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Prevalence and correlates of willingness to participate in a rectal microbicide trial among men who have sex with men in Bangkok

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Rectal microbicides (RMs) hold promise as a HIV prevention method to reduce transmission among men who have sex with men (MSM). To assess RM trial feasibility in Bangkok, we measured prevalence and correlates of willingness to participate among Thai MSM observational cohort participants. Between April 2006 and December 2010, 1744 MSM enrolled in the Bangkok MSM Cohort Study; at 12 months, RM trial participation willingness was measured. We evaluated correlates of RM trial participation willingness using logistic regression analysis. Participants completing the 12-month visit (81.4%, n = 1419) had a mean age of 27.3 years (SD = 6.1), and 65.5% and 86.1% reported having a steady partner or anal intercourse (AI) in the past four months, respectively. Most (79.1%, n = 1123) participants reported willingness to participate in an RM trial, which, in multivariable analysis, was independently associated with insertive only (adjusted odds ratio [AOR] = 3.25, 95% CI: 1.82–5.81) or receptive/versatile role AI (AOR = 3.07, 95% CI: 1.88–5.01), and being paid for sex (AOR = 12.15, 95% CI: 1.67–88.21) in the past four months, and believing that people with AIDS look sick (AOR = 1.92, 95% CI: 1.23–2.98). Of hypothetical RM trial features to increase enrollment likelihood, the most (91.1%) compelling was that the study be approved by the Thai ethics committee, followed by the study site offering evening hours (88.9%). Reasons not to participate were not wanting a rectal examination (29.5%) or fluid collected from the penis or anus (24.6%) and not wanting the placebo (23.0%). RM trial participation willingness was high, particularly for those with greater HIV acquisition risk, within this Thai MSM cohort, suggesting feasibility of an RM trial. Addressing potential barriers to trial entry may be useful in educational materials to optimize recruitment.

Keywords: rectal microbicide; men who have sex with men; clinical trial; HIV; prevention

Introduction

In the last decade, there has been significant progress in development of biomedical HIV prevention interventions (Abdool Karim et al., 2010; Grant et al., 2010; Rerks-Ngarm et al., 2009). Microbicide development has expanded, including products formulated for dual compartment and rectal use, as receptive anal intercourse (AI) carries greater HIV acquisition risk than vaginal intercourse (Kilmarx et al., 2008; Poynten et al., 2009; Ventuneac et al., 2010). Preliminary safety studies demonstrate that several candidate rectal microbicide (RM) products have *in vitro* activity against HIV without compromising epithelial integrity; Phase 1 and 2 trials are under way to determine product safety (Dezzutti et al., 2012; Li et al., 2012; Liu, Qu, Guo, & Sun, 2011; Richardson-Harman, Mauck, McGowan, & Anton, 2012). However, RM efficacy rests both on action against HIV and on acceptability and willingness of individuals at risk to use the product (McGowan, 2011). Among men who have sex with men (MSM), studies indicate that lubricant use with AI is normative in the USA and Peru (Carballo-Diéguez et al., 2000, 2008; Gross, Buchbinder, Celum, Heagerty, & Seage, 1998; Kinsler et al., 2010). Lubricant use was reported more frequently than condom use, suggesting men who typically do not use condoms may be amenable to an RM formulated as a lubricant (Carballo-Diéguez et al., 2000; Kinsler et al., 2010). In several studies, most MSM were interested in RM use and willing to participate in trials (Carballo-Diéguez et al., 2000; Gross et al., 1998; Kinsler et al., 2010). However, differences in lubricant use and RM product preferences within the USA and with other countries indicate that context must be considered in product development (Kinsler et al., 2010; Mantell et al., 2005; McGowan, 2010, 2011). Further prevention modalities are urgently needed among Bangkok MSM populations due to a concentrated HIV epidemic with high incidence rates and continued suboptimal condom use (van Griensven et al., 2009, 2013; Centers for Disease Control & Prevention, 2013). There are few data regarding RM trial participation willingness among Asian MSM populations, though Thai sites are included in other HIV prevention trials among MSM (McGowan, 2011). Willingness to

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participate in clinical trials varied from 86% for oral preexposure prophylaxis, 70% for vaccine trials, and 30% for circumcision trials among MSM in northern Thailand; no RM trial interest data were collected (Chariyalertsak et al., 2011). This study was performed within an observational cohort of Bangkok MSM to measure prevalence and correlates of RM trial participation willingness, with results intended to guide product design and counseling guides for impending RM trials.

