

Willingness to Participate in Future HIV Prevention Studies Among Gay and Bisexual Men in Scotland, UK: A Challenge for Intervention Trials

Lisa M. McDaid · Graham J. Hart

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Abstract This article examines willingness to participate in future HIV prevention research among gay and bisexual men in Scotland, UK. Anonymous, self-complete questionnaires and Orasure™ oral fluid samples were collected in commercial gay venues. 1,320 men were eligible for inclusion. 78.2% reported willingness to participate in future HIV prevention research; 64.6% for an HIV vaccine, 57.4% for a behaviour change study, and 53.0% for a rectal microbicide. In multivariate analysis, for HIV vaccine research, greater age, minority ethnicity, and not providing an oral fluid sample were associated with lower willingness; heterosexual orientation and not providing an oral fluid sample were for microbicides; higher education and greater HIV treatment optimism were for behaviour change. STI testing remained associated with being more willing to participate in microbicide research and frequent gay scene use remained associated with being more willing to participate in behaviour change research. Having an STI in the past 12 months remained significantly associated with being willing to participate in all three study types. There were no associations between sexual risk behaviour and willingness. Although most men expressed willingness to participate in future research, recruitment of high-risk men, who have the potential to benefit most, is likely to be more challenging.

Keywords Men who have sex with men · HIV prevention · Vaccines · Microbicides · Behaviour change · Trial participation

Introduction

A resurgence in diagnosed HIV has been noted among men who have sex with men (MSM) in North America, Western Europe and Australia [1], and MSM remain the group most at risk of acquiring HIV in the UK, with estimated prevalence of 5% [2]. New HIV prevention strategies are needed and current policy initiatives set prevention as key to efforts to combat the epidemic among MSM in the UK [2, 3].

A recent review of randomized controlled trials (RCTs) of interventions to reduce the sexual transmission of HIV infection found only five of 37 had positive effects (all biomedical—three male circumcision, one STI treatment and care and one vaccine trial), and only one, non-biomedical intervention, targeted MSM [4]. Evidence of the potential effectiveness of behavioural HIV prevention interventions for MSM is growing, but few have included biological endpoints to measure HIV or sexually transmitted infection (STI) acquisition [5]. Although male circumcision has been shown to reduce the risk of HIV acquisition among heterosexual men [6], there is not the same evidence for MSM [7]; a finding recently supported by our own data [8]. In addition, it appeared unlikely that a RCT of male circumcision would be viable in this population, with only 14% reporting that they would be willing to participate in a research study on circumcision and HIV prevention [8]. So far, the Preexposure Prophylaxis Initiative (iPrEx) Study is the only biomedical intervention with biological endpoints to have demonstrated efficacy in

L. M. McDaid (✉)
MRC/CSO Social and Public Health Sciences Unit,
4 Lilybank Gardens, Glasgow G12 8RZ, UK
e-mail: l.mcdaid@sphsu.mrc.ac.uk

G. J. Hart
Faculty of Population Health Sciences,
University College London, London, UK

MSM [9]. The lack of effect in most RCTs is argued to be partly the result of design and implementation problems; an issue requiring consideration in future studies [4]. Indeed, assessing the acceptability and feasibility of future prevention efforts prior to initiating interventions is an important part of their development [10–13].

Since 1996, we have surveyed the HIV-related sexual behaviour of MSM in Scotland [14–22]. In 2008, we examined men's current and potential future contact with HIV prevention efforts and this article describes the extent to which MSM were willing to participate in future HIV prevention research, the factors associated with this, and the implications for future interventions with this population.

Methods

The 2008 Medical Research Council (MRC) Gay Men's Survey collected anonymous, self-complete questionnaires and (Orasure™) oral fluid specimens. Time and location sampling was used to recruit a representative sample of men from commercial gay venues (12 bars and 2 saunas) in Glasgow and Edinburgh, Scotland's two largest cities. Bars were surveyed over a 2-week period in the early (7:00–9:00 p.m.) and late (9:00–11:00 p.m.) evening, and no bar was visited twice in the same evening. At the end of the 2-week period, each bar had been visited at both time points on each day of the week. Saunas were surveyed over two early evening periods (5:00–7:00 p.m.) and two weekend late afternoon periods (4:00–6:00 p.m.). Temporary fieldworkers were employed to distribute questionnaires and all men present or entering the venues were invited to participate. Of 2,138 men approached, 1,514 men participated in the survey (70.8% response rate [RR]); 1,508 completed questionnaires (70.5% RR) and 1,277 provided oral fluid samples (59.7% RR). 54 (3.6%) heterosexual men who reported no sexual contact with men in the previous 12 months were excluded from the sample.

