

**HIV Oral Testing Infographic Experiment (HOTIE)**

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Study Protocol and Statistical Analysis Plan

## **Introduction**

In the United States, approximately 1.1 million persons are living with HIV. Despite novel pharmacological breakthroughs, comprehensive models of health care, and targeted HIV testing initiatives, over 160,000 persons are still unaware of their HIV serostatus. Emerging adult, sexual minority, men of color are disproportionately affected. Premised on the National AIDS Strategy's focus on identifying new HIV infections through increased HIV testing, the purpose of this formative pilot study is to develop and test an integrated HIV self-testing strategy that utilizes a simplicity-model approach to HIV self-testing in emerging adult sexual minority men of color.

The overall study will focus on: (a) understanding facilitators and barriers to HIV self-testing among emerging adult MSM, (b) designing a HIV self-testing infographic that utilizes a simplicity model, (c) finalizing the HIV self-testing infographic with input from a leadership group of HIV community members, (d) conducting a pilot clinical trial with 300 emerging adult (ages 18-34), sexual minority, men of color to test if a collaboratively-designed HIV self-testing infographic can facilitate accurate and effective understanding of how to self-test for HIV when compared to paper-based, HIV self-testing information.

By conducting this study, we will gain beneficial insights necessary for presenting HIV self-testing instructions in a meaningful, relevant, and comprehensible way. The results of this pilot study have the potential to inform strategies regarding how self-testing instructions can be worded or visually presented in order to break both literacy and language barriers that affect testing utilization and results accuracy.

## **Methods**

The HOTIE intervention was a sequential, mixed methods pilot randomized controlled trial. Mixed methods were an appropriate study design as we sought to describe the context for needing to develop an HIV self-testing infographic and the process of steps that lead to testing

of the infographic. The study methods are consistent with the approaches for conducting mixed methods research by Curry and Nunez-Smith.

Participants were recruited online from a HIPAA-compliant data management national survey panel recruitment company. Participants were screened for eligibility online. Once considered eligible, they were informed about the purpose, risks and benefits of the study and then completed an online consent to participate or decline to participate. Those who consented to participate were then randomly assigned, using automated random selection to either the intervention group (HIV self-testing infographic) or to the control group (HIV self-testing text-based instructions). The primary outcome was comprehension of the HIV Self-testing Infographic and Usefulness, Ease of Use, Ease of Learning and Satisfaction of the HIV Self-testing Infographic. Health literacy was a secondary outcome. More detailed information on the development and design of the infographic can be found elsewhere.

## **Measures**

Sociodemographic data collected will include age (in years), gender, sexual attraction, race-ethnicity, educational attainment, employment status, annual income, and other information to characterize the sample. Outcomes of interest include health literacy, oral HIV self-testing knowledge, HIV knowledge, oral HIV self-testing infographic usability as well as PrEP use, familiarity, and attitudes. The following instruments will be administered.

***Oral HIV self-testing knowledge.*** Oral HIV self-testing knowledge will be assessed using an Oral HIV self-testing questionnaire. The Oral HIV self-testing questionnaire will assess accuracy in using oral HIV self-testing kits. Correct responses will be coded as “1” and incorrect responses “0”. Responses to the five-items will be summed to yield a total Oral HIV self-testing knowledge score ranging from 0 to 5.

**Oral HIV self-testing infographic usability questionnaire.** The Oral HIV self-testing infographic usability questionnaire is a 14-item measure designed to assess usefulness and usability of the HIV oral self-testing infographic. The Oral HIV self-testing infographic usability questionnaire was derived from the Usefulness, Satisfaction, and Ease Questionnaire[1]. Responses will be recorded using a 7-point Likert scale ranging from *strongly disagree* (1) to *strongly agree* (7). This measure assessed four domains that included usefulness of the HIV oral self-testing infographic (M = 5.47, SD = 1.40; Cronbach's  $\alpha$  = .92), ease of use of the HIV oral self-testing infographic (M = 5.51, SD = 1.23; Cronbach's  $\alpha$  = .85), ease of learning using the HIV oral self-testing infographic (M = 5.41, SD = 1.37; Cronbach's  $\alpha$  = .86), and satisfaction with the HIV oral self-testing infographic (M = 5.34, SD = 1.33; Cronbach's  $\alpha$  = .79). Responses to the 14-item measure will be summed to yield a mean score on usability among experimental group participants only ranging from 15 to 98.

