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Research paper

The longer-term effects of access to HIV self-tests on HIV testing frequency in high-risk gay and bisexual men: follow-up data from a randomised controlled trial

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ABSTRACT

Background: A wait-list randomised controlled trial in Australia (FORTH) in high-risk gay and bisexual men (GBM) showed access to free HIV self-tests (HIVSTs) doubled the frequency of HIV testing in year 1 to reach guideline recommended levels of 4 tests per year, compared to two tests per year in the standard-care arm (facility-based testing). In year 2, men in both arms had access to HIVSTs. We assessed if the effect was maintained for a further 12 months.

Methods: Participants included GBM reporting condomless anal intercourse or > 5 male partners in the past 3 months. We included men who had completed at least one survey in both year 1 and 2 and calculated the mean tests per person, based on the validated self-report and clinic records. We used Poisson regression and random effects Poisson regression models to compare the overall testing frequency by study arm, year and testing modality (HIVST/facility-based test).

Findings: Overall, 362 men completed at least one survey in year 1 and 343 in year 2. Among men in the intervention arm (access to HIVSTs in both years), the mean number of HIV tests in year 2 (3·7 overall, 2·3 facility-based tests, 1·4 HIVSTs) was lower compared to year 1 (4·1 overall, 1·7 facility-based tests, 2·4 HIVSTs) (RR:0·84, 95% CI:0·75-0·95, p=0·002), but higher than the standard-care arm in year 1 (2·0 overall, RR:1·71, 95% CI:1·48-1.97, p<0·001). Findings were not different when stratified by sociodemographic characteristics or recent high risk sexual history.

Interpretation: In year 2, fewer HIVSTs were used on average compared to year 1, but access to free HIVSTs enabled more men to maintain higher HIV testing frequency, compared with facility-based testing only. HIV self-testing should be a key component of HIV testing and prevention strategies.

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Research in context

Evidence before this study Frequent HIV testing among high-risk populations is key to increasing the timeliness of HIV diagnoses, initiation of early treatment, and prevention of HIV transmission. Provision of free HIV self-testing (HIVST) kits has been proven in randomised trials to be effective in increasing the uptake and frequency of HIV testing among gay and bisexual men (GBM) in the short-term, but there is no evidence if the effect is sustained over a longer period, and if effects vary according to socio-demographic characteristics.

Added value of this study We found that higher-risk GBM who had access to free HIVSTs were able to maintain higher HIV testing frequencies after two years compared to men who only had access to facility-based testing. In addition, we found a higher proportion of migrants continued using HIVST compared to non-migrant men. Although fewer HIVSTs were used in year 2, on average 1·4 extra tests were conducted due to having access to HIVST. This study expands the literature by formally evaluating for the first time the maintenance effect of free HIV self-testing on the frequency of HIV testing in groups of high-risk gay and bisexual men, including among migrant men who have disproportionately higher rates of HIV diagnoses and undiagnosed HIV in Australia.

Implications of all the available evidence The findings affirm the importance of the HIVST technology as a way to increase and sustain testing frequency for GBM, including among migrant men.

1. Introduction

HIV self-testing (HIVST) has been shown to be an effective tool in overcoming barriers to traditional facility-based HIV testing services, such as stigma, distance, and a long waiting time for results [1-3]. Observational and randomised controlled trials (RCTs) have shown HIVSTs are acceptable in a broad range of settings and populations and increase the uptake and frequency of HIV testing [4-8]. In response, in 2016 the World Health Organization (WHO) published guidelines recommending HIVSTs be offered as a supplement to traditional HIV testing services, as a strategy to meet the UNAIDS HIV diagnosis target of 95% by 2025 [9]. By the end of 2020, there were 88 countries that had implemented policies to support the sale of HIVSTs [10,11]. However, these changes in policy did not always translate to the widespread use of the technology, with only 41 countries implementing HIVSTs [11].

To maximise the uptake and impact of this new technology, international efforts have provided significant funding to support the scale-up of HIVSTs in low-and-middle-income countries, particularly in sub-Saharan Africa, where there is a higher incidence of HIV and limited laboratory infrastructure [12]. High-income countries have also been interested in the technology as a strategy to reach specific high-risk populations who face barriers to testing (i.e. migrants), and in turn to reduce undiagnosed HIV infections, a key UNAIDS target [13,14]. However, the enthusiasm of promoting HIVSTs in high-income countries has been tempered by concerns about the reduced accuracy and longer window periods of HIVSTs, compared to laboratory tests, potentially leading to acute infections being missed, which may disproportionately contribute to new infections [15-17]. One mathematical modelling study in the US predicted that the replacement of facility-based testing with HIVSTs with a longer window period may actually increase HIV prevalence among gay and bisexual men (GBM) [18]. In contrast, a mathematical modelling study conducted in Australia found that even if HIVSTs are 9% less sensitive, they would still provide a benefit at a population level if high-risk GBM supplement their facility-based testing with HIVSTs, particularly if HIVSTs are targeted to GBM who have never tested or test infrequently [6].

Thus, understanding the HIV testing frequency achieved among higher risk men due to access to HIVSTs, and whether HIVSTs are used to supplement or replace facility-based testing are key data to monitor in order to determine whether the potential benefits of HIVSTs are being maximised. RCTs conducted in the United States, Hong Kong, mainland China, and Australia [5,19-21] found that access to HIVSTs increased HIV testing frequency among GBM, and men supplemented their facility-based testing with HIVSTs, rather than replacing it. However, in these studies, men were only followed up for 12-15 months. It is unclear if the same uptake and frequency will be sustained over a longer period due to enthusiasm and interest in novel technologies, which sometimes may not be sustained over longer periods of time [22]. Previous methodological papers suggest the longer and more realistic effects of a health intervention should be evaluated by following up the original clinical trial participants over a longer period [23,24]. To our knowledge, there have been no studies which have investigated if the levels of HIV testing observed in an HIVST RCT were maintained beyond 15 months.

