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**HIV self-testing for men who have sex with men (MSM) in England
and Wales: a multi-method study of self-testing intervention
development and evaluation**

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Abstract

Background

Undiagnosed HIV among men who have sex with men (MSM) remains a significant public health challenge in the UK. Higher rates of recent and repeat HIV testing are necessary to ensure recent falls in HIV incidence among MSM in parts of England and Wales are fully reproduced nationally. HIV self-testing (HIVST) is the latest in a long line of HIV testing interventions, which has been developed to reduce barriers to testing for those at risk of acquiring the virus. An HIV Self-testing Public Health Intervention (SELPHI) is the first randomised controlled trial (RCT) delivering free HIVST kits to MSM in Europe. SELPHI has two interventions and aims to assess whether HIVST can increase diagnosis of prevalent HIV infections (intervention A) and reduce the time between infection and diagnosis for those at on-going risk of new HIV infections (intervention B). Social sciences have been at the heart of SELPHI, contributing to formative, implementation and evaluation research.

This thesis seeks to develop an understanding of the potential contribution of HIVST to the well-being of MSM in England & Wales. It contributes significantly to the academy by developing a comprehensive evidence base enabling policy makers and service providers to optimise HIVST service delivery.

Methods

This work is conceptually grounded in implementation science and uses the Behaviour Change Wheel (BCW), which includes the COM-B model of behaviour change to provide a framework for intervention development and to understand participant outcomes. A pragmatic, multi-method approach has been taken whereby the optimal data collection methods have been carefully selected based on their suitability to answer the research questions.

Results

This thesis includes three studies presented over five published papers. The first is a formative study (contributing to papers 1 and 2) of qualitative focus group discussions with MSM which produces new understandings of the diversity of their values and preferences with regard to HIVST. This study also interrogates narrative understandings of the potential use of the technology, demonstrating HIVST use may be limited to when MSM do not perceive significant risk, except in the context of significant barriers to service access. The second study (contributing to paper 3) is a mixed methods interrogation of the implementation pilot, demonstrating high feasibility and acceptability of an HIVST intervention delivered to MSM through the SELPHI study. The final study (contributing to papers 4 and 5) is an evaluative analysis of qualitative in-depth interviews with individuals who have undergone HIVST, showing high acceptability and varying intervention performance across groups. The utility of COM-B as a model for understanding behaviour change in relation to HIVST is examined in paper 5.

Conclusions

Online delivery of HIVST to MSM is feasible and acceptable; contexts of use and intervention performance will vary across groups. A number of intervention adaptations can be made to increase acceptability and the potential reach of HIVST interventions. The absence of a robust concept of need in COM-B means that this model may be sub-optimal in designing HIVST interventions, and perhaps interventions which meet needs generated by social norms.

Declaration

I, T Charles Witzel, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

Dedication

I dedicate this work to my disability, my biggest challenge and greatest asset. Neurodivergence has enabled me to think in ways others do not; a source of frustration, motivation and, occasionally, inspiration. Thank you, tangled brain.

Acknowledgments

My thesis has truly taken a village and I have many people to thank.

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Statement of contribution

This thesis has been embedded within a broader programme of work as part of a multi-institutional NIHR funded programme grant titled PANTHEON (Prevention and Testing for HIV: Economics and Outcomes of Novel Approaches). At the centre of PANTHEON sits SELPHI (An HIV Self-Testing Public Health Intervention), the HIV self-testing randomised controlled trial to which this work contributes.

I began work on PANTHEON in March 2015 as a research assistant and have since been elevated to co-investigator. The team I have worked within is known internally as workstream one (WS1), which is largely separate from workstream two (WS2), the clinical trial group responsible for RCT delivery. WS1 contains all feasibility work for the trial and has had responsibility for all social sciences aspects of the programme grant.

Within WS1 I have had primary responsibility for the design, conduct and analysis of the studies included in this thesis, with guidance and support from my more senior colleagues. The aims and objectives used for each study have been produced by me with input from my wider team. For each study used in this thesis I have created the data collection instruments, conducted the research, designed the analysis tools and carried out the analysis.

