



HHS Public Access

Author manuscript

J Acquir Immune Defic Syndr. Author manuscript; available in PMC 2020 February 01.

Published in final edited form as:

J Acquir Immune Defic Syndr. 2019 February 01; 80(2): e23–e29. doi:10.1097/QAI.0000000000001888.

Perceived versus calculated HIV risk: Implications for Pre-exposure prophylaxis uptake in a randomized trial of men who have sex with men

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Abstract

Background: Inaccurate HIV risk perception by men who have sex with men (MSM) is a barrier to HIV prevention. Providing information about objective HIV risk could improve preexposure prophylaxis (PrEP) uptake.

Methods: PrEP Accessibility Research & Evaluation 2 (PrEPARE2) was a randomized controlled trial of MSM to determine if an objective risk score affects future PrEP uptake. Participants completed a baseline survey to assess demographics, risk behaviors and HIV self-perceived risk (SPR). The survey generated a calculated HIV risk score (CalcR), estimating HIV risk based on reported condomless anal intercourse and sexually transmitted infections, and was provided to individuals in the intervention arm. Participants were contacted 8 weeks later to determine if they initiated PrEP.

Results: Of 171 participants (median age 32; 37% Hispanic or Non-Hispanic Black; median 5 sexual partners in past 6 months), 81% had heard of PrEP, and 57% thought they were good PrEP candidates. SPR had poor agreement with CalcR ($\kappa=0.176$) with 38% underestimating their HIV risk. At week 8, only 14 of 135 participants had initiated PrEP with no difference between arms (CalcR 11%, control 10%, $p>0.99$). The most common reason for not starting PrEP was low HIV risk perception. There was a relative decrease in SPR over time ($p=0.06$) but no difference between arms ($p=0.29$).

Conclusion: Providing an objective HIV risk score alone did not increase PrEP uptake. HIV testing performed at testing sites may be a crucial time to correct misperceptions about risk and initiate same-day PrEP given enthusiasm for PrEP on testing day to facilitate greater uptake.

Keywords

Pre-exposure prophylaxis; HIV risk perception; Men who have sex with men

Introduction

Three decades after the onset of the AIDS epidemic, men who have sex with men (MSM) continue to bear a disproportionate burden of HIV, accounting for 67% of incident infections in the United States.¹ The development and licensure of oral pre-exposure prophylaxis (PrEP) with tenofovir disoproxil fumarate and emtricitabine (TDF/FTC) has raised hope in changing this trajectory.² Promising trials over the past several years suggest that taking PrEP substantially reduces the risk of HIV infection in high-risk populations including MSM.^{3–6} Oral TDF/FTC has been available through some demonstration projects and is currently covered by most public and private insurance providers, but may require financial assistance through the drug manufacturer or other patient assistance programs.^{7,8}

Despite high efficacy and insurance coverage, PrEP has not been evenly implemented in high-risk communities, which may result in a blunted population level impact.^{9,10} In our previous study Pre-Exposure Prophylaxis Accessibility Research and Evaluation (PrEPARE), we examined barriers to adopting this mode of HIV prevention among MSM.¹¹ Most subjects were concerned about long-term side effects, daily pill-taking or cost, of which cost/insurance coverage continues to be a significant barrier to PrEP uptake and continuation.¹² However, an additional 35% did not want to take PrEP because they did not perceive themselves to be at high risk for HIV infection. In contrast to their self-perceived risk, over half of these responders reported unprotected receptive anal sex exposure in the previous 12 months and 7% reported having at least 25 different sex partners. These findings highlight the strong disconnect between an individual's perceived risk for infection and their actual risk that would be estimated by behavioral and demographic risk factors.

Risk perception is an individual's subjective appraisal of the likelihood of an undesirable outcome. Within the context of HIV, it is the perception of the risk of acquiring HIV and the seriousness afforded to seroconversion. It is inherently difficult to study because it encompasses both conscious and unconscious thought processes. What confounds the situation further is that medical professionals themselves cannot reach a consensus on what degree of unsafe behavior should define low-, moderate-, and high-risk populations.^{13,14} Data has shown that low self-perceived risk may contribute to increased incidence of HIV in marginalized populations and that there is a great divide between perception and behavior.^{15–19} Reconciling perceived risk, real-life behaviors, and validated risk indices is essential to effectively implement preventive measures such as PrEP.^{20–23}

Throughout the course of biomedicine, this reconciliation has often been achieved through the development of objective risk calculators. Incidence of cardiovascular disease and osteoporosis, for example, have been drastically reduced through the use of Framingham and DXA scores, respectively.^{24–26} The provision and use of an HIV risk score is hoped to yield similar effects. In 2014, the Center for Disease Control and Prevention (CDC) published the HIV Incidence Risk Index for MSM (HIRI-MSM), the only nationally established HIV risk calculator for MSM.^{22,27} In this trial, we use this risk tool as well as a newly developed HIV risk tool, based on specific HIV transmission events among MSM.