Methods

Study population

Between April 2006 and November 2010, 1744 MSM enrolled in the Bangkok MSM Cohort Study (BMCS), an observational cohort study among MSM in Bangkok, Thailand. The study methodology has been described elsewhere (van Griensven et al., 2010, 2013). Briefly, participants were Thai men aged ≥18 years residing in the Bangkok metropolitan area reporting penetrative oral or anal sex with another man in the past six months. Men were recruited using nonprobability sampling from venues regularly patronized by MSM, the Internet, a male sexual health clinic, and through outreach workers and presented to the Silom Community Clinic (SCC) for enrollment and all study activities. A total of 1977 men were recruited and 1777 (89.9%) met inclusion criteria. Of 1777 eligible men, 33 (1.9%) did not want to participate in the study. Consented participants returned every four months for HIV testing, medical, and behavioral assessments, with supplemental testing for herpes simplex 1 and 2 (HSV-1 and 2) virus and syphilis (with Rapid Plasma Reagin and *Treponema pallidum* antibody testing) at 12-month intervals. All men received 500 Baht (US$15.60) for time and travel compensation at each visit. Lubricants and condoms were provided at no cost to all participants.

The protocol of this study was approved by the Ethical Review Committee for Research in Human Subjects of the Thailand Ministry of Public Health and by the Office of the Associate Director of Science of the US Centers for Disease Control and Prevention.

Measures

Data were collected from all participants at baseline and each four-month follow-up visit eliciting sociodemographic characteristics (e.g., age, education, employment status, and living situation), HIV knowledge and awareness, and in the past four months, drug and alcohol use (frequency and type, used to increase sexual pleasure), and sexual behavior (number of steady, casual, and transactional partners, condom use, and group sex). Age and education were considered as categorical variables using the same divisions as prior analyses for comparability (van Griensven et al., 2010, 2013). An RM trial supplement was administered to all participants completing the 12-month visit. A brief hypothetical RM study was described, with the script including the definition of microbicide, documented microbicide safety among women, and the putative trial being voluntary and including a placebo arm (see Supplementary material for script). Participants were then asked, "How willing would you be to join a study like that?" RM trial participation willingness was assessed on a five-point scale (definitely willing, probably willing but need to think about it, not willing and not unwilling, probably not willing, and definitely not willing) and was dichotomized into "willing" (definitely willing and probably willing), and "probably not willing, and definitely not willing" for the other responses. The participants in neutral group (not willing and not unwilling) were excluded to prevent a classification error. Potential reasons to consider joining or not joining a trial were also explored, with participants responding yes or no to a listed reason, such as desire for regular HIV testing. These reasons were formulated based on investigator expertise and review of the available literature. Participants were also asked whether they would use an RM product and with what frequency pending product availability.

The questionnaire was administered using an audio computer-assisted self-interview (ACASI) in a private and quiet area at the study site to ensure confidentiality and to encourage candid disclosure of risk behavior. Use of ACASI has been shown to offer many advantages for data collection in several HIV/AIDS studies, especially the assessment of sensitive and stigmatized behavioral data or disclosure of HIV risk behavior, than other methods (Dolezal et al., 2012; Le & Vu, 2012; Sylvia et al., 2014).

Data analysis

Descriptive statistics were generated to characterize the study population available at 12 months and RM trial participation willingness. Agreement with statements describing motivating factors to participate or not participate in an RM trial was quantified by proportions; differences between HIV-positive and HIV-negative men were assessed with chi-square or exact test, as appropriate. Logistic regression analysis was performed to assess correlates of RM trial participation willingness. Variables associated at the $p = 0.10$ level in bivariate analysis were included in the multivariable model constructed with manual forward selection using likelihood ratio test. Variables included in the final model retained statistical

significance at a level of $p = 0.05$ (two-sided). Data analysis was performed using SPSS 17.0 (SPSS Inc., Chicago, IL, USA).

Results

Characteristics of the participants

Of 1744 baseline BMCS participants, 1419 (81.4%) completed the RM trial supplement at 12 months, whose demographic and behavioral characteristics are displayed in Table 1. About 50% of participants had education beyond secondary or vocational school and 59% reported receptive or versatile AI at cohort entry (Table 1).