The questionnaires included tried and tested measures of demographics, HIV testing history and sexual risk behaviour in the past 12 months used in our surveys since 1996 [14–22]. New questions were pilot tested with the target population, and amended as necessary, prior to initiating the survey. The question on willingness to take part in future research was "We are looking for new ways to prevent HIV. Should the following research studies take place, which would you be willing to take part in?", with participants asked to select 'yes', 'no' or 'don't know' for behaviour change programme (e.g. support using condoms); using rectal microbicides (e.g. special lube to prevent HIV); HIV vaccine; and circumcision (surgical removal of foreskin). The four categories were chosen to reflect prevention methods either available (behaviour

change and circumcision) or under continuing development (vaccines and microbicides) [4]. Willingness to participate in circumcision research was particularly low (13.9%), as has been reported elsewhere [8], and is excluded from the analyses in this article.

Oral fluid specimens were analysed at the West of Scotland Specialist Virology Centre (screened for anti-HIV using an enzyme immunoassay; positives re-screened, and repeat reactives confirmed using Western Blot). Data were analysed with SPSS 15.0. Logistic regression was used to estimate odds ratios and 95% confidence intervals (CI). Ethical approval was granted by University of Glasgow, Faculty of Medicine Ethics Committee.

Men with missing data on any of the willingness to participate variables are excluded from these analyses ($N = 134$). In multivariate analysis, when compared to the 1,320 men included in the analyses, men who did not answer the willingness questions were significantly more likely to have been surveyed in saunas (12.7% of men who did not answer the questions vs. 5.5% of men who did, adjusted odds ratio [AOR] = 2.33, 95% CI 1.24–4.39, $P = 0.009$), more likely to be aged 26 years or over (81.4% vs. 70.5%, AOR = 1.79, 95% CI 1.09–2.95, $P = 0.023$), less likely to have further (29.0% vs. 38.6%, AOR = 0.43, 95% CI 0.24–0.76, $P = 0.004$) or higher (40.9% vs. 46.0% AOR = 0.46, 95% CI 0.26–0.78, $P = 0.005$) education, more likely to believe that 'new drug therapies make people with HIV less infectious' (33.3% vs. 16.0%, AOR = 1.76, 95% CI 1.02–3.05, $P = 0.042$), and were more likely to have not provided an oral fluid sample (29.1% vs. 14.4%, AOR = 2.13, 95% CI 1.36–3.34, $P = 0.001$). There were no other significant differences in sexual health service use, perceived HIV status, or sexual risk behaviour.

Results

Sample Characteristics

Sample characteristics are shown in Table 1. The majority of the sample were surveyed in bars and identified as gay. The median age of participants was 33 years (range 16–73 years); 76.6% lived in the Glasgow or Edinburgh areas. Only 3.1% reported being from a minority ethnic group. Approximately half reported degree or post-graduate education; 47.9% visited the gay scene at least once a week. Just under half had been tested for HIV or other STIs in the past 12 months; 3.6% had an HIV-positive oral fluid sample (4.2% of those who provided samples). Most men (96.2%) reported some sexual contact in the past 12 months; 26.9% reported 10 or more partners; 12.4% reported UAI with 2 or more partners; 25.2% reported UAI

Table 1 Sample characteristics ($N = 1,320$)

	<i>n</i>	%
<i>Demographics</i>		
Survey location		
Edinburgh	545	41.3
Glasgow	775	58.7
Survey venue		
Bar	1,247	94.5
Sauna	73	5.5
Sexual orientation		
Gay	1,187	90.5
Bisexual	108	8.2
Straight	16	1.2
Age		
16–25 years	385	29.5
26–35 years	381	29.2
36–45 years	379	29.0
46+ years	160	12.3
Area of residence		
Glasgow	549	42.7
Edinburgh	436	33.9
Rest of Scotland	208	16.2
Rest of UK	66	5.1
Overseas	28	2.2
Ethnicity		
White (UK, Irish or other)	1,276	96.9
Minority ethnic group ^a	41	3.1
Qualifications		
Secondary (statutory school level)	190	15.4
Further/vocational	475	38.6
Degree/post-graduate	567	46.0
Frequency of gay scene use		
Once month or less	323	24.9
2/3 times a month	354	27.3
1/2 times a week	444	34.2
4/5 times a week	178	13.7
HIV treatment optimism 1		
Disagree	944	74.6
Agree	321	25.4
HIV treatment optimism 2		
Disagree	1,063	84.0
Agree	202	16.0
<i>Sexual health</i>		
HIV test in the past 12 months		
No	675	52.4
Yes	614	47.6
Other STI test in the past 12 months		
No	713	54.5
Yes	595	45.5

