Ms. Ward are the facilitators of Tweet, a group program to help transgender women engage in HIV prevention and care services, through Henry Ford Health System. Together our team brings complementary skills and knowledge to the proposed study.

VII. Study Design

In this R21, we propose to adapt, integrate, and pilot a culturally-relevant multicomponent trauma-informed intervention, which includes peer-led individual sessions, an adaptation of SSP group-level intervention (the TSoCP SSP), and a GBV and gender affirmation needs screening aimed at improving HIV Care Continuum outcomes.[59-61] We will achieve this through the use of the ADAPT-ITT model, which is a systematic framework used previously by Drs. Gamarel, Harper, and Ms. Jadwin-Cakmak for adapting HIV interventions.[62,63] ADAPT-ITT is a pragmatic framework for adapting interventions that includes eight prescriptive phases.[62] Table 2 outlines how the ADAPT-ITT model will be applied to the multicomponent intervention for TWOC detailing the planned activities during each phase of the model.

Aim 1, completed in Phase I of the parent study, is to conduct a systematic adaptation of the intervention components for TWOC, with a focus on the unique aspects of GBV experienced by TWOC, gender affirmation needs, and engagement in the HIV continuum of care. To achieve this aim, we have conducted interviews with TWOC (n=10) and key stakeholders (n=5-10; i.e., organization leaders, healthcare providers) to inform the adaptation and implementation process. Phase I of the parent study included "ADAPTT-ITT Phases 4-7" (see Table 2 below).

Aim 2, the focus of the current protocol, is to evaluate the feasibility and acceptability of the of the trauma-informed intervention to improve HIV Care Continuum outcomes including the development of community-informed strategies for subsequent RCTs. Process and outcomes measures will also be collected to assess feasibility, performance, and program impact.[67] Phase II of the parent study involves "ADAPT-ITT Phase 8," which involves conducting a one-arm pilot of the adapted TSoCP SSP behavioral intervention (see Table 2 below).

Table 2. Adaptation process using ADAPT-ITT

ADAPT-ITT Phase	Project Stage	Methodology
1. Assessment	Preliminary Studies (pre-proposal)	Assessed preliminary data and consulted experts
2. Decision		Identified peer navigation, SSP, violence screening as interventions to be adapted
3. Administration		Made initial decisions about elements to be adapted
4. Production	Preparation	Consult with community partners and CAB
5. Topic Experts	Formative Data Collection	Conduct qualitative interviews with key stakeholders and TWOC to gather curriculum-specific input
6. Integration	Adaptation and Training	Analyze data to refine manuals and develop training materials
7. Training		Generate training manual and conduct training with PHE
8. Testing	RCT	Conduct one-arm pilot.

VII-1. Intervention Overview

The *TSoCP SSP* intervention (referred to as "***Kickin' it with the Gurlz***" with participants and in intervention materials) includes 8 weekly group sessions focused on topics related to

understanding trauma and PTSD, healing from trauma, and taking care of your health and well-being. Each group session will be co-facilitated by two PHEs who identify as transgender women of color, and will include up to 12 transgender women of color participants. Each group session will last 2 hours. (See Appendix XII-1. Group Sessions Manual). In addition to group sessions, participants will have 1-on-1 sessions with a PHE as part of the intervention. 1-on-1 intervention sessions will focus on identifying health-related needs and linking participants to affirming healthcare referrals and community resources, as well as individualized follow-up from group sessions (see Appendix Y. Resource and Referral List). During enrollment visit study procedures, participants will complete a Violence and Gender Affirmation Screener (see Appendix XII-3. Violence & Gender Affirmation Screener) that PHEs will access that collects participant needs related to violence and safety as well as medical and legal gender affirmation; additional needs and priorities will be assessed through conversation. The first introductory 1-on-1 session will occur before the start of group sessions. Participants have the choice of attending optional additional 1-on-1 sessions with a PHE during the 8 weeks they are attending group sessions, up to once a week.

VII-2. Assessing Acceptability and Feasibility

To assess feasibility, we will monitor rates of outreach, recruitment, eligibility, enrollment, attendance, retention, and assessment completion. PHEs will complete a structured "intervention log" after each session to assess fidelity to intervention, time needed, and feasibility of delivering the intervention curriculum as designed (see Appendix XII-4. Intervention Log). To assess acceptability, we will use a modified version of the Client Satisfaction Questionnaire (see Appendix XII-5. Adapted Client Satisfaction Questionnaire), which participants will complete at the end of each group and individual session. We will also assess acceptability using data on participants' reactions to various program components gathered from PHEs "intervention logs". We will also explore the feasibility and acceptability of verifying HIV care engagement and viral load data by asking participants to sign releases to contact their provider and/or clinic for verification of their self-reported health care behaviors. Feasibility will be evaluated by monitoring staff hours required to verify data and rates of verifiable engagement reports. Acceptability of our verification methods by participants will be assessed by rates of agreement to provide consent to contact providers (90% or higher will be considered acceptable) and will be explored during exit interviews with participants and staff. Finally, we will conduct 30-minute exit interviews at the conclusion of the program with both participants and program staff to gather qualitative feedback about the structure, content, and experience of the intervention. Participant exit interviews will also explore barriers to RCT designs and implementation. (See Appendix XII-6. Exit Interview Guide – Participants, Appendix XII-7. Exit Interview Topic Guide – Program Staff).