Reported sexual and drug use behaviors

In the past four months, most participants (86.1%) reported AI, two-thirds reported having at least one steady partner, and nearly all reported at least one casual partner, with a mean of 1.9 (SD ± 3.9) steady and 5.1 (SD ± 7.4) casual partners (Table 1). Approximately 10% of participants reported paid sex, either as giving or receiving payment. Reported consistent condom use ranged between 61.3% with steady partners, 75.3% when paid for sex, 76.9% with casual partners, and 78.1% when clients in paid sexual encounters. Less than 10% of participants reported recent binge drinking or use of club or erectile dysfunction drugs (Table 1).

RM trial participation willingness

All men were asked to indicate RM trial participation willingness: 58.1% ($n = 824/1419$) were definitely willing, 21.1% ($n = 299$) were probably willing, 13.5% ($n = 191$) were not sure, 5.1% ($n = 73$) were probably not willing, and 2.3% ($n = 32$) were definitely not willing. If an effective RM gel became available, nearly all (97.3%, $n = 1381/1419$) men said they would use it. Most men stated they would always use the RM gel during AI (93.4%, $n = 1325$) and would still use a condom during AI even if RM gel was also used (93.7%, $n = 1329$).

Regarding reasons to consider RM trial participation, over 90% agreed that all listed reasons were important motivating factors, with the exception of concern over personal HIV risk (Table 2). Potential reasons for not participating in an RM trial included not wanting a rectal examination or penile or anal specimens collected and not wanting to receive a placebo, stated by more than 20% of participants (Table 2). Features enhancing likelihood of joining an RM trial were having Thai Ministry of Public Health ethical approval and evening hours at the study site (Table 2). The impact of prevalent HIV infection on trial entry reasons was also assessed (Table 2). No reasons differed significantly by HIV status overall; though, among men willing to join RM trials, HIV-positive men were less likely to agree with having a regular HIV test as a trial entry reason while they were more likely to be motivated to determine whether a microbicide was effective for HIV prevention. For reasons to decline trial entry, HIV-positive men were significantly more likely to decline based on perceived disagreement with entry by family and/or friends.

Factors associated with RM trial participation willingness

In bivariate logistic regression analysis, education below secondary school and, in the past four months, binge drinking, using club drugs, being paid for sex, and insertive and receptive AI were significantly associated with RM trial participation willingness (Table 3). In addition, agreeing that people with AIDS usually appear ill and being diagnosed with HSV-2 antibody at enrollment were positively associated with RM trial participation willingness (Table 3). Consistent condom use was not associated with trial participation willingness (data not shown).

In multivariable analysis, having AI, being paid for sex in the past four months, and reporting that AIDS patients appear ill were independently associated with RM trial participation willingness (Table 3).

Discussion

Most BMCS participants reported RM trial participation willingness, particularly those with recent risk behaviors. We did not inquire about RM awareness but high trial participation interest levels have been recorded among MSM with low RM awareness levels in New York (Carballo-Diéguez et al., 2000; Nodin, Carballo-Diéguez, Ventuneac, Balan, & Remien, 2008). However, among an Australian MSM cohort, RM trial participation willingness was relatively low at 24% in 2006–2007 (Poynten et al., 2010). Among this group, RM awareness was also low (14%) and associated with unwillingness to participate in an RM trial, which the authors associated with knowledge of rectal toxicity within nonoxynol-9 trials (Poynten et al., 2010). Thus, context is important in determining presentation of and receptivity to RM product trials.

In this context of an ongoing observational cohort study in Bangkok, most participants agreed that contributing to HIV prevention knowledge, preventing future infections for self and others, and personal receipt of testing and health care were important motivating factors for trial entry. We acknowledge that these aspects may have similarly motivated men to participate in the BMCS and, thus, may not be generalized to all Bangkok MSM. Concern regarding one's own risk of HIV did not receive

Table 1. Participant characteristics by willingness to participate in an RM trial among Thai MSM in Bangkok, Thailand, 2006–2010 (n = 1419).