Table 1 continued

	<i>n</i>	%
HIV status (oral fluid specimen result)		
HIV-negative	1,080	82.1
HIV-positive	47	3.6
Did not provide oral fluid specimen ^b	189	14.4
<i>Sexual risk behaviour in the past 12 months</i>		
Number of sexual partners		
Less than 10	932	73.1
10 or more	343	26.9
Number of anal sex partners		
Less than 10	1,126	89.2
10 or more	136	10.8
Number of unprotected anal intercourse (UAI) partners		
0/1 partner	1,126	87.6
2 or more partners	160	12.4
UAI with casual partners		
No	1,013	78.8
Yes	273	21.2
UAI with partners of unknown/discordant HIV status		
No	962	74.8
Yes	324	25.2
STI		
No	1,198	91.4
Yes	113	8.6

HIV treatment optimism 1 'I am less worried about HIV infection now that treatments have improved', *HIV treatment optimism 2* 'I believe that new drug therapies make people with HIV less infectious'

^a Black African, Black Caribbean, Indian, Pakistani, Chinese, Arab, Latin American & Other/Mixed

^b An additional 4 samples were not returned from the laboratory

with partners of unknown/discordant HIV status; and 8.6% had had an STI in the past 12 months.

Willingness to Participate in Future HIV Prevention Research Studies

A majority (1,032; 78.2%) of men reported willingness to participate in future HIV prevention research studies, with most being willing to participate in research for an HIV vaccine (64.6%); 20.4% were not willing and 15.0% did not know (Table 2). Again, most men (758; 57.4%) reported being willing to participate in a behaviour change study; 26.6% were not and 16.0% did not know. Rectal microbicide studies were less popular, with 53.0% reporting willingness to take part in these; 28.9% were not willing and 18.2% did not know. Overall, 935 men (70.8%) reported that they were willing to take part in biomedical (either vaccine or microbicide) research studies.

Table 2 Willingness to participate in future HIV prevention research studies ($N = 1,320$)

	Willingness to participate					
	Yes		No		Don't know	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
HIV vaccine	853	64.6	269	20.4	198	15.0
Behaviour change programme	758	57.4	351	26.6	211	16.0
Using rectal microbicides	699	53.0	381	28.9	240	18.2

Factors Associated with Willingness to Participate in Future HIV Prevention Research Studies

Table 3 shows the factors associated with willingness to participate in future HIV prevention studies ('no' and 'don't know' responses were combined in these analyses as the comparison group). The odds of willingness to participate in each of the future HIV prevention research studies were higher among men who had had an HIV or other STI test, and men who reported having had an STI, in the past 12 months. Willingness to take part in HIV vaccine or microbicide research was lower among older men and men who did not provide oral fluid samples. Willingness was lower for men who resided out with the UK and in men from minority ethnic groups for vaccine research, and among straight men for microbicide research. The likelihood of being willing to take part in a behavioural research study was lower among men with degree or post-graduate education and among men who agreed with the HIV treatment optimism statement 'I am less worried about HIV infection now that treatments have improved'. It was higher among men who visited the gay scene once or twice a week and men reporting 10 or more anal sex partners in the past 12 months. Among HIV-positive men, 72.3% reported being willing to take part in a behavioural research study, compared with 57.9% of HIV-negative men. There were no differences in the proportions of HIV-positive and HIV-negative men reporting willingness to participate in biomedical research, nor between diagnosed and undiagnosed HIV-positive men in willingness to participate in any of the research studies.

Factors significant at the bivariate level were entered into a multivariate model for each of the HIV prevention research studies (Table 4). Having an STI in the past 12 months remained significantly associated with being willing to participate in all three study types. For HIV vaccine research, greater age, minority ethnicity, and not providing an oral fluid sample were associated with lower willingness, while heterosexual orientation and not providing an oral fluid sample were for microbicide research.

