Secure: Strengthening Community Responses to Economic Vulnerability among Trans Women

Phase II Pilot RCT Research Protocol

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I. Acronyms

AE: Adverse event

ART: Anti-retroviral therapy

BIPOC: Black, Indigenous, and other People of Color

CAB: Community Advisory Board

CBO: Community-based organization

Co-I: Co-Investigator

CHC: Corktown Health Center

DMA: Detroit Metro Area

EE: Economic Empowerment

EHE: Ending HIV Epidemic

GLMM: Generalized linear mixed model

HIVRR: HIV Risk Reduction

IRB: Institutional Review Board

LGBT: Lesbian, gay, bisexual, transgender

MI: Multiple Imputation

MLE: Maximum likelihood model

NIH: National Institutes of Health

PD: Project Director

PHE: Peer Health Educator

PHI: Protected health information

PI: Principal Investigator

PrEP: Pre-Exposure Prophylaxis

RA: Research Associate

RCT: Randomized Controlled Trial

SAE: Serious adverse event

TSoCP: Trans Sistas of Color Project

U-M SPH: University of Michigan School of Public Health

II. Study Objectives

This protocol outlines the research procedures for Phase II of "*Secure*" (R34-MH-130207), a microeconomic intervention to improve HIV prevention and care continua outcomes among transgender (trans) women of color. Phase I of this study (HUM00215727) included formative qualitative work to adapt a microeconomic intervention called EMERGE for trans women of color in Detroit, develop program materials, and review study procedures. The objective of Phase II of this study (the current application, HUM00239691) is to conduct a small randomized controlled trial (RCT) of the *Secure* program to evaluate feasibility and acceptability of the adapted intervention among a sample of N=40 trans women of color living in Detroit, MI.

Specific Aims

In the United States (US), Black, Indigenous, and other transgender women of color (herein "BIPOC trans women") experience cyclical, interlocking systems of structural and institutional oppression rooted in racism and transphobia.[1,2] This pervasive and systemic intersectional racism and transphobia fuels economic vulnerability (e.g., in education, employment, and housing) among BIPOC trans women.[3-5] An estimated 38.5% of Black trans people in the US live below the poverty line.[6] Our recent survey with BIPOC trans women in Detroit confirmed these economic hardships locally, finding that 66.7% of respondents earn less than $1,000 per month, 78.3% are experiencing food insecurity, 39% are homeless or unstably housed, and just 18.3% report being able to get by in their current financial situation.[7] Together, this cycle of intersecting racism, transphobia, and economic vulnerabilities create conditions that fuel the extreme HIV inequities seen among BIPOC trans women in the US, including high HIV prevalence, low uptake of pre-exposure prophylaxis among those not living with HIV, and low uptake and adherence to antiretroviral therapy among those living with HIV.[8-13] Approximately 19-21% of trans women are living with HIV in the US;[14-16] with evidence suggesting racial/ethnic inequities. Black, Latina, and other trans women of color represent the majority of cases (51%, 29%, and 11%, respectively).[17,18]

Microeconomic interventions – designed to improve financial standing by increasing income generation and access to financial resources through entrepreneurship, cash transfers, and training — have the potential to address structural factors underlying HIV risk.[19] Over the past few years, several BIPOC trans-led organizations have integrated microeconomic strategies, such as emergency assistance (i.e., unconditional cash grants) into usual care.[20] However, our formative work in Detroit highlighted a need for additional supports to improve financial standing, including components of a US-based microeconomic intervention to mitigate HIV risk among Black cisgender people developed and piloted by one of the PIs.[21-23]

In alignment with the Ending the HIV Epidemic (EHE) plan and NIH priority areas for reducing HIV incidence,[24,25] the goal of this study is to develop and pilot test an HIV status-neutral, gender-affirming microeconomic intervention to decrease economic vulnerability and thereby promote HIV prevention (HIV testing and PrEP use) and care (viral suppression) among BIPOC trans women in Detroit, Michigan, an EHE priority jurisdiction.[26,27] The gender-affirming microeconomic intervention named, "*Strengthening Community Responses to Economic Vulnerability among Trans Women (Secure)"* builds on our community's existing usual care (UC) microeconomic intervention of: (1) an emergency unconditional cash grant (averaging $200)[20] and (2) peer and legal support to obtain legal gender affirmation (i.e., legal name and gender markers on identification documents).[26-28] The 12-week microeconomic intervention (*Secure*) will include our community partners' UC plus: (1) weekly educational sessions on economic empowerment (i.e., job acquisition, income generation through micro-business, and financial literacy) and HIV prevention and care; (2) employment-focused mentoring; (3) weekly social media posts of job openings in Detroit; and (4) an unconditional grant ($1,200) for use towards acquiring self-led or formal employment. The specific aims are to:

III-1. Aim 1: Assess the feasibility of the *Secure* intervention to be implemented in the Detroit transgender community setting.

III-2. Aim 2: Evaluate the acceptability of the *Secure* intervention to improve HIV prevention and care continua outcomes.

To achieve these aims, we will recruit and randomize 40 BIPOC trans women, aged ≥ 18 years, to intervention or a waitlist control for 12 weeks (e.g., 20 trans women per arm). Participants will complete baseline, end of program, and 3-month follow-up surveys. Immediately following the intervention program end, participants will also complete a qualitative exit interview regarding their experience. The specific feasibility benchmarks are to a) achieve a recruitment rate of at least 5-6 participants per month; b) maintain a retention rate of 70% or higher; and c) obtain estimates of outcomes (less than 10% missing data) and ensure measures and data collection are suitable to explore if participants who receive the intervention will report increased HIV prevention and care outcomes post-intervention compared to those in the control condition. We will also gather information from participants during exit interviews and interviews with key stakeholders and staff delivering the intervention to identify strategies for sustainability with BIPOC trans women in US-based settings, and we will use these data and input from our community advisory board (CAB) to refine the intervention for a future efficacy trial.

The proposed study has the potential for high public health impact by evaluating the feasibility and acceptability of a community-centered microeconomic intervention. Our focus on BIPOC trans women is in line with the prioritization of sexual and gender minority communities for health disparities research,[31,32] and NIH funding priorities to address social-structural drivers of inequities in both the HIV prevention and care continuum.[25] Study findings will provide the necessary groundwork to examine intervention efficacy and implementation processes in a future, large-scale trial.

III. Background Information

Trans women represent one of the populations at highest risk for HIV infection.[33] Approximately 19-21% of trans women in the US are living with HIV.[14-16] Evidence suggests substantial racial/ethnic inequities in HIV with Black, Latina, and other trans women of color representing the majority of the cases among trans women.[17,18,34] The HIV Prevention and Care Continuum frameworks emphasize the need for reducing HIV transmission and acquisition risk via consistent condom use, regular HIV testing, pre-exposure prophylaxis (PrEP) among HIV-negative individuals, and engagement and retention in HIV care in addition to uptake, adherence, and persistence to antiretroviral therapy (ART) to achieve virologic control among persons living with HIV.[35-37] There are notable inequities in HIV prevention and care continua outcomes among BIPOC trans women.[38,39] For example, evidence suggests that BIPOC trans women have a 40% lower odds of lifetime HIV testing and 50% lower odds of HIV testing in the past 12 months compared with gay/bisexual men.[40] Studies also indicate very low PrEP uptake (3 to 32% use among PrEP-eligible trans women),[41,42] and low rates of virologic control (68 to 70%) among trans women living with HIV.[38,43-52] Thus, interventions are needed that address inequities across both the HIV prevention and care continuum among BIPOC trans women in the US.[38,51,52]

Due to the convergence of structural racism and transphobia, BIPOC trans women experience high rates of income insecurity, [26,53-56] unstable housing,[4,53,55-58] and unemployment.[54,56,58,59] Unemployment rates among BIPOC trans women have been estimated to be nearly four times higher than the national average,[60] with many trans women living below the poverty line (29-63%),[54,60] and reporting unstable housing in their lifetime (30-49%).[60,61] Research suggests that persons experiencing economic hardship are less likely to prioritize HIV prevention and care in the face of needing to meet basic needs (i.e., housing, food), resulting in lower rates of HIV testing,[62] PrEP initiation,[63] ART adherence and engagement in HIV care.[64] Systemic racism and transphobia compound the economic vulnerability experienced by BIPOC trans women, placing them at heightened risk for HIV.[10] HIV prevalence in lower-income urban areas in the US is 2 to 5 times higher than the national average, and individuals living below the poverty line are twice as likely to be living with HIV.[65,66] Many BIPOC trans women are forced to turn to illegal means of securing income and housing, such as survival sex work, which increases their risk for HIV.[67] Evidence suggests that economic inequities are exacerbated by a lack of employment-based health insurance coverage and the necessary funds to pay for gender affirming medical care (e.g., hormones), which may also contribute in part to engagement in survival sex work.[60,68,69] Additionally, over a third of BIPOC trans women have not been able to have their name or gender marker changed due to financial costs, a significant barrier to seeking work and accessing sexual health services.[60] In the US, state and federal legal identification documents are often required to access education, employment, housing, and health care facilities, including HIV and related PrEP/ART services.[70] BIPOC trans women who lack legal gender affirmation are at greater risk for economic vulnerabilities,[71,72] which fuel HIV inequities.[73] Conversely, evidence suggests that having employment acquisition support in the form of linkages to jobs, financial assistance, and having legal gender affirmation needs met is associated with improvements in indicators of economic status (i.e., income and housing).[56] Employment acquisition support may also better enable vulnerable BIPOC trans women to attain gender affirming medical care (e.g., prescribed hormones), ultimately experiencing less discrimination.[56] Behavioral interventions that address economic vulnerability that have only been exacerbated due the COVID-19 pandemic have the potential to alleviate HIV inequities among BIPOC trans women.[61,74,75]

Despite alarming rates of racism, transphobia, and economic vulnerability, it is important to underscore that US BIPOC trans women are resilient and resourceful and find creative ways to leverage existing community and individual assets to address systemic oppression, unmet gender affirmation needs, and economic hardships in their communities.[76-79] In 2017, the Trans Sistas of Color Project (TSoCP) launched a mutual aid fund that consists of a no-strings-attached microgrant (i.e., unconditional grant) for up to $500 for one-time emergency assistance to BIPOC trans women in Detroit. During the COVID-19 pandemic, many other US-based trans-led organizations and BIPOC trans communities have found ways to support their communities through the provision of mutual aid and organized advocacy for justice.[80,81] Additionally, several trans-led organizations have formed legal partnerships that provide counsel in obtaining legal gender affirmation.[28] Therefore, the proposed *Secure* microeconomic intervention ("Strengthening Community Responses to Economic Vulnerability") is named after and premised on the principle of strengthening BIPOC trans communities in their endeavor to address underlying economic, legal, and other structural determinants of health. Our pilot work highlighted the multitude of benefits of existing community-led structural-level interventions in Detroit. However, our team also identified areas for improvement, which included adding

components from the MPI's previously piloted microeconomic intervention for Black cisgender persons called EMERGE, which includes skill building for income generation, financial literacy, unconditional cash grants for self-led or formal employment costs, and employment-focused mentorship.[21-23]

Microeconomic interventions are designed to improve financial status by increasing entrepreneurship, savings, and/or employment, thereby addressing the structural factors underlying HIV risk in economically marginalized individuals. Microeconomic strategies have included business loans, personal savings accounts, microgrants, vocational training, financial and business training, insurance provision, career planning, and employment-focused mentoring.[21] Integrated microeconomic and HIV prevention strategies are predominately implemented in low-income countries among cisgender populations.[82] In international settings, microeconomic interventions have been shown to improve savings,[82] as well as other HIV prevention and care continua outcomes, such as HIV communication,[83,84] condom use,[83-87] HIV testing,[84] viral suppression,[88] and sexual risk-taking attitudes and behaviors.[86,89-91] To date, BIPOC trans women have largely been omitted from HIV prevention-focused microeconomic intervention trials.[92,93] Due to pervasive systemic barriers, traditional employment options may not always be considered viable poverty alleviation strategies for many BIPOC trans women.[94,95] That is, BIPOC trans women may be forced to turn to illegal means of securing income and housing, such as survival sex work and selling drugs and other informal income generating strategies.[67,96-98] Owning assets (i.e., microenterprise) can give BIPOC trans women a sense of stability and enable them to expand their vision of possible and healthier opportunities.[99,100] Evidence suggests that the effects of cash incentives on HIV risk behaviors is mixed and often attenuates after incentives cease.[23,88] However, increased skills, social networks, and resources for BIPOC trans women engaged in microenterprise may offer more sustainable, self-perpetuated incentives that target economic vulnerabilities contributing to HIV inequities.[10] Microeconomic interventions can also extend beyond income generation and focus on enhancing skills (i.e., industriousness, perseverance, persistence) that support long-term safe sex, PrEP and/or ART medication adherence, and job acquisition and retention.[21] Some microeconomic interventions have been critiqued because they require participants to repay loans and thereby incur debt; however, many do not require repayment.[23,88] In line with MPI Jennings Mayo-Wilson's prior microeconomic intervention, we propose to provide microgrants for use towards income generation (i.e., self-led microenterprise or costs related to gaining formal employment) that do not require repayment.[21] A gender-affirming microeconomic intervention, such as the proposed *Secure* project, that builds on existing community services has the potential to sustainably reduce economic vulnerabilities and HIV inequities among BIPOC trans women in the US through employment-focused microgrant support, improved financial literacy, job announcements, and employment-focused mentoring.