Characteristics	Total, *n* (%)	Willing, *n* (%)	Neutral, *n* (%)	Unwilling, *n* (%)
Total	1419 (100)	1123 (79.1)	191 (13.5)	105 (7.4)
Age group				
18–21	224 (15.8)	180 (16.0)	34 (17.8)	10 (9.5)
22–29	765 (53.9)	614 (54.7)	102 (53.4)	49 (46.7)
≥30	430 (30.3)	329 (29.3)	55 (28.8)	46 (43.8)
Education				
Less than secondary school	116 (8.2)	96 (8.5)	16 (8.4)	4 (3.8)
Completed secondary or vocational school	629 (44.3)	516 (45.9)	80 (41.9)	33 (31.4)
University education and above	674 (47.5)	511 (45.5)	95 (49.7)	68 (64.8)
HIV diagnosed at cohort entry				
Yes	285 (20.1)	229 (20.4)	34 (17.8)	22 (20.9)
No	1134 (79.9)	894 (79.6)	157 (82.2)	83 (79.1)
T. pallidum *antibody at cohort entry*				
Yes	67 (4.7)	59 (5.3)	5 (2.6)	3 (2.9)
No	1352 (95.3)	1064 (94.7)	186 (97.4)	102 (97.1)
HSV-2 antibody at cohort entry				
Yes	270 (19.0)	227 (20.2)	31 (16.2)	12 (11.4)
No	1149 (81.0)	896 (79.8)	160 (83.8)	93 (88.6)
Binge drinking (*past 4 m*)[a]				
Yes	119 (8.4)	106 (9.4)	10 (5.2)	3 (2.9)
No	1300 (91.6)	1017 (90.6)	181 (94.8)	102 (97.1)
Used club drugs (*past 4 m*)[b]				
Yes	107 (7.5)	96 (8.5)	10 (5.2)	1 (0.9)
No	1312 (92.5)	1027 (91.5)	181 (94.8)	104 (99.0)
Anal sex position with male (*past 4 m*)				
Insertive only	388 (27.3)	310 (27.6)	55 (28.8)	23 (21.9)
Receptive only or both	835 (58.8)	681 (60.6)	104 (54.4)	50 (47.6)
No anal sex	196 (13.8)	132 (11.8)	32 (16.8)	32 (30.5)
Being paid for sex by male sexual partners (*past 4 m*)				
Yes	161 (11.3)	144 (12.8)	16 (8.4)	1 (1.0)
No	1258 (88.7)	979 (87.2)	175 (91.6)	104 (99.0)
Met casual partner on Internet (*past 4 m*; *n = 953*)				
Yes	426 (44.7)	353 (46.2)	49 (38.3)	24 (39.3)
No	527 (55.3)	411 (53.8)	79 (61.7)	37 (60.7)
Ever had group sex				
Yes	212 (14.9)	180 (16.0)	20 (10.5)	12 (11.4)
No	1207 (85.1)	943 (84.0)	171 (89.5)	93 (88.6)

Table 1 (*Continued*)

Characteristics	Total, *n* (%)	Willing, *n* (%)	Neutral, *n* (%)	Unwilling, *n* (%)
Ever used lubricant				
Yes	1329 (93.7)	1059 (94.3)	177 (92.7)	93 (88.6)
No	90 (6.3)	64 (5.7)	14 (7.3)	12 (11.4)
Agree with statement				
People with AIDS usually look very sick (*n* = 1418)				
Agree	612 (43.2)	504 (44.9)	76 (39.8)	32 (30.5)
Disagree	806 (56.8)	618 (55.1)	115 (60.2)	73 (69.5)
AIDS is common among MSM (*n* = 1418)				
Agree	470 (33.1)	390 (34.8)	53 (27.7)	27 (25.7)
Disagree	948 (66.9)	732 (65.2)	138 (72.3)	78 (74.3)
Biomedical markers				
Incident HIV in first year of study (*n* = 1134 HIV-negative at entry)				
Yes	55 (4.9)	47 (5.3)	5 (3.2)	3 (3.6)
No	1079 (95.1)	847 (94.7)	152 (96.8)	80 (96.4)
Incident HSV-2 in first year of study (*n* = 1149)				
Yes	81 (7.0)	60 (6.7)	15 (9.4)	6 (6.4)
No	1068 (93.0)	836 (93.3)	145 (90.6)	87 (93.6)
Incident *T. pallidum* antibody at 12 m (*n* = 1352)				
Yes	18 (1.3)	15 (1.4)	2 (1.1)	1 (1.0)
No	1334 (98.7)	1049 (98.6)	184 (98.9)	101 (99.0)

[a]Got drunk 2–3 times per week or more in the past four months among those who used alcohol.
[b]Club drugs = marijuana, ecstasy, methamphetamine, ketamine, cocaine, and gamma hydroxybutyrate.
n = number; *m* = months.