VIII. Study Procedures

VIII-1. COVID-19 Safety

Before the COVID-19 pandemic, the proposed study activities were to occur in-person. In response to the pandemic, we have altered plans so that all study procedures have an option to occur virtually without in-person activity. However, the qualitative formative research conducted in Phase I indicated that many from the focus population had a strong preference for study activities to occur in-person when possible, and that certain activities (specifically, individual and group intervention sessions and the exit interview) are anticipated to provide greater potential benefit to participants if delivered in person. Given this, if we are able to do conduct activities in-

person safely, and if we obtain approval from the U-M Office of Research and the HBHS IRB, these study activities will occur in person.

Before conducting any in-person interaction, the PI will complete the University of Michigan Human Research Activation procedures to outline the specific COVID-19 safety procedures that will be followed during all in-person interactions between study staff and/or participants, based on current guidelines. The PI will also submit for approval an IRB amendment at that time with updates to the study procedures in alignment with the approved COVID-19 safety procedures for in-person activities. No in-person research activities will occur until both approvals are received.

VIII-2. Recruitment

Consistent with our ongoing and prior studies, we will employ a multi-pronged outreach strategy to recruit trans women of color, including 1) Online recruitment: Banner ads and digital flyers will be placed social media platforms used by TW, such as the Trans Sistas of Color Facebook page; 2) Print Ads: Flyers will be placed in healthcare and social service agencies in the Detroit Metro Area where transgender women seeks services; 3) Outreach: If safe and approved to do in-person, study staff will also conduct outreach in areas where transgender women congregate. Through decades of experience, the Trans Sistas of Color Project has identified optimal sites, days, and times to reach transgender women including the bars, clubs, street corners, mini markets, restaurants, boutiques, wig shops, and nail salons. Recruitment and promotional activities and materials will be discussed at Community Advisory Board (CAB) meetings.

VIII-3. Eligibility Screening

Those interested in the study will call the study RA, who will provide more information about the study (see Appendix XII-11. Screener Script). Interested potential participants will complete an eligibility survey programmed into Qualtrics. The same eligibility survey will be utilized for the current study (focused on engagement in HIV care for transgender women of color who are living with HIV) as for our concurrent study, which will evaluate the feasibility, acceptability, and initial efficacy of the *TSoCP SSP* for transgender women of color who are HIV-negative or have an unknown status, with a goal of improving engagement in HIV prevention services ("*A multicomponent intervention to address gender-based violence in HIV prevention for women: Phase 2";* HUM00190671). Potential participants who meet eligibility criteria outlined in Section X-2.1 Inclusion Criteria will be informed that they are eligible for the study and given the choice to continue to the informed consent. Potential participants who are ineligible for this study but who are eligible for the concurrent study focused on HIV care (HUM00190671) will be informed they are eligible for that study, and will be given the choice to continue to that study's informed consent, following the HIV prevention study's protocol. Potential participants who are ineligible for both studies will be informed that they are ineligible to participate and thanked for their time. (See Appendix XII-12. Eligibility Survey.)

VIII-4. Enrollment Procedures

The enrollment study visit will consist of 4 components: informed consent, locator form, baseline survey, and violence and gender affirmation screener. All 4 components will be programmed into Qualtrics and completed by the participant online. If the enrollment visit occurs in person, she may complete the Qualtrics surveys on a tablet with assistance from the study RA as needed. If the enrollment visit occurs virtually, the study RA will send participants a link to complete the Qualtrics surveys on their own personal device.

VIII-4.1. Informed Consent. Eligible participants who indicate they are interested will be linked to the Informed Consent (see Appendix XII-9. Consent Form), which will be programmed into Qualtrics and linked to their Study ID. Given the sensitive nature of data collected we will request a waiver of documentation of informed consent. After providing informed consent, participants will be asked if they are willing to provide a medical release; if willing, participants will be directed to a separate Qualtrics survey to complete the medical release, so that their medical information will not be linked to the consent form. Participants will also be asked to provide contact information for their primary health care provider and HIV healthcare provider and to sign a release of information. This information will be used to facilitate obtaining data related engagement in HIV treatment services, including lab test results indicating viral load. Participants may decline to provide a medical release and still participate in the study.

VIII-4.2 Locator Form. After informed consent is obtained, participants will complete a Locator Form in a Qualtrics survey. Participants will be asked for a working cell phone number. Participants will be asked to provide additional contact sources including but not limited to email, social media (e.g., Facebook, Twitter, Instagram, Snapchat) usernames. Participants will also be asked to provide valid contact information for a family member and/or friend who can be called in the event the participant cannot be reached by phone or email, as well as locations where they typically spend time and could be reached if necessary. Participants will be asked if messages can be left at the numbers provided. Staff will not leave messages unless expressly permitted to do so by the participant, which will be documented on this form. If permission is given to leave messages, study staff will assure participants that messages left with a family member or friend will only ask that the participant contact study staff and will not include any protected health information (PHI) or information related to study participation. (See Appendix XII-13. Locator Form.)