In this study, we investigated if informing high-risk MSM in San Diego County of their calculated HIV risk would affect their uptake of PrEP and alter their perceived risk. We hypothesized that even though MSM would underestimate their risk of HIV acquisition, informing them of their calculated risk would create durable alterations in risk perception and would increase PrEP uptake.

Methods

Study Procedures:

From April 2014 to June 2016, participants were recruited from three San Diego HIV testing sites. All participants tested negative by a rapid HIV antibody testing followed by HIV nucleic acid amplification testing. Inclusion criteria were verified verbally by an independent interviewer who enrolled the subject and included: HIV-negative by rapid test, MSM over 18 years old, and at least 1 act of condomless anal intercourse with an HIV-positive partner or partner of unknown status in the last 6 months. Exclusion criteria included current active usage of PrEP, inability to provide written consent, lack of significant risk for acquiring HIV, and/or signs or symptoms suggestive of acute HIV infection.

Eligible subjects were randomized 1:1 by computer program to the intervention or control arm. All subjects were given an iPad survey that assessed demographics, self-perceived risk and risk behavior questions and generated an objective risk score. The iPad survey contained 32 total questions with 3 main components: 3 questions assessing their level of self-perceived risk (SPR), 12 demographic questions, and 16 questions assessing risk behaviors used to calculate two different objective risk scores, the HIRI-MSM and the CalcR scores, described below in more detail. The survey was only offered in English, and all participants referred for the study were proficient in English.

After completing the survey, participants in the intervention arm were provided their CalcR score result compared to the average risk of HIV seroconversion in MSM, which was then further categorized as low, moderate, high or very high risk, with a short explanation of each category. These results were given to the intervention arm both on the iPad as well as verbally by the interviewer. Both groups received standard risk reduction counseling along with a brief description of PrEP and how to access it on their own if desired, but no prescriptions or study drug were provided.

Participants were contacted by phone 8 weeks after the enrollment/survey date (week 0) to determine whether they initiated PrEP or not (defined as having taken a single dose or more of PrEP in the 8 week period) and to reassess their HIV risk. They were also asked to complete an online survey (week 12) with questions about self-perceived risk and recent risk behaviors to calculate a second CalcR score.

The study plan and subsequent changes were approved by the University of California San Diego Human Research Protections Program Institutional Review Board. The first 76 subjects were mailed a \$5 gift card after completing the follow up phone call and online survey. To increase enrollment, the subsequent 95 subjects were given a \$5 gift card after enrollment and a second \$5 gift card upon study completion.

HIV Risk Measures

A. Objective

HIRI-MSM: As described above, the HIRI-MSM was developed through statistical analysis of behavioral and HIV testing data from two large prospective studies including 6654 MSM participants.²² The HIRI-MSM uses the following seven questions to generate an HIV risk score: age, number of MSM partners, number of HIV positive partners, instances of unprotected receptive anal intercourse, instances of unprotected insertive anal intercourse, use of amphetamines, and use of poppers over the last 6 months.²² Scores range from 0 to 47; scores of 10 or higher confer substantial HIV risk and should prompt providers to discuss HIV prevention strategies including PrEP.²⁷