Table 2. Differences regarding reasons for possible RM trial participation among MSM stating definite or probable willingness to enter an RM trial compared to those neutral and unwilling to enter a trial in Bangkok, Thailand, 2006–2010[a] (n = 1419).

	Overall affirmative responses		Affirmative responses among men willing to participate (n = 1123)		Affirmative responses among men neutral to participate (n = 191)		Affirmative responses among men unwilling to participate (n = 105)	
	HIV-positive, n (%)	HIV-negative, n (%)	HIV-positive, n (%)	HIV-negative, n (%)	HIV-positive, n (%)	HIV-negative, n (%)	HIV-positive, n (%)	HIV-negative, n (%)
Total	285 (100)	1134 (100)	229 (100)	894 (100)	34 (100)	157 (100)	22 (100)	83 (100)
Reasons to participate								
To make it possible for MSM to reduce risk for HIV	281 (98.6)	1107 (97.6)	228 (99.6)	884 (98.9)	34 (100)	153 (97.5)	19 (86.4)	70 (84.3)
To have a regular sexual health checkup	278 (97.5)	1099 (96.9)	225 (98.3)	873 (97.7)	33 (97.1)	152 (96.8)	20 (90.9)	74 (89.2)
To learn more about HIV	279 (97.9)	1103 (97.3)	227 (99.1)	884 (98.9)	34 (100)	152 (96.8)	18 (81.8)	67 (80.7)
To help prevent HIV in Thailand	281 (98.6)	1095 (96.6)	227 (99.1)	874 (97.8)	34 (100)	149 (94.9)	20 (90.9)	72 (86.8)
To contribute to science and knowledge about HIV	281 (98.6)	1102 (97.2)	228 (99.6)	886 (99.1)	34 (100)	151 (96.2)	19 (86.4)	65 (78.3)
To have a regular HIV test	268 (94.0)	1108 (97.7)	219 (95.6); p = 0.003	882 (98.7)	32 (94.1)	153 (97.5)	17 (77.3)	73 (88.0)
To find out whether the microbicide is effective for preventing HIV	273 (95.8)	1040 (91.7)	223 (97.4); p = 0.045	841 (94.1)	33 (97.1)	141 (89.8)	17 (77.3)	58 (69.9)
To have protection from HIV from the study microbicide product	258 (90.5)	1019 (89.9)	208 (90.8)	827 (92.5)	32 (94.1)	135 (86.0)	18 (81.8)	57 (68.7)
I would participate in a trial because of concern about my risk for HIV	229 (80.4)	894 (78.8)	180 (78.6)	608 (68.0)	24 (70.6)	89 (56.7)	13 (59.1)	41 (49.4)
Reasons to decline trial entry								
I don't want to undergo a rectal exam	64 (22.5); p = 0.004	354 (31.2)	42 (18.3)	214 (23.9)	11 (32.4); p = 0.030	83 (52.9)	11 (50.0)	57 (67.7)
I don't want fluid collected from my penis or anus	61 (21.4)	288 (25.4)	38 (16.6)	161 (18.0)	12 (35.3)	76 (48.4)	11 (50.0)	51 (61.5)
I don't want to receive a placebo	57 (20.0)	270 (23.8)	43 (18.8)	177 (19.8)	4 (11.8); p = 0.009	54 (34.4)	10 (45.5)	39 (47.0)
The trial would require too much of my time	39 (13.7)	177 (15.6)	18 (7.9)	93 (10.4)	8 (23.5)	49 (31.2)	13 (59.1)	35 (42.2)
I don't want to have my blood drawn	22 (7.7)	96 (8.5)	12 (5.2)	48 (5.4)	3 (8.8)	20 (12.7)	7 (31.8)	28 (33.7)
My family/friends would not want me to join	28 (9.8); p < 0.001	51 (4.5)	22 (9.6); p < 0.001	30 (3.4)	2 (5.9)	12 (7.6)	4 (18.2)	9 (10.8)
I don't want to take HIV tests	13 (4.6)	25 (2.2)	7 (3.1)	16 (1.8)	0 (0.0)	2 (1.27)	6 (27.3); p = 0.017	7 (8.4)
Factors potentially increasing trial interest								
Knowing the study has been approved by the Thai MOPH	256 (89.8)	1037 (91.4)	217 (94.8)	839 (93.8)	26 (76.5); p = 0.033	141 (89.8)	13 (59.1)	57 (68.7)
Participants can come to the clinic in the evening	248 (87.0)	1014 (89.4)	211 (92.1)	832 (93.1)	26 (76.5)	129 (82.2)	11 (50.0)	53 (63.9)
Knowing that the microbicide has been successful in other studies of men	221 (77.5)	884 (78.0)	190 (83.0)	724 (81.0)	22 (64.7)	114 (72.6)	9 (40.9)	46 (55.4)
Receive a high level of compensation for time and travel	76 (26.7)	370 (32.6)	64 (27.9)	292 (32.7)	8 (23.5)	54 (34.4)	4 (18.2)	24 (28.9)