VIII-4.3 Baseline Survey. After completing the Locator Form, participants will be linked to the Baseline Survey on Qualtrics (see Appendix XII-8. Survey Measures). The baseline survey will take approximately 40 minutes to complete. If a participant indicates she would like to take the baseline survey at a later time, or exits the survey before completion, the RA will contact the participant and send her a link to complete the survey at a later date.

VIII-4.4 Violence & Gender Affirmation Screener. Immediately after completing the baseline survey, participants will be linked to the Violence and Gender Affirmation Screener (see Appendix XII-3. Violence and Gender Affirmation Screener). Participants will be informed that their PHEs will receive the information entered into this screener.

VIII-5. Intervention Procedures

VIII-5.1 1-on-1 Sessions. Once a participant has completed enrollment procedures, she will be connected to one of the Peer Health Educators (PHEs). The PHE will reach out and schedule an initial individual session with the participant. In the initial individual session, the PHE will get to know the participant and answer any questions she may have about the *TSoCP SSP* intervention, including group sessions. The PHE will review the participant's responses on the Violence and Gender Affirmation Screener (see Appendix XII-3. Violence and Gender Affirmation Screener) and discuss immediate safety and referral needs with the participant. Once immediate needs are addressed, the PHE will discuss other needs related to healthcare, gender affirmation, and community resources; together the PHE and participant will determine which referrals to prioritize. Participants may choose how frequently they would like to have

additional individual sessions throughout the intervention period (through the end of the group sessions), up to once a week. Individual sessions may be delivered in-person in a private space at the Ruth Ellis Center, by phone, or by Zoom. Mode of contact/interaction for individual sessions will be dependent on current guidelines and approvals related to COVID-19; if/when in-person research activities are not permitted, all sessions will be virtual and occur by Zoom or phone. If/when in-person research activities are allowed, then PHEs will defer to the participant's preference. Regardless of the location/format of individual sessions, PHEs will ensure they are in a location that maintains the participant's privacy. PHEs may follow up with participants in between individual sessions to facilitate referrals and connection to community resources. (See Appendix XII-16. Individual Sessions Guide, and Appendix XII-2. Individual Session Resources and Referrals List.)

VIII-5.2 Group sessions. After all participants in one group cohort have been enrolled and had an initial individual session with their PHE, weekly group sessions will commence. Group sessions will include participants in this study, as well as another study our research team has running concurrently, "*A multicomponent intervention to address gender-based violence in HIV prevention for women: Phase 2"* (HUM00190671); that study involves testing the feasibility, acceptability, and initial efficacy of the *TSoCP SSP* intervention on engagement in the HIV prevention continuum of care and mental health outcomes among transgender women who are HIV negative or have an unknown HIV status in the Detroit Metro Area. Group sessions will be held once a week for eight weeks (see Appendix XII-1. Group Sessions Manual). Group sessions will either occur in-person in a private room at Ruth Ellis Center or virtually via Zoom, depending on current guidelines and restrictions related to COVID-19. It is possible that due to inclement weather or an emergency situation, session(s) may need to be rescheduled. In this event, a group session may be rescheduled for a later time that week or postponed to the following week; if a session is postponed by one week, this would delay the end of the intervention (as well as follow up assessments and exit interview) by one week. Participants will be encouraged to attend all group sessions; however, if a participant misses session(s), she will still be allowed to remain in the intervention and attend future sessions. If a participant misses a group session, whenever feasible, she will be offered the opportunity to review the group session content with a PHE in an individual session before the next group.

VIII-6. Follow Up Visits

The preferred timeframe for all follow-ups is within 14 days prior to or 28 days after the target study visit date. If the participant is unable to complete the necessary study procedures within this timeframe, study staff will work with the participant to identify a day as soon as possible to complete the procedures. Scheduling of study procedures will not be recalibrated based on the actual date that the study procedures were completed. The exit interview, immediate-, and 1-month post-intervention follow-up assessment must be based on the elapsed time from the date of final session completion.

VIII-5.1 Exit Interview. After completion of the final group session, participants will complete a brief in-depth interview about their experiences with the intervention to further assess acceptability and generate strategies for conducting research and RCTs with similar communities. Exit interviews with participants will be conducted by the study RA or Project Director, will last approximately 30 minutes, and will be audio-recorded. Exit interviews may occur in-person at the Ruth Ellis Center, by phone, or by Zoom (See Appendix XII-6. Exit Interview Guide – Participants).

VIII-5.2 Post-Intervention Follow Up Survey. After completion of the final group session, participants will receive a link to complete a follow up survey on Qualtrics. The follow up survey will take approximately 30 minutes to complete. If in person, the Qualtrics survey may be completed on a study tablet; otherwise the participant will receive a link to complete the survey on her own personal device.

VIII-5.3 1-Month Post-Intervention Follow Up Survey. One month after the final group session, participants will receive a link to complete a second and final follow up survey on Qualtrics. The follow up survey will take approximately 30 minutes to complete. If in person, the Qualtrics survey may be completed on a study tablet; otherwise the participant will receive a link to complete the survey on her own personal device.