We aimed to assess the longer-term effects of access to HIVSTs on HIV testing frequency in the FORTH (Frequency of Oral Rapid Testing at Home) Study. FORTH was a wait-list RCT which showed access to free HIVST doubled the frequency of testing in high-risk GBM over a 12-month period, with participants supplementing their facility-based testing with HIVSTs [19]. The wait-list design of FORTH enabled all participants to have access to free HIVST kits in the second year, providing a unique opportunity to evaluate whether the increase in HIV testing frequency observed in year 1 was maintained in year 2. In addition, we also investigated if men continued to supplement their facility-based testing with HIVSTs. Furthermore, the design of study enabled us to assess if the effects were maintained among higher-risk men and sub-populations such as migrant men, who are well known to face additional barriers to accessing HIV testing at clinical services, and have the higher rates of undiagnosed HIV among Australian GBM [25,26].

2. Methods

2.1. Study participants and design

Data were derived from the FORTH trial which involved high risk GBM being randomised (1:1) to receiving multiple free HIVST kits and accessed to facility-based testing (intervention arm) or standard-care (access to facility-based testing only) [19]. The participants assigned to the intervention arm were offered four oral fluid HIVST kits (OraSure Technologies, Bethlehem, PA, USA) at en-

rolment, and were able to request additional free HIVST kits, once at a time, capped at 12 HIVST kits per year. They were also able to access free HIV and sexually transmitted infection (STI) testing at health facilities of their choice as usual. Participants assigned to the standard-care arm were able to access HIV and STI testing at a health facility in the first year, after which they gained access to four free HIVSTs. Thus, in year 2 of the study, all participants (intervention and standard-care arm) had access to free HIVSTs.

From the 1st December 2013 through to the 5th February 2015, 362 men from three urban sexual health clinics and two community-based clinics in Australia were enrolled and randomly assigned to either the intervention arm (n=182) or the standard-care arm (n=180) [27]. The last follow-up survey was on March 18th, 2017. Eligibility criteria included male gender identity, self-identification as gay or bisexual, never having been diagnosed with HIV, being aged 18 or older, reporting condomless anal intercourse or >5 male partners in the past 3 months, and the ability to understand English and provide informed consent [19,27].

2.2. Study assessments

Participants in both study arms were asked to complete a brief online survey every 3 months over 2 years which included questions on the number of HIVST kits that they had used to test themselves, to test a partner, or given to someone else, since their last survey. Other information, such as participant demographic information and recent sexual behavior were also collected. Further details about the study design have been published [19,27].

2.3. Study outcomes

The primary outcome was the overall frequency of HIV tests (both HIVSTs and facility-based tests) in any 12-month period in year 1 and 2, represented by the mean annual number of HIV tests. The number of facility-based tests and self-tests in any 12-month period were also reported separately as secondary outcomes. HIV self-testing was based on self-reported data from each follow-up survey and was checked against dispensing logs. Where there were discrepancies, we adjusted the self-testing frequency according to the difference between reported number of self-testing kits and the provided number of self-testing tests in the log. For example, if a participant reported using more self-tests than had been provided to him, the excess number of kits was deducted for the analysis. Facility-based testing was sourced from clinical records if participants reported HIV testing at clinics other than the study clinics [27]. Consistent with the FORTH RCT [19], if participants did not complete all 3-monthly questionnaires (i.e. had missing surveys), we used available survey and clinic data to impute the number of HIV tests in a year, applying the testing frequency in the periods where no surveys were completed. A sensitivity analysis was also conducted restricting the analysis to participants for whom there was complete survey data, as well as by assuming that participants who did not provide survey had not used any HIV self-tests in the same period. The primary outcome excluded the following tests: any tests performed at enrolment, any tests used on other people instead of participants, and any tests performed after a confirmed positive or false-reactive self-test result.

2.3.1. Sample size

This is secondary analysis of a wait-list control RCT. The sample size calculations for the RCT have been published elsewhere [19].

2.3.2. Statistical analysis

Descriptive analyses were used to summarise the participants' demographic and behavioural characteristics and reasons for changes in testing patterns.

We then compared the primary and secondary outcomes across study arms, study year and testing modality (HIVST vs facility-based testing), using the combinations below (see Figure 1):

1 To compare the longer-term effects of access to HIVSTs to standard of care (Table 2);
2 To compare the longer-term effects of access to HIVSTs with shorter-term effects of access to HIVSTs (Table 3)
3 To compare the shorter-term effects of access to HIVSTs after a long waiting time with the shorter-term effects after immediate access to HIVSTs (Table 4).

We compared differences in the study outcomes between subgroups based on their risk behaviour (number of male partners, ever engaged in condomless sex (CAIC) and group sex, in the past 6 months) and socio-demographics (age, country of birth and employment status). We classified participants as 'older' if they were aged above the mean of the sample and as migrants if they were born outside Australia.

We also did a sensitivity analysis restricted to participants who had completed the final quarterly survey in year 1 and year 2 (Supplement Table 1–3). As each survey asked about testing since their last survey, then those who completed the last survey in the year would have reported their full testing history over the 12 months, even if they missed some quarterly surveys.

We used Poisson regression for comparisons of testing frequency among different groups of men (intervention versus control arm) and random effects Poisson regression models to compare testing frequency between the same groups of men. Bonferroni corrections were applied to tests with multiple comparisons for an overall change in testing frequency. All data were analysed in Stata 14.