CalcR Score: The CalcR Score was developed as an alternative tool to evaluate HIV risk based on patient-specific HIV transmission events. The score is generated from a mathematical equation that focuses on sexual transmission methods and biological factors that may increase HIV acquisition: condomless receptive and insertive anal intercourse acts and sexually transmitted infections (STIs) including gonorrhea, chlamydia, syphilis and herpes. It previously included shared needle events via injection drug use (IDU) but was removed due to extremely few self-reported IDU events in this study and a previous study using the CalcR Score.²⁸ It incorporates event frequencies over the last month and established event probabilities of HIV transmission due to condomless anal intercourse acts²⁹ or STI occurrence.³⁰ As sex frequency is a potential driver of HIV and STI risk among MSM, estimates of sex frequency combined with estimates of HIV risk per sexual act may be useful to model risk by sexual behaviors.³¹ In addition, the short time frame employed reduces recall bias, which may occur in highly sexually active cohorts.^{32,33} The calculated risk score is extrapolated to the percent likelihood of HIV seroconversion in one year if their sexual activities persisted at the same rate and is categorized into low (<0.12%), moderate (0.12–0.59%), high (0.6–5.9%) and very high (>5.9%) risk groups. Classification is based on the average percent likelihood of HIV seroconversion among MSM in the United States.³⁴ Further details on the CalcR score are available in Supplementary Materials. The CalcR score has not been validated in prospective clinical studies primarily due to the specific data collected, which include condomless anal sex act frequency per partner over a short period of time. Traditional sexual risk surveys among MSM elicit information regarding sexual behaviors including number of sex partners over long recall periods (e.g., 3 or 6 months) despite the known effect of number of sex acts (or possible HIV exposures) on HIV acquisition risk.³⁵

B. Subjective

Self-perceived risk score (SPR score): The SPR score is based on three questions about self-perceived HIV risk adopted from a validated HIV self-perceived risk survey²¹ using Likert scales: (i) How likely is it that you will become HIV positive in the next year? (0=extremely unlikely; 1= very unlikely; 2=somewhat likely; 3=very likely; 4=extremely likely) (ii) How likely is it that you will become HIV positive in your lifetime? (0=extremely unlikely; 1= very unlikely; 2=somewhat likely; 3=very likely; 4=extremely likely) and (iii) My gut feeling is that I will NOT get infected with HIV (0=strongly disagree; 1= disagree;

2=somewhat disagree; 4=agree; 5=strongly agree). SPR score was calculated as the sum of 3 questions and ranged from 0–13 and were divided into four risk categories: Low (0–3), Moderate (4–6), High (7–9), and Very High (10–13). The SPR score was obtained at weeks 0 and 12.

Self-perceived Likelihood of HIV Acquisition (LHA score): The LHA score is the percent likelihood from 0–100% that participants thought they would become HIV-infected in the next year. At weeks 0 and 12 it was obtained through survey, and at week 8 it was reported to the study coordinator by phone.

Statistical analysis

Baseline characteristics were summarized and compared between study arms using Wilcoxon Rank Sum test for continuous variables and Fisher's exact test for categorical variables. Cross-tabulation was used to compare SPR versus CalcR and HIRI-MSM risk categories. Cohen's Kappa Coefficient was calculated to assess the agreement between the subjective and objective risk measures. Self-perceived underestimation of HIV risk was defined if SPR score category was below the CalcR risk category.

The primary outcome was the initiation of PrEP at week 8. Fisher's exact test was used to compare the proportions between the study arms. Secondary outcomes included the proportion of those considering PrEP and change in objective and subjective risk measures. Wilcoxon signed rank test was used to assess the overall change and Wilcoxon Rank Sum test was used to compare the change between study arms. A p-value of <0.05 was considered statistically significant. No adjustments were made for multiple comparisons. Statistical analyses were performed in R (<http://cran.r-project.org>), version 3.3.3.

Results

Participant Flow and Baseline Characteristics:

A total of 204 MSM were approached for the study if they expressed interest in the study and potentially met study criteria based on information they provided to HIV testing counselors during testing. Thirty-three of these individuals were ineligible to participate due to lack of sufficient risk (i.e. did not have any condomless anal sex with a HIV positive or unknown status partner) or already on PrEP. One-hundred and seventy-one were enrolled and randomized to control or intervention arms. Retention was 79% (n=135) for the primary endpoint at week 8 and 67% (n=119) at week 12 (See Figure 1). Of 171 participants enrolled, the median age was 32 (IQR 25–42), 29% identified as Latino, 60% as White and 8% as Black. Ninety-two percent had some college or more, 55% earned less than \$3000 per month and 16% were uninsured. The median number of sexual partners in the past 6 months was 5 (IQR 3–10). Thirty percent of participants reported drug use in the past 6 months with 5% using methamphetamines and 14% using amyl nitrates (i.e. poppers). Although only n=7 (4%) had used PrEP before, 81% had heard of PrEP and 57% thought they would be a good candidate to take PrEP. Objective and subjective measures of risk were balanced between arms. See Table 1 for further details.