VIII-7. Participant Incentives

To incentivize participation, participants in the one-arm trial will receive $40 for baseline, $35 for immediate post-intervention, and $50 for the 1-month post-interventions follow-up surveys, as well as $20 for attending each group session and completing an exit interview. Incentives will be provided in the form of a gift card. Participants will also be compensated for their travel for assessments (transportation provided through Uber or Lyft or a $20 gas card) and intervention sessions that are conducted in person, and provided a meal at in-person group sessions. To receive an incentive, participants will complete a brief incentive survey programmed into Qualtrics. (See Appendix XII-14. Incentive Survey.)

VIII-8. Retention Strategies

Our team has extensive experience in retaining transgender women of color in research studies. Much of our success can be attributed to our community-engaged approach to research efforts, including TSoCP serving our community partners located at the Ruth Ellis Center, which provides services for young adults and is in close proximity to Corktown Health Center, which provides healthcare services for all study participants regardless of age. Using these methods, our prior studies with transgender women of color have regularly yielded follow-up rates above 80%-90%. We will apply our rigorous multi-pronged approach to ensure high rates of follow-up.

Study staff are trained to emphasize several times throughout the enrollment process that it is critical that we be able to reach participants for follow-up. Participants will complete a detailed Locator Form with multiple methods of contact information after consenting to be in the study, which will aid in follow up. Staff will inquire about and update any changes to contact information at each study visit. We also request that participants inform study staff if any of their contact information changes. Participants are told that it is important that we reach them to see how they are doing, regardless of whether they respond to the intervention components, whether or not they engage in HIV care, whether or not they are doing well or poorly; that their participation in the study could increase scientific knowledge about whether this program is meaningful to the community; that their research information will be confidential; and that we are grateful for their contribution to the study. When participants are seen in-person, they will be given Ms. Trammell's business card, which is filled in with their approximate follow-up appointment date and the incentive amount.

Follow-up status and challenges will be routinely reviewed at weekly staff meetings. If follow-up rates fall, we will use a proactive management approach to identify the root source of the challenges and troubleshoot potential solutions. This may include meetings with our CAB to brainstorm solutions or modifying procedures.

IX. Data Collection and Management

IX-1. Data Collection Methods

Data collection is the responsibility of the study trained staff under the supervision of the PI. Data will be collected on study specific electronic forms (templates) in a study specific database. These forms will be completed on an ongoing basis during the study. Additional data elements will be abstracted from medical records and entered directly into a study designed database. Additional participant data will be collected using computerized self-report surveys, therefore, participants will enter their own data (except in the case when the PI provides approval for a research staff person to enter data for a participant, e.g. when a participant is physically unable or is illiterate). Finally, qualitative data will be collected in the form of an in-depth interview.

IX-2. Storage and Security

We will utilize Qualtrics and a study designed REDCap database for secure remote data collection. Interested potential participants will contact the study RA by phone; the RA will assign the potential participant a unique Study ID, and enter her contact information into the secure REDCap database. The Study RA will then send the potential participant a unique link to a Qualtrics eligibility screener survey, which will not contain/gather any personally identifiable data but will include the unique study ID. For those potential participants who screen eligible and provide informed consent to enroll in the study, their screener data will be linked to the rest of their longitudinal data (by continuing to use the same Study ID throughout the study). The purpose of linking screener data to baseline data is to reduce participant burden by not re-asking questions multiple times (e.g., rather than asking about experiences of trauma in childhood and adulthood in the screener and then again at baseline, this allows us to only ask once). For those potential participants who screen ineligible and those who screen eligible but do not provide informed consent to enroll in the study, we will remove the identifier (study ID) from the screener data and we will delete their contact information from the REDCap database, both within 2 weeks of screening ineligible. De-identified (and unlinked to study ID) screener data will be kept for ineligible/not enrolled potential participants in order to report on reasons for ineligibility at the end of the study.

The surveys completed by participants will run as web browser applications on a University of Michigan Qualtrics account or the study designed REDCap database. Participants will receive an individual link to access the survey on either Qualtrics or REDCap. Participant surveys will be coded by their study ID number and will not be linked to personally identifying information. Participants cannot access or change previously entered data through the web-based application. No data are stored on the local personal computer, but are transmitted in real time to the secure server at the University of Michigan. Study staff will enter data into the study designed REDCap database. Logging in to the application requires a unique User ID and password. As with participant-entered data, no data entered by study staff are stored on the local personal computer, but are transmitted in real time to the secure server at the University of Michigan. All data will be identified by a unique study ID number. Study staff will enter data from a private location (office at Ruth Ellis Center, School of Public Health, or from home while working remotely) where the information cannot be seen by others who are not listed on the IRB application.

Identifiers will be retained for six months after completion of data collection for enrolled participants. Identifiers for potential participants who are ineligible or who are eligible but do not enroll in the study will be deleted within two weeks.