Ethics review and approval for this study was provided by the South Eastern Sydney Local Health District Human Research Ethics Committee (HREC) and Alfred Hospital HREC.

2.3.3. Role of the funding source

The FORTH project received support from the National Health and Medical Research Council of Australia (Grant 568971). The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

3. Results

3.1. Study population and attrition rate

Of the 362 FORTH study participants enrolled in the study, 343 (95%) completed at least one follow-up survey in year 1 (178 intervention arm, 165 standard-care arm), 286 (79%) completed at least 3 surveys, and 296 (86%) completed the final survey in year 1.

In year 2, 279 men (77%) completed at least one follow-up survey (144 intervention arm, 135 standard-care arm). Of these, 206 (74%) completed at least 3 surveys and 201 (72%) completed the final survey in year 2 (Figure 1). The mean follow-up time was 317 days for the intervention arm and 330 days for the standard-care arm, with 42 days extrapolated to calculate the study outcomes.

3.2. Characteristics of the participants (Table 1)

Among the total of 343 men, the mean age of participants was 36 years in the intervention arm and 35 years in the standard-care arm. Overall, most participants self-identified as gay, had a university degree or higher, had a full-time job and had worked in a professional or managerial role. Half the participants reported having more than 10 male partners in the past 6 months, over half of the participants reported that they had had condomless anal sex in the past 6 months, and about two-thirds reported having any

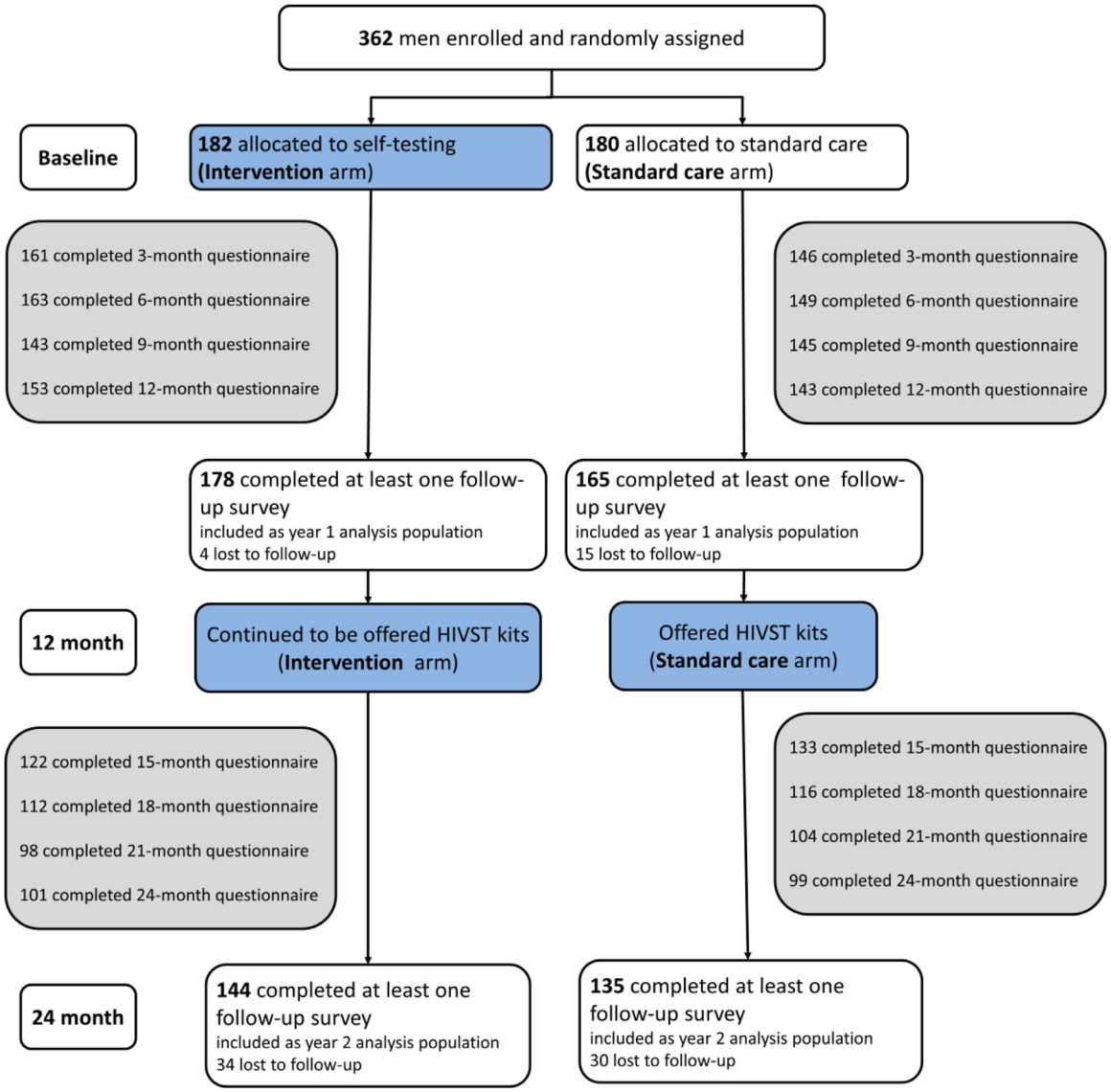

Figure 1. Trial flowchart
*All men who completed at least one follow-up questionnaire in year 1 or year 2.

group sex in the past 6 months. Demographic characteristics and sexual behaviour were similar among men who completed any survey in year 1 and 2, and men who completed the final survey in year 1 and 2, except men who completed the final survey were slightly older (Table 1). In total, five men were newly diagnosed with HIV over the 2-year study period (4 using a HIVST and 1 using a laboratory test); all four men with a reactive HIV self-test result had confirmatory laboratory testing, were linked to care and started HIV treatment.