Comparison of Subjective and Objective HIV Risk

Based on the self-perceived risk (SPR) score, n= 90 (53%) considered themselves low-risk, n=65 (38%) moderate risk and n=16 (9%) high or very high risk. The median CalcR score was 0.26% (IQR 0.1–0.44%) with n=60 (35%) categorized as low risk, n=79 (46%) as moderate risk and n=32 (19%) as high or very high risk. Thus, n=65 (38%) underestimated their HIV risk, n=83 (49%) had concordant predictions and n=23 (13%) overestimated their risk (Kappa=0.176) (See Table 2). The thirty-two MSM in the CalcR high risk category were particularly poor at estimating their risk with over 90% underestimating their risk. Using the HIRI-MSM score, the mean HIRI-MSM score was 18 (SD 8) with n=24 (14%) categorized as low risk and n=147 (86%) as high risk. When comparing SPR score with HIRI-MSM, n=75 (44%) underestimated their risk, n=87 (51%) had concordant predictions and only n=9 (5%) overestimated their risk (Kappa=0.053) (See Table 3).

Comparison of Objective HIV Risk Scores:

Table 4 shows the comparison between the CalcR risk and HIRI-MSM risk. Only 8 of the 111 individuals in the moderate/high CalcR risk group were classified as low risk by the HIRI-MSM. However nearly three-quarters (44/60) of the individuals considered low risk by CalcR were classified as high risk by HIRI-MSM, resulting in overall moderate concordance (Kappa=0.226) (See Table 4).

PrEP Uptake

At week 8, n=135 participants were reached for follow up, notably n=76 (88%) in the intervention arm and n=59 (69%) in the control arm (p=0.003). Attrition rate for the primary endpoint was 21%, with these participants unreachable by phone despite repeated call attempts. Of the 135 reached for follow up, only n=14 (10%) started PrEP including n=8/76 (11%) who received their risk score and n=6/59 (10%) who did not. Nearly 70% (n=93) thought about starting PrEP with n=54 (71%) in the intervention and n=39 (66%) in the control. There were no differences by arm in either PrEP uptake or consideration. We did find that higher risk participants by CalcR were more likely to be on PrEP at follow up compared to those with lower risk regardless of risk score receipt (15% in high and moderate risk groups versus 2% in the low risk group (p=0.042). Of the 121 participants who did not start PrEP, the most common reasons were low self-perceived risk (36%) and concerns about side effects (19%) with no difference by arm. Of note, n=18 (15%) reported waiting to get into a study or see a provider to get PrEP. We included these participants as having reached the primary endpoint and observed a slight separation in PrEP uptake in the intervention and control groups but still no statistically significant difference (28% versus 19%, p=0.31). A complete summary of participants' reasons for not going on PrEP is shown in Table 5.

Change in Subjective HIV Risk

SPR was compared at baseline and week 12. There was a trend towards decreased self-perceived risk overall (median=0, IQR: -2-1, p=0.06) but no difference between study arms (p=0.29). The likelihood of HIV acquisition (LHA) score was compared at baseline, week 8 and week 12. Overall, there was a significant decrease in LHA score from baseline to week 8 (median=-3.6%, IQR: -15-5.5%, p=0.006) but no difference by study arm (p=0.604).

From baseline to week 12, there was a trend towards decreased LHA overall (median= -1.8%, IQR: -11.5-5%, p=0.06) but no difference by study arm (p=0.39). There was no change in perceived PrEP candidacy between baseline and week 12 (57% versus 58%, p>0.99).

Discussion

Despite enrolling a high-risk population of MSM who often underestimated their risk for HIV acquisition, providing an objective HIV risk score to individuals did not increase their likelihood of starting or even considering PrEP. Our study suggests that by itself, a risk score elucidating actual HIV risk may not be enough to increase PrEP uptake. However, individuals who received their HIV risk score were more likely to follow up, which might indicate some acknowledgment of true risk and interest in PrEP. An assessment of HIV risk may be a starting point for further discussion around prevention methods.