We will conduct a qualitative exit interview with participants at the end of the intervention sessions. The qualitative interviews will either be conducted in a private room at the Ruth Ellis Center, by phone, or by Zoom. If conducted by phone or by Zoom, participants will be instructed to join the interview from a private location where they cannot be overheard by others. The interviewer will ensure she is in a private space where she cannot be overheard by others. The in-depth interviews will be audio-recorded using an external recording device. After the interview, the audio file will be immediately uploaded to a password protected Box folder and deleted from the recording device. The audio files will be retained until the interviews are thematically analyzed; this will be completed and the audio files deleted within 6 months of completing data collection. Because the audio files contain identifying information (the participant's voice), and because the exit interviews do not need to be linked to participants' surveys or other longitudinal data, we will remove even the participants' unique study ID from the files when storing them in order to maximally protect the participants' privacy. Participants will also be instructed not to share their name or other identifying information on the interview recording.

Data will be stored in a password-protected database on University of Michigan computer that requires a separate ID and password. We will take the following additional steps to protect subjects from the risk of a breach in confidentiality. 1) All project staff will sign a confidentiality agreement requiring them to keep private the information obtained in this study. 2) All data will be collected using coded ID numbers; no surveys or other data that we collect will contain identifying information. 3) All hard copy materials (e.g., signed consent forms, tracking information) will be stored in a locked file cabinet in the office of Dr. Gamarel or the Project Director (as appropriate). 4) Only aggregate data that cannot be used to identify individuals will be included in any reports released to other agencies or for publication. Identifying information linking participants to their study ID number will be stored in a separate location from data including the participants' study ID number and separate from any information including the participants' names (such as the contact database), and will be password-protected accessible only to authorized members of the study team. Confidentiality policies and procedures are reviewed with all new staff and reviewed annually with current staff.

X. Human Subjects Research Protections

X-1. Protection of Human Subjects

This human subjects' research meets the definition of "Clinical Research." All procedures will be conducted in accordance with 45 CFR Part 46 and will be approved by the University of Michigan Human Research Protections Program's Institutional Review Board (IRB). The study will also be registered with ClinicalTrials.gov.

X-2. Inclusion and Exclusion Criteria

X-2.1 Inclusion criteria. Research participants must be (1) at least 18 years old; (2) assigned male at birth; (3) identifies as female, transgender woman, or another feminine gender identity; (4) self-identifies as a person of color (any racial/ethnic identity except non-Hispanic white); (5) self-reports positive HIV status; (6) history of trauma (i.e., endorses at least 2 items on the adapted Trauma History Screener which includes IPV and experiencing or witnessing other forms of violence;[15,59] (7) living in the Detroit Metro Area or willing to travel to Detroit for in-person sessions; (8) English-speaking; and (9) willing and able to provide informed consent.

X-2.2 Exclusion criteria. Evidence of severe cognitive impairment or active psychosis that may impede ability to provide fully informed consent, determined by the Ms. Trammel (RA) and Dr. Gamarel in consultation with Dr. Harper.

X-2.3 Rationale for Involving Proposed Populations. This study targets transgender women of color who are living with HIV. This population has been selected due to their high prevalence of HIV infection and exposure to violence, and because there are limited culturally-responsive evidence-based trauma-informed violence prevention interventions to improve HIV care continuum outcomes developed for this priority population. Vulnerable populations such as fetuses, neonates, pregnant women, prisoners, or institutionalized individuals will not be involved. This research will not involve children under the age of 18. All enrolled participants will receive a local resource sheet for HIV prevention and care services and mental health services. Any unexpected ethical issues that arise with our study population will be discussed during regularly scheduled meetings with PI Dr. Gamarel and Co-I Dr. Harper, a clinical psychologist.

X-3. Informed Consent

Informed consent will be obtained before conducting any study activities. Participants will access the consent form online via a Qualtrics survey. The online consent will also include a video of the study team reading through and explaining the informed consent document to ensure that participants understand study procedures, their rights, and the risks associated with the disclosure of information likely to be interpreted as abuse and required to be reported by study staff. Because this study involves no more than minimal risk, we will request a waiver of documentation of informed consent. See the Section VIII-4.1 Informed Consent for procedures and Appendix XII-9. Consent Form for additional information.

Once enrolled in the study, the PI or Project Director will reach out to study participants to ask them to provide a medical release of information (HIPAA authorization) to the researchers from their HIV care provider; participants will be informed that this is optional and that their status in the study will not change if they choose to not release their medical records.

X-4. Risk/Benefit Assessment

X-4.1. Potential Risks.

Potential risks to subjects are considered minimal and include: (1) potential discomfort during the assessment/data collection process; (2) breaches of privacy and confidentiality; and (3) potential coercion.

Potential discomfort during the assessment/data collection process. It is possible that participants may experience some discomfort in responding to questions during completion of the interviews. It is also possible that participants will experience distress in responding to quantitative questions about violence, mental health, substance use, and HIV-related behaviors.

Potential breach of confidentiality. One of the primary potential risks to participants is breach of confidentiality. It is possible that data collection could result in breach of confidentiality. For participants in the proposed project, breach of confidentiality in self-report data could reveal they are engaging in illegal behavior (i.e., breaking laws against drug use possession and use of controlled substances). However, the risk of breach of confidentiality is also modest, given the safeguards protecting participants' data. Given the nature of the group-level intervention, there is also the possibility that confidentiality can be broken. However, the informed consent and the Peer Health Educators will continually reinforce the importance of confidentiality at the beginning and throughout each session.