**Health literacy.** The Short Assessment of Health Literacy-English, or SAHL-E is an 18-item measure designed to assess an English-speaker's ability to read and understand common medical terms [2]. The test contains a printed common medical term, a key word (the correct response), and a distractor word. Responses will be recorded dichotomously with either *false* (0) or *true* (1). Prior studies have demonstrated good internal consistency ranging from .80 to .89 [2]. Responses to 18-items will be summed to yield a total score on Health literacy ranging from 0 to 18. Higher scores indicate greater health literacy.

**HIV knowledge.** The Brief HIV Knowledge Questionnaire (HIV-KQ18)[3] is an 18-item true or false response measure that distinguishes understanding about HIV transmission, prevention, and consequences. Correct responses will be coded as "1" with incorrect responses coded as "0". Prior studies have demonstrated good internal consistency ranging from 0.75 - 0.89 [3]. The measure has been identified as suitable for those with low health literacy [3]. Responses to the 18-items will be summed to yield a total score on HIV knowledge ranging from 0 to 18.

**PrEP Use, Familiarity, and Attitudes.** PrEP Use, Familiarity, and Attitudes will be assessed using three separate multiple-choice questions. PrEP use will be assessed using the question: “PrEP is the use of a medication taken before having sex as protection against HIV infection. Are you currently taking PrEP?” and measured dichotomously (0 = No, 1 = Yes). PrEP familiarity will be assessed using the question: “Truvada is a pill that HIV negative people can take to prevent HIV. This is called PrEP or Pre-Exposure Prophylaxis. How familiar are you with Truvada also called PrEP?” Responses will be collected using a three-item Likert scale from 1 (not familiar or I do not know about PrEP) to 3 (Familiar or I know about PrEP). PrEP attitudes will be measured using the question “How do you feel about HIV-negative people taking Truvada as PrEP to prevent transmission of HIV?” Responses will be collected using a four-point Likert scale from 1 (extremely negative) to 4 (extremely positive).

**Statistical Analysis Plan.** Post-hoc power analysis estimates will be performed using G\*Power [4]. Analyses indicated that based on a type I error rate set at .05 and conservative effect size of .4 [5], and sample of 322 participants randomly assigned to experimental and control groups in this RCT study, we will have .95 power to reject the null hypothesis with our oral HIV self-testing knowledge questionnaire [5]. Analyses will be conducted in STATA. Between-group differences will be examined using chi-square and independent samples t-tests to determine significant sociodemographic differences. Between-group differences using independent samples t-tests will also be examined on outcomes including oral HIV self-testing knowledge, HIV knowledge, and health literacy. Cases with missing data will be excluded from the analyses.

## References

1. Lund, A.M., *Measuring usability with the use questionnaire*<sup>12</sup>. Usability interface, 2001. **8**(2): p. 3-6.
2. Lee, S.Y.D., et al., *Short assessment of health literacy—Spanish and English: a comparable test of health literacy for Spanish and English speakers*. Health services research, 2010. **45**(4): p. 1105-1120.
3. Carey, M.P. and K.E. Schroder, *Development and psychometric evaluation of the brief HIV Knowledge Questionnaire*. AIDS education and prevention, 2002. **14**(2): p. 172-182.
4. Faul, F., et al., *Statistical power analyses using G\* Power 3.1: Tests for correlation and regression analyses*. Behavior research methods, 2009. **41**(4): p. 1149-1160.
5. Faul, F., et al., *G\* Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences*. Behavior research methods, 2007. **39**(2): p. 175-191.