MSM that test at dedicated HIV testing sites may be prime for discussion and even initiation of PrEP. Although there are individuals that regularly test who may be part of the “worried well,” 65% of our study population was found to be at substantial objective risk of HIV acquisition based on CalcR score and 85% with the HIRI-MSM score at baseline. The reason for this discrepancy between CalcR and HIRI-MSM risk scores is likely due to a higher dependency of objective HIV risk related to condomless sex acts during a discrete period of time in CalcR compared to a composite of behavioral factors in HIRI-MSM over a longer time course. This difference could be interpreted as CalcR missing individuals with certain high-risk behaviors (e.g. methamphetamines). Alternatively, CalcR scores may be more accurate because it recognizes that non-injection drug use does not in itself confer HIV risk-- it is the associated sexual acts that are pertinent. In addition, the shorter time period used in CalcR score decreases the potential for recall bias. Out of the 14 individuals who initiated PrEP, it is worth noting that 93% of these PrEP users had moderate (n=9) or high (n=4) objective HIV risk. This finding not only indicates that PrEP was appropriately used by those at substantial risk for HIV in our study but also suggests that the CalcR risk score may be a useful tool to predict which individuals will start PrEP. To determine if patient-specific HIV transmission events can accurately predict HIV acquisition, further validation of CalcR is needed against an HIV acquisition data set with event level data for STIs and the number of sex acts that preceded HIV incident cases.

In addition, despite no statistically significant change in self-perceived HIV risk throughout the study, there was a trend towards lower self-perceived risk at follow up. Studies have found that perceived elevated risk is a common reason for HIV testing which underscores the importance of discussing and offering PrEP around HIV testing.^{36,37} After receiving risk reduction counseling, individuals may also believe they can make behavioral changes to gain better control over their HIV risk. Thus, affording individuals time and space to consider PrEP and other HIV prevention strategies could ultimately dissuade them from starting PrEP.

As in previous studies, many individuals underestimated their risk of HIV acquisition compared to actual risk.³⁸⁻⁴⁰ Low perceived HIV risk has been shown to be related to erroneous beliefs about HIV transmission and epidemiology.^{41,42} Thus, PrEP screening in

MSM should include education about behaviors that increase HIV acquisition risk. Beyond HIV knowledge, HIV risk perception in MSM is likely influenced by non-epidemiologic factors including relationship type, partner trust and perceived threat of HIV infection⁴³, which objective risk scores do not take into account. As a result, there may be instances when objective risk is overestimated and subjective risk is more accurate. Further research is needed to understand the constructs that shape HIV risk perception which may lead to better alignment of subjective and objective HIV risk as well as more appropriate HIV prevention interventions for MSM.

The study had several limitations. Most significantly, the study was underpowered due to initial slow study uptake as well as attrition at week 8. In addition, follow up at 8 weeks may not have been sufficient time to reach the primary endpoint. As a result, it is difficult to draw final conclusions about PrEP uptake and consideration. Data capture was different at all 3 time points due to study constraints with the use of an iPad survey at the study site at baseline, verbal report through phone call to the study coordinator at week 8 and an online survey to be completed at the participant's choosing at week 12. Similar to HIRI-MSM, our intervention also does not adjust for viral load of partnership and therefore can overestimate actual risk for individuals who have partners with suppressed viral loads. Assessing viral status of HIV-infected partners is difficult as it relies on accurate knowledge of partners' HIV status, ART use, and adherence. Providing ranges of risk probability with and without partner viral suppression could be a strategy to improve the validity of CalcR scores. Finally, as previously discussed, the CalcR score and categories have not yet been validated in prospective studies of HIV incidence due to data element incompatibility with traditional sexual behavior questions.

In this cohort of at-risk MSM, providing an objective HIV risk score alone did not increase future PrEP uptake or change self-perceived HIV risk despite most recognizing PrEP candidacy. Discordance between perceived and actual risk may be a barrier to effective PrEP implementation, and efforts to develop population-specific HIV risk tools that combine an assessment of both local epidemiological and behavioral risk. Nevertheless, since HIV risk perception may be slightly higher around HIV testing, HIV testing may be a crucial time to help correct misperceptions about HIV risk and acquisition and initiate same day PrEP to facilitate greater uptake.

Acknowledgements:

We would like to thank our study participants for their time and contributions. We would like to thank the HIV testing sites (The AntiViral Research Center, Lead the Way and Family Health Centers The Night Clinic) for allowing us to conduct our study.

