







Comprehensive HIV Prevention Package for MSM in Southern Africa: Pilot Study

PHASE III OF THE SIBANYE HEALTH PROJECT

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The Sibanye Health Project

Phase I: Comprehensive literature review and summary of current knowledge of HIV prevention interventions

Phase II: Mathematical modelling of HIV transmission in Southern African MSM

Phase III: Qualitative studies and a pilot study of the acceptability of the prevention package

Study Objectives

The overarching objective:

To develop and evaluate the acceptability and uptake of a combination package of biomedical, behavioral and community-level HIV prevention interventions and services for MSM in South Africa(SA).

Primary Objectives:

- 1. Determine acceptability of the HIV prevention package.
- 2. Determine uptake of individual elements of the HIV prevention package.
- 3. Determine incidence of HIV, STIs and unprotected anal intercourse(UAI).
- Understand HIV risk and prevention behaviors among MSM.

Study Design

- Funded by NIH Research Project Grant Program(R01)
- Longitudinal cohort study
- •200 MSM
- Follow-up period: 1 year
- Study sites: Cape Town and Port Elizabeth(100 MSM each site)

Study Population

Study Size: 200 MSM (80% HIV- MSM, 20% HIV+ MSM)

Inclusion:

- Male sex at birth
- Anal sex with another man in the past 12 months
- ≥18 years of age
- Resident of the study city
- Able to complete study instruments in English, Xhosa or Afrikaans (the predominant local languages in CT and PE)
- Has a phone
- Willing to provide contact information
- Willing to provide written informed consent

Intervention Package

Community-level interventions:

- LGBT sensitization
- Community mobilization

Individual-level intervention:

- Various condom and compatible lubricant
- Couples voluntary HIV counseling and testing (CVCT)
- HIV testing and risk reduction counseling

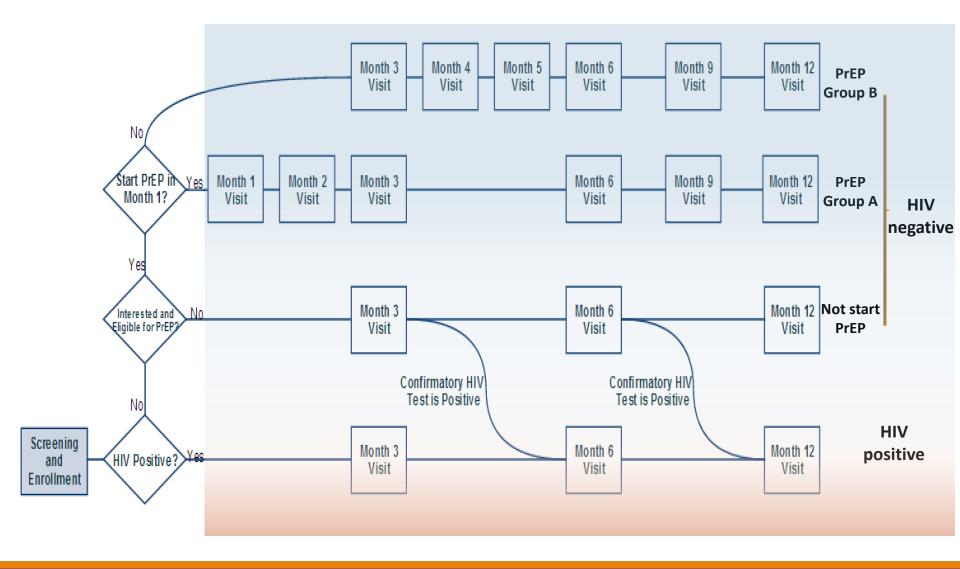
For HIV- and eligible MSM:

- Pre-exposure prophylaxis (PrEP)
- Post-exposure prophylaxis (PEP)

For HIV+ MSM:

Linkage to care

Visit Scheme



Primary study endpoints

 Retention in the cohort – Assess ability of the study to retain participants for full study period

Proportion of enrolled participants who attend all subsequent study visits through the 12 month visit

2. Use of PrEP — Assess uptake of PrEP by study participants

Proportion of enrolled participants eligible for PrEP at the baseline and 3-month study visits who choose to initiate PrEP 1-month later at the 1 and 4 month visits.

3. Incident HIV infection

Number of seroconversions during follow-up among those who are HIV-uninfected at baseline.

Progress

- MCC and IRB approval obtained
- •NIH visit in September, 2014
- Site activation is scheduled in September, 2014
- Enrollment is scheduled in October, 2014

