

ATN YMHP

Aims: In collaboration with three ATN4 clinic sites (Los Angeles, Miami, Philadelphia), our goals are to better understand HIV-prevention focused self-management behaviors among HIV-negative YMSM, and to study the implementation of YMHP to improve portability and scalability. The clinic sites will help us to assess and address practical problems at the frontline of service provision to pave the way for a comprehensive program to reduce HIV infection among YMSM that reflects the complexities of real world adolescent HIV clinics.

1. Adapt YMHP for clinic and phone delivery by existing HIV clinic staff (community health workers, CHWs) who work with YMSM ages 15-24. We will conduct focus groups with staff to obtain input on how best to implement YMHP to maximize feasibility, acceptability, and sustainability, as well as issues with adapting the YMHP for delivery to YMSM ages 15-18 and for phone delivery.
2. Compare the effectiveness of clinic-based versus phone-based delivery of YMHP in the context of health care access. In order to inform future implementation, we will test the effectiveness of YMHP delivered via these two modalities.
 - a. Assess the cost-effectiveness of both delivery formats of YMHP to enhance the likelihood of uptake of this best evidence intervention. We hypothesize that phone-based will be more cost-effective than clinic-based.
 - b. Assess the *Five Components of the Self-Management Model* and how these components vary over time, are directly improved by the interventions, and mediate intervention effects.
3. Test a sustainable model of YMHP implementation in real world adolescent clinics. We will utilize local supervisors within the clinic setting to sustain the CHWs fidelity to delivering the MI-based YMHP intervention. We will monitor fidelity throughout the trial and conduct assessments and qualitative interviews with key stakeholders to determine the barriers and facilitators of YMHP implementation utilizing the *Exploration, Preparation, Implementation, Sustainment model (EPIS)*.

We will achieve our aims over two phases of the study.

Phase I: We will conduct research (Exploration and Preparation phases of EPIS model) to obtain implementation feedback to best adapt YMHP for clinic-based CHWs, further incorporate PrEP navigation services, and expand the YMHP protocol to be relevant for TBMI. We will train a minimum of 2 CHWs at each clinic drawing on the ISC to apply best-practices in training. Once CHWs demonstrate competence according to the MITI, we will move to Phase 2.

Phase II: We will recruit and enroll 270 YMSM, ages 15-24, 90 at each of the three sites. Sessions will be audio-recorded for MITI fidelity coding, and CHWs and supervisors will be given implementation support throughout. Prior to implementation, immediately at the conclusion of the intervention delivery phase, and one year after, the ISC will conduct interviews with CHWs, supervisors, and clinic leaders to obtain information about the barriers and facilitators of implementation and sustainment.

Target n: 270 YMSM across three sites (90 per site), 135 in each condition.

Eligibility Criteria:

Inclusion Criteria:

Exclusion Criteria:

- HIV-negative test result from the past 90 days
- 15-24 years of age
- Born biologically male or currently identifying as male
- Sex with men in the past 90 days
- ≥ 5 days of illicit drug use in the past 90 days
- ≥ 1 episode of CAS in the past 90 days, *or* a positive STI test result in the past 90 days.
- Living in the LA, Miami, or Philadelphia metropolitan areas
- Able to communicate in English
- Serious cognitive or psychiatric impairments
- Currently taking Truvada as Pre-Exposure Prophylaxis (PrEP)

Enrollment & Assessments:

Screening

1. YMSM tests HIV-negative at clinic site or through mobile testing efforts
2. Patient is offered opportunity to participate in YMHP
3. Brief screener via iPad

Baseline Visit (\$25)

1. Informed Consent process
2. STI testing
3. Recent drug use test (E-Z Split Key Cup)
4. Brief CASI (via iPad)
5. Randomization to YMHP in person or by phone

YMHP Intervention Sessions (4 sessions, \$10 per session)

1. *Session 1:* CHW will elicit the client's view of the problem using standard MI techniques, building motivation for change by eliciting and reinforcing change talk and clarifying the youth's own personal priorities (through a structured values card sort activity).
 1. Youth will choose which behavior to discuss first (sexual risk or substance use)
 2. Personalized feedback is delivered.
 3. The CHW will discuss options for a behavior change plan, and, if the client is willing to proceed, the client sets goals.
 4. The session ends with MI strategies to evoke the youth's ideas about how to take steps towards change, consolidate the youth's commitment to the plan, and problem-solving.
2. *Session 2:* follows the same format for the second target behavior.
3. *Sessions 3-4:* the CHW will review the change plan, continue to elicit and reinforce change talk, problem-solve barriers, consolidate commitment, and address maintenance of behavior change.

Immediate Post-Test Assessment (3 months after BL) and every 3 months thereafter for 15 months (\$30 at 3M/Immediate Post-Test; \$35 at 6M; \$40 at 9M; \$45 at 12M; \$50 at 15M)

1. Brief CASI
2. HIV/STI Testing (only at 6M and 12M after BL)