Higher education level and greater HIV treatment optimism were associated with not being willing to take part in behaviour change research. STI testing remained associated with being more willing to participate in microbicide research and frequency of gay scene use remained associated with being more willing to participate in behaviour change research.

Discussion

This is the first study to assess future willingness to participate in prevention research studies among community-based surveys of gay and bisexual men in Scotland. First, there are some limitations to note when considering these results. This was a bar and sauna sample so only men who visit the venues surveyed have the opportunity to participate, and our findings should be interpreted within this context. Willingness to participate in prevention research could be different among men who did not answer these questions and in the wider population of gay men who do not frequent the commercial gay scene. Participants were only asked if they would be willing to participate in future research studies, not why this may or may not be the case. As the question was hypothetical, we cannot assume that willingness would equal actual participation. No description of what could be involved in taking part in such research was provided. However, the results provide interesting insight into men's willingness to participate in such studies and this is important for planning future interventions and HIV prevention efforts.

Just over three quarters of the men surveyed reported that they were willing to participate in future HIV prevention research studies, with greater willingness to participate in biomedical than behavioural studies. It is particularly interesting to note that willingness to participate in these studies was considerably higher than the level of willingness to participate in male circumcision research in this population [8]. The former have to date, for the most part, not shown a positive effect on reducing HIV transmission [4], while the latter is the biomedical intervention with, arguably, the greatest effect on (albeit hetero) sexual transmission [4]. This raises the query of whether men are aware of male circumcision as HIV prevention, and its limited potential as an intervention for MSM [7], or whether there is some other reason that such an intervention is unattractive to them. It is also interesting to note that willingness to participate in biomedical research was lower among men who did not provide oral fluid samples to be tested for HIV. When men who did and did not provide oral specimens were compared only age was significantly different, with men aged 26 + years less likely to provide samples [8]. It is possible that men who did not provide

Table 3 Factors associated with willingness to take part in future HIV prevention research studies ($N = 1,320$)

	Willing to take part in HIV vaccine study			Willing to take part in rectal microbicide study			Willing to take part in HIV prevention behaviour change study			
	<i>N</i>	%	OR (95% CI)	<i>n</i>	%	OR (95% CI)	<i>n</i>	%	OR (95% CI)	<i>P</i> value
<i>Sample characteristics</i>										
<i>Survey location</i>										
Edinburgh	343	62.9	1	285	52.3	1	305	56.0	1	
Glasgow	510	65.8	1.13 (0.90–1.42)	414	53.4	1.05 (0.84–1.30)	453	58.5	1.11 (0.89–1.38)	0.368
<i>Survey venue</i>										
Bar	812	65.1	1	660	52.9	1	718	57.6	1	
Sauna	41	56.2	0.69 (0.43–1.11)	39	53.4	1.02 (0.64–1.64)	40	54.8	0.89 (0.56–1.44)	0.640
<i>Sexual orientation</i>										
Gay	781	65.8	1	640	53.9	1	689	58.0	1	
Bisexual	61	56.5	0.68 (0.45–1.01)	52	48.1	0.79 (0.54–1.18)	54	50.0	0.72 (0.49–1.07)	0.107
Straight	7	43.8	0.40 (0.15–1.09)	3	18.8	0.20 (0.06–0.70)	8	50.0	0.72 (0.27–1.94)	0.519
<i>Age</i>										
16–25 years	276	71.7	1	226	58.7	1	230	59.7	1	
26+ years	570	62.0	0.64 (0.50–0.83)	469	51.0	0.73 (0.58–0.93)	520	56.5	0.88 (0.69–1.12)	0.284
<i>Area of residence</i>										
Glasgow	361	65.8	1	301	54.8	1	330	60.1	1	
Edinburgh	280	64.2	0.94 (0.72–1.22)	231	53.0	0.93 (0.72–1.20)	251	57.6	0.90 (0.70–1.16)	0.421
Rest of Scotland	136	65.4	0.98 (0.70–1.38)	103	49.5	0.81 (0.59–1.11)	118	56.7	0.87 (0.63–1.20)	0.399
Rest of UK	42	63.6	0.91 (0.54–1.55)	36	54.5	0.99 (0.59–1.65)	32	48.5	0.63 (0.37–1.04)	0.072
Overseas	13	46.4	0.45 (0.21–0.97)	12	42.9	0.62 (0.29–1.33)	14	50.0	0.66 (0.31–1.42)	0.290
<i>Ethnicity</i>										
White (UK, Irish or other)	834	65.4	1	679	53.2	1	735	57.6	1	
Minority ethnic group ^a	18	43.9	0.42 (0.22–0.78)	19	46.3	0.76 (0.41–1.42)	21	51.2	0.77 (0.42–1.44)	0.417
<i>Qualifications</i>										
Secondary (statutory school level)	133	70.0	1	105	55.3	1	122	64.2	1	
Further/vocational	313	65.9	0.83 (0.58–1.19)	264	55.6	1.01 (0.72–1.42)	271	57.1	0.74 (0.52–1.05)	0.090
Degree/post-graduate	355	62.6	0.72 (0.50–1.02)	290	51.1	0.85 (0.61–1.18)	310	54.7	0.67 (0.48–0.94)	0.022
<i>Frequency of gay scene use</i>										
Once month or less	199	61.6	1	161	49.8	1	175	54.2	1	
2/3 times a month	225	63.6	1.09 (0.80–1.48)	183	51.7	1.08 (0.80–1.46)	185	52.3	0.93 (0.68–1.25)	0.617
1/2 times a week	295	66.4	1.23 (0.92–1.66)	246	55.4	1.25 (0.94–1.67)	282	63.5	1.47 (1.10–1.97)	0.009
4/5 times a week	123	69.1	1.39 (0.94–2.06)	100	56.2	1.29 (0.89–1.86)	107	60.1	1.28 (0.88–1.85)	0.200