3.3. HIV testing frequency in Year 2 (intervention arm) vs Year 1 (standard-care arm) (Table 2)

The mean overall HIV testing frequency per person in year 2 among men in the intervention arm who had access to HIVSTs was higher than year 1 of the standard-care arm who only had access to facility-based testing (3·7 vs 2·0, RR:1·71, 95%CI:1·48-1·97, p<0·001). Similar findings were observed in all subgroups, including men who reported CAIC in the last 6 months (4·0 vs 2·1, RR:1·72, 95%CI: 1·43-2·06, p<0·001), group sex in the last 6 months (3·9 vs 2·0, RR:1·71, 95%CI:1·42-2.06,p<0.001), more than 10 partners in the last 6 months (4·0 vs 2·1, RR:1·65, 95%CI:1·35-2·01, p<0.001), men aged 36 years or older (3·6 vs 2·1, RR: 1·62, 95%CI: 1·31-2·00, p<0·001), migrant men (3·8 vs 1·9, RR:1·95, 95%CI:1·53-2·50, p<0·001), and men without a full-time job (4·2 vs 2·0, RR:1·77, 95%CI:1·39-2·26, p<0·001).

There was no difference in the mean facility-based HIV testing frequency by study arm or year, or among subgroups. Among men in the intervention arm in year 2, HIVSTs contributed 1·4 tests per person to the overall testing frequency, with similar findings among socio-demographic and behavioural subgroups.

3.4. HIV testing frequency in Year 2 vs Year 1(intervention arm) (Table 3)

The mean overall HIV testing frequency per person declined between year 2 and year 1 among men in the intervention arm who had access to HIVSTs for two years consecutively (3·7 vs 4·1, RR:0·84, 95%CI:0·75-0·95, p=0·002); and among subgroups including men who reported CAIC in the last 6 months (4·0 vs 4·6, RR:0·83, 95%CI: 0·71-0·96, p=0·01), group sex in the last 6 months (3·8 vs 4·4, RR:0·80, 95%CI:0·68-0·93, p=0·005), and

Table 1
Baseline characteristics of all men who completed at least one follow-up questionnaire.

	Year 1 Men completed any surveyn= 343		Year 2 Men completed any surveyn= 279	
	Intervention arm (n=178)	Standard- care arm (n=165)	Intervention arm (n=144)	Standard-care arm (n=135)
Age (years) (mean, SD)	35·8 (9·1)	34·8 (9·1)	36·3(11·1)	35·2(11·0)
Highest level of education				
Up to high school/diploma	83 (47%)	63 (38%)	64 (44%)	50 (37%)
Undergraduate	53 (30%)	60 (36%)	47 (33%)	50 (37%)
Postgraduate	41 (23%)	42 (25%)	32 (22%)	35 (26%)
Employed full-time				
Yes	124 (70%)	103 (62%)	99 (69%)	86 (64%)
No	53 (30%)	62 (38%)	44 (31%)	49 (36%)
Country of birth				
Australia	109 (61%)	111 (67%)	89 (62%)	93 (69%)
Overseas	69 (39%)	54 (33%)	55 (38%)	42 (31%)
Sexual identity				
Gay/homosexual	165 (93%)	151 (92%)	137 (95%)	126 (93%)
Bisexual or other	13 (7%)	14 (8%)	7 (5%)	9 (7%)
Gay social engagement	4·3 (1·1)	4·1 (1·2)	4·3 (1·4)	4·1 (1·6)
Male partners in the past 6 months				
≤10	90 (51%)	84 (51%)	70 (49%)	70 (52%)
>10	88 (49%)	81 (49%)	74 (51%)	65 (48%)
CAIC* in the past 6 months				
Yes	108 (61%)	107 (65%)	83 (58%)	73 (54%)
No	69 (39%)	58 (35%)	60 (42%)	62 (46%)
Group sex in the past 6 months				
Yes	106 (60%)	99 (60%)	86 (60%)	80 (59%)
No	72 (40%)	66 (40%)	58 (40%)	55 (41%)

Data are n(%) or mean (SD). Participants with missing data were included in the denominator.
*CAIC=condomless anal intercourse with casual partner(s).

more than 10 male partners in the last 6 months (4·0 vs 4·9, RR:0·74, 95%CI: 0·63-0·87, p<0·001). There was no significant difference in the mean overall HIV testing frequency between year 1 and 2 for older men (3·6 vs 4·1, RR:0·86, 95%CI: 0·72-1·02, p=0·08), migrant men (3·8 vs 4·1, RR: 0·91, 95%CI: 0·75-1·10, p=0·36) or men without a full-time job (3·8 vs 4·2, RR: 0·96, 95%CI: 0·78-1·22, p=0·80).

The mean facility-based HIV testing frequency per person was higher in year 2 compared with year 1 (2·3 vs 1·7, RR:1·24, 95%CI:1·04-1·47, p=0·02), and among men who reported CAIC in last 6 months (2·6 vs 1·9, RR:1·29, 95%CI:1·04-1·60, p=0·02) and men without a full-time job (2·7 vs 1·5, RR:1·51, 95%CI:1·10-2·06, p=0·01), but no other subgroups. In contrast, the mean number of HIVSTs per person was lower in year 2 compared with year 1 (1·4 vs 2·4, RR:0·57, 95%CI:0·47-0·68, p<0·001), and among all subgroups.