IV. Study Design

To provide preliminary data on intervention feasibility and acceptability, N=40 trans women of color living in Detroit will be enrolled into a pilot RCT. Participants will be randomized into one of two conditions, 1) the intervention arm who will immediately receive the 12-week microeconomic intervention, *Secure*, in addition to standard community-based programming currently provided by TSoCP and Fair Michigan; and 2) a waitlist control arm who will receive TSoCP and Fair Michigan's programming as standard of care to serve as the comparison group, and who will ultimately be offered the *Secure* intervention after the 3-month comparison follow-up period. The standard of care available to both experimental arms upon enrollment includes TSoCP's one-time $250 emergency assistance funds and Fair Michigan's legal gender affirmation support.

Each condition receives survey assessments at baseline prior to randomization, post-program following the intervention arm's completion of the 12-week *Secure* program, and 3-months after the intervention arm's completion of the *Secure* program (approximately 24 weeks after completion of the baseline survey). Additionally, qualitative exit interviews are conducted within one month of completion of the *Secure* program for both the intervention and waitlist control conditions.

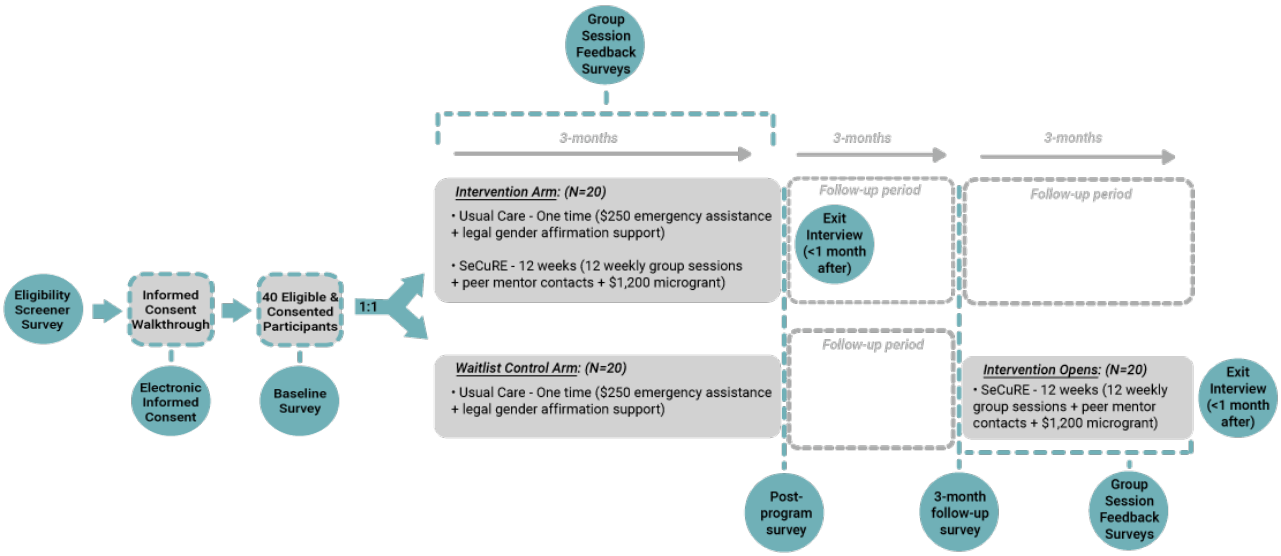

Figure 1. Overview of Secure Study Design and Data Collection

VI-1. Study Settings

The proposed study will take place at the Ruth Ellis Center, a community center that serves homeless and at-risk sexual and gender minority youth and young adults of color. The Ruth Ellis Center also hosts social events and serves as a safe space that many BIPOC trans people regardless of their age utilize to get their basic needs met (e.g., food, linkage to community resources) and to socialize with peers and role models in their community. Importantly, the Ruth Ellis Center has been the fiduciary of TSoCP and provides a supportive space to develop and implement programs, including Fair Michigan's legal gender affirmation services for BIPOC trans women.

VI-2. Pilot Randomized Controlled Trial Arm Overview

Waitlist Control Arm: The BIPOC trans women randomized into the control arm (n=20) will initially receive only standard of care derived from the existing community-based services of TSoCP and Fair Michigan during the 12-week period following randomization. Standard of care services include:

1. One-time Emergency Assistance: Participants will receive up to $250 in emergency assistance funds to pay for immediate needs (e.g., housing, bills, food).
2. Linkage to Legal Gender Affirmation Support: All participants will have access to legal name/gender marker change through Fair Michigan.

Additionally, after the RCT follow-up period is complete (i.e., after completion of two follow-up surveys occurring at 12 and 24 weeks after baseline survey completion), waitlist control participants will be offered delayed access to the same *Secure* intervention that is provided

immediately to intervention arm participants. The *Secure* program components are described below.

Experimental *Secure* Intervention (12 weeks): The BIPOC trans women randomized into the intervention arm (n=20) will be enrolled in the 12-week *Secure* program after randomization, in addition to the standard of care services described above. The *Secure* program includes the four following components:

1. 12 weekly Economic Empowerment (EE) and HIV Risk Reduction (HIVRR) Educational Sessions lasting 2 hours each and will be conducted in-person with approximately 8-10 participants. Session topics will focus on income acquisition assistance through skill development and goal setting relating to job-seeking (i.e., resumes, job application, interviewing), income generation through micro-business (i.e., self-employment, entrepreneurship, accessing clients, making a profit), and financial literacy (i.e., budgeting, managing credit). To address the relationship between economic vulnerability and HIV risk, session topics will also focus on knowledge and uptake of biomedical HIV prevention and treatment strategies (i.e., use of PrEP/ART) with particular attention to discussion of participants' financial constraints and trade-offs to protecting against HIV, and how safer income generation can be leveraged to reduce their risk of HIV transmission or acquisition (i.e., paying for travel to PrEP/ART clinics, acquiring higher-paying employment or health insurance, or refusing condomless sex work). Peer health educators (PHEs) will co-facilitate the interactive sessions, including role-play, discussions, games, and demonstrations. Each session will prioritize gender-affirming principles of social cohesion, mutual support, and identify affirmation.
2. Employment-Focused Mentorship where participants will meet with an employment-focused mentor weekly (~30 minutes/week) to assist her in acquiring or maintaining employment, initiating or expanding self-led income generation, or navigating financial decisions, including planning for use of their study-provided microgrants (see below). With the help of our team, we will identify approximately 8 mentors. Mentors will be offered an honorarium of $450 per mentee.
3. Weekly Job Postings where study team members will collate three social media announcements each week (i.e., Instagram, Facebook) with job openings in the greater Detroit metropolitan area.
4. Employment-Focused Microgrant of $1,200 (amount based on the first US government stimulus check; repayment not required). Each participant will be provided with the $1,200 in either one single payment or two separate payments of $600 to use to support income generation – either in engaging in self-led employment (i.e., purchasing business supplies, marketing, communication, and travel for selling hand-made goods and services, etc.) or in engaging in formal employment (i.e., traveling to job interview, paying for licensure or skills course, paying for gender transition supports to reduce employment discrimination, etc.). With their mentors, participants will develop an individualized *Secure* income generation plan that outlines how they will spend their microgrant.

VI-3. Assessing Acceptability & Feasibility

While our survey data collection includes measures to assess PrEP use among participants not living with HIV and viral load among participants living with HIV, our primary outcome is focused on descriptive analyses of the feasibility and acceptability indices. We will assess intervention target outcomes (i.e., HIV prevention and care), hypothesized mediators (e.g., economic improvement, gender affirmation), and background variables in baseline, immediate post-program, and 3-month post-program follow-up surveys. These measures will be used to assess feasibility and acceptability.

To assess feasibility, we will monitor rates of outreach, recruitment, eligibility, enrollment, session attendance, retention, and assessment completion. Study team members will meet with PHEs the day following each group session to assess fidelity to intervention, time needed, and feasibility of delivering the interventions as designed. The information gathered from these meetings will be filled out by study team members in case report forms. To assess acceptability, we will modify previous intervention satisfaction evaluation surveys currently being used in our study with BIPOC trans women and implemented at the end of each session. We will also assess acceptability using data on participants' reactions to various program components gathered from post-group feedback sessions with PHEs.

In line with recommendations by NIH and the research methods literature, given the sample size and intent of the pilot study we will not conduct a formal test of outcomes or attempt to obtain an estimate of effect size.[123-136] We will consider engagement in HIV prevention and care as an exploratory outcome defined as PrEP use and ≥ 80% adherence among those not living with HIV and suppressed HIV viral load among those living with HIV, collected via self-report. These analyses will be conducted as a feasibility check to ensure all measures required to construct the primary outcome and that moderators and mediators for a larger formal RCT are present and will yield analyzable data.

VI-4. Analytical Design

VI-4.1 Acceptability & Feasibility analyses.

The principal analytical aim of the pilot RCT is to measure feasibility and acceptability and evaluate whether feasibility and acceptability benchmarks are met. To fulfill this objective, frequency tables for all variables and measures of central tendency and variability for continuous variables will characterize the sample and quantify the intervention feasibility and acceptability outcomes. We will address incomplete data via direct maximum likelihood estimation (MLE) or multiple imputation (MI)[150] assuming that incomplete data arise from a conditionally random (MAR) mechanism[151] and include sensitivity analyses to evaluate the robustness of the MAR assumption. The proposed analyses will be conducted using validated algorithms in the general purpose statistical programs SAS or Stata. All statistical software programming code will be fully documented to enable future code review, transparency, and results reproducibility.

VI-4.2 Exploratory analyses.

To fulfill our secondary goal of generating preliminary effects of the intervention on the primary HIV serostatus-neutral HIV prevention and care engagement outcome, proportions of the outcome will be plotted by group over time to describe overall patterns of change across time in the *Secure* intervention group and the control group. Hypothesis testing will be de-emphasized in line with NIH[152] and research methods literature cautions[153,154] regarding the instability of inferential results from small-scale pilot studies. With that caveat, we anticipate that following the *Secure* intervention, intervention participants will exhibit higher odds of the HIV prevention and care outcome relative to control group participants in a time-averaged comparison of the post-baseline intervention and control groups' outcome proportions. This exploratory comparison will be performed at alpha=.05 in a generalized linear mixed model (GLMM) suitable for this binary outcome. Repeated observations from each participant will be the unit of analysis. Alpha will be set at 5% for this exploratory analysis.

VI-4.3 Power analyses.