The exception to this is paper 3, where some of the demographic questions used in analysis were not designed by myself, but rather, within the broader study team. For this paper I designed the quantitative analysis which was carried out by the trial statistician Leanne McCabe.

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² Figures embedded within publications are not listed included in this list in order to preserve formatting and readability in results papers.

Glossary

Apps – geolocation social sexual networking applications

ART – anti-retroviral therapy

BCW – Behaviour Change Wheel

BT – baseline test

CAI – condomless anal intercourse

FSW – female sex workers

GMSS 2014 – Gay Men’s Sex Survey 2014

HIVSS – HIV self-sampling

HIVST – HIV self-testing

IS – implementation science

MSM – men who have sex with men

nBT – no baseline test

nRT – no repeat testing

PANTHEON - Prevention and Testing for HIV: Economics and Outcomes of Novel Approaches

PHE – Public Health England

PrEP – pre-exposure prophylaxis

RCT – randomised controlled trial

RDT – rapid diagnostic test

RT – repeat testing

SELPHI – An HIV Self-Testing Public Health Intervention

SoC – standard of care

STIs – sexually transmitted infections

THT – Terrence Higgins Trust

WHO – World Health Organization

1. Background & literature review

In this first section of my thesis I begin by outlining some of the key considerations regarding HIV testing in the UK, including the history of HIV testing intervention development. I then describe the development and introduction of HIV self-testing (HIVST) before reviewing relevant literature in the UK and internationally. Finally, I describe SELPHI, the largest HIVST randomised controlled trial (RCT) of HIVST in a high-income setting, a trial much of my thesis wraps around.

The HIVST literature review which begins at section 1.2 is drawn from a systematic mapping exercise which is a collaboration led by myself, involving the World Health Organization (WHO) and others (protocol available in appendix 1). I established this systematic map to capture all HIVST literature published in the academic press as it emerged, with searches updated monthly. I took this approach in recognition that the HIVST literature was rapidly developing during the early stages of my PhD. This systematic map has supported the development of 4 separate systematic reviews, and an update to the WHO HIVST guidelines launched Dec 1st 2019 (1), and in which I took an active role leading the key populations meta-analysis and the qualitative analysis for the values and preferences review. Although this section is not drawn from these reviews, I used the results of this map for my literature search to illuminate key areas of enquiry. Further, sections of my literature review are an updated version of an invited review I wrote for *Current Opinion in Infectious Diseases* (2).

1.1 HIV testing in the UK

The HIV epidemic among men who have sex with men (MSM) in the UK remains a significant public health challenge. Reducing the time between HIV infection and diagnosis is a key goal with national guidelines recommending MSM test annually, or more frequently in the presence of additional risk factors, such as condomless anal intercourse (CAI), sexualised drug use or diagnosis of a sexually transmitted infection (STIs) (3, 4). Rapid diagnosis of HIV has implications not just for individual health, with evidence indicating that suppressive antiretroviral therapy (ART) is beneficial at any CD4 count, but also for onward transmission of HIV (5-7). Sixty to eighty percent of HIV transmissions are thought to occur from those as yet undiagnosed and often in the early stages of HIV infection where risk of onward transmission is greatest (8-10). The 'Test and Treat' approach has been enshrined in the UNAIDS global 90-90-90 targets which aim, by 2020, to achieve 90% of people with HIV being diagnosed, 90% of those diagnosed taking ART, and 90% of those on ART achieving virological suppression (11). The UK has been successful in this regard; in 2017 92% of people with HIV knew their status, 98% of those were receiving treatment and 97% of those receiving treatment had achieved virological suppression (12). Evidence suggests that frequency of testing remains sub-optimal however, with 25% of MSM in the UK having never tested for HIV and 50% not testing annually (12-15). Ever and repeat testing is also vital for effective use of pre-exposure prophylaxis

(PrEP), a key driver in the decreases observed in HIV incidence (16). Further, there is growing concern about individuals who fall into the remaining gaps in this cascade. It is possible that the focus on reaching each 90% will mean the most disadvantaged with the highest needs will be overlooked, thereby potentially exacerbating health inequalities (17).