3.5. HIV testing frequency in Year 2 (standard-care arm) vs Year 1 (intervention arm) (Table 4)

The mean overall HIV testing frequency was lower in men who first gained access to HIVSTs in Year 2 (standard-care arm) compared with men who gained access in Year 1 (intervention arm) (3·0 vs 4·1, RR:0·72, 95%CI:0·64-0·82, p<0·001). Similar findings were observed for all subgroups including men who reported CAIC in the last 6 months (3·3 vs 4·6, RR:0·74, 95%CI:0·63-0·87, p=0·001), group sex in the last 6 months (2·9 vs 4·4, RR:0·68, 95%CI:0·58-0·80, p<0·001), more than 10 partners in the last 6 months (3·1 vs 4·9, RR:0·65, 95%CI:0·55-0·77, p<0·001), men aged 36 years or over (3·1 vs 4·1, RR:0·75, 95%CI: 0·62-0·90, p=0·003), migrant men (3·2 vs 4·1, RR: 0·78, 95%CI: 0·62-0·96, p=0·02) and men without a full-time job (2·9 vs 3·8, RR: 0·80, 95%CI: 0·64-0·99, p=0·04).

The mean overall facility-based HIV testing frequency per person was higher in men who first gained access to HIVSTs in Year 2 (standard-care arm) compared with men who gained access in Year 1 (intervention arm) (2·3 vs 1·7, RR:1·31, 95%CI:1·12-1·55, p<0·001). Similar findings were observed for men who reported CAIC in the last 6 months (2·6 vs 1·9, RR:1·35, 95%CI:1·10-1·66, p<0·001), men aged 36 years or over (2·4 vs 1·7, RR:1·42, 95%CI: 1·12-1·69, p=0·005), migrant men (2·6 vs 1·6, RR:1·41, 95% CI: 1·06-1·86, P=0·02), and men without a full-time job (2·3 vs 1·5, RR:1·48, 95%CI:1·11-1·97, p=0·01). In contrast, the mean HIVST frequency per person was lower in men who first gained access to HIVSTs in year 2 (standard arm) compared with men who gained access in Year 1 (intervention arm) overall (0·7 vs 2·4, RR: 0·30, 95% CI: 0·23-0·38, p<0·001) and among all subgroups.

3.6. Secondary distribution of HIV self-testing kits

In year 1, approximately one quarter participants (26.5%) from intervention arm distributed one or more kits to their partner or someone else. In year 2, only 11.2% participants in the intervention arm gave one or more HIVST kits to their partner or someone else, while 9.7% participants in the standard-care arm distributed kits to others. In total, 103 and 98 self-tests kits were distributed in year 1 and year 2 respectively.

4. Discussion

We followed participants in a wait-list RCT longitudinally for a second year and found that high levels of overall HIV testing were maintained in those who received HIVST availability first in year 1, with year 2 testing levels 80% higher than for men with access to facility-based testing only. Notably, there was a small reduction in overall HIV testing frequency between year 1 and year 2, due to men using fewer HIVSTs. However self-testing still contributed an average of 1·4 additional tests per person to the overall testing frequency of 3·7 in year 2, and enabled men to come close to the current Australian guideline recommending HIV testing every 3 months [28].

The small decline in overall HIV testing between year 1 and year 2 among men in the intervention arm was due to 42% fewer HIVSTs being conducted, while 35% more facility tests were done.

Table 2
Year 2 HIVST access among men in the intervention arm vs Year 1 (no access) among men in the standard-care arm.

Subgroup and type of testing	Standard-care arm in year 1 (HIV self-testing 0 months)		Intervention arm in year 2 (HIV self-testing 2 years)		Rate Ratio (95% CI)	P-value
	Number of tests	Tests per year (95% CI)	Number of tests	Tests per year (95% CI)		
Overall HIV tests (HIVST 0 year n=165; HIVST 2 years n=144)						
Self-tests and facility-based	330	2·0 (1·7-2·3)	533	3·7 (3·1-4·2)	1.71 (1·48-1·97)	p<0.001
Facility-based	330	2·0 (1·7-2·3)	331	2·3 (1·8-2·7)	1.03 (0·87-1·20)	p=0·62
Self-tests	NA	NA	202	1·4 (1·1-1·7)	NA	NA
CAIC in last 6 months (HIVST 0 year n=107; HIVST 2 years n=83)*						
Self-tests and facility-based	225	2·1 (1·7-2·6)	332	4·0 (3·2-4·9)	1·72 (1·43-2·06)	p<0·001
Facility-based	225	2·1 (1·7-2·6)	216	2·6 (2·0-3·3)	1.08 (0·88-1·32)	p=0·46
Self-tests	NA	NA	116	1·4 (1·0-1·8)	NA	NA
Ever have group sex (*HIVST 0 year n=99; HIVST 2 years n=86)*						
Self-tests and facility-based	198	2·0 (1·6-2·3)	335	3.9 (3·0-4·6)	1·71 (1·42-2·06)	p<0·001
Facility-based	198	2·0 (1·6-2·3)	215	2·5 (1·8-3·1)	1·08 (0·87-1·32)	p=0·49
Self-tests	NA	NA	120	1·4(1·0-1v8)	NA	NA
>10 male partners in the past 6 months (*HIVST 0 year n=81; HIVST 2 years n=74)*						
Self-tests and facility-based	170	2·1 (1·7-2·5)	296	4·0 (3·0-5·0)	1·65 (1·35-2·01)	p<0·001
Facility-based	170	2·1 (1·7-2·5)	192	2·6 (1·9-3·4)	1·07 (0·86-1·33)	p=0·54
Self-tests	NA	NA	104	1·4 (0.9-1·8)	NA	NA
Age > 35 (HIVST 0 year n=66; HIVST 2 years n=70)						
Self-tests and facility-based	139	2·1 (1·5-2·7)	252	3·6 (2·9-4·3)	1·62 (1·31-2·00)	p<0·001
Facility-based	139	2·1 (1·5-2·7)	139	2·1 (1·4-2·8)	0.90 (0·71-1·13)	p=0·38
Self-tests	NA	NA	113	1·5 (1·2-1·9)	NA	NA
Migrant men (HIVST 0 year n=54; HIVST 2 years n=55)						
Self-tests and facility-based	103	1·9 (1·4-2·4)	209	3·8 (3·1-4·5)	1·95 (1·53-2·50)	p<0·001
Facility-based	103	1·9 (1·4-2·5)	121	2·2 (1·7-2·7)	1·07 (0·81-1·46)	p=0·63
Self-tests	NA	NA	88	1·6 (1·1-2·0)	NA	NA
Part-time job or unemployed (HIVST 0 year n=62; HIVST 2 years n=44)						
Self-tests and facility-based	124	2·0 (1·6-2·4)	185	4·2 (2·9-4·8)	1·77 (1·39-2·26)	p<0·001
Facility-based	124	2·0 (1·6-2·5)	119	2·7 (1·7-3·7)	1·11 (0·84-1·46)	p=0·47
Self-tests	NA	NA	66	1·5 (0·9-2·2)	NA	NA