Although the main purpose of this study is to determine preliminary feasibility and acceptability and to visualize changes in outcomes and mechanisms of change over time rather than to perform formal hypothesis tests, we conducted several power analyses using NCSS PASS 21 [156] to supply additional information. Assuming power=.80, α=.05, and N=32 participants available at the last follow-up, we computed confidence interval widths for a) proportions for binary variables and b) means for continuous variables measuring feasibility and acceptability. For example, for the study enrollment proportion, assuming α=.05, power=.80, and

the 80% enrollment benchmark, the width of the confidence interval for single proportions is 29.8% (standardized distance to the limit: .40). For continuous variables, the distance from the mean to the confidence limit is .36. For mixed models proposed to explore group differences in outcomes, the minimum detectable proportion increase in HIV care and prevention ranged from 33.7% to 42.8% (standardized effect size *h*=.75-.92; odds ratios=4.94-7.56). Taken collectively, this study is powered to detect small to medium distances to confidence limits for descriptive statistics to assess feasibility and acceptability (primary goal) and large effects for preliminary effectiveness effects (secondary goal), though, as noted above, formal hypothesis testing will not be the focus of this pilot study.

V. Study Procedures

VII-1. COVID-19 Safety

The group session element of the *Secure* intervention is designed for in-person delivery while the mentorship component and study assessments may take place in-person or remotely. While the study team has successfully administered remote, at-home alternatives among trans women of color, previous experience in Detroit has demonstrated the strong preference for in-person activities among community members when possible. If levels of COVID-19 risk and community spread increase to the point that in-person group sessions are not safe, we will submit an amendment with virtual intervention procedures. All U-M affiliated study team members will complete the Environmental Health Services course entitled, “Working Safely at U-M” (EHS_OHS_COVIDW) and will be provided appropriate personal protection equipment when facilitating any in-person study activity (i.e., sterile single use masks). Partnered organizational sites where in-person study activities will be held (i.e., Ruth Ellis Center) have their own COVID-19 risk reduction procedures that are in accordance with city and state health department guidelines.

VII-2. Recruitment

We will employ a multi-pronged outreach strategy to recruit BIPOC trans women including 1) Online recruitment: Banner ads and posts will be placed on social media platforms used by trans women of color (Facebook, Instagram); 2) Print Ads: Flyers will be placed in healthcare and social service agencies in Detroit; 3) Outreach: Our study research associate (RA) will conduct outreach in areas where BIPOC trans women congregate in Detroit. (See “Recruitment Materials” Appendices.)

VII-3. Eligibility Screening

Recruitment materials provide a study phone number or email to contact the study team about interest in participating.

VII-3.1 Eligibility Criteria.

To be eligible to participate, trans women will need to self-report being, (1) at least 18 years old; (2) assigned male at birth; (3) self identifies as female, transgender woman, or another feminine gender identity; (4) self identifies as a person of color (i.e., any racial/ethnic identity except non-Hispanic white); (5) reports earning less than $32,800 gross annual income (current living wage in Michigan); (6) reports condomless sex in the past 6 months; (7) lives in Detroit, MI greater metropolitan area (~50 mile radius); and (8) speaks English.

VII-3.2 Eligibility Screening Survey.

A member of the U-M study team will contact interested individuals by phone, share additional information about the study, and answer any questions

they may have. The study team member will then ask the interested individual if they would like to take a brief survey to see if they are eligible for the study. If yes, the study team member will send the interested individual a link to the eligibility screening survey via text message or email, depending on the interested individual's preference. (See "Eligibility Screener Script" Appendix.)

In the eligibility screening survey, the interested individual will first be asked to provide electronic consent to the screening process that at a minimum collects their first and last name. Those who consent will then be asked demographic questions associated with the eligibility criteria. The survey will take no longer than 5 minutes to complete and is not incentivized. To obscure which responses are eligible for participation, individuals will be asked all questions even if prior answers had already made them ineligible for the study. Additionally, if ineligible for any response, the screener survey will not detail which question(s) disqualified their ability to participate.

If eligible, the potential participant will be asked to provide their date of birth and contact information for enrollment next steps, and informed that a member of the study team will contact them to conduct the informed consent process. Information collected from eligible respondents will include their date of birth, phone number, email address, and home postal address. This contact information will be automatically uploaded to the HIPAA compliant participant management software, Ripple, and recorded on a profile card. Each new profile cards will be assigned a randomly generated 17-character Study ID number by the Ripple platform (ex: k6uPBYjIJ4PrGFXh8).

Respondents who screen ineligible will be asked if they are interested in participating in any future research studies. If they reply yes, they will be asked to provide an email address where they may be contacted again. Ineligible screening respondents will have their first and last name, ineligible reason, and potentially email automatically uploaded to the Ripple software where it will be recorded on a profile card. No other contact information will be collected from ineligible screening respondents. (See "Eligibility Screener Survey" Appendix.)

VII-4. Enrollment Procedures

The enrollment process will consist of up to 4 components: informed consent, baseline survey completion, enrollment activity, and randomization. These activities can be completed in person at Ruth Ellis or at-home remotely.

VII-4.1. Informed Consent:

Eligible potential participants who indicate they are interested in joining the study will need to complete an informed consent walkthrough with U-M a study team member either remotely by phone or video call, or in-person in a private location at the Ruth Ellis Center. If remote, potential participants will be emailed a link to the Informed Consent document, which will be programmed into Qualtrics and linked to their randomly generated 17-character Study ID number. If in-person, this survey may be pulled up on a study team laptop or tablet. A member of the study team will read through the consent document with the potential participant and answer any questions they may have related to the study design, incentives, and procedures. The study team member will then ask the potential participant several questions to ensure their understanding of the study procedures, and provide additional clarification if needed. The potential participant will then be asked to proceed to the final page of the Qualtrics survey, where they will be asked whether they consent to join the research study and to provide their electronic signature and the date. To aid in follow-up (e.g., if participants' phone number changes or their phone is shut off), those who consent will be asked to provide additional optional contact sources including social media (e.g., Facebook, Twitter, Instagram, Snapchat) usernames, contact information for a family member and/or friend who can be called in an emergency situation and/or 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. (See "Informed Consent Process Script" and "Informed Consent Programmed in Qualtrics" Appendices.) If a potential participant chooses not to consent, they will be thanked for their time and will not be able to proceed with the rest of the enrollment process.

VII-4.2 Baseline Survey: After consenting to participate, potential participants will be asked to complete an online Qualtrics programmed baseline survey. (See "Baseline Survey" Appendix.) The survey should take approximately 40 minutes to complete and will be connected to their assigned Study ID. If they are in-person with the study team member at Ruth Ellis, they may complete the survey on the study team laptop or tablet; if remote they will be sent a link via email and/or text message to complete on their personal device. If a participant requests to complete the survey at another time during an in-person study visit or exits out of the survey remotely before completion, study team members will attempt contact via phone call, email, or text to remind about completing the survey and provide their unique Qualtrics survey link if they are no longer able to locate it. In order to receive their incentive, at the end of the Qualtrics survey, participants will be asked to provide their name, mailing address, email address, and social security number (required for incentive reconciliation for tax purposes due to the amount of funds provided over the study period). An IRB approved study team member will securely store participants' social security number in a restricted Dropbox folder. (For specific incentive amount, see Section VII-8. Participant Incentives and Other Funds Provided.)

VII-4.4 Randomization: After all previous enrollment activities are completed, participants will be randomized in a 1:1 ratio into *Secure* intervention or the TSoCP/Fair Michigan standard of care waitlist control condition using a computerized secure and fraud-resistant procedure used in our team's prior studies. Assignment will occur until there is sufficient enrollment to form a group. A member of the study team will contact the participant to them know whether they are in the immediate intervention arm or the waitlist control arm. (See "Randomization Survey" Appendix.)

VII-5. Intervention Arm Procedures

During the approximately 12-week intervention period, participants who are randomized to the intervention arm will receive the Secure program components (in-person group sessions, individual mentorship, microgrant funds, and weekly job announcements), in addition to standard of care services (one-time emergency assistance funds, referral to legal gender affirmation services), as described below.

VII-5.1 In-Person Group Sessions. When planning group session attendance, the study team will track enrolled participants newly randomized to the intervention arm. Once a sufficient number of intervention arm participants have been amassed, a study team member will assign them into a cohort. They will be contacted by U-M study staff over the phone, email, or text message to coordinate their participation in the group session content of *Secure*. Participants who state they are no longer able to commit to the group session series will be put back into the queue to be possibly included in a later cohort. Otherwise, participants will be reminded about each weekly in-person group session two days before and the morning of via text message. From these point on, those participants will have their weekly group session together once a week at the Ruth Ellis Center.

There are 12 group sessions total that will be completed over approximately a 12-week period. (See "Group Sessions" Appendix for group session content.) Ideally each group will include 10-

12 participants, with a minimum of 4 participants and a maximum of 14 participants. The group content focuses on micro-business development, entrepreneurship, financial literacy, and HIV/STI prevention and care. The group sessions will be facilitated by two BIPOC trans women that are a part of the study implementation team.

Secure group sessions will occur in a private room. Members of the study team will explain the confidentiality expectations of the group. Participants will be required to agree not disclose information about any other participant attending to anyone outside of the group including that they are participating in the *Secure* study. Participants will be allowed to join the group late. The room where the group will take place will include free food and non-alcoholic beverages for those in attendance. The two group facilitators present will explain that they reserve the right to ask any participant to leave during the session if they are being overly disruptive to the content delivery. Participants who miss one or more of their 12 weekly group sessions will not be offered make-up sessions. Participant attendance and any reason(s) given for absences will be documented.

After each group session ends, participants will complete a 6-question group session feedback survey programmed in Qualtrics. (See "Group Session Feedback Survey" Appendix.) They will then receive their incentive for attending. In addition to their incentive for session attendance, participants will be provided with transportation via Uber/Lyft to/from Ruth Ellis Center for the study session or, if they provide their own transportation, a gift card to reimburse them for gas money. (For specific incentive and transportation reimbursement amounts, see Section VII-8. Participant Incentives and Other Funds Provided.)

VII-5.2 Individual Mentorship. After the first two group sessions, intervention arm participants will be connected with a mentor for additional employment-focused instruction on a semi-weekly basis for approximately 30 minutes during each contact. Mentors will be identified by the study team and CAB who: 1) Identify as a person of color (any race/ethnicity other than white non-Hispanic), 2) Are 25 years of age or older, 3) Have varied job and business expertise working in the Detroit Metropolitan area and/or urban metropolitans similar to Detroit, and, 4) have demonstrated experience working alongside trans communities. Each *Secure* mentor included in the study will be assigned to one or more participants from an active cohort for one-on-one meetings where they will discuss issues related to employment, income generation, financial decision-making, and planning how to best spend their microgrant.

Participants will be put into contact with their assigned mentor by a member of the study team either by phone, email, or text message depending on participant and mentor preference. Available dates and times to speak with mentors will be based on each individual mentor's schedule and workload. Mentor contacts can be completed either remotely or in-person in any combination over the 12-week period. Depending on mentor and mentee comfort, remote contact options may include video calls, phone calls, or text messages. If the mentor contacts occur via phone or video call, the mentor will check with the participant to make sure they are in a safe and private location, or will reschedule for another time. In-person mentorship meetings are only offered to take place at the Ruth Ellis Center. No incentives or transportation will be offered for mentor sessions.

VII-5.3 Microgrant Funds: After the group session where participants finalize their micro-business plan detailing how they will strategically spend their study provided microgrant funds, participants will be eligible to receive one or two installments of the $1,200 microgrant. A U-M study team member will disburse the funds to the participant in-person at Ruth Ellis Center where they will be required to sign and date a form documenting their receipt of the funds and

consenting to several stipulations regarding the fund transfer. The form will explain that after receiving the funds, participants will be solely responsible for the allotted funds and will not be provided with a replacement if their funds are lost or stolen. (See "Microgrant Disbursement Form" Appendix.) Participants' receipt of microgrant funds will be recorded within their individual participant profile within the Ripple platform. While group session facilitators and mentor contacts will ask about the funds to follow-up on the participant's individual micro-business plan, participants will not be required to provide receipts or any documentation detailing how the funds were spent. Follow-up surveys and qualitative exit interviews will assess how funds were spent only through self-report.

VII-5.4 Weekly Job Announcements: The final component of the *Secure* intervention will be receiving weekly job postings in the Detroit Metro Area compiled by U-M study staff. The postings will be shared via study Facebook and Instagram pages to all intervention arm participants in an active cohort over the approximately 12-week intervention period. Study staff will search for local job opportunities that require skillsets and educational backgrounds that are representative of the active cohort participants. Prior to sharing, collated job postings will be vetted by the study team.