[a]RM trial participation willingness was assessed on a five-point scale (definitely willing, probably willing but need to think about it, not willing and not unwilling, probably not willing, and definitely not willing) and was categorized into "willing" (definitely willing and probably willing), "neutral" (not willing and not unwilling), or "not willing" for the other responses. Differences were assessed with chi-square or exact test with significant p-values ($p < 0.05$) reported.

Table 3. Participant characteristics associated with willingness to participate in an RM trial among Thai MSM by bivariate and multivariable logistic regression analysis in Bangkok, Thailand, 2006–2010 (n = 1128).

Characteristics	Total, *n* (%)	Willing, *n* (%)	Unwilling, *n* (%)	Unadjusted odds ratio (95% CI)	Adjusted odds ratio (95% CI)
Total	1228 (100)	1123 (91.4)	105 (8.6)		
Age group					
18–21	190 (15.5)	180 (16.0)	10 (9.5)	2.52 (1.24–5.11)	
22–29	663 (54.0)	614 (54.7)	49 (46.7)	1.75 (1.15–2.68)	
≥30	375 (30.5)	329 (29.3)	46 (43.8)	1	
Education					
Less than secondary school	100 (8.1)	96 (8.5)	4 (3.8)	3.19 (1.14–8.96)	
Completed secondary or vocational school	549 (44.7)	516 (45.9)	33 (31.4)	2.08 (1.35–3.21)	
University education and above	579 (47.1)	511 (45.5)	68 (64.8)	1	
HIV diagnosed at cohort entry					
Yes	251 (20.4)	229 (20.4)	22 (20.9)	0.97 (0.59–1.58)	
No	977 (79.6)	894 (79.6)	83 (79.0)	1	
T. pallidum *antibody at cohort entry*					
Yes	62 (5.0)	59 (5.3)	3 (2.9)	1.88 (0.58–6.12)	
No	1166 (94.9)	1064 (94.7)	102 (97.1)	1	
HSV-2 antibody at cohort entry					
Yes	239 (19.5)	227 (20.2)	12 (11.4)	1.96 (1.06–3.64)	
No	989 (80.5)	896 (79.8)	93 (88.6)	1	
Binge drinking (*past 4 m*)[a]					
Yes	109 (8.9)	106 (9.4)	3 (2.9)	3.54 (1.10–11.36)	
No	1119 (91.1)	1017 (90.6)	102 (97.1)	1	
Used club drugs (*past 4 m*)[b]					
Yes	97 (7.9)	96 (8.5)	1 (0.9)	9.72 (1.34–70.44)	
No	1131 (92.1)	1027 (91.5)	104 (99.0)	1	
Anal sex position with male (*past 4 m*)					
Insertive only	333 (27.6)	310 (27.6)	23 (21.9)	3.27 (1.84–5.80)	3.25 (1.82–5.81)
Receptive only or both	731 (59.5)	681 (60.6)	50 (47.6)	3.30 (2.04–5.34)	3.07 (1.88–5.01)
No anal sex	164 (13.4)	132 (11.8)	32 (30.5)	1	1
Being paid for sex by male sexual partners (*past 4 m*)					
Yes	145 (11.8)	144 (12.8)	1 (1.0)	15.29 (2.12–110.47)	12.15 (1.67–88.21)
No	1083 (88.2)	979 (87.2)	104 (99.0)	1	1