*CAIC=condomless anal intercourse with casual partner(s); NA =nonapplicable; Note that the overall change in testing frequency were statistically significant after allowing for a 3-test Bonferroni correction; Rate ratio >1 means more tests in the intervention arm in year 2, vice versa.

Table 3
Year 2 of HIVST access among men in the intervention arm vs Year 1 of HIVST access among men in the intervention arm.

Subgroup and type of testing	Intervention arm in year 1 (HIV self-testing 1 year)		Intervention arm in year 2 (HIV self-testing 2 years)		Rate Ratio (95% CI)	P-value
	Number of tests	Tests per year (95% CI)	Number of tests	Tests per year (95% CI)		
Overall (year 1 n=178; year 2 n=144)						
Self-tests and facility-based	730	4·1 (3·7-4·5)	533	3·7 (3·1-4·2)	0·84 (0·75-0·95)	p=0·002
Facility-based	303	1·7 (1·4-1·9)	331	2·3 (1·8-2·7)	1·24 (1·04-1·47)	P=0·02
Self-tests	427	2·4 (2·2-2·7)	202	1·4 (1·1-1·7)	0·57 (0·47-0·68)	p<0·001
CAIC in last 6 months (year 1 n=108; year 2 n=83)*						
Self-tests and facility-based	497	4·6 (4·0-5·2)	332	4·0 (3·2-4·9)	0·83 (0·71-0·96)	p=0·01
Facility-based	205	1·9 (1·4-2·3)	216	2·6 (2·0-3·3)	1·29 (1·04-1·60)	p=0·02
Self-tests	291	2·7 (2·4-3·1)	116	1·4 (1·0-1·8)	0·57 (0·48-0·68)	p<0·001
Group sex in the past 6 months (year 1 n=106; year 2 n=86)						
Self-tests and facility-based	466	4·4 (3·9-4·9)	327	3·8 (3·0-4·7)	0·80 (0·68-0·93)	p=0·005
Facility-based	212	2·0 (1·6-2·4)	215	2·5 (1·8-3·1)	1·04 (0·92-1·41)	p=0·23
Self-tests	254	2·4 (2·1-2·7)	112	1·3 (1·0-1·8)	0·57 (0·48-0·68)	p<0·001
>10 male partners in the past 6 months *(year 1 n=90; year 2 n=70)*						
Self-tests and facility-based	441	4·9 (4·2-5·6)	280	4·0 (3·0-5·0)	0·74 (0·63-0·87)	p=0·00
Facility-based	198	2·2 (1·7-2·7)	182	2·6 (1·9-3·4)	1·05 (0·85-1·30)	p=0·67
Self-tests	243	2·7 (2·3-3·1)	98	1·4 (0·9-1·8)	0·48 (0·37-0·61)	p<0·001
Age > 35 *(year 1 n=83; year 2 n=70)*						
Self-tests and facility-based	340	4·1 (3·4-4·8)	252	3·6 (2·9-4·3)	0·86 (0·72-1·02)	p=0·08
Facility-based	141	1·7 (1·2-2·1)	147	2·1 (1·4-2·8)	1·24 (0·96-1·60)	p=0·10
Self-tests	199	2·4 (2·0-2·9)	105	1·5 (1·2-1·9)	0·57 (0·48-0·68)	p<0·001
Migrant men (year 1 n=69; year 2 n=55)						
Self-tests and facility-based	283	4·1 (3·4-4·9)	209	3·8 (3·1-4·5)	0·91 (0·75-1·10)	p=0·36
Facility-based	110	1·6 (1·2-2·1)	121	2·2 (1·7-2·7)	1·19 (0·90-1·56)	p=0·23
Self-tests	173	2·5 (2·0-3·0)	88	1·6 (1·1-2·0)	0·57 (0·48-0·68)	p<0·001
Part-time job or unemployed (year 1 n=53; year 2 n=44)						
Self-tests and facility-based	201	3·8 (3·1-4·4)	185	4·2 (2·9-4·8)	0·97 (0·78-1·22)	p=0·80
Facility-based	80	1·5 (1·0-2·0)	119	2·7 (1·7-3·7)	1·51 (1·10-2·06)	p=0·01
Self-tests	121	2·3 (1·8-2·6)	66	1·5 (0·9-2·0)	0·57 (0·48-0·68)	p<0·001

*CAIC=condomless anal intercourse with casual partner(s). Note that the overall change in testing frequency were statistically significant after allowing for a 3-test Bonferroni correction. Rate ratio <1 means less tests in the intervention arm in year 2, vice versa.