VII-5.5 Standard of Care: During the intervention period, in addition to receiving the *Secure* program components described above, intervention arm participants will also receive standard of care services, described in detail below in Section VII-6.1 One-time Emergency Assistance Funds and Section VII-6.2 Legal Gender Affirmation Support.

VII-6. Waitlist Control Arm Procedures

During the approximately 12-week intervention period, participants who are randomized to the intervention arm will receive only standard of care services (one-time emergency assistance funds, referral to legal gender affirmation services). After the intervention period and the follow-up assessments are complete, participants in the waitlist control group will be offered access to the *Secure* program if they are interested in receiving it. These components are described below.

VII-6.1 One-time Emergency Assistance Funds: During an active intervention arm cohort's receipt of the *Secure* intervention content, both intervention and waitlist control condition participants will receive a one-time payment of $250 to help pay for immediate needs such as housing, bills, food, etc. The $250 in emergency assistance funds that will be provided to participants is an existing community service that is available regardless of participation in this study; however, the grant budget includes covering $250 in emergency assistance to program participants. A U-M study team member will disburse the funds to the participant in-person at Ruth Ellis Center where they will be required to sign and date a form documenting their receipt of the funds and consenting to several stipulations regarding the fund transfer. The form will explain that after receiving the funds, participants will be solely responsible for the allotted funds and will not be provided with a replacement if their funds are lost or stolen. (See "Emergency Assistance Disbursement Form" Appendix.) Participants' receipt of these funds will be recorded within their individual participant profile within the Ripple platform. Participants will not be required to provide receipts or any documentation detailing how these funds were spent. Follow-up surveys and qualitative exit interviews will inquire what they spent the money only through self-report.

VII-6.2 Legal Gender Affirmation Support: At any time during an active intervention arm cohort's receipt of the *Secure* intervention content, both intervention and waitlist control condition participants may request to be referred to Fair Michigan Trans Renaming Program that provides

assistance with legal name/gender marker changes. A participant's utilization of these services will be recorded within their individual participant profile within the Ripple platform.

VII-6.3 Waitlist Control *Secure* Content Access: After the 12-week period when an active intervention arm cohort completes the *Secure* program content (i.e., completion of group session 12 when participants graduate from the program), both the intervention and waitlist control conditions will enter into a 3-month follow-up period. After the waitlist control arm participants complete a follow-up survey at the end of the 3-month follow-up period, they will be offered the opportunity to receive the *Secure* program. If interested, waitlist control participants will be placed into a group cohort and will follow the same study procedures outlined for intervention arm participants in section VII-5 over another approximately 12-week period.

VII-7. Follow Up Assessments and Additional Intervention Fidelity Documentation

VII-7.1 Follow-up Survey Assessments: After completing all the intervention or waitlist control study activities, participants will receive an immediate post-program follow-up survey following the completion of the intervention arm content (i.e., completion of group session), approximately 3-months from when they completed the baseline assessment. Then three months after post-program follow-up survey, both conditions will complete a final 3-month follow-up survey. The post-program and 3-month follow-up assessments will consist of online Qualtrics programmed surveys and disseminated over email and text message for remote completion. Survey hyperlinks will be unique for each participant with embedded metadata containing their Study ID number, and will not include personally identifying information. (See "Follow Up Survey" Appendix.)

VII-7.2 Qualitative Exit Interviews: After completion of the final *Secure* group session, both intervention and waitlist control arm participants (who opt in to receive the delayed intervention) will complete an in-depth exit interview about their experiences with their condition's study activities to further assess acceptability and generate strategies for conducting research and RCTs with similar communities. The exit interview will occur within one month of the last group session. Exit interviews with participants will be conducted by a member of the U-M study team will last approximately 30 minutes, and will be audio-recorded, then transcribed and reviewed for accuracy and to remove any identifying information. Exit interviews may occur in-person at the Ruth Ellis Center or remotely by phone or Zoom. If the exit interview occurs in person it will be conducted in a private room where others cannot overhear them. If the exit interview occurs remotely, when scheduling the interviewer will ask the participant to be in a safe place where others cannot overhear them. Before beginning the interview, the interviewer will confirm the participant is in a safe and private location; if they are not, the interview will be rescheduled. (See "Exit Interview Guide" Appendix.)

VII-7.3 Additional Intervention Fidelity Documentation: U-M study staff will have regular meetings with group session facilitations to gather additional information related to intervention fidelity and acceptability, including which content/activities were covered in the session, what elements went well, what they would consider changing, and what challenges they experienced. This information will be saved in a Word document stored in a secure Dropbox folder only accessible to IRB approved study staff. (See "Secure Group Session Facilitator CRF" Appendix.)

VII-8. Participant Incentives and Other Funds Provided

For every group session participants attend, they will receive $20 for their attendance (up to $240 if all group sessions are attended). Additionally, participants will receive either

transportation to/from Ruth Ellis via Uber or Lyft, or $20 to reimburse them for gas expenses if they provide their own transportation (up to $240). Additionally, food will be provided at each session. To incentivize study activity completion, participants will receive $40 for completing the baseline survey, $40 for the post-program follow up survey, and $50 for the final 3-month follow up survey. Participants will receive $30 for completing an exit interview after completing the *Secure* program. Lastly, if participants complete all assessment activities (i.e., surveys and exit interview), they will receive a $50 completion bonus. In total, participants may receive up to $690 for completing these study activities.

These incentives related to group session attendance and assessment completion are earned separately from the one-time $250 emergency assistance fund transfer and the $1,200 microgrant fund transfer offered in the *Secure* program (total $1,450). In total, participants may earn up to $2,140 through participation in the study. All incentives will be dispersed after each study activity is completed regardless of whether they are randomized to the intervention or waitlist control condition.se

VII-9. Retention Strategies

Our team has extensive experience in retaining TWOC in research studies. Much of our success can be attributed to our community-engaged approach to research efforts, including our collaborations with TSoCP and Ruth Ellis. Using these methods, our prior studies with BIPOC trans women have regularly yielded follow-up rates above 80%-85%. 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 provide multiple forms of contact information after consenting to participate. 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 prevention or care services, 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. At the beginning of the study, participants will be provided with an overview of all study activities, which will be filled in with their approximate follow-up dates and the incentive amount of each activity.

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.

VIII. Data Collection and Management

VIII-1. Data Collection Methods

Data collection is the responsibility of the study trained staff under the supervision of the PI and Co-Investigator/Research Director. Participant identifiable information and data on completion of study specific activities will be recorded in the HIPAA compliant Ripple participant management software. This data will be stored in participant profile cards that will be updated on an ongoing basis throughout the study period. Additional participant data will be collected using

computerized self-report online surveys programmed in Qualtrics. For these surveys, participants will enter their own data (except in the case when the PI or Co-I/Research Director 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 in-depth interviews audio recorded over Zoom or in-person at Ruth Ellis Center and uploaded to a U-M Dropbox folder accessible only to study staff for storage.

VIII-2. Storage and Security

We will utilize Qualtrics programmed surveys (e.g., electronic informed consent, baseline survey, group session feedback survey, post-program survey, and 3-month follow-up survey) and a HIPAA-compliant participant management software called Ripple to capture and track enrolled participant information throughout the RCT. Individuals who are interested in the study and want to see if they are eligible to participate will be sent a unique hyperlink to a Ripple programmed eligibility screener survey. The screener survey will collect the full name of all individuals who consent to screening; for those who are eligible, the participant will be asked to enter their contact information (i.e., email, phone number, address). A participant profile card with these data will be created in the Ripple platform for potential participants who screen eligible, where they will be identified as potential participants and assigned a randomly generated 17-character Study ID number. Study staff will then meet with potential participants either in person or virtually to go through the informed consent process. Documentation of informed consent will be captured using Qualtrics, which will include their randomly assigned Study ID as metadata. After consent is provided potential participants will be able to complete the baseline survey disseminated via email or text message with their Study ID embedded as metadata. At the end of that survey, they will be requested to provide their social security number for U-M HSIP reconciliation purposes, due to the total amount of incentives and program funds provided. Participant social security numbers will be stored in a password protected excel spreadsheet in an access restricted Dropbox folder. Further participant survey assessments (the post-program survey, the 3-month follow-up survey, and the group feedback surveys) will be linked as longitudinal data only through the Study ID metadata included in those Qualtrics surveys.

Potential participants who screen ineligible will be asked if they are interested in hearing about other studies that they may qualify for; those who are will be asked to provide contact information (email address, phone number), which will be retained along with their name in the Ripple database. For potential participants who screen ineligible and do not wish to be contacted for future studies and those who screen eligible but do not provide informed consent to enroll, we will remove any identifiers from the screener data (i.e. email address and/or phone number). We will retain ineligible or non-consenting potential participant profile cards in Ripple to avoid duplicate enrollment attempts during recruitment and we will delete their contact information from the Ripple database at the end of the study. De-identified (and unlinked to assigned 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.

Participant personal identifiable information will be stored in Ripple (www.ripplescience.com), a secure web application designed for the storing and management of personally identifying information of research participants. Ripple was initially developed at the University of Michigan to provide a user-friendly, web-based secure interface where research teams can centralize the storage and management of research participants' personal

information, including name, Study ID, demographics, and study workflow (e.g., group session appointments, date/amount of microgrant fund receipt, date of emergency assistance fund receipt). Participant information managed with Ripple is private and secure. This information is kept in a fully encrypted format inside dedicated databases that are segregated from other Ripple accounts and thus only authorized study staff will have access to the study data. Likewise, Ripple infrastructure complies with the privacy and security guidelines of the HIPAA, including 2048-bit data encryption in transit and at rest, automatic logoff, audit trail, daily backups in triplicate dedicated servers, firewall, custom access permission for lab members, zxcvbn password strength estimation, and enterprise administrative safeguards to prevent unauthorized staff from accessing participant information. Furthermore, Ripple is used only for storing personally identifiable information of participants and is not used to capture other research data (e.g., Qualtrics programmed surveys, exit interviews audio files, etc.). This ensures that the personally identifiable information and research data are segregated. Only IRB approved U-M study staff will have account logins to the Ripple database and will be able to view / edit participant identifiable information for study management purposes.

The baseline and follow up surveys completed by participants will run as web browser applications that will be programmed using Qualtrics. Participants will receive an individual link to access the survey via email or text message. Apart from the eligibility screener survey and the electronic informed consent, participant surveys will not be linked to personally identifiable information and will be encoded with their Study ID number. Participants cannot access or change previously entered data through their individualized Qualtrics survey hyperlinks once they are completed. Survey data will be securely transmitted in real time to server systems managed by Qualtrics using transport layer security (TLS) encryption (also known as HTTPS) and will not be stored locally on the electronic devices that participants use to complete their surveys. Only IRB approved U-M study staff will have access to the Qualtrics account where raw survey responses are stored. Any survey datasets that are downloaded for quality assurance checks or study management purposes will only be temporarily stored on U-M encrypted computer systems. After any necessary work has been completed with the survey datasets, IRB approved staff may store a de-identified Excel spreadsheet in a restricted access Dropbox folder, but they are required to delete the dataset from their individual computer system by moving it to their system's trash bin and clearing the bin before the close-of-business that same day.

We will also conduct a qualitative exit interview with each participant, within one month of their last *Secure* group session. 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 safe, private location where they cannot be overheard by others. The interviewer will ensure they are in a private space where they cannot be overheard by others, and participants will be instructed to refrain from sharing any identifiable participant information during the live interview recording. 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 restricted access Dropbox folder and deleted from the physical recording device. Audio files will be transcribed and then reviewed for accuracy, with any identifying information removed from the transcript. The audio files will be retained until the interviews are thematically analyzed, within one year of completion of data collection, at which point they will be deleted from Dropbox. Fully de-identified transcripts of the exit interviews will be retained for future use in secondary analyses.

Study staff will enter case report form and process evaluation data collected from group session facilitators and mentors into the study designed case report form Word Documents that will be stored in a Dropbox folder only accessible to IRB approved U-M study staff. Any mention of participants in these collected process data will be recorded only in reference to their Study ID and will not include any personal identifying information.