Potential Coercion. The risk of coercion is also low, as the total amount of compensation during the study is modest in comparison to the amount of effort required by participants. See Section VIII-7. Participant Incentives for more information.

X-4.2. Protection Against Risk.

We have made every attempt to minimize risks to participants throughout the study protocol, including loss of privacy or confidentiality and psychological and physical discomfort. Based on our prior experiences, we believe that our planned procedures (described below) will be highly effective for minimizing risk.

Minimizing Discomfort or distress during research. All study staff will follow an aggressive set of safety procedures to make sure that participants receive a high level of monitoring which will meet IRB standards. Because there is potential for psychological discomfort due to the research topic, we will make every effort to create a secure and trustworthy environment prior to conducting study visits at the Ruth Ellis Center or virtually. Participants will be reminded often that they may refuse to answer any question and that they may end their participation at any point during the interview, during the intervention sessions, exit interview, or survey assessments. Participants experiencing mild distress during the session, interview, or assessments will be offered to take a small break or to reschedule the assessment or session at a later date. In the unlikely event that a participant experiences considerable distress, they will be offered a voluntary suicide risk assessment (see Appendix XII-10. Suicide Risk Assessment) and appropriate referral. If any person is judged by PI to be a danger to self or others, or judged to be in grave danger due to medical or other conditions, the decision will be made to break confidentiality in order to inform law enforcement authorities to intervene in order to prevent an adverse event. All staff will receive yearly training for identifying suicide/homicide risk and/or dangerous intoxication, and de-escalation of agitated or angry persons and are trained to appropriately evaluate and respond to these circumstances. In addition, our resource listings will include emergency housing shelters, programs, clinicians, and support groups specializing in

relationship abuse and violence. All participants will be informed that they can withdraw at any point in time.

Minimizing the risks to privacy of individuals or confidentiality of data. The study consent form will inform participants of confidentiality guidelines and standards. Given the nature of the group-level intervention, there is also the possibility that confidentiality can be broken. However, the informed consent process and the Peer Health Educators (PHEs) will continually reinforce the importance of confidentiality at the beginning and throughout each session. Strict confidentiality will be maintained and all data will be coded by a unique individual study number. Personal identifier records will be kept in a secure password-protected location accessible to only authorized members of the study team, and any files with identifying information will be stored separately from other study data. Records will be kept confidential to the level allowed by law and only the staff assigned to the study will have access to non-anonymous records. Information provided by study participants will not be released to outside sources unless written consent is provided by the study participant.

All research data will be kept in locked cabinets. Screening ID numbers will be used to identify specific forms. Any files that link participant's names with an ID number will be stored separately in a locked file. No released presentation or publications will identify study participants individually. The exceptions to confidentiality are those defined by law and include suspicion of child abuse, elder abuse, and threat of imminent action on suicidal or homicidal ideation. Participants will be informed of the exceptions to confidentiality in the consent process. The University of Michigan Institutional Review Board and NIH representatives will have limited access to records (i.e. the IRB may request a review of the associated chart). Prior to any sharing of data sets, all personal identifiers will be removed. Data will only be shared with other researchers who have received IRB approval and who have agreed not to identify specific study participants and who will destroy or return dataset information after completing their analyses. All assessment and intervention procedures will be closely supervised by the PI. All audio recordings will be erased upon completion of data analysis. All in-person study activities will be conducted in a private room at the Ruth Ellis Center or virtually by Zoom or phone.

This study involves a group-level intervention. Before potential participants are screened and in the informed consent document, participants will be informed that the study will involve participating in group sessions with other community members. Participants will be informed that given the nature of the group-level intervention, there is also the possibility that confidentiality can be broken. However, the informed consent process and the Peer Health Educators (PHEs) will continually reinforce the importance of keeping information shared within the group private at the beginning of the study and throughout each group session. This will include reviewing a set of "ground rules" established and agreed to during the first group session, which includes keeping information shared during the group confidential. At the start of group sessions, participants will also be reminded that they do not have to share any personal information during the group and may decline to answer any questions. If group sessions are able to occur in-person, they will occur in a private room at the Ruth Ellis Center. If group sessions must occur virtually, they will occur using a secure Zoom platform. Participants will be instructed to join the Zoom group from a private location where the group conversation will not be overheard by others. Participants will also be asked to utilize headphones with a microphone to join the Zoom group session, so that if other people are nearby a participant during a Zoom group session, they are unable to hear things said by other participants. Headphones with a microphone will be provided to participants who need them at the start of the study.

Minimizing potential for coercion. Any study that pays a stipend may engender coercion. Eliminating the possibility of coercion by not awarding stipends would make it impossible to conduct many studies, and would shortchange participants who provide time and energy, and may incur costs such as bus, Lyft/Uber, taxi, or car fares. The resolution of this problem is to insure that stipends are not inappropriately large, to probe potential subjects to make sure they have not been coerced, and to give persons who may have been coerced the opportunity not to enroll in the study in a manner that will protect them from retribution by the person coercing them. See Section VIII-7. Participant Incentives for amounts. The visit stipends proposed are in use in similar HIV prevention studies and have been reviewed by our own and other IRBs for potential coerciveness.