Table 4
Year 1 access among men in the intervention arm vs Year 2 HIVST access among men in the Standard-care arm.

Subgroup and type of testing	Intervention arm in year 1(HIVST 1 year) Number of tests	Tests per year (95% CI)	Standard-care arm in year 2 (HIVST 1 year) Number of tests	Tests per year (95% CI)	Rate Ratio (95% CI)	P-value
Overall HIV tests (HIVST randomised in year 1 n=178; HIVST randomised in year 2 n=135)						
Self-tests and facility-based	730	4·1 (3·7-4·5)	405	3·0 (2·6-3·4)	0·72 (0·64-0·82)	p<0·001
Facility-based	303	1·7 (1·4-2·0)	311	2·3 (2·0-2·6)	1·31 (1·12-1·55)	p<0·001
Self-tests	427	2·4 (2·2-2·7)	94	0·7 (0·5-0·9)	0·30 (0·24-0·38)	p<0·001
CAIC* in last 6 months (*HIVST randomised in year 1 n=104; HIVST randomised in year 2 n=73*						
Self-tests and facility-based	478	4·6 (4·0-5·2)	241	3·3 (2·8-3·9)	0·74 (0·63-0·87)	p<0·001
Facility-based	198	1·9 (1·5-2·3)	190	2·6 (2·1-3·1)	1·35 (1·10-1·66)	p<0·001
Self-tests	280	2·7 (2·4-3·1)	51	0·7 (0·4-1·0)	0·30 (0·22-0·40)	p<0·001
Ever have group sex (*HIVST randomised in year 1 n=106; HIVST randomised in year 2 n=80)*						
Self-tests and facility-based	466	4·4 (3·9-4·9)	232	2·9 (2·5-3·4)	0·68 (0·58-0·80)	p<0·001
Facility-based	212	2·0 (1·6-2·4)	192	2·4 (2·0-2·8)	1·20 (0·98-1·47)	p=0·07
Self-tests	254	2·4 (2·1-2·7)	40	0·5 (0·3-0·8)	0·24 (0·17-0·33)	p<0·001
>10 male partners in the past 6 months (*HIVST randomised in year 1 n=88; HIVST randomised in year 2 n=65)*						
Self-tests and facility-based	431	4·9 (4·2-5·6)	202	3·1 (2·6-3·6)	0·65 (0·55-0·77)	p<0·001
Facility-based	194	2·2 (1·7-2·7)	163	2·5 (2·0-2·9)	1·11 (0·90-1·37)	p=0·32
Self-tests	237	2·7 (2·3-3·1)	39	0·6 (0·3-1·0)	0·26 (0·18-0·36)	p<0·001
Age > 36 *(HIVST randomised in year 1 n=83; HIVST randomised in year 2 n=56)*						
Self-tests and facility-based	340	4·1 (3·4-4·8)	174	3·1 (2·5-3·6)	0·75 (0·62-0·90)	p=0·003
Facility-based	141	1·7 (1·2-2·1)	134	2·4 (1·9-2·9)	1·42 (1·12-1·69)	p=0·005
Self-tests	199	2·4 (2·0-2·9)	40	0·7 (0·4-1·1)	0·31 (0·21-0·44)	p<0·001
Migrant men (HIVST randomised in year 1 n=69; HIVST randomised in year 2 n=42)						
Self-tests and facility-based	283	4·1 (3·4-4·9)	134	3·2 (2·5-3·9)	0·78 (0·62-0·96)	p=0·02
Facility-based	110	1·6 (1·2-2·1)	109	2·6 (2·0-3·2)	1·41 (1·06-1·86)	p=0·02
Self-tests	173	2·5 (2·0-3·0)	25	0·6 (0·4-0·9)	0·31 (0·21-0·47)	p<0·001
Part-time job or unemployed (HIVST randomised in year 1 n=53; HIVST randomised in year 2 n=49)						
Self-tests and facility-based	201	3·8 (3·1-4·5)	142	2·9 (2·3-3·6)	0·80 (0·64-0.99)	p=0·04
Facility-based	80	1·5 (1·0-2·0)	113	2·3 (1·8-2·8)	1·48 (1·11-1·97)	p=0·01
Self-tests	121	2·3 (1·8-2·6)	29	0·6 (0·3-0·9)	0·32 (0·21-0·47)	p<0·001

*CAIC=condomless anal intercourse with casual partner(s). Note that the overall change in testing frequency were statistically significant after allowing for a 3-test Bonferroni correctio. Rate ratio <1 means less tests in the standard-care arm in year 2, vice versa.

Similarly, fewer HIVSTs were used by men who gained access to the HIVSTs after 12 months, compared to those who gained access immediately. There are three possible explanations for these findings. First, HIVSTs were not commercially available in Australia when the FORTH trial commenced, and men who participated in the trial were the first in Australia to be able to use them. It has been consistently shown that people are more inclined to adopt new behaviours at times when their enthusiasm and motivation is high [29]. However, after 12 months this initial enthusiasm may have waned. Second, as described in qualitative research undertaken in the FORTH study, some men had concerns about the longer window period of HIVSTs, which may have resulted in them losing some interest in using the technology [17]. Third, PrEP (pre-exposure prophylaxis) became available through large government-funded implementation trials in 2016-2018 [30,31] requiring 3-monthly facility testing, and less need for HIVSTs. However this is likely to only have affected a small subset of men, as coverage of PrEP in Australia was low (6%) among GBM in this time period [32].