Table 3 continued

	Willing to take part in HIV vaccine study			Willing to take part in rectal microbicide study			Willing to take part in HIV prevention behaviour change study					
	N	%	OR (95% CI)	P value	n	%	OR (95% CI)	P value	n	%	OR (95% CI)	P value
HIV treatment optimism 1												
Disagree	616	65.3	1		515	54.6	1		561	59.4	1	
Agree	203	63.2	0.92 (0.70–1.19)	0.514	163	50.8	0.86 (0.67–1.11)	0.241	168	52.3	0.75 (0.58–0.97)	0.027
HIV treatment optimism 2												
Disagree	688	64.7	1		563	53.0	1		613	57.7	1	
Agree	131	64.9	1.01 (0.73–1.38)	0.972	115	56.9	1.17 (0.87–1.59)	0.300	116	57.4	0.99 (0.73–1.34)	0.949
Sexual health												
HIV test in the past 12 months												
No	412	61.0	1		328	48.6	1		355	52.6	1	
Yes	417	67.9	1.35 (1.07–1.70)	0.010	355	57.8	1.45 (1.16–1.81)	0.001	381	62.1	1.47 (1.18–1.84)	0.001
Other STI test in the past 12 months												
No	431	60.4	1		337	47.3	1		384	53.9	1	
Yes	416	69.9	1.52 (1.21–1.92)	<0.001	357	60.0	1.67 (1.34–2.09)	<0.001	367	61.7	1.38 (1.11–1.72)	0.004
HIV status (oral fluid specimen result)												
HIV-negative	718	66.5	1		586	54.3	1		625	57.9	1	
HIV-positive	32	68.1	1.08 (0.58–2.01)	0.820	28	59.6	1.24 (0.69–2.25)	0.475	34	72.3	1.90 (0.99–3.65)	0.052
Did not provide oral fluid specimen	100	52.9	0.57 (0.42–0.77)	<0.001	82	43.4	0.65 (0.47–0.88)	0.006	97	51.3	0.77 (0.56–1.05)	0.094
Sexual risk behaviours in past 12 months												
Number of sexual partners												
Less than 10	598	64.2	1		483	51.8	1		529	56.8	1	
10 or more	226	65.9	1.08 (0.83–1.40)	0.568	190	55.4	1.15 (0.90–1.48)	0.258	197	57.4	1.03 (0.80–1.32)	0.829
Number of anal intercourse partners												
Less than 10	714	63.4	1		587	52.1	1		630	56.0	1	
10 or more	97	71.3	1.44 (0.97–2.12)	0.070	82	60.3	1.39 (0.97–2.00)	0.073	90	66.2	1.54 (1.06–2.24)	0.024
Number of unprotected anal intercourse (UAI) partners												
0/1 partner	717	63.7	1		585	52.0	1		646	57.4	1	
2 or more partners	113	70.6	1.37 (0.96–1.97)	0.087	96	60.0	1.39 (0.99–1.94)	0.057	89	55.6	0.93 (0.67–1.30)	0.676
UAI with casual partners												
No	649	64.1	1		523	51.6	1		584	57.7	1	
Yes	181	66.3	1.10 (0.83–1.46)	0.494	158	57.9	1.29 (0.98–1.69)	0.067	151	55.3	0.91 (0.70–1.19)	0.488
UAI with partners of unknown/discordant HIV status												
No	611	63.5	1		503	52.3	1		559	58.1	1	
Yes	219	67.6	1.20 (0.92–1.57)	0.185	178	54.9	1.11 (0.86–1.43)	0.408	176	54.3	0.86 (0.67–1.11)	0.234