X-4.3. Potential benefits of the proposed research to the subjects and others

Potential benefits include the following. First and foremost, all participants will receive a referral list of services in Southeastern, Michigan. Participants may improve in care as a result of their participation in the study, which could have a positive impact on their health. Participants are also provided with the opportunity to spend time talking about feelings and experiences, and they may gain insight into violence and HIV prevention. Participants in our previous studies have indicated that they benefited from this opportunity and that the prospect of providing information for the possible future benefit of transgender women of color was motivating for them. Furthermore, participants in our prior research projects have indicated a desire to be contacted for future studies, indicating the positive opportunities participation may provide. Given that the risks to subjects are considered to be minimal, the risk-benefit ratio is deemed favorable. Study procedures are carefully developed and followed to minimize risks. The potential social and psychological risks to participants described are reasonable given the need to adapt and pilot test culturally-relevant evidence-based violence prevention interventions to improve engagement in the HIV care continuum among transgender women.

X-4.4. Importance of the knowledge to be gained

The proposed study has the potential for high public health impact by evaluating the feasibility, acceptability, and preliminary efficacy of an adapted, evidence-based prevention program to address violence and HIV engagement in care outcomes among a highly vulnerable and overlooked population disproportionately impacted by HIV. Our focus on transgender women of color is in line with the prioritization of sexual and gender minority communities for health disparities research, as well as the strategies of the new HHS plan for ending the U.S. HIV epidemic. Study findings will provide the necessary groundwork to examine the efficacy of intervention in a future, large-scale clinical trial. Findings also have the potential to provide a "blueprint" to guide future research efforts with transgender women of color who are often embedded in close-knit communities with few existing services. Given the substantial health risks associated with documented inequities in violence and HIV outcomes and the relatively minority risks to participants, the importance of the potential knowledge to be gained relative to the subject risk is favorable.

X-9. Study Withdrawal and Discontinuation

A participant may be discontinued from the study at any time if the participant, the investigator, or the Sponsor feels that it is not in the participant's best interest to continue. All participants are free to withdraw from participation at any time, for any reason, specified or unspecified, and without prejudice. Reasonable attempts will be made by the investigator to provide a reason for participant withdrawals. The reason for the participant's withdrawal from the study will be specified in the study records.

The following is a list of possible reasons for early study termination:

- Participant withdrawal of consent.
- Participant is not compliant with study procedures.
- Participant relocates outside of study geographic area.
- Adverse event, inclusive of participant distress, that in the opinion of the investigator would be in the best interest of the participant to discontinue study participation.
- Protocol violation requiring discontinuation of study participation.
- Sponsor request for early termination of study.

XI. Data Safety and Monitoring Plan

XI-1. Safety and Monitoring

The Study PI Dr. Gamarel will conduct oversight of internal monitoring of participants' safety and data integrity. The Study PI will also be supported by Co-Investigator Dr. Harper who will participate in the development and administration of the data and safety monitoring plan. Both Dr. Gamarel and Dr. Harper have extensive experience with HIV prevention clinical trials. Dr. Gamarel and Dr. Harper are experienced at training study staff in handling sensitive and confidential data and in the handling, storage and processing of confidential data. Certain routine administrative, personnel, physical security, information management, and computer system or network security practices are always in place given the University of Michigan's policies. See protocol Section IX. Data Collection and Management for procedures to ensure data security and integrity. See protocol Section X-4.2 Protection Against Risk for procedures to ensure participant safety.

Given the relatively low level of risk involved for participants, we do not plan to have a data safety and monitoring board (DSMB) unless asked to establish one by NIH. However, in any case we will monitor for any serious adverse events caused by study participation and report them to the University of Michigan's IRB and NIH as appropriate and as described below. We will have several mechanisms to ensure data integrity.

XI-2. Contents of Monitoring

Monitoring is done of all procedures to ensure that they conform to the approved protocol; of unforeseen circumstances that might arise and affect safety; of all reports of serious adverse events as defined in 38 CFR 46 and the FDA 312.32 (death, life-threatening experience, new or prolonged hospitalization, persistent or significant disability/incapacity); of other significant adverse events (adverse events that lead to drop out by participant or termination by the investigator, or medical treatment needed to prevent withdrawal); of unexpected adverse events resulting from the study; of expected adverse events; unanticipated problems involving risk to participants, serious or continuing non-compliance, and protocol violations.

XI-3. Frequency of Monitoring

Data and safety monitoring will be a component of regularly-scheduled weekly meetings with the study team. Meetings will involve a review of collected data (including adverse events, unanticipated problems, and participant withdrawals) to determine whether there is any change to the anticipated benefit-to-risk assessment of study participation and whether the study should continue as originally designed, should be changed, or should be terminated. Dr. Gamarel will ultimately be responsible for participant safety, protocol violations, and ongoing evaluation of the study's progress. If necessary, Dr. Gamarel will make appropriate recommendations for changes in protocol. The University of Michigan IRB will conduct the monitoring at the continuing reviews as scheduled, whenever modification requests are considered, and upon receiving reports of SAEs and AEs from the PI or anyone else. The NIMH PO will monitor the study upon receipt of annual progress reports and whenever other information is received.