Our stratified analysis showed that access to HIVSTs resulted in higher levels of HIV testing compared with facility-based testing alone, in higher-risk men and other subgroups, including migrants. In addition, we found a higher proportion of migrants continued using HIVST compared to non-migrant men. These findings are encouraging as HIV incidence is higher in these groups, and access to HIVSTs may result in earlier HIV detection. Migrants are a particularly important subgroup considering recent surveillance data showing much higher rates of HIV diagnoses and undiagnosed HIV among migrant GBM compared to non-migrant GBM [33,34]. Between 2014 and 2017, HIV diagnoses among migrant GBM remained largely unchanged compared to a 49% reduction in Australia-born men in the same period [33,34]. HIVSTs combined with peer-based strategies may be an important way to reach migrant men who are concerned about attending mainstream clinical services for HIV testing [14,35].

During the study, participants were provided with free HIVSTs in person or via the postal service, with considerable social marketing undertaken to recruit the participants [19,27]. To maintain higher levels of HIV testing outside of the FORTH study, a variety of access points and delivery mechanisms for HIVSTs are needed to meet the needs of all men [36]. In Australia, the atomo finger-prick HIVST (cost of $25 AUD plus postage fee, in 2020), is the only HIVST currently approved for sale by the Australian Therapeutic Goods Administration (TGA) [37], but it can only be purchased online or through a few specific AIDS Councils, and there are complex regulations before these organisations can order them. Further, the atomo test cannot be promoted, which is likely to be hindering uptake [38]. In other countries, there is a mixture of commercial and publicly funded programs, with variation in the type of HIVST kit used. A recent discrete choice experiment (DCE) of GBM in Australia showed that participants had preferences for accessing HIVSTs from online stores, pharmacy, and at sex-on-premises venues - a modality recently trialled in New Zealand [39]. The DCE participants also had a strong preference for free or low-cost HIVSTs, like the FORTH trial. Providing free or low cost HIVSTs is particularly important for newly arrived migrant men who don't have access to subsidised health care in Australia [38].

Our study has several limitations to consider when interpreting the findings. First, the sample size was designed for the RCT, which enabled us to examine the primary outcome in the study population overall, but we only had power to assess a 10% or higher difference in larger subgroups which represented more than 20% of the study population. Second, the follow-up time was lower in year 2 than year 1, which may have introduced some attrition bias [40]. However, we only extrapolated 6 weeks to the study outcome in year 2, so even if no HIVSTs were used in this period, the maximum impact would have been a reduction in HIVST testing frequency from 1·4 to 1·2 in the intervention arm and 0·7 to 0·6 in the standard-care arm. We also found there was no differential attrition between the arms, and no major difference in characteris-

tics or the primary outcome among men who completed any survey in each year, versus the final survey. Third, migrants included in the study were required to be able to understand English, and we did not ask how long they had resided in Australia, so they may not be fully representative of all migrant men at higher risk of HIV in Australia. Finally, the HIVSTs used in this study were OraSure kits, provided free of charge to participants. Although OraSure kits are not commercially available in Australia, they are available in many other countries. We do not believe the type of test (oral fluid or finger-prick) would greatly affect the generalisability of our results, as an RCT in China among men who have sex with men showed the use of finger-prick self-tests also increased HIV testing [21]. Further, a systematic review showed that oral fluid self-tests were only slightly preferred over finger stick tests, albeit with variation across countries, key populations and previous testing experiences [41]. However, as the kits in our study were provided free, it is unknown if our results are generalisable to settings where GBM need to pay for HIVSTs. In Australia, the current commercially available finger-stick test costs $25 AUD ($20 USD), with $15 AUD ($11 USD) postage, which has been reported to be an acceptable price point of most GBM although migrants GBM would prefer cheaper or free tests [38,42]. Overall, to achieve and maintain a high frequency of self-testing among GBM and other priority populations, countries should remove all cost barriers associated with HIV testing.

In conclusion, higher-risk GBM who had access to free HIVSTs were able to maintain higher HIV testing frequencies after two years compared to men who only had access to facility-based testing only. Although fewer HIVSTs were used in year 2, on average 1·4 extra tests were conducted due to having access to HIVST. Moreover, in year 2, GBM continued to supplement their existing facility-based testing with HIVSTs. The findings emphasise the importance of undertaking evaluations that assess the enduring effect of interventions. The findings also affirm the importance of the HIVST technology as a way to increase and sustain testing frequency for GBM, including migrant men. However, there is a need for further implementation research to evaluate the effect of making HIVSTs available in settings other than online.

Declaration of Competing Interest

BRB and RJG received a grant from Gilead Sciences outside the submitted work. ML reports grant from Gilead Sciences, Janssen-Cilag and ViiV Healthcare outside the submitted work. DPC reports personal fees from Atomo Diagnostics. All other authors declare there are no conflicts of interest.

Contributors

This manuscript is original research that has not been published previously, nor is it under review with any other journal. RJG and MSJ conceived the initial FORTH trial. YZ was responsible for concept development for this secondary analysis including design, data management, analysis of study data and led the writing of the manuscript. MSJ, RJG, KSS, GP, BRB, MH, and PK was involved in the concept and data collection. MSJ and ML provided advice for data analysis. All authors contributed to the interpretation of results, provided advice of the draft, and approved the final draft of submission.

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Ethics Committee Approval

Ethical review and oversight for FORTH project was provided by the South Eastern Sydney Local Health District and Alfred Health Human Research Ethics Committees.

Data sharing statement

The study protocol is available for sharing.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.lanwpc.2021.100214.

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