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) With the exception of the eligibility screener survey, the electronic informed consent, and the fund disbursement documentation, all other collected data will only be identified and linked via the 17-character Study ID number and will remain separate no surveys or other data that we collect will contain identifying information. 3) Any hard copy materials 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. Personally identifiable information linking participants to their Study ID number will be stored in Ripple, separate from survey stored in Qualtrics servers and interview data stored in Dropbox that is only demarcated with the participants' Study ID number.

Participant identifiable information will be retained for six months after completion of the study. After this point, all identifiable information except for zip code will be deleted from the Ripple participant software leaving only the Study ID as the linking criteria for all other collected data related to an individual participant. Data coded by Study ID that has been unlinked to participant identifiable information will be retained for secondary analyses, as well as record keeping purposes per NIH grantee requirements for 3 years. We will retain name and contact information (unlinked to any participant data) for participants who consented to being contacted for future research studies, as well as individuals who screen ineligible who indicated they would like to be contacted about future research studies, in an excel file stored in a U-M Dropbox folder, separate from study data, where access is limited to the PI and IRB approved study staff. De-identified quantitative data will be provided to the National Institute of Mental Health Data Archive (NDA) as part of a data sharing agreement required as a condition of funding.

IX. Human Subjects Research Protections

IX-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 Research Protections Program's Institutional Review Board (IRB). The study will also be registered with ClinicalTrials.gov.

IX-2. Inclusion and Exclusion Criteria

IX-2.1 Inclusion criteria. Participants must (1) at least 18 years old; (2) assigned male at birth; (3) self identifies as female, transgender woman, or another feminine gender identity; (4) self identifies as a person of color (i.e., any racial/ethnic identity except non-Hispanic white); (5) reports earning less than $32,800 gross annual income; (6) reports any condomless sex in the past 6 months; (7) lives in Detroit, MI greater metropolitan area (~50 mile radius) as evidenced by a government-issued ID or mailing address; and (8) speaks English.

IX-2.2 Exclusion criteria. Evidence of severe cognitive impairment or active psychosis that may impede ability to provide fully informed consent, determined by U-M study staff and PI Dr. Gamarel in consultation with Dr. Harper.

IX-2.3 Rationale for Involving Proposed Populations. This study targets trans women of color who are HIV-negative, do not know their HIV status, or are living with HIV. This population has been selected due to their high prevalence of HIV infection and limited engagement in HIV prevention and care services and because there are limited culturally responsive, evidence-based, microeconomic interventions to improve HIV prevention 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.

IX-3. Informed Consent

Informed consent will be obtained before conducting any study activities. Participants will access the electronic consent form online via a Qualtrics programmed survey. Participants will be required to complete a remote or in-person informed consent walkthrough with study staff explaining key content presented 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. As part of the informed consent process, study staff will answer any questions that potential participants have and assess their understanding of the information provided. Documentation of informed consent will be collected via the Qualtrics consent form.

IX-4. Risk/Benefit Assessment

IX-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 undue influence.

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 personal finances, stigma, 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) or out their transgender identity by association. However, the risk of breach of confidentiality is also minimal, given the safeguards protecting participants' data. Given the nature of the group-level intervention, there is also the possibility that privacy can be broken by other participants. However, the informed consent and the group session facilitators will continually reinforce the importance of confidentiality at the beginning and throughout each session, and participants will be required to agree to maintain the privacy of other group members prior to joining the group sessions. They will also remind participants that they do not have to share anything in the group sessions that they do not wish to share.

Potential Undue Influence. Given the $1,200 microgrant and $250 emergency assistance funds allotted to enrolled participants, there may be a risk of undue influence associated with participating in the research program. To help mitigate this risk, the microgrant funds will not be advertised during active study recruitment. Additionally, participants will only receive the microgrant payment in the *Secure* intervention once they have developed a concise microbusiness plan with their group session facilitators and assigned mentor to help strategically use the funds. In this way, the microgrant is not provided without the participant's thoughtful engagement with the *Secure* program's professionalization content and guided utility of the funds. Lastly, the $250 emergency assistance is an active social service that is provided by TSoCP in the Detroit community and would be available whether or not a BIPOC trans woman of color enrolled in *Secure* study.

IX-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, psychological discomfort, and undue influence. 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 exit interviews, during the intervention group sessions, and during survey assessments. Participants experiencing mild distress during the group sessions, surveys, or exit interviews will be offered to take a small break or to reschedule at a later date. In the unlikely event that a participant experiences considerable distress, they will be offered a voluntary suicide risk assessment and appropriate referral. (See "Suicide Risk Assessment" Appendix.) If any person is judged by the 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 U-M staff will receive yearly training for identifying suicide risk, and Ruth Ellis staff / TSoCP members who will be the program facilitators are trained on 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 gender affirmation support groups. (See “Detroit Area Resource List” Appendix.) 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 the confidentiality guidelines and standards that structure this project.

All participant survey data and exit interview audio files will be linked by a unique individual Study ID number. Personal identifiable information (e.g., first and last name, email address, phone number, social media accounts, external family or friend contacts, etc.) will be stored in our HIPAA compliant participant management software, Ripple, and will only be accessible to authorized IRB-approved members of the study team. The social security numbers collected for HSIP reconciliation of incentives will be stored in a password protected Excel spreadsheet kept in a restricted access Dropbox folder. Other data collected from participants such as the Qualtrics surveys or exit interviews will be stored separately from personally identifiable data. Records will be kept confidential to the level allowed by law and only IRB approved 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.

The ability to link personally identifiable information to the other participant data labelled only with the Study ID number will be managed by user role access to the Ripple participant management platform. No released presentation or publications will identify study participants individually. Because this study is funded by the National Institutes of Health, data collected in this study is automatically covered by a Certificate of Confidentiality. 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 informed consent walkthrough. The U-M 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, who have agreed not to identify specific study participants, and who will destroy or return dataset information after completing their analyses. These shared dataset files will be uploaded to shared Dropbox folders with access restricted only to those researchers requiring access. 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. During the informed consent walkthrough, participants will be informed that the study will involve participating in group sessions with other shared identity 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 group session facilitators will continually reinforce the

importance of keeping information shared within the group private at the beginning of the study and throughout each group session. Participants will be required to agree to keeping other participants' information private and confidential before joining the group sessions. 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. Group sessions will occur in a private room at the Ruth Ellis Center.

Minimizing potential for undue influence. Any study that pays a stipend may engender undue influence. Eliminating this possibility 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 ensure 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. The group session study visit stipends proposed are in use in similar HIV prevention studies and have been reviewed by our own and other IRBs for potential undue influence.

In addition to typical incentives for completing study activities, this study includes a microeconomic intervention. The $1,200 microgrant is in alignment with the first stimulus check and MPI Jennings Mayo-Wilson's promising NIH-funded pilot study (a similar microeconomic intervention that provided group sessions and a microgrant to African American youth in Baltimore), which serves as the basis for the current project. The microgrant funds associated with the *Secure* program will not be advertised during recruitment. The $250 in emergency assistance funds that will be provided to participants is an existing community service that is available regardless of participation in this study.

IX-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 the Detroit metro area. Participants may improve their engagement in HIV prevention or HIV 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 gender affirmation and HIV services. Additionally, the professionalization content and microgrant funds provided by the *Secure* program may help participants initiate microbusiness development and improve personal financial status. Participants in our previous studies have indicated that they benefited from the opportunity to participate in group-based research studies with other BIPOC trans women, and that the prospect of providing information for the possible future benefit of BIPOC trans women 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 test culturally-relevant evidence-based microeconomic interventions to improve engagement in the HIV continuum of prevention and care among BIPOC trans women.

IX-4.4. Importance of the knowledge to be gained

The proposed study has the potential for high public health impact by evaluating the acceptability and feasibility of an adapted, evidence-based microeconomic intervention to

address health outcomes among a highly vulnerable and overlooked population disproportionately impacted by HIV. Our focus on BIPOC trans women is in line with the prioritization of sexual and gender minority communities for health disparities research, as well as the strategies of the new EHE plan for ending the U.S. HIV epidemic. Findings also have the potential to provide a "blueprint" to guide future intervention implementation efforts with BIPOC trans women who are often embedded in close-knit communities with few existing services. Given the substantial health risks associated with documented inequities in HIV outcomes and the relatively minor risks to participants, the importance of the potential knowledge to be gained relative to the participant risk is favorable.

IX-5. Study Withdrawal and Discontinuation

A participant may be discontinued from the study at any time if the participant, the MPIs, 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.
- Participant creates a hostile environment for study staff.
- Sponsor request for early termination of study.

X. Data Safety and Monitoring Plan

X-1. Safety and Monitoring

The study MPIs Dr. Gamarel and Dr. Jennings Mayo-Wilson will conduct oversight of internal monitoring of participants' safety and data integrity. The MPIs will also be supported by Co-Investigators Laura Jadwin-Cakmak and Dr. Gary Harper who will participate in the development and administration of the data and safety monitoring plan. The study team has extensive experience with HIV prevention clinical trials. The MPIs 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 U-M policies.

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

X-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; of unanticipated problems involving risk to participants; of serious or continuing non-compliance; and of protocol violations. (See "Adverse Event and Unanticipated Problems Log" Appendix.)

X-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. MPIs will ultimately be responsible for participant safety, protocol violations, and ongoing evaluation of the study's progress. If necessary, MPIs will make appropriate recommendations for changes in protocol. The U-M IRB will conduct the monitoring at the continuing reviews as scheduled, whenever modification requests are considered, and upon receiving reports of adverse events (AEs) and serious adverse events (SAEs) from the MPIs or anyone else. The NIMH PO will monitor the study upon receipt of annual progress reports and whenever other information is received.

X-4. Adverse Events

We define AEs and SAEs as follows: An AE is any unfavorable and unintended diagnosis, symptom, 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 MPIs deem to represent significant hazards.

X-5. Reporting Plan

All AEs and SAEs will be reported regardless of their relationship to the study intervention. The study team will document all AEs and unanticipated problems. We will detect AEs and SAEs during participant visits and via survey responses and exit interviews. 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 U-M IRB. The U-M PI or Project Director will prepare the appropriate IRB documentation and review it with MPIs 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 U-M 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, PI or Co-I 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 U-M IRB.

MPIs 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. MPIs 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 MPIs learning of the event. Deaths related to study participation will be reported within 5 business days of learning of the event by MPIs 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 because 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. 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.

X. List of Appendices / Study Documents

- Recruitment materials
  - Social media post
  - Print flyer
- Eligibility screener script
- Eligibility screener survey
- Informed Consent Script
- Informed Consent Document
- Randomization Survey
- Baseline Survey
- Group Sessions
- Group Session Feedback Survey
- Microgrant Disbursement Form
- Emergency Assistance Disbursement Form
- Follow Up Survey
- Exit Interview Guide
- Secure Group Session Facilitator Guide
- Suicide Risk Assessment
- Detroit Area Resources

XI. Amendments

This space in the protocol will be used to document any future amendments.

XI-1. Ame00148836

This amendment includes minor changes to the eligibility screening survey and eligibility screening script, the baseline and follow up surveys, and the exit interview guide. We have also added two documents in Section 44: a template to capture any social harms reported by participants throughout the course of the study that do not rise to the level of an adverse event, and a post-group session facilitator fidelity and feedback survey that will be completed by intervention facilitators (not participants) after each group session. These changes and justification for each proposed change are described below. The study protocol has not been updated, as the proposed changes do not alter the procedures described in the study protocol.

In Section 8-1. Recruitment, we have made a minor update to the Eligibility Screener Script to make sure participants are aware that we will ask them about their identity, income, and sexual behavior in the eligibility screener. Also in Section 8-1 we have updated the Eligibility Screening Survey to remove the question that asks participants about HIV status, because HIV status is not an eligibility criterion (the study is HIV status-neutral and includes those living with HIV, those not living with HIV, and those who are unsure of their status), and in response to feedback that community members are not comfortable answering this question until after they have completed the informed consent process.

In Section 29.1, we have made updates to the Baseline Survey and Follow Up Survey. None of the constructs measured have been changed, though we altered some of the measures used to assess the constructs to align more closely with other NIH network studies. We also cut some items because in testing the survey was taking more than the allotted time as described in the consent form. Lastly, we made minor edits to the exit interview guide, to make questions more open-ended, and to ensure we are learning about any potential social harms participants may have experienced that were not reported to facilitators or the research team previously.