Table 3 (*Continued*)

Characteristics	Total, *n* (%)	Willing, *n* (%)	Unwilling, *n* (%)	Unadjusted odds ratio (95% CI)	Adjusted odds ratio (95% CI)
Met casual partner on Internet (*past 4 m*; *n* = *825*)					
Yes	377 (45.7)	353 (46.2)	24 (39.3)	1.32 (0.78–2.26)	
No	448 (54.3)	411 (53.8)	37 (60.7)	1	
Ever had group sex					
Yes	192 (15.6)	180 (16.0)	12 (11.4)	1.48 (0.79–2.76)	
No	1036 (84.4)	943 (84.0)	93 (88.6)	1	
Ever used lubricant					
Yes	1152 (93.8)	1059 (94.3)	93 (88.6)	2.13 (1.11–4.10)	
No	76 (6.2)	64 (5.7)	12 (11.4)	1	
Agree with statement					
People with AIDS usually look very sick (*n* = 1227)					
Agree	536 (43.7)	504 (44.9)	32 (30.5)	1.86 (1.21–2.86)	1.92 (1.23–2.98)
Disagree	691 (56.3)	618 (55.1)	73 (69.5)	1	1
AIDS is common among MSM (*n* = 1227)					
Agree	417 (34.0)	390 (34.8)	27 (25.7)	1.54 (0.98–2.42)	
Disagree	810 (66.0)	732 (65.2)	78 (74.3)	1	
Biomedical markers					
Incident HIV in first year of study (*n* = 977 HIV-negative at entry)					
Yes	50 (5.1)	47 (5.3)	3 (3.6)	1.48 (0.45–4.86)	
No	927 (94.9)	847 (94.7)	80 (96.4)	1	
Incident HSV-2 in first year of study (*n* = 989)					
Yes	66 (6.7)	60 (6.7)	6 (6.4)	1.04 (0.44–2.48)	
No	923 (93.3)	836 (93.3)	87 (93.6)	1	
Incident *T. pallidum* antibody at 12 months (*n* = 1166)					
Yes	16 (1.4)	15 (1.4)	1 (1.0)	1.44 (0.19–11.05)	
No	1150 (98.6)	1049 (98.6)	101 (99.0)	1	

[a]Got drunk 2–3 times per week or more in the past four months among those who used alcohol.
[b]Club drugs = marijuana, ecstasy, methamphetamine, ketamine, cocaine, and gamma hydroxybutyrate.
CI = confidence interval; *n* = number; *m* = months.

the same high level of agreement, potentially due to underestimation of personal risk, reflected by ongoing high HIV incidence in this cohort (van Griensven et al., 2013). HIV-positive status had little impact on positive motivators for trial entry. Among men willing to participate, it is not surprising that regular HIV testing within a trial would hold less appeal for those with an existing HIV diagnosis. The desire to know whether RM products were effective may be more pronounced among HIV-positive men due to interest in protecting current and future partners. Factors influencing hypothetical trial acceptability were also explored and those reflecting safety precautions within the study or those that made participation more convenient were most frequently endorsed. The SCC is open from 16:00 to 21:00 five nights/week and has become an established resource for health and social work needs (Berry, Escobar, & Pitorak, 2012). Evening hours are convenient to the BMCS population, the vast majority of whom are students and/or working, and provide a replicable model to optimize service and study activity utilization.

Conversely, several reasons for not wanting to participate in an RM trial were stated by a higher proportion of those not interested in trial participation, including not wanting penile or rectal fluid swabs collected or regular rectal examinations and not wanting to receive a placebo. These preferences are similar to reported deterrents to trial entry among MSM in the USA in 1995 (Gross et al., 1998). BMCS participants were requested to have rectal and (for a minority until urine testing was performed) urethral swab collection at trial entry for *Neisseria gonorrhea* and *Chlamydia trachomatis* testing; this experience, which is often considered painful, may have been the first such examination for many participants as purchase of antibiotics without a prescription in Thailand provides the option for self-treatment (Lawung et al., 2012). Interestingly, HIV-positive men were less likely to disagree with need for rectal examination, possibly due to increased interest in preserving good health. Approximately 10% of men in the BMCS did not consent to anal specimen collection at enrollment. Providing detailed information on rectal examinations may improve men's RM trial entry receptivity. HIV-positive men were also more likely to agree that friends and family would not support their participation, possibly due to perceived fears about negative impact on the potential participant's health. Other studies assessing RM trial interest have focused on whether MSM would use an RM product with proven HIV prevention efficacy and also on desired product characteristics but less so on motivations to enter a trial (Carballo-Diéguez et al., 2000, 2008; Kinsler et al., 2012). Further formative work is needed to explore trial participation reasons such that perceived negative aspects can be factually addressed in recruitment and enrollment materials in a context-appropriate fashion (McGowan, 2011).

