

## **MiST Pathways Study Protocol and Statistical Analysis Plan**

**Study Title:** Migration, Social Bonds, Transnationalism, and HIV Prevention Pathways Among African Immigrants.

**NCT Number:** [To be added once assigned]

**Date:** April 27, 2026

### **1. Introduction**

HIV remains a pressing public health concern among African immigrant communities in the United States, who account for a disproportionate share of new HIV diagnoses relative to their population size. Despite the availability of effective prevention tools such as HIV self-testing (HIVST) and pre-exposure prophylaxis (PrEP), uptake remains low in this population. Existing prevention strategies rarely address the relational and structural contexts, shaped by migration, transnational family obligations, and shifting gender norms, that influence prevention engagement.

The MiST-Pathways Study (Migration, Social Bonds, Transnationalism, and HIV Prevention Pathways Among African Immigrants) is a community-engaged, mixed-methods pilot and proof-of-concept study designed to generate foundational evidence on how migration-shaped relational contexts influence engagement with HIV testing, HIVST, and PrEP among first-generation African immigrants in the United States. The study integrates qualitative methods, an African-centered deliberative approach (Palava Hut Conversations), and a proof-of-concept intervention assessment to ensure that findings are both empirically grounded and community-driven.

### **2. Study Objectives**

#### **Primary Objectives:**

- To identify distinct relationship typologies and migration-related relational mechanisms that influence HIV testing, HIV self-testing, and PrEP decision-making among first-generation African immigrants (Aim 1).
- To co-develop and prioritize a relationship-tailored HIV prevention intervention component through Palava Hut Conversations, an African-centered deliberative method (Aim 2).
- To evaluate the feasibility, acceptability, and appropriateness of the prioritized intervention component using validated implementation science measures (Aim 3).

#### **Secondary Objectives:**

- To assess directional pre-post change in HIV testing intention, willingness to use HIV self-testing, interest in PrEP, and readiness for relationship-based prevention communication following exposure to the intervention component (Aim 3).
- To generate implementation-relevant data to inform refinement for a future R34 relationship-centered HIV prevention intervention development study.

### 3. Study Design

This is a sequential, single-arm, mixed-methods pilot and proof-of-concept study conducted across three phases. The study is guided by a relational-socioecological framework that positions relationships as central mechanisms linking individual, interpersonal, and structural determinants of HIV prevention behavior, with migration operating as a structural force that reshapes these relational dynamics.

Each phase builds directly on the findings of the prior one, ensuring that the intervention component tested in Aim 3 is grounded in empirical evidence and community priorities rather than researcher-imposed assumptions.

Aim	Description
<b>Aim 1 — Typology Identification</b>	Qualitative interviews (n=15) and structured survey (n=75) to identify relationship typologies and relational mechanisms shaping HIV prevention decision-making
<b>Aim 2 — Community Co-Development</b>	Three Palava Hut Conversations (n=30 total) to validate Aim 1 findings and co-develop and prioritize relationship-tailored intervention components
<b>Aim 3 — Proof-of-Concept Assessment</b>	Single-arm pre-post assessment (n=24) of the prioritized intervention component, including baseline survey (T0), intervention exposure, post-intervention survey (T1), and optional cognitive interviews for a subset of participants

### 4. Study Population

**Sample Size:**

<b>Aim 1 — Structured Survey</b>	75 participants
<b>Aim 1 — In-Depth Qualitative Interviews</b>	15 participants
<b>Aim 2 — Palava Hut Conversations</b>	30 participants (three sessions, approximately 10 per session)
<b>Aim 3 — Proof-of-Concept Assessment</b>	24 participants
<b>Total Enrollment</b>	144 participants

Approximately 175-200 individuals may be screened to achieve the target enrollment of 144 participants across all aims.

**Eligibility Criteria:**

**Inclusion:**

- Age 18 to 50 years at the time of enrollment
- Self-identify as a first-generation African immigrant (born in an African country and currently residing in the United States)
- Currently reside in New York or Massachusetts
- Able to communicate in English at approximately a 3rd-grade reading level

- Have access to a smartphone or computer with internet capability sufficient to participate in Zoom and/or WhatsApp-based study activities
- Willing and able to provide informed consent

**Exclusion:**

- Under 18 years of age
- Do not self-identify as a first-generation African immigrant
- Do not reside in New York or Massachusetts
- Unable to provide informed consent
- Do not have access to technology required for virtual participation (Zoom and/or WhatsApp)

No exclusions will be made based on sex, gender identity, sexual orientation, income level, or immigration documentation status.

## 5. Study Intervention

The intervention component delivered in Aim 3 will be co-developed and prioritized through the Palava Hut Conversation deliberation process in Aim 2. It is therefore not fully specified in advance of Aim 2 completion; its exact format will reflect the priorities identified by community participants.