Lastly, in Section 44. Additional Documents, we have included a template on which any social harms reported by participants due to their participation in the study (e.g., losing their microgrant funds) that do not rise to the level of an adverse event will be recorded. Additionally, we have added a post-group session facilitator fidelity and feedback survey to Section 44. This survey will not be taken by participants, but instead used by facilitators to indicate fidelity to and feedback regarding group session content. Lastly, track changed documents of all documents updated in this amendment have been uploaded to Section 44.

XI-2. Ame00156620

This amendment is to update the study team (Section 1.3), adding research staff member. They will both assist with data management.

XI-3. Ame00157187

This amendment is to update the study team (section 1.3), adding a research staff member. They will assist with analyzing exit interview data.

XI-4. Ame00160383

This amendment is to reduce the number of intervention group sessions and remove the exit interview received by the waitlist control group (described in the protocol, Section 5.1.1).

We propose to reduce the number of group sessions provided to the waitlist control condition from 12 sessions to 5 sessions. All waitlist control participants are currently receiving the intervention. They have received a majority of the intervention components, including four group sessions, connection to a mentor for mentorship, and the microgrant payments totaling $1,200 to invest in their business or other professional development goals.

NIH originally funded this study as an RCT where the control condition received only standard of care, which consists of programs currently available in community settings. We proposed and received approval from NIH to alter the study design so that we also provided the SeCuRE intervention to the control group using a waitlist design, and planned to use PI's discretionary funds to cover the additional expenses. We have now completed all research activities that were originally proposed to and approved by NIH – that is, we completed enrollment, the intervention condition received the SeCuRE intervention and completed an exit interview, and all participants completed the baseline and follow up surveys.

Our research team has been greatly affected by multiple grant terminations. Because of this, we no longer have sufficient funds to finish the remaining group sessions and conduct exit interviews for the waitlist control group, which is leading us to submit this amendment.

XII. References

1. Bailey M, Trudy. On misogynoir: citation, erasure, and plagiarism. *Feminist Media Studies.* 2018:1-7.
2. Wirtz AL, Poteat T, Malik M, Glass N. Gender-based violence against transgender people in the United States: A call for research and programming. *Trauma, Violence, & Abuse.* 2018:1-15. PMID: 29439615
3. Palazzolo SL, Yamanis TJ, et al. Documentation status a contexual determinent of HIV risk among young transgender Latinas. *LGBT Health.* 2016;3(2):132-138.
4. Fletcher JB, Kisler KA, Reback CJ. Housing status and HIVrisk behaviors among transgender women in Los Angeles. *Arch Sex Behav* 2014;43:1651-1661.
5. Operario D, Nemoto T. HIV in transgender communities: Syndemic dynamics and a need for multicomponent interventions. *J Acquir Immune Defic Syndr.* 2010;55:S91-S93.
6. Badgett MVL, Choi SK, Wilson BDM. *LGBT Poverty in the United States: A study of differences between sexual orientation and gender identity groups.* UCLA Williams Institute; October 2019 2019.
7. University of Michigan Institute for Research on Women & Gender. Empowering the Love Her Collective: Participatory reesarch with and for transgender women of color. 2021. https://irwg.umich.edu/news/empowering-love-her-collective. Accessed August 20, 2021.
8. Richmond KA, Burnes T, Carroll K. Lost in trans-lation: Interpreting systems of trauma for transgender clients. *Traumatology.* 2012;18(1):45-57.
9. Smith LR, Yore J, Triplett DP, Urada L, Nemoto T, Raj A. Impact of Sexual Violence Across the Lifespan on HIV Risk Behaviors Among Transgender Women and Cisgender People Living With HIV. *J Acquir Immune Defic Syndr.* 2017;75(4):408-416.
10. Jennings Mayo-Wilson L, Benotsch EG, Grigsby SR, et al. Combined effects of gender affirmation and economic hardship on vulnerability to HIV: a qualitative analysis among US adult transgender women. *BMC Public Health.* 2020;20:1-17. PMC7249630
11. Sevelius J, Patouhas E, Keatley J, Johnson M. Barriers and facilitators to engagement and retention in care among transgender women living with Human Immunodeficiency virus. *Ann Behav Med.* 2014;47(1):5-16.
12. Sevelius JM. Gender affirmation: a framework for conceptualizing risk behavior among transgender women of color. *Sex roles.* 2013;68(11-12):675-689.
13. Sevelius JM, Keatley J, Calma N, Arnold E. 'I am not a man': Trans-specific barriers and facilitators to PrEP acceptability among transgender women. *Global Public Health.* 2016.
14. Baral SD, Poteat T, Stromdahl S, Wirtz AL, Guadamuz TE, Beyrer C. Worldwide burden of HIV in transgender women: a systematic review and meta-analysis. *Lancet Infect Dis.* 2013;13(3):214-222. PMID23260128
15. Becasen JS, Denard CL, Mullins MM, Higa DH, Sipe TA. Estimating the prevalence of HIV and sexual behaviors among the US transgender population: A systematic review and meta-analysis, 2006–2017. *Am J Public Health.* 2019;109(1):e1-e8.
16. Song W, Mulatu MS, Rao S, Wang G, Kudon H, Z.,, O'Connor K. HIV partner service delivery among transgender women—United States, 2013—2017. *MMWR Morb Mortal Wkly Rep.* 2020;69(2):35-39.
17. Herbst J, Jacobs E, Finlayson T, McKleroy V, Neumann M, Crepaz N. Estimating HIV prevalence and risk behaviors of transgender persons in the United States: A systematic review. *AIDS Behav.* 2008;12(1):1-17.
18. Clark H, Babu AS, Wiewel EW, Opoku J, Crepaz N. Diagnosed HIV infection in transgender adults and adolescents: results from the National HIV Surveillance System, 2009–2014. *AIDS Behav.* 2017;21(9):2774-2783.

19. Arrivillaga M, Salcedo JP. A systematic review of microfinance-based interventions for HIV/AIDS prevention. *AIDS Educat Prev.* 2014;26(1):13-27.
20. Knoppow ES. Trans Sistas of Color Project distributes care packages to those in need because of COVID-19. *Pride Source*2020. https://pridesource.com/article/trans-sistas-of-color-project-distributes-care-packages-to-those-in-need-because-of-covid-19/#:~:text=As%20of%20Saturday%2C%20in%20response,unstable%20housing%20and%20the%20elderly. Accessed April 11, 2021.
21. Mayo-Wilson LJ, Coleman J, Timbo F, et al. Acceptability of a feasibility randomized clinical trial of a microenterprise intervention to reduce sexual risk behaviors and increase employment and HIV preventive practices (EMERGE) in young adults: a mixed methods assessment. *BMC Public Health.* 2020;20(1):1-16. PMC7709242
22. Mayo-Wilson LJ, Glass NE, Ssewamala FM, et al. Microenterprise intervention to reduce sexual risk behaviors and increase employment and HIV preventive practices in economically-vulnerable African-American young adults (EMERGE): protocol for a feasibility randomized clinical trial. *Trials.* 2019;20(1):1-14. PMC6637550
23. Jennings Mayo-Wilson L, Coleman J, Timbo F, et al. Microenterprise Intervention to Reduce Sexual Risk Behaviors and Increase Employment and HIV Preventive Practices Among Economically-Vulnerable African-American Young Adults (EMERGE): A Feasibility Randomized Clinical Trial. *AIDS Behav.* 2020;24:3545-3561. PMC7667139
24. End the HIV Epidemic. 2020. https://www.hrsa.gov/ending-hiv-epidemic#:~:text=Background,fewer%20than%203%2C000%20per%20year. Accessed April 11, 2021.
25. NIH Strategic Plan for HIV and HIV-related Research. 2021. https://www.oar.nih.gov/sites/default/files/NIH_StrategicPlan_FY2021-2025.pdf. Accessed May 20, 2021.
26. Gamarel KE, Jadwin-Cakmak L, King WM, et al. Stigma experienced by transgender women of color in their dating and romantic relationships: Implications for gender-based violence prevention programs. *J Interpers Violence.* in press. PMC816464638
27. Sevelius JM, Gutierrez-Mock L, Zamudio-Haas S, et al. Research with Marginalized Communities: Challenges to Continuity During the COVID-19 Pandemic. *AIDS Behav.* 2020:1. PMC7228861
28. Kucharski E. Fair Michigan hosts transgender name change clinic. In: Pride Souce; 2019. https://pridesource.com/article/fair-michigan-hosts-transgender-name-change-clinics/ Accesed April 11, 2021.
29. Wingood GM, DiClemente RJ. The ADAPT-ITT model: a novel method of adapting evidence-based HIV Interventions. *J Acquir Immune Defic Syndr.* 2008;47:S40-S46.
30. Trammell R, Burks C, Campbell BA, et al. Love Her Collective: Utilizing paticipatory-based research principles to improve the lives of trans women of color in Detroit, Michigan. Oral Presentation presented at National Transgender Health Summit; April 13, 2019, 2019; Oakland, CA.
31. Healthy People 2020. Lesbian, Gay, Bisexual, and Transgender Health. https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health. Accessed March 27, 2019.
32. Pérez-Stable EJ. Sexual and Gender Minorities Formally Designated as a Health Disparity Population for Research Purposes. 2016; https://www.nimhd.nih.gov/about/directors-corner/messages/message_10-06-16.html. Accessed March 27, 2019.
33. Poteat T, German D, Kerrigan D. Managing uncertainty: a grounded theory of stigma in transgender health care encounters. *Soc Sci Med.* 2013;84:22-29. PMID: 23517700

34. Diagnoses of HIV Infection in the United States and Dependent Areas, 2018: Transgender Persons. 2020. https://www.cdc.gov/hiv/library/reports/hiv-surveillance/vol-31/content/transgender.html Accessed April 11, 2021.
35. McNairy M, El-Sadr W. A paradigm shift: focus on the HIV prevention continuum. *Clin Infect Dis.* 2014;59(suppl_1):S12-S15.
36. Horn T, Sherwood J, Remien RH, et al. Towards an integrated primary and secondary HIV prevention continuum for the United States: a cyclical process model. *J Inter AIDS Soc.* 2016;19(1):21263.
37. Kay ES, Batey DS, Mugavero MJ. The HIV treatment cascade and care continuum: updates, goals, and recommendations for the future. *AIDS Res Therapy.* 2016;13(1):1-7.
38. Reisner SL, Jadwin-Cakmak L, Hughto JMW, Martinez M, Salomon L, Harper GW. Characterizing the HIV Prevention and Care Continua in a Sample of Transgender Youth in the US. *AIDS Behav.* 2017;21(12):3312-3327. PMC5795332
39. Bukowski LA, Chandler CJ, Creasy SL, Matthews DD, Friedman MR, Stall RD. Characterizing the HIV Care Continuum and Identifying Barriers and Facilitators to HIV Diagnosis and Viral Suppression Among Black Transgender Women in the United States. *J Acquir Immune Defic Syndr.* 2018;79(4):413-420.
40. Pitasi MA, Oraka E, Clark H, Town M, DiNenno EA. HIV testing among transgender women and men—27 states and Guam, 2014–2015. *MMWR Morb Mortal Wkly Rep.* 2017;66(33):883.
41. Kuhns LM, Reisner SL, Mimiaga MJ, Gayles T, Shelenich M, Garofalo R. Correlates of PrEP indication in a multi-site cohort of young HIV-uninfected transgender women. *AIDS Behav.* 2016;20(7):1470-1477.
42. Poteat T, Wirtz A, Malik M, et al. A gap between willingness and uptake: findings from mixed methods research on HIV prevention among black and Latina transgender women. *J Acquir Immune Defic Syndr* 2019;82(2):131. PMC7807529
43. Schulden J, Song B, Barros A, et al. Rapid HIV testing in transgender comunities by community-based organizations in three cities. *Public Health Rep.* 2008;123(Supplement 3):101-114.
44. Grant RM, Anderson PL, McMahan V, et al. Uptake of pre-exposure prophylaxis, sexual practices, and HIV incidence in men and transgender women who have sex with men: a cohort study. 2014(1474-4457 (Electronic)).
45. Deutsch M, Glidden D, Sevelius J, et al. Preexposure chemoprophylaxis for HIV prevention in transgender women: A subgroup analysis of the iPrEx trial. *Lancet HIV.* 2015;2(12):512-519.
46. Millett GA, Peterson JL, Flores SA, et al. Comparison of disparities and risks of HIV infections in black and other men who have sex with men in Canada, UK, and USA: a meta-analyses. *Lancet.* 2012;380(9839):341-348.
47. Vermund SH. The contiuum of HIV Care in the Urban United States: Black men who have sex with men (MSM) are less likely than white MSM to receive antiretroviral therapy. *J Infect Dis.* 2017;216(7):790-794.
48. Gebo KA, Fleishman JA, Conviser R, et al. Racial and gender disparities in receipt of highly active antiretroviral therapy persist in a multistate sample of HIV patients in 2001. *J Acquir Immune Defic Syndr.* 2005;38(1):96-103.
49. Thrasher AD, Earp JAL, Golin CE, Zimmer CR. Discrimination, distrust, and racial/ethnic disparities in antiretroviral therapy adherence among a national sample of HIV-infected patients. *J Acquir Immune Defic Syndr.* 2008;49(1):84-93.
50. Mugavero MJ, Lin H-Y, Allison JJ, et al. Racial disparities in HIV virologic failure: do missed visits matter? *J Acquir Immune Defic Syndr.* 2009;50(1):100.