The public health drive to increase testing rates has led to a significant evolution in the types of HIV testing interventions available, and the assays used within these interventions, facilitating incremental evolution of testing approaches seeking to overcome testing barriers. These barriers occur at patient, health care provider, health care service and health system level (18). Commonly cited examples of barriers to HIV testing for MSM in high income settings include: fear of a positive result; concern about stigma from health care providers; concern about confidentiality; service inaccessibility; the emotional impact of the time between undergoing testing and receiving the result; concerns about the time between infection and the ability of tests to detect HIV (the 'window period') and a lack of risk perception which reduces motivation to test (18-20).

The initial tests developed in 1985 relied upon antibodies to detect HIV and required a laboratory to process, leading to significant waiting times for results and long window periods between infection and potential detection (21). Responding to concerns related to waiting for the outcome of laboratory run tests, the development and introduction of rapid diagnostic tests (RDTs) in the late 1990s facilitated the provision of results on the same day when testing in clinical settings (22, 23). These developments were coupled with improvements in testing technology; tests with higher sensitivity were developed by including assays which measured the presence of additional antibodies, and by 1999, antigens, with 4th generation tests significantly reducing window periods while improving performance (21, 24).

In the UK, from the mid-2000s, RDTs were utilised in community based testing programmes, expanding testing to settings including bars, nightclubs, sex on premise venues, community centres and other social venues in a response to limited accessibility of clinics and concerns related to stigma and homophobia (25, 26). Prompted again by barriers of privacy, stigma and inconvenience, HIV testing moved into the domestic sphere with the introduction of HIV self-sampling (HIVSS) in 2012 and self-testing in 2015 (27, 28).

Following intensive multifaceted prevention interventions aimed at MSM in the UK, new HIV diagnoses are showing declines in this group. However, these recent falls in new infections are not distributed evenly; with surveillance data indicating that London has seen the largest falls in new diagnoses, with the south of England, the midlands and the east of England also showing declines (12). Diagnoses among MSM in Wales have also fallen rapidly (12). Although initially slow to fall in

ethnic minority MSM, new diagnoses are beginning to fall in black MSM with less steep falls observed in Asian MSM, while increases have been observed among Latin American MSM (12). Further increases in HIV testing coupled with combination prevention activities are required to sustain these changes and to ensure they are distributed more equitably across the geographical and social groups of MSM. Indeed, evidence suggests a number of health inequalities exist amongst socio-demographic groups of MSM related to health service access, rates of diagnoses of STIs alongside variable prevalence and incidence of HIV (29, 30). This poses a serious challenge to the viability of sustained reductions in HIV incidence.

1.2 HIV self-testing

In contrast to HIVSS where a person takes a sample and posts it to a laboratory (and typically receives the results via text message), HIVST involves an individual taking their own sample, processing it and interpreting their own result (2). A positive result from HIVST is not a diagnosis; this requires the individual to attend a clinical setting and undergo confirmatory testing using approved clinical testing algorithms (2, 31, 32).

In the early period of the epidemic, HIV was viewed as an exceptional disease by policy makers and clinicians because of the immense social and personal impact of an HIV diagnosis, as well as the potential for criminalisation in many settings (33, 34). As a result of this exceptionalism, HIVST was made illegal in many countries, including the UK, due to concerns over the potential for adverse psychological reactions with a positive result in the absence of effective treatments as well as the potential for coercive use (35). In recent years, the shift in perception of HIV for health professionals and affected communities from a nearly universally fatal illness to a chronic manageable condition with near normal life expectancy has led to changing attitudes towards the psychological impact of HIV diagnosis (2, 36, 37). These changes have led to a more permissive policy environment around testing, and increasing numbers of countries enacting laws or repealing legislation in order to facilitate the introduction of HIVST. The UK legalised HIVST on April 1st 2014, with the first commercially available CE marked test released the following year (Biosure™) (2).

As efforts continue to expand HIV testing, HIVST has been officially adopted on a global policy level, with the World Health Organization (WHO) incorporating HIVST into their Consolidated Guidelines on HIV testing services in July 2015 (38) and official HIVST guidance being published in December 2016 (39).