Receiving payment for sex may compromise the ability to negotiate or use condoms, which was independently associated with RM trial entry willingness. This association may reflect potential appeal of a product that can be applied hours before sexual activity (Liu et al., 2012; Mimiaga, Reisner, Tinsley, Mayer, & Safren, 2009; Morineau et al., 2011). Participants reporting recent AI may be cognizant of their risk and also interested in a product that could replace condoms. We did not query whether an RM product would be used instead of condoms but the high percentage of participants reporting interest in using an RM product with proven efficacy may speak to this potential exchange, as noted among Latino MSM in New York (Carballo-Diéguez et al., 2000). The association between RM trial participation willingness and perceiving that AIDS patients appear ill may reflect greater awareness of the natural history of HIV infection and thus greater interest in prevention measures. This question was asked only at enrollment; perceptions regarding correlation of appearance with AIDS may have changed throughout the first year of the cohort period. Condom use with any type of partner was not significantly associated with RM trial interest; further research is needed regarding the connection between HIV knowledge, personal risk assessment, and use of prevention measures as RM products and other modalities become available (McGowan, 2011; Poynten et al., 2010).

Of note, HIV diagnosis at cohort entry was not associated with RM trial participation willingness, despite lack of perceived personal benefit reported by HIV-positive MSM in New York (Nodin et al., 2008). Incident HIV, HSV-2, or syphilis, potentially reflecting increased risk behaviors, were not associated with RM trial participation willingness, which may be secondary to small numbers of incident infections at 12 months and because 12-month laboratory results were not available to participants before questionnaire completion.

Participants for this sub-study may differ from MSM elsewhere in Bangkok and had already completed between one and three BMCS visits, potentially developing trusting relationships with the study staff. This experience might have influenced individuals' willingness, with observed levels of RM trial willingness not generalizable to other Thai MSM populations. However, the BMCS is an observational cohort and does not involve an investigational product or intervention; thus, men may not have been fully aware of a potentially higher risk level within an RM trial, which could influence their decisions when counseled for entry into such a trial. A much lower percentage of Australian MSM cohort participants reported RM trial participation willingness, suggesting that prior study entry may not

positively predispose individuals to trial entry (Poynten et al., 2010).

There are additional limitations that must be considered. Questions regarding RM trial participation willingness were asked of participants retained at 12-month follow-up, potentially selecting men who are more likely to participate and have higher compliance with study protocols. Some consideration should be given to those lost to follow-up, representing approximately 20% of original participants, whose inclusion may have altered these results. Reasons for trial participation were not based on formative work and were asked as yes/no questions, possibly not capturing salient reasons for or concerns surrounding potential RM trial participation. A qualitative component has been recommended by other investigators to better elucidate RM product preferences and likelihood of use (Clark et al., 2013; Nodin et al., 2008). This approach could inform RM trial counseling but was not conducive to the ACASI data collection system used for this study.

In summary, most men reported willingness to participate in an RM trial, particularly those who reported higher levels of HIV risk behaviors or HIV self-risk perception, and a potential RM trial was perceived to be beneficial to participants and to the MSM community. Thus, RM trials among Thai MSM in Bangkok appear to be acceptable. However, education about HIV risk and trial participation, particularly the necessity of examinations, may help to increase RM trial interest among this population. Further studies should explore lubricant product preferences among Thai MSM and their partners to tailor RM candidate products to the Thai context prior to larger RM efficacy trials (McGowan, 2011).

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Supplementary material

Supplementary material is available via the "Supplementary" tab on the article's online page (http://dx.doi.org/10.1080/09540121.2014.913763).

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