51. Kalichman SC, Hernandez D, Finneran S, Price D, Driver R. Transgender women and HIV-related health disparities: falling off the HIV treatment cascade. *Sexual Health.* 2017;14(5):469-476.
52. Jin H, Restar A, Biello K, et al. Burden of HIV among young transgender women: factors associated with HIV infection and HIV treatment engagement. *AIDS Care.* 2019;31(1):125-130.
53. Clark K, Fletcher JB, Holloway IW, Reback CJ. Structural inequities and social networks impact hormone use and misuse among transgender women in Los Angeles County. *Arch Sex Behav.* 2018;47(4):953-962.
54. Gamarel KE, Reisner SL, Laurenceau J-P, Nemoto T, Operario D. Gender minority stress, mental health, and relationship quality: A dyadic investigator of transgender women and their cisgender male partners. *J Fam Psychol.* 2014;28(4):437-447. PMC4122619
55. da Silva DT, Bouris A, Voisin D, Hotton A, Brewer R, Schneider J. Social networks moderate the syndemic effect of psychosocial and structural factors on HIV risk among young black transgender women and men who have sex with men. *AIDS Behav.* 2020;24(1):192-205.
56. Hill BJ, Crosby R, Bouris A, et al. Exploring transgender legal name change as a potential structural intervention for mitigating social determinants of health among transgender women of color. *Sex Res Social Policy.* 2018;15(1):25-33.
57. Lacombe-Duncan A, Newman PA, Bauer GR, et al. Gender-affirming healthcare experiences and medical transition among transgender women living with HIV: a mixed-methods study. *Sexual health.* 2019;16(4):367-376.
58. Kuhns LM, Hotton AL, Perloff J, et al. Evaluation of Translife care: an intervention to address social determinants of engagement in HIV care among transgender women of color. *AIDS Behav.* 2019:1-7.
59. Raiford JL, Hall GJ, Taylor RD, Bimbi DS, Parsons JT. The role of structural barriers in risky sexual behavior, victimization and readiness to change HIV/STI-related risk behavior among transgender women. *AIDS Behav.* 2016;20(10):2212-2221.
60. James S, Herman J, Rankin S, Keisling M, Mottet L, Anafi M. The report of the 2015 US transgender survey. 2016.
61. Wilson EC, Turner C, Arayasirikul S, et al. Housing and income effects on HIV-related health outcomes in the San Francisco Bay Area–findings from the SPNS transwomen of color initiative. *AIDS Care.* 2018;30(11):1356-1359.
62. Golub SA, Gamarel KE. The impact of anticipated HIV stigma on delays in HIV testing behaviors: Findings from a community-based sample of men who have sex with men and transgender women in New York City. *AIDS Patient Care STDS.* 2013;27(11):621-627. PMC3820140
63. Golub SA, Gamarel KE, Rendina HJ, Surace A, Lelutiu-Weinberger C. From efficacy to effectiveness: Facilitators and barriers to PrEP acceptability and motivations for adherence among MSM and transgender women in New York City. *AIDS Patient Care STDs.* 2013;27(4):248-254. PMC3624632
64. Hotton AL, Perloff J, Paul J, et al. Patterns of exposure to socio-structural stressors and HIV care engagement among transgender women of color. *AIDS Behav.* 2020;24(11):3155-3163.
65. CDC. Characteristics Associated with HIV Infection Among Heterosexuals in Urban Areas with High AIDS Prevalence — 24 Cities, United States, 2006–2007. Center for Disease Control and Prevention (CDC). *Morbidity and Mortality Weekly Report (MMWR).* 2011;60(31):1045-1072.
66. CDC. Today's HIV/AIDS Epidemic - December 2013. *Center for Disease Control and Prevention.* 2013:1-4.

67. Reisner SL, Bailey Z, Sevelius J. Racial/ethnic disparities in history of incarceration, experiences of victimization, and associated health indicators among transgender women in the US. *Women Health.* 2014;54(8):750-767.
68. Quinn VP, Nash R, Hunkeler E, et al. Cohort profile: Study of Transition, Outcomes and Gender (STRONG) to assess health status of transgender people. *BMJ Open.* 2017;7(12):e018121.
69. Deutsch MB. Gender-affirming surgeries in the era of insurance coverage: developing a framework for psychosocial support and care navigation in the perioperative period. *J Health Care Poor Underserved.* 2016;27(2):386-391.
70. Haas AP, Eliason M, Mays VM, et al. Suicide and suicide risk in lesbian, gay, bisexual, and transgender populations: Review and recommendations. *J Homosex.* 2010;58(1):10-51.
71. Brown TNT, Herman J. Voter ID laws and their added costs for transgender voters. *Williams Institute.* 2016.
72. Bradford J, Reisner SL, Honnold JA, Xavier J. Experiences of transgender-related discrimination and implications for health: results from the Virginia Transgender Health Initiative Study. *Am J Public Health.* 2013;103(10):1820-1829.
73. Reisner SL, Chaudhry A, Cooney E, Garrison-Desany H, Juarez-Chavez E, Wirtz AL. 'It all dials back to safety': A qualitative study of social and economic vulnerabilities among transgender women participating in HIV research in the USA. *BMJ Open.* 2020;10(1):e029852.
74. MacCarthy S, Izenberg M, Barreras JL, Brooks RA, Gonzalez A, Linnemayr S. Rapid mixed-methods assessment of COVID-19 impact on Latinx sexual minority men and Latinx transgender women. *PloS one.* 2020;15(12):e0244421.
75. Poteat TC, Reisner SL, Miller M, Wirtz AL. Vulnerability to COVID-19-related Harms Among Transgender Women With and Without HIV Infection in the Eastern and Southern US. *J Acquir Immune Defic Syndr.* 2020;85(4):e67-e69. PMC7722524
76. SF mayor's budget includes $4 million for trans, HIV subsidies over 2 years. 2020. https://www.ebar.com/news/news//296268 Accessed April 11, 2021.
77. Washtenaw County prosecuter partners with the LGBTQ justifice project. 2021. https://www.mlive.com/news/ann-arbor/2021/03/washtenaw-county-prosecutor-partners-with-lgbtq-justice-project.html. Accesed April 11, 2021.
78. Activist Jeyne Poindexter is fighting for Black trans women. 2020. https://www.hourdetroit.com/community/activist-jeynce-poindexter-is-fighting-for-a-seat-at-the-blm-table-for-black-trans-women/ Accessed April 11, 2021.
79. Trans Sistas of Color Project distributes care packages to those in need because of COVID-19. 2020.
80. Resourcing trans-led organizations and building power for trans communities. 2020. https://nonprofitquarterly.org/resourcing-trans-led-organizations-and-building-power-for-trans-communities/. Accessed April 11, 2021.
81. Eqaulity NCfT. COVID-19 Mutual Aid and Emergency Funds. 2021; https://transequality.org/covid19/mutual-aid-and-emergency-funds. Accessed April 11, 2021.
82. Sherman S, Hunter K,. Evidence-based structural interventions for HIV prevention: microenterprise and vulnerable populations. In: *Structural Interventions for HIV Prevention: Optimizing Strategies for Reducing New Infections and Improving Care.* Oxford University Press; 2018:179-190.
83. Kim J, Ferrari G, Abramsky T, et al. Assessing the incremental effects of combining economic and health interventions: the IMAGE study in South Africa. *Bull World Health Organ.* 2009;87(11):824-832.

84. Pronyk PM, Kim JC, Abramsky T, et al. A combined microfinance and training intervention can reduce HIV risk behaviour in young female participants. *AIDS.* 2008;22(13):1659-1665.
85. Boungou Bazika JC. Effectiveness of small scale income generating activities in reducing risk of HIV in youth in the Republic of Congo. *AIDS Care.* 2007;19 Suppl 1:S23-24.
86. Odek WO, Busza J, Morris CN, Cleland J, Ngugi EN, Ferguson AG. Effects of micro-enterprise services on HIV risk behaviour among female sex workers in Kenya's urban slums. *AIDS Behav.* 2009;13(3):449-461.
87. Rosenberg MS, Seavey BK, Jules R, Kershaw TS. The role of a microfinance program on HIV risk behavior among Haitian women. *AIDS Behav.* 2011;15(5):911-918.
88. Ssewamala FM, Dvalishvili D, Mellins CA, et al. The long-term effects of a family based economic empowerment intervention (Suubi+ Adherence) on suppression of HIV viral loads among adolescents living with HIV in southern Uganda: Findings from 5-year cluster randomized trial. *Plos One.* 2020;15(2):e0228370. PMC7010288
89. Ssewamala FM, Han CK, Neilands TB, Ismayilova L, Sperber E. Effect of economic assets on sexual risk-taking intentions among orphaned adolescents in Uganda. *Am J Public Health.* 2010;100(3):483-488. PMC2820050
90. Ssewamala FM, Ismayilova L, McKay M, Sperber E, Bannon W, Jr., Alicea S. Gender and the effects of an economic empowerment program on attitudes toward sexual risk-taking among AIDS-orphaned adolescent youth in Uganda. *J Adoles Health.* 2010;46(4):372-378.
91. Sherman SG, Srikrishnan AK, Rivett KA, Liu SH, Solomon S, Celentano DD. Acceptability of a microenterprise intervention among female sex workers in Chennai, India. *AIDS Behav.* 2010;14(3):649-657.
92. Cui RR, Lee R, Thirumurthy H, Muessig KE, Tucker JD. Microenterprise development interventions for sexual risk reduction: a systematic review. *AIDS Behav.* 2013;17(9):2864-2877.
93. Jennings L. Do men need empowering too? A systematic review of entrepreneurial education and microenterprise development on health disparities among inner-city black male youth. *J Urban Health.* 2014;91(5):836-850. PMC4199443
94. Gamarel KE, King WM, Mouzoon R, et al. A “tax” on gender affirmation and safety: costs and benefits of intranational migration for transgender young adults in the San Francisco Bay area. *Cult Health Sex.* 2020:1-16. PMC7956137
95. Nadal KL, Davidoff KC, Fujii-Doe W. Transgender women and the sex work industry: Roots in systemic, institutional, and interpersonal discrimination. *J Trauma Dissociation.* 2014;15(2):169-183.
96. Reisner SL, Hughto JMW, Dunham EE, et al. Legal protections in public accommodations settings: A critical public health issue for transgender and gender-nonconforming people. *Milbank Quart.* 2015;93(3):484-515.
97. White Hughto JM, Pachankis JE, Willie TC, Reisner SL. Victimization and depressive symptomology in transgender adults: The mediating role of avoidant coping. *J Counsel Psychol.* 2017;64(1):41.
98. White Hughto JM, Reisner SL, Pachankis JE. Transgender stigma and health: A critical review of stigma determinants, mechanisms, and interventions. *Soc Sci Med.* 2015;147:222-231.
99. Jennings L, Shore D, Strohminger N, Allison B. Entrepreneurial development for US minority homeless and unstably housed youth: A qualitative inquiry on value, barriers, and impact on health. *Childr Youth Serv Rev.* 2015;49:39-47.
100. Poteat T, Jennings Mayo-Wilson L, Pereira N, Wright BN, Smout SA. US transgender women’s preferences for microeconomic interventions to address structural