This research was supported by funds from California HIV/AIDS Research Program Grant PR15-SD-021 (to Sheldon Morris), CFAR Core Grant NIH grant P30 AI036214 (to Sonia Jain) and National Institutes of Health Grant KL2TR001444 (to Jill Blumenthal).

Jill Blumenthal is a Gilead US PrEP Advisor and a Gilead Educational Grant Recipient for another PrEP-related project.

Richard Haubrich is now an employee of Gilead Sciences, although not when the study started or was conducted.

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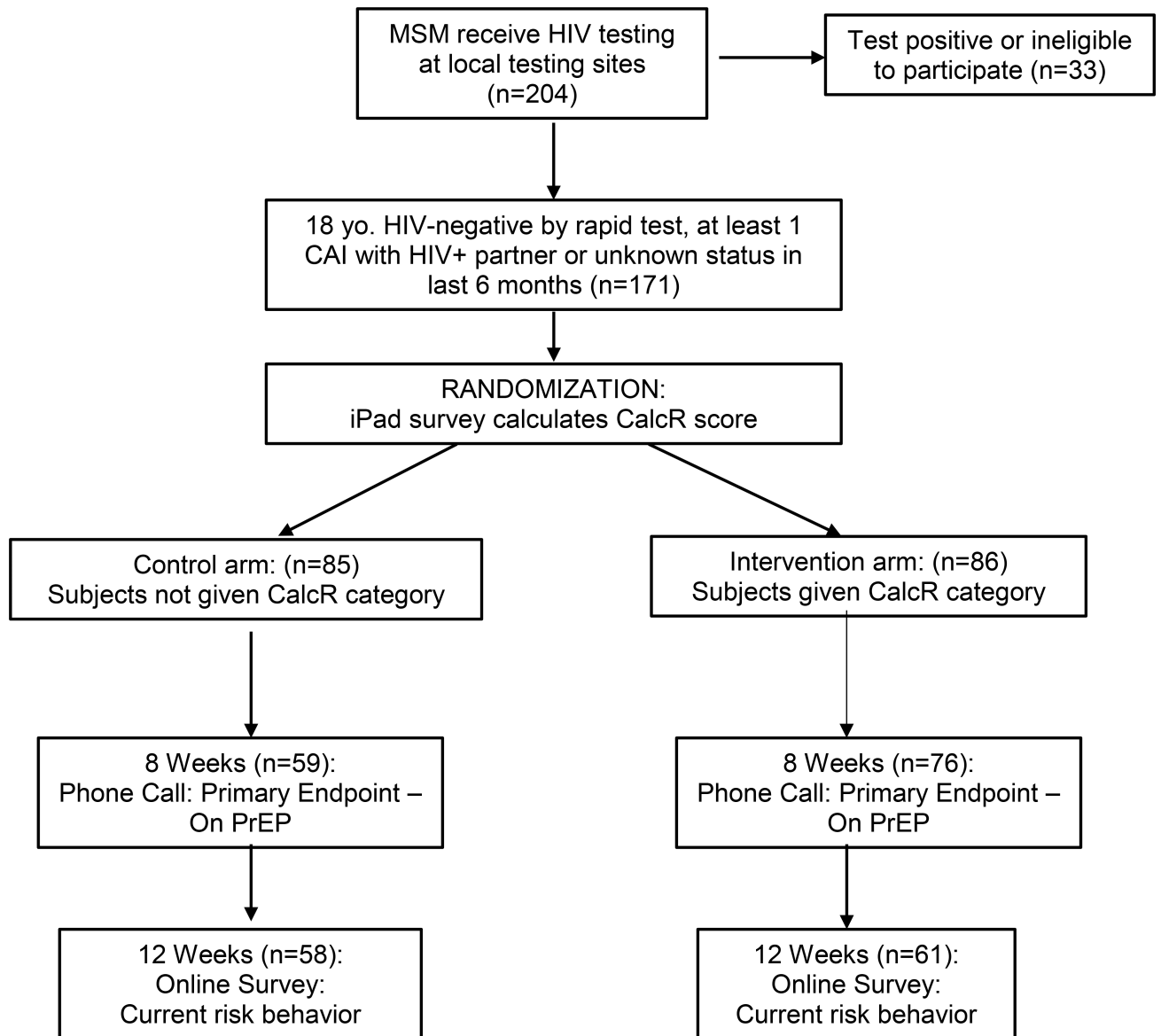


Figure 1: Participant Study Flow

Table 1.