Table 3 continued

	Willing to take part in HIV vaccine study			Willing to take part in rectal microbicide study			Willing to take part in HIV prevention behaviour change study					
	N	%	OR (95% CI)	P value	n	%	OR (95% CI)	P value	n	%	OR (95% CI)	P value
STI												
No	758	63.3	1		615	51.3	1		668	55.8	1	
Yes	89	78.8	2.15 (1.35–3.43)	0.001	79	69.9	2.20 (1.45–3.35)	<0.001	85	75.2	2.41 (1.55–3.75)	<0.001

OR odds ratio, 95% CI 95% confidence interval, HIV treatment optimism 1 'I am less worried about HIV infection now that treatments have improved', HIV treatment optimism 2 'I believe that new drug therapies make people with HIV less infectious'

^a Black African, Black Caribbean, Indian, Pakistani, Chinese, Arab, Latin American & Other/Mixed

samples have concerns about participating in any kind of biomedical research.

A review of (mainly North American) HIV vaccine preparedness studies found willingness to participate in vaccine trials ranged from 23% to 94% among MSM [23]. Here, almost two-thirds of men expressed willingness to participate in HIV vaccine research studies. This is considerably higher than the proportion reported in the only other UK study of this topic among MSM; 23% reported likelihood of participating in an HIV vaccine trial in a London gym-based survey of MSM [24]. It is possible that men see these as having the greatest potential benefits to themselves and their community, and both personal and altruistic reasons have been identified as motives for participating in previous trials [25]. However, a US study of MSM's knowledge and acceptability of biomedical interventions found vaccines were the most commonly known intervention types [26], so it could be that men are simply more likely to have heard of these. Half of the men surveyed said that they were willing to participate in a rectal microbicide research study. This compares to a previous American study, in which around two-thirds of gay men reported they would be willing to participate in microbicide trials [27].

Although one vaccine trial has reported (limited) positive results [28], it is unlikely that a vaccine will become available in the immediate future, with considerable further research required [28, 29]. So far, all of the microbicide candidates are for vaginal rather than rectal use [4], and few acceptability research studies have been conducted among MSM [30]. If HIV vaccine and rectal microbicide trials were to be initiated with MSM in the UK, further research would be required to assess the factors that could facilitate or prevent participation in this population. Education and community mobilisation could increase willingness to participate in such studies [31], and consideration should be given to describing trial protocols to potential participants as part of assessing willingness to join research projects.

There is continuing interest in the potential for behavioural interventions among MSM in Scotland [3], and over half of the men surveyed indicated willingness to participate in this type of research. However, men who were treatment optimistic, and less worried about HIV now treatments had improved, were less likely to be willing to do so. Although only a minority of MSM are optimistic (see Table 1 and as noted elsewhere [32, 33]), associations between treatment optimism and sexual risk behaviour have been recognised [32–34]. Increases in sexual risk behaviour cannot be fully accounted for by increasing treatment optimism [35–37], but this issue nevertheless remains a challenge and something to consider during recruitment for a behaviour change research study.

Table 4 Factors associated with willingness to take part in future HIV prevention research studies: multivariate logistic regression ($N = 1,320$)