HIVST has been promoted by policy makers and professionals as a low cost alternative to facility-based testing, reducing barriers such as stigma and opportunity cost while increasing patient choice and enhancing autonomy (2, 32, 40). The potential role for HIVST in expanding testing to new groups

and enabling increased testing frequency in those at highest risk is mooted (2, 40). Evidence to support these assertions is scarce in Europe more broadly and the UK specifically.

HIVST also has potential application in combination HIV prevention initiatives such as the targeted expansion of testing, treatment and pre-exposure prophylaxis (PrEP) (40, 41). HIVSTs are available using a whole blood sample, usually from a finger prick, or using oral fluid. Only blood-based self-tests are commercially available in the UK at this time, although oral fluid self-tests are widely available in other countries (2). HIVSTs are currently only available using 2nd and 3rd generation assays, meaning that window periods are typically around 6 to 12 weeks long, although RDTs which use 4th generation assays exist which will likely be repackaged for future self-testing use (2).

A note on terminology: as in much of the published literature (42-52), in this thesis I use the term 'positive' rather than 'reactive' when referring to an HIVST result that suggests HIV infection. Although these results clinically would be referred to as reactive (53), all available HIVSTs in the UK describe such a result as a positive in the instructions and it is therefore how end users understand and interpret these tests. This reflection of language is especially important for qualitative health research which seeks to develop nuanced understandings of how individuals perceive and experience their own health (54, 55).

1.3 Existing HIVST evidence

The HIVST evidence base in Europe generally, and the UK specifically, is not as well developed as in other WHO regions. The existing evidence also largely relates to acceptability and values and preferences studies, with limited data from pilot and demonstration projects.

Acceptability studies seek to understand which populations might have need for an intervention, how different groups might respond to implementation and whether the intervention in question (or its constituent components) meets their needs (56). To aid in intervention planning, values and preferences studies examine how local contexts and differences in populations influence the way that preferences related to interventions are constructed (57). For HIVST, both study types tend to include participants who have not actually experienced HIVST themselves and to whom the intervention is therefore hypothetical. For that reason, this evidence base must be carefully evaluated, acknowledging the limitations of this approach. For example, when innovations in interventions are considered without prior experience, concerns around one's own abilities to engage with an intervention or to carry out the required steps may be exaggerated as individuals will usually not have had sufficient time to familiarise themselves with the technology in question (2). Another issue is that populations do not take-up interventions evenly, and there will be key differences in the motivations and real-world use of those who take up the intervention at various

stages of roll-out (58). Rogers describes five categories of adopters of novel innovations: innovators, early adopters, early majority, late majority and laggards (59). Through processes of cultural dissemination surrounding the use of novel technologies, later adopters and laggards learn from innovators and early adopters through diffusion through cultures (59, 60). It has been argued that this process of cultural dissemination has occurred with PrEP, which was first provided in England in 2012 through the PROUD study, and could be replicated with the experience of HIVST in European countries (61). Nevertheless, attending to this evidence of hypothetical potential HIVST users remains worthwhile because it provides an indication of how populations are likely to engage with the technology, and whether interventions are acceptable as well as how they might be tailored to ensure they are feasible and effective, while still countering concerns raised in early research.

Table 1 details the features and findings of key HIVST studies conducted in Europe to date. When reviewing this evidence base, some key insights emerge.

Generally speaking, confidentiality, convenience, immediacy and the opportunity to increase testing frequency are commonly cited benefits of HIVST (27, 28, 32, 48, 49, 62-64). Barriers include concerns around dislocation from care pathways, the possibility of coercive testing practices and perceived issues with self-efficacy and kit accuracy (27, 47, 65).

Firstly, as discussed above, the majority of published studies are prospective in that very few individuals had experienced HIVST (66), or were conducted with stakeholders (67). There are however two demonstration projects included, both of which include important insights for HIVST service development regarding intervention reach and potential delivery settings (68, 69).

