WISEWOMAN Study Protocol and Statistical Analysis Plan

Study Title: Co-Developing a Women-Centered HIV Prevention Intervention to Reduce Stigma, Increase HIV Self-Testing, and Improve PrEP Awareness and Uptake in Ghana
NCT Number: [To be added once assigned]
Date: May 1,2025

1. Introduction

HIV remains a pressing public health concern in Ghana, particularly among young women aged 18 to 35 who face high rates of new infections. Despite the availability of effective prevention methods such as HIV self-testing (HIVST) and pre-exposure prophylaxis (PrEP), uptake remains low due to stigma, limited awareness, and lack of culturally relevant health services.

The WISEWOMAN Study (Women-Informed Strategies for Engagement) is a community-based intervention designed to co-develop and pilot test a youth-friendly, women-centered HIV prevention program. The study integrates Human-Centered Design (HCD) and participatory methods to ensure that the intervention aligns with the lived realities of young women in Ghana.

2. Study Objectives

Primary Objectives:

- To assess the uptake of HIV self-testing (HIVST) among participants after exposure to the intervention.
- To assess willingness to initiate or use PrEP.
- To evaluate the feasibility and acceptability of the intervention using validated implementation science measures.

Secondary Objectives:

- To explore the appropriateness and cultural relevance of the intervention.
- To assess changes in HIV-related stigma.
- To examine participants' perceptions of the intervention's scalability and sustainability.

3. Study Design

This is a single-arm, mixed-methods interventional study with two phases:

1. **Co-development Phase**: A one-day participatory workshop involving young women and community partners will be conducted to identify preferred HIV prevention strategies and co-design the intervention.
2. **Pilot Phase**: A 4-week pilot study will evaluate the feasibility, acceptability, and preliminary impact of the co-developed intervention.

The intervention will be delivered through WhatsApp-based messaging and virtual engagement, supplemented by peer support and group discussions.

4. Study Population

Sample Size:

- Co-development Workshop: 15 participants (10 young women, 5 community stakeholders)
- Pilot Study: 50 young women (25 from Greater Accra, 25 from Eastern Region)

Total: 65 participants

Eligibility Criteria:

Inclusion:

- Identify as female and aged 18–35
- Reside in Greater Accra or Eastern Region of Ghana
- Sexually active or perceive themselves at risk for HIV
- Access to a mobile phone with WhatsApp
- Willing to provide informed consent

Exclusion:

- Individuals with cognitive impairments limiting participation
- Those outside the specified age or geographic criteria
- Prior participation in the co-development workshop (for pilot participants)

5. Study Intervention

The intervention consists of a youth-informed HIV prevention curriculum delivered through WhatsApp. It includes:

- Daily or weekly informational messages
- Multimedia and interactive content on HIVST and PrEP
- Peer-led discussions
- Stigma reduction conversations
- Prompts encouraging uptake of HIVST and PrEP

6. Outcome Measures

Primary Outcomes:

1. **Uptake of HIVST** – Measured via self-report and confirmed by photo or message verification.
2. **Willingness to Use PrEP** – Assessed using pre-post surveys with Likert-scale behavioral intention items.
3. **Feasibility** – Measured using the Feasibility of Intervention Measure (FIM).
4. **Acceptability** – Measured using the Acceptability of Intervention Measure (AIM).

Secondary Outcomes:

1. **Stigma Reduction** – Change in stigma scores using adapted stigma scales.
2. **Appropriateness** – Measured using the Intervention Appropriateness Measure (IAM).
3. **Sustainability and Scalability** – Qualitative feedback from post-intervention interviews.

7. Data Collection Procedures

Quantitative Data:

- Pre- and post-intervention surveys administered via REDCap
- Implementation outcome scales: AIM, FIM, IAM (5-point Likert)
- WhatsApp engagement analytics (frequency of response, message views)

Qualitative Data:

- Transcripts from workshop and WhatsApp discussions
- In-depth interviews with a subset of 10 pilot participants

8. Statistical Analysis Plan

Quantitative Analysis:

- **Descriptive statistics** will summarize participant demographics, HIV knowledge, and intervention engagement.
- **Paired t-tests** or **Wilcoxon signed-rank tests** will compare pre- and post-intervention scores for HIVST uptake, PrEP willingness, and stigma.
- **Mean scores** for AIM, FIM, and IAM will be calculated and reported with standard deviations and 95% confidence intervals.
- **Uptake of HIVST** will be summarized as a proportion and analyzed with confidence intervals.

Qualitative Analysis:

- All transcripts and open-ended responses will be analyzed thematically using Braun & Clarke’s reflexive thematic analysis.

- NVivo or Dedoose will be used for coding and organization.
- A triangulation matrix will compare quantitative and qualitative findings to identify convergent and divergent themes.

9. Data Management and Monitoring

- All electronic data will be stored on encrypted, password-protected servers.
- Identifiable data (e.g., WhatsApp numbers) will be stored separately and de-identified before analysis.
- Weekly internal check-ins with the research team will monitor protocol adherence and troubleshoot challenges.

10. Ethical Considerations

- The study is approved by the University at Buffalo IRB and will seek approval in Ghana (Ensign Global College IRB)
- Informed consent will be obtained verbally via WhatsApp.
- Participants may withdraw at any point without penalty.
- Participants will receive compensation for their time and data will be handled with strict confidentiality measures.