XI-4. Adverse Events

We define adverse events (AEs) and serious adverse events (SAEs) as follows: An AE is any unfavorable and unintended diagnosis, symptom, sign (including an abnormal laboratory finding), syndrome or disease which either occurs during the study, having been absent at baseline, or if present at baseline, appears to worsen. AEs will be reported regardless of their

relationship to the study intervention. An SAE is any adverse event that results in death, is life-threatening, or places the participant at immediate risk of death, requires or prolongs hospitalization, causes persistent or significant disability or incapacity, or any other condition which Study PI Dr. Gamarel deem to represent significant hazards.

XI-5. Reporting Plan

All AEs and SAEs will be reported regardless of their relationship to the study intervention. The study team will document all adverse events and unanticipated problems (see Appendix XII-15. Adverse Events and Unanticipated Problems Log). We will detect AEs and SAEs during participant visits and via survey responses. Any serious adverse events that are observed and/or reported will be immediately reported to Dr. Gamarel. We will report all AEs and SAEs by alerting the University of Michigan IRB. The Research Director will prepare the appropriate IRB documentation, and review it with Drs. Gamarel and Harper and determine severity and relation to study participation. As for all clinical trials, these events will be classified along the following dimensions: 1) severity; 2) whether it was expected or not; and 3) the extent to which it was related to study participation. A report detailing all AEs and SAEs will be submitted to the University of Michigan IRB. SAEs will require expedited reporting (i.e., within 24 hours of the PI becoming aware of the SAE). For events that are judged to be ongoing, the Project Director will make weekly calls to the participant to collect updated data regarding the event. This process will continue until the PI determines that the event is terminated, at which time a follow-up report will be submitted to the University of Michigan IRB.

PI Dr. Gamarel will promptly inform the NIMH PO and IRB of any changes in recruitment or in the protocol relevant to safety as the study is being performed. Dr. Gamarel will notify the NIMH PO of any actions taken by the IRB during continuing study review and of any major changes in the status of the ongoing protocol that would only occur with IRB approval. Such changes would include but are not limited to: amendments to the protocol, temporary suspension of participant accrual or of the protocol, any changes in informed consent or IRB approval status, termination of participant accrual or of the protocol, or other problems or issues that could affect the human subjects in the study. SAEs, unanticipated problems involving risk to participants or others, and AEs will be reported the NIMH PO within 10 business days of Dr. Gamarel learning of the event. Deaths related to study participation will be reported within 5 business days of learning of the event by Dr. Gamarel to the NIMH PO. Any serious or continuing noncompliance concerns will be reported to the NIMH PO within 10 business days of the IRB determination and suspension or termination of IRB approval will be promptly reported to the NIMH PO within 3 business days of receipt. The NIMH PO will be provided copies of these reports and informed of any actions taken by the IRB as a result of such events. As mandated by law, we will notify officials if a participant reports intentions to harm him/herself or others, or reports child abuse or abuse of an elder. Co-I Dr. Harper is a clinical psychologist who will be available on call in case of any psychological adverse events. In the event a participant were to report a need or interest in treatment for psychiatric disorder, or distress, an appropriate referral to resources will be provided based on an extensive list of referral resources maintained at the Ruth Ellis Center. All events and protocol violations related to the study will be reported annually in the Progress Report sent to the NIMH PO.

XII. Protocol Amendments

XXII-1. Ame00113458

The University of Michigan is no longer requiring completion of the Human Research Activation Checklist to authorize in-person research activities. All research procedures will adhere to current University guidelines and IRB-approved procedures; if/when University COVID-19 guidelines change, we will adjust procedures accordingly, obtaining IRB approval as appropriate.

The informed consent process will not accessed online via a Qualtrics survey; instead, informed consent be led by the Study RA by phone, Zoom, or in-person in a private office (in alignment with current COVID-19 guidelines). The Study RA will call potential participants who are identified as eligible in the eligibility survey. She will read the consent form to the participant, answer any questions she may have, confirm the participant understands the study procedures, and obtain verbal informed consent. The Study RA will document the informed consent process and whether the participant consented to study procedures in the study database.

XIII. References

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XIV. List of Separate Appendices

List of separate study appendices include:

XII-1. Group Sessions Manual
XII-2. Individual Sessions Resource and Referral List - Draft
XII-3. Violence and Gender Affirmation Screener
XII-4. Intervention Log
XII-5. Adapted Client Satisfaction Questionnaire
XII-6. Exit Interview Guide – Participants
XII-7. Exit Interview Topic Guide – Program Staff
XII-8. Survey Measures
XII-9. Consent Form
XII-10. Suicide Risk Assessment
XII-11. Screener Script
XII-12. Eligibility Survey
XII-13. Locator Form
XII-14. Incentive Survey
XII-15. Adverse Events and Unanticipated Problems Log
XII-16. Individual Sessions Guide