determinants of HIV vulnerability: a qualitative assessment. *BMC Public Health.* 2021;21(1):1-15. PMC8281671
101. Reisner SL, Jadwin-Cakmak L, Sava L, Liu S, Harper GW. Situated Vulnerabilities, Sexual Risk, and Sexually Transmitted Infections' Diagnoses in a Sample of Transgender Youth in the United States. *AIDS Patient Care STDS.* 2019;33(3):120-130. PMC6442265
102. Trauma-informed approach and trauma-specific interventions. 2017. https://www.samhsa.gov/nctic/trauma-interventions. Accessed August 20, 2021.
103. Garcia J, Parker C, Parker RG, Wilson PA, Philbin M, Hirsch JS. Psychosocial Implications of Homophobia and HIV Stigma in Social Support Networks: Insights for High-Impact HIV Prevention Among Black Men Who Have Sex With Men. *Health Educat Behav.* 2016;43(2):217-225.
104. Kelly JA, St Lawrence JS, Diaz YE, et al. HIV risk behavior reduction following intervention with key opinion leaders of population: an experimental analysis. *Am J Public Health.* 1991;81(2):168-171.
105. Dworkin SL, Blankenship K. Microfinance and HIV/AIDS prevention: assessing its promise and limitations. *AIDS Behav.* 2009;13(3):462-469.
106. Stratford D, Mizuno Y, Williams K, Courtenay-Quirk C, O'leary A. Addressing poverty as risk for disease: recommendations from CDC's consultation on microenterprise as HIV prevention. *Public Health Rep.* 2008;123(1):9-20.
107. Jennings L, Lee N, Shore D, et al. US minority homeless youth's access to and use of mobile phones: Implications for mHealth intervention design. *J Health Commun.* 2016;21(7):725-733. PMID: 27232544
108. Myers JE, Braunstein SL, Xia Q, et al. Redefining prevention and care: a status-neutral approach to HIV. Paper presented at: open forum infectious diseases 2018.
109. Operario D, Kuo C, Sosa-Rubí SG, Gálarraga O. Conditional economic incentives for reducing HIV risk behaviors: integration of psychology and behavioral economics. *Health Psychology.* 2013;32(9):932.
110. Gamarel KE, Reyes LA, Trammell R, Jennings Mayo-Wilson, L, Neilands, T.B., Reyes, L.A.. Identifying and addressing economic vulnerability in public health programs with, for, and by transgender women of color in Detroit. American Public Health Association; 2021; Denver, CO.
111. Operario D, Gamarel KE, Iwamoto M, et al. Couples-focused prevention program to reduce HIV risk among transgender women and their primary male partners: Feasibility and promise of the Couples HIV Intervention Program. *AIDS Behav.* 2016. PMC5179320
112. Michigan Department of Community Health. *Annual HIV Surveillance Report for Michigan.* 2016.
113. Rosenberg ES, Millett GA, Sullivan PS, del Rio C, Curran JW. Understanding the HIV disparities between black and white men who have sex with men in the USA using the HIV care continuum: a modelling study. *Lancet.* 2014;1:e112-118.
114. Guest G, Namey M, Chen M. A simple method to assess and report thematic saturation in qualitative research. *PLoS One.* 2020;15(5):e0232076.
115. Gamarel KE, Comfort ML, Wood T, Neilands TB, Johnson MO. A qualitative analysis of male couples' coping with HIV: Disentangling the "we". *J Health Psychol.* 2016;21(10):2125-2137. PMC4815963
116. Golub SA, Gamarel KE, Surace A. Demographic differences in PrEP-related stereotypes: Implications for implementation. *AIDS Behav.* 2017;21(5):1229-1235. PMC4701641
117. Radix A, Lelutiu-Weinberger C, Gamarel KE. Satisfaction and health care utilization of transgender and gender non-comforming individuals in NYC: A community-based participatory study. *LGBT Health.* 2014;1(4):302-308. PMID: 26789858

118. Saberi P, Gamarel KE, Neilands TB, et al. Ambiguity, ambivalence, and apprehension of taking HIV-1 pre-exposure prophylaxis among male couples in San Francisco: A mixed methods study. *PLoS ONE.* 2012;7(11):e50061. PMC3498189
119. Nemoto T, Operario D, Keatley J, Villegas D. Social context of HIV risk behaviors among male-to-female transgender of colour. *AIDS Care.* 2004;16(6):724-735.
120. Srivastava A, Thompson SB. Framework Analysis: A Qualitative Methodology for Applied Policy Research. *J Admin Gov.* 2009;42(2):72-79.
121. Bauermeister JA, Goldenberg T, Connochie D, Jadwin-Cakmak L, Stephenson R. Psychosocial Disparities Among Racial/Ethnic Minority Transgender Young Adults and Young Men Who Have Sex with Men Living in Detroit. *Transgend Health.* 2016;1(1):279-290. PMC5549380
122. Gamarel KE, Darbes LA, Hightow-Weidman L, Sullivan P, Stephenson R. The Development and Testing of a Relationship Skills Intervention to Improve HIV Prevention Uptake Among Young Gay, Bisexual, and Other Men Who Have Sex With Men and Their Primary Partners (We Prevent): Protocol for a Randomized Controlled Trial. *JMIR Res Protoc.* 2019;8(1):e10370. PMC6746068
123. US Department of Health and Human Services. Pilot Studies: Common Uses and Misuses. In: National Institutes of Health; 2021.
124. Jairath N, Hogerney M, Parsons C. The role of the pilot study: A case illustration from cardiac nursing research. *App Nursing Res.* 2000;13(2):92-96.
125. Lancaster GA, Dodd S, Williamson PR. Design and analysis of pilot studies: recommendations for good practice. *J Eval Clin Pract.* 2004;10(2):307-312.
126. Kraemer HC, Mintz J, Noda A, Tinklenberg J, Yesavage JA. Caution regarding the use of pilot studies to guide power calculations for study proposals. *Arch Gen Psych.* 2006;63(5):484-489.
127. Arain M, Campbell MJ, Cooper CL, Lancaster GA. What is a pilot or feasibility study? A review of current practice and editorial policy. *BMC Med Res Methodol.* 2010;10:67.
128. Becker PT. Publishing pilot intervention studies. *Res Nurs Health.* 2008;31(1):1-3.
129. Eldridge SM, Lancaster GA, Campbell MJ, et al. Defining Feasibility and Pilot Studies in Preparation for Randomised Controlled Trials: Development of a Conceptual Framework. *PLoS One.* 2016;11(3):e0150205.
130. Kistin C, Silverstein M. Pilot Studies: A Critical but Potentially Misused Component of Interventional Research. *JAMA.* 2015;314(15):1561-1562.
131. Kraemer HC, Mintz J, Noda A, Tinklenberg J, Yesavage JA. Caution regarding the use of pilot studies to guide power calculations for study proposals. *Arch Gen Psychiatry.* 2006;63(5):484-489.
132. Lancaster GA. Pilot and feasibility studies come of age! *Pilot Feasibility Stud.* 2015;1(1):1.
133. Lancaster GA, Dodd S, Williamson PR. Design and analysis of pilot studies: recommendations for good practice. *J Eval Clin Pract.* 2004;10(2):307-312.
134. Leon AC, Davis LL, Kraemer HC. The role and interpretation of pilot studies in clinical research. *J Psychiatr Res.* 2011;45(5):626-629.
135. Thabane L, Hopewell S, Lancaster GA, et al. Methods and processes for development of a CONSORT extension for reporting pilot randomized controlled trials. *Pilot Feasibility Stud.* 2016;2:25.
136. Thabane L, Ma J, Chu R, et al. A tutorial on pilot studies: the what, why and how. *BMC Med Res Methodol.* 2010;10:1.
137. Kelly PJ, Kyngdon F, Ingram I, Deane FP, Baker AL, Osborne BA. The Client Satisfaction Questionnaire-8: Psychometric properties in a cross-sectional survey of people attending residential substance abuse treatment. *Drug Alc Rev.* 2018;37(1):79-86.

138. Sobell LC, Sobell MB. Timeline follow-back. In: *Measuring Alcohol Consumption.* Springer; 1992:41-72.
139. Gamarel KE, Golub SA. Closeness discrepancies and intimacy interference: Motivations for HIV prevention behavior in primary romantic relationships. *Pers Soc Psychol Bull.* 2019;45(2):270-283. PMC6377335
140. Sevelius J. Gender affirmation: A framework for conceptualizing risk behavior among transgender women of color. *Sex Roles.* 2013;68(11-12):675-689.
141. Sevelius J, Chakravarty D, Neilands TB, et al. Evidence for the Model of Gender Affirmation: The Role of Gender Affirmation and Healthcare Empowerment in Viral Suppression Among Transgender Women of Color Living with HIV. *AIDS Behav.* 2019:1-8. PMID: 31144131
142. Aldana SG, Liljenquist W. Validity and reliability of a financial strain survey. *J Fin Couns Planning.* 1998;9(2):11.
143. Jefferson K, Neilands T, Sevelius J. Transgender women of color: discrimination and depression symptoms. *Ethn Inequal Health Soc Care.* 2014;6(4):121-136. PMC4205968
144. Murphy A, Steele H, Steele M, Allman B, Kastner T, Dube SR. The clinical Adverse Childhood Experiences (ACEs) questionnaire: Implications for trauma-informed behavioral healthcare. In: *Integrated Early Childhood Behavioral Health in Primary Care.* Springer; 2016:7-16.
145. Andersen JP, Blosnich J. Disparities in adverse childhood experiences among sexual minority and heterosexual adults: Results from a multi-state probability-based sample. *PloS one.* 2013;8(1):e54691.
146. King WM, Jadwin-Cakmak L, Trammell R, Gamarel KE. Structural vulnerability and health outcomes among trans women of color in Detroit. in progress.
147. Blevins CA, Weathers FW, Davis MT, Witte TK, Domino JL. The posttraumatic stress disorder checklist for DSM-5 (PCL-5): Development and initial psychometric evaluation. *J Traumatic Stress.* 2015;28(6):489-498.
148. Radloff LS. The CES-D scale a self-report depression scale for research in the general population. *Appl Psychol Meas.* 1977;1(3):385-401.
149. Spitzer RL, Kroenke K, Williams JB, Löwe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. *Arch Internal Med.* 2006;166(10):1092-1097.
150. Schafer JL, Graham JW. Missing data: Our view of the state of the art. *Psychol Methods.* 2002;7(2):147-177.
151. Little JWA, Rubin DA. *Statistical analysis with missing data.* New York: John Wiley and Sons; 1987.
152. Medicine NCfCaI. Pilot Studies: Common Uses and Misuses. 2020; https://www.nccih.nih.gov/grants/pilot-studies-common-uses-and-misuses. Accessed December 9th 2020.
153. Kraemer HC, Mintz J, Noda A, Tinklenberg J, Yesavage JA. Caution regarding the use of pilot studies to guide power calculations for study proposals. *Arch Gen Psych.* 2006;63(5):484-489.
154. Leon AC, Davis LL, Kraemer HC. The role and interpretation of pilot studies in clinical research. *J Psych Res.* 2010.
155. Valeri L, VanderWeele TJ. Mediation Analysis Allowing for Exposure-Mediator Interactions and Causal Interpretation: Theoretical Assumptions and Implementation with SAS and SPSS Macros. *Psychol Methods.* 2013;18(2):137-150.
156. *NCSS PASS 2021* [computer program]. Version 21. Kaysville, Utah: NCSS Statistical Software; 2021.
157. Lang DL, DiClemente RJ, Hardin JW, Crosby RA, Salazar LF, Heterzberg VS. Threats of cross contamination on effects of a sexual risk reduction intervention: Facts or fiction. *Prev Sci.* 2009;10(3):270-275.