Demographics and Baseline Risk Behaviors

	Control n=85 N (%)	Intervention n=86 N (%)	Total n=171 N (%)
Age **	36 (27–44)	30 (24–40)	32 (25–42)
Race			
White	51 (60%)	51 (59%)	102 (60%)
Black	7 (8%)	6 (7%)	13 (8%)
Other	27 (32%)	29 (34%)	56 (33%)
Ethnicity			
Latino	20 (26%)	26 (31%)	46 (29%)
Education*			
Some college or higher	81 (95%)	76 (88%)	157 (92%)
Monthly income			
<\$3000	39 (48%)	50 (63%)	89 (55%)
Insurance			
Public	12 (14%)	13 (15%)	25 (15%)
Private	53 (62%)	53 (62%)	106 (62%)
None	15 (18%)	13 (15%)	28 (16%)
Number of partners last 6 months **	5 (3–10)	5 (3–10)	5 (3–10)
Substance Use	23 (27%)	29 (34%)	52 (30%)
Methamphetamine Use	4 (5%)	4 (5%)	8 (5%)
Popper Use	10 (12%)	14 (16%)	24 (14%)
PrEP Awareness	71 (84%)	68 (79%)	139 (81%)
Prior PrEP Use	3 (4%)	4 (5%)	9 (5%)
Perceived PrEP Candidacy	47 (55%)	50 (58%)	97 (57%)
SPR Score **	3 (2–5)	4 (3–5)	3 (2–5)
SPR HIV Transmission Score **	14 (4–32)	16 (10–28)	15 (6–29)
CalcR Score **	0.23 (0–0.42)	0.26 (0.1–0.51)	0.26 (0.1–0.44)
HIRI-MSM **	18 (11–23)	18 (14–22)	18 (13–22)

** P-values <0.05

Median (interquartile range)

Table 2.

Objective Compared to Subjective HIV Risk: (CalcR vs. SPR)

		CalcR			
		Low	Moderate	High/V.High	Total
SPR	Low	42 (25%)	36 (21%)	12 (7%)	90
	Moderate	10 (6%)	38 (22%)	17 (10%)	65
	High/V. high	8 (5%)	5 (3%)	3 (2%)	16
	Total	60	79	32	171

49% concordant (Green); 38% underestimated risk (Red); 14% overestimated risk (Orange) (Kappa=0.176)

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Table 3.

Objective Compared to Subjective HIV Risk: (HIRI-MSM Score vs. SPR)

		HIRI-MSM		
		Low	High	Total
SPR	Low	15 (9%)	75 (44%)	90
	> Low	9 (5%)	72 (42%)	81
	Total	25	146	171

51% concordant (Green); 44% underestimated risk (Red); 5% overestimated risk (Orange) (Kappa=0.053)

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Table 4.

Comparison of Objective HIV Risk: (CalcR vs. HIRI-MSM)

		HIRI-MSM		
		Low	High	Total
CalcR	Low	16 (9%)	44 (26%)	60
	Moderate/High	8 (5%)	103 (60%)	111
	Total	24	147	171

69% concordant (Green); 26% high risk HIRI-MSM/ low risk CalcR (Red); 5% high risk CalcR/ low risk HIRI/MSM (Orange) (Kappa=0.226)

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Table 5.

Reported Reasons for Not Going on PrEP

Reason	Control (n=53)	CalcR (n=68)	Total (n=121)
Did not think at risk	18 (34%)	25 (37%)	43 (36%)
Side effects/toxicity	12 (23%)	11 (16%)	23 (19%)
Waiting to get into study or see doctor to get it	5 (9%)	13 (19%)	18 (15%)
No insurance or physician	6 (11%)	7 (10%)	13 (11%)
Too expensive	6 (11%)	3 (4%)	9 (7%)
Wanted more data/info	2 (4%)	3 (4%)	5 (4%)
Stigma	1 (2%)	1 (2%)	2 (2%)
No free study available	0	1 (2%)	1 (1%)
HIV+ by Nucleic Acid Test	1 (2%)	0	1 (1%)
Other	2 (4%)	4 (6%)	6 (5%)

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