The intervention will be non-medical and behavioral in nature. It will be delivered remotely via Zoom in a standardized facilitation structure and will focus on relationship-based HIV prevention communication and decision-making within migration-shaped relationship contexts. Depending on the component prioritized in Aim 2, the intervention may include:

- Structured relationship communication prompts
- Scenario-based discussions illustrating HIV prevention decision-making in relationship contexts
- Culturally grounded decision support frameworks
- Guided reflection exercises about prevention communication and disclosure

## 6. Outcome Measures

**Primary Outcomes:**

1. **Acceptability of intervention** - measured using the Acceptability of Intervention Measure (AIM). The intervention will be considered acceptable if at least 75% of participants rate it as acceptable or very acceptable, and at least 75% rate it as culturally relevant.
2. **Feasibility of intervention** - measured using the Feasibility of Intervention Measure (FIM).
3. **Appropriateness of intervention** - Measured using the Intervention Appropriateness Measure (IAM).

**Secondary Outcomes:**

1. **Change in HIV testing intention** - assessed using pre- and post-intervention surveys with Likert-scale behavioral intention items.

2. **Change in willingness to use HIV self-testing and interest in PrEP** - assessed using pre- and post-intervention surveys.
3. **Change in readiness to discuss HIV prevention within relationships** - assessed using pre- and post-intervention surveys.

## 7. Data Collection Procedures

### Quantitative Data:

- Eligibility screening administered via REDCap.
- Structured survey on relationship characteristics, HIV prevention awareness, and behaviors (Aim 1) administered via REDCap.
- Baseline (T0) and post-intervention (T1) surveys administered before and immediately after the intervention session (Aim 3), via REDCap.
- Implementation outcome scales: AIM, FIM, IAM (5-point Likert)

### Qualitative Data:

- Audio-recorded semi-structured in-depth interviews with a subset of Aim 1 participants
- Audio-recorded Palava Hut Conversation sessions, including facilitator notes, decision logs, and prioritization matrices (Aim 2)
- Audio-recorded cognitive interviews with a subset of Aim 3 participants

## 8. Statistical Analysis Plan

### Quantitative Analysis

Given the pilot and proof-of-concept nature of this study, all quantitative analyses are descriptive. The study is not powered for hypothesis testing.

#### Aim 1 Survey Analysis:

- Descriptive statistics (frequencies, proportions, means, standard deviations) will summarize participant demographics, relationship characteristics, HIV testing history, HIVST and PrEP awareness, and prevention behaviors.
- Findings will be stratified by relationship typology categories identified through qualitative analysis.

#### Aim 3 Survey Analysis:

- Mean scores and standard deviations will be calculated for AIM, FIM, and IAM scales.
- The 75% acceptability threshold will be assessed as the proportion of participants scoring 4 or 5 (acceptable or very acceptable) on the AIM and on the cultural relevance item.
- Pre-post change in HIV testing intention, HIVST willingness, PrEP interest, and communication readiness will be summarized as mean change scores (T1 minus T0) with 95% confidence intervals.

- All analyses will be conducted using statistical software.

#### **Qualitative Analysis:**

- All interview and Palava Hut Conversation transcripts will be analyzed using thematic analysis.
- Aim 1 analysis will focus on identifying relationship typologies and migration-related relational mechanisms influencing HIV prevention decision-making.
- Aim 2 deliberation outputs, including facilitator notes, decision logs, and prioritization matrices, will be synthesized using rapid qualitative methods to produce a ranked list of intervention components.
- Aim 3 cognitive interview data will undergo rapid thematic analysis focused on implementation-relevant constructs: acceptability, feasibility, appropriateness, perceived fit, usability, and evidence of mechanism activation.
- NVivo or Dedoose will be used for qualitative coding and organization.

### **9. Data Management and Monitoring**

- All electronic data will be stored on secure, password-protected University at Buffalo systems, including REDCap, the UB network drive, UB Box, and UB OneDrive, which require university authentication and role-based access controls.
- Each participant will be assigned a unique study identification number at enrollment. Identifiable information (name, phone number, email address) will be stored separately from research data and linked to the study ID through a code key maintained in a separate, restricted-access file.
- Audio recordings will be labeled using study ID numbers only. De-identified transcripts will be used for all qualitative analysis.
- The code key will be destroyed once data analysis is complete and there is no longer a need to re-contact participants, or within three years after study closure, whichever occurs first.
- Zoom sessions will use password-protected meeting links and waiting room features. WhatsApp communication will occur only through private messaging.
- No paper records will be maintained. No medical records or third-party data sources will be accessed.

### **10. Ethical Considerations**

- The study is approved by the University at Buffalo Institutional Review Board (IRB Approval Number: STUDY00010347).
- The study is funded by the Center for Interdisciplinary Research on AIDS (CIRA) 2026 Pilot Projects, Yale University.
- Informed consent will be obtained prior to participation in any study activity. Verbal informed consent will be used for all aims except Aim 1 survey participants, who will complete an electronic consent statement programmed within REDCap before beginning the survey. Consent materials will be delivered via email or WhatsApp before scheduled sessions.

- Participants may withdraw at any point without penalty. Withdrawal will not affect access to services, benefits, community resources, insurance, healthcare access, or immigration status.
- Participants may skip any question, turn off their camera during group sessions, and use a pseudonym during Palava Hut Conversations to protect their privacy.
- Referrals to mental health and community resources will be available through Multicultural Community Family Services (MCFS) if participants experience distress.