	Willing to take part in HIV vaccine study			Willing to take part in rectal microbicide study			Willing to take part in HIV prevention behaviour change study		
	AOR	95% CI	<i>P</i> value	AOR	95% CI	<i>P</i> value	AOR	95% CI	<i>P</i> value
Sexual orientation									
Gay				1					
Bisexual				0.82	0.55–1.23	0.334			
Straight				0.22	0.06–0.79	0.020			
Age									
16–25 years	1			1					
26+ years	0.69	0.53–0.90	0.007	0.78	0.61–1.00	0.052			
Area of residence									
Glasgow	1								
Edinburgh	0.95	0.72–1.24	0.680						
Rest of Scotland	0.95	0.67–1.34	0.759						
Rest of UK	1.03	0.59–1.78	0.925						
Overseas	0.55	0.25–1.20	0.132						
Ethnicity									
White (UK, Irish or other)	1								
Minority ethnic group ^a	0.39	0.20–0.74	0.004						
Qualifications									
Secondary (statutory school level)							1		
Further/vocational							0.73	0.51–1.04	0.080
Degree/post-graduate							0.64	0.45–0.91	0.013
Frequency of gay scene use									
Once month or less							1		
2/3 times a month							0.95	0.70–1.29	0.737
1/2 times a week							1.45	1.07–1.95	0.016
4/5 times a week							1.13	0.77–1.66	0.536
HIV treatment optimism 1									
Disagree							1		
Agree							0.75	0.57–0.97	0.030
HIV test in the past 12 months									
No	1			1			1		
Yes	1.09	0.78–1.52	0.609	1.02	0.74–1.39	0.915	1.30	0.95–1.80	0.105
Other STI test in the past 12 months									
No	1			1			1		
Yes	1.29	0.92–1.80	0.138	1.46	1.06–2.01	0.020	0.98	0.71–1.36	0.911
HIV status (oral fluid specimen result)									
HIV-negative	1			1					
HIV-positive	1.04	0.54–2.00	0.912	1.09	0.59–2.02	0.775			
Did not provide oral fluid specimen	0.62	0.45–0.86	0.004	0.70	0.51–0.96	0.029			
Number of anal intercourse partners in past 12 months									
Less than 10							1		
10 or more							1.27	0.85–1.88	0.239
STI in past 12 months									
No	1			1			1		
Yes	1.85	1.14–3.03	0.014	1.82	1.18–2.82	0.007	2.22	1.39–3.53	0.001

OR odds ratio, 95% CI 95% confidence interval, HIV treatment optimism 1 'I am less worried about HIV infection now that treatments have improved'

^a Black African, Black Caribbean, Indian, Pakistani, Chinese, Arab, Latin American & Other/Mixed

Future willingness to participate in vaccine, microbicide or behaviour change research studies was greater among service users, particularly among men who reported having had an STI in the past 12 months. This suggests existing services may be appropriate venues within which to recruit men for future research. Intervention delivery in these settings has previously been identified as a characteristic of successful interventions among people living with HIV [38], though a wider range of recruitment settings may be necessary to recruit sufficient numbers, and relevant risk groups, of MSM [39]. Willingness to participate in behaviour change was also higher among HIV-positive men, a group for whom, to date, behavioural interventions have proven largely ineffective [38].

Previous research found men at higher risk of HIV were more likely to be willing to take part in HIV vaccine trials [23]. Here, the lack of association between sexual risk behaviours (other than having had an STI in the past 12 months) and such willingness suggests it may be difficult to recruit adequate numbers of men at higher risk of HIV (particularly beyond the clinical setting); a finding that has implications for the design (and cost) of such future research. Sherr et al. estimated that a minimum of 15,000 HIV-negative men would need to be approached to recruit 1,000 high-risk HIV-negative men into a vaccine trial (based on a willingness to participate rate of 6.9%) [24]. Our study identified 189 men (12.5% of the total survey sample) who tested HIV-negative, reported UAI with partners of unknown or discordant HIV status in the past 12 months and were willing to participate in an HIV vaccine research study. With a 70.5% survey RR, over 10,000 men would have to be approached to achieve a sample size of 8,000 men in order to recruit 1,000 such high-risk HIV-negative men into a trial.

To be adequately powered to show effect on HIV incidence, trials require large sample sizes. A definitive phase III trial with 95% power to detect an effect with a 60% effective vaccine would require approximately 6,000 participants from a population with annual 2% HIV incidence [40]. Based on the figures noted above, 60,000 men would have to be approached to achieve this sample size, requiring large multi-centre (and even multi-country) studies.

Combination prevention, which incorporates biomedical and behavioural, as well as social and structural, interventions has been argued as the way forward for HIV prevention [41]. The detailed assessment of the acceptability and feasibility of such interventions is vital [10–13], particularly to avoid the flaws that can lead to ‘flat’ results [4]. Our findings suggest recruitment of high-risk men, who have the potential to benefit most from such interventions, is likely to be challenging, time consuming, and hence costly. The best means of facilitating this should be examined through feasibility studies, prior to initiating intervention trials.

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