The prospective nature of most of the data means that although we can have an understanding of HIVST's potential, the current evidence base is insufficient to provide a broader overview of the contexts in which target populations might use HIVST. Further, three of the studies from Europe reporting on previous lifetime HIVST use were conducted before licenced, regulated tests were widely available in these countries. Kits being used were therefore unregulated RDTs bought online in three studies (66, 70, 71). One demonstration project used an RDT intended for clinical use which was adapted without formative research, raising potential concerns around usability (69). Two studies found moderate to high willingness to use a potentially regulated (but at the time hypothetical) HIVST (15, 66).

Table 1: Key HIVST studies from Europe

1st author & year	Setting & sample	Data collection	Study type	Aim	Key findings
Flowers 2016 (28)	Scotland Quant: 999 MSM Qual: 12 expert FGDs with 55 MSM and key informants	Mixed methods exploratory design.	Acceptability	To describe awareness and willingness to use the self-test and the perceived barriers and facilitators to implementation.	<ul style="list-style-type: none"> • Self-test awareness was moderate among MSM (55%), and willingness to use was high (89%). • Greater awareness associated with higher educational attainment & previous STI testing. • Willingness to use was associated with meeting sexual partners online. • Experts highlighted the overall acceptability of self-testing; it was understood as convenient, discreet, accessible, and with a low burden to services. • Ambivalence related to reduced opportunities to engage with services, wider health issues and the determinants of risk.
Gibson 2016 (69)	UK 394 (77%) males, 119 (23%) females. 352 (72%) urban, 135 (28%) rural	Demonstration project	Feasibility & acceptability	To determine feasibility/acceptability of HIV home/self-testing.	<ul style="list-style-type: none"> • 513 oral fluid kits posted (adapted version of professional use orasure test). • 19% of sample completed study follow-up. 73% were men who have sex with men (MSM). 47% had never tested previously; 37% MSM had never tested. • 2 infections identified, partner notification identified one further. • HIVST reduced barriers to clinic access and to using blood based tests.
Greacen 2012 (72)	France 5908 HIV negative MSM aged 18+	Online cross-sectional survey	Acceptability	To identify whether men who have sex with men (MSM) who use dating or sex websites or gay or HIV community websites would be interested in accessing these tests if reliable ones were authorised, their reasons for being interested or not, and independent variables associated with being interested.	<ul style="list-style-type: none"> • 86.5% (5109/5908) reported interest in using HIVST. <p><u>Variables associated with higher interest:</u> Never tested, tested >12 months ago, CAI with casual partner, not open about sexuality, living in town >100,000 inhabitants, living in family with a wife and/or children or with one's parents, having 2 to 50 casual partners in preceding 12 months, being employed or self-employed, low & medium levels of education.</p> <p><u>HIVST motivators</u></p>

1st author & year	Setting & sample	Data collection	Study type	Aim	Key findings
					<ul style="list-style-type: none"> • Convenience, accessibility, can do it at home. • Rapidity obtaining test results. • Privacy, discretion, confidentiality, anonymity.
Greacen 2016 (67)	France, French West Indies, Guiana 72 key informant experts	Online qualitative study using Delphi method	Acceptability	To identify and compare the information and support needs of the different target population groups.	<p>263 policy & health service recommendations groups into eight themes</p> <p><u>Themes</u></p> <ol style="list-style-type: none"> 1. Communicating at both national and community levels about self-test arrival 2. Providing information adapted to the different community groups' needs 3. Providing counselling on self-test use and access to care 4. Making self-tests available to all in terms of accessibility and cost 5. Preparing community healthcare and screening systems for the arrival of the self-test 6. Approving only high quality self-tests 7. Defending self-test users' legal rights 8. Considering how to evaluate self-test use
Ickenroth 2010 (73)	The Netherlands 6700 internet users	Two-step cross-sectional survey	Acceptability	To validate findings about the frequency of self-testing and to investigate consumers' follow-up behaviour after performing a self-test by assessing the actions taken by self-testers.	<ul style="list-style-type: none"> • 1.9% had used an HIVST • Most self-testers in study had confidence in their result.
Saunders 2017 (74)	UK 200 HIV negative or untested GUM attendees	Observational feasibility study	Feasibility	To assess the ability of lay users attending a sexual health service to perform the BioSure HIV Self-Test and to correctly interpret the result of the self-tests.	<ul style="list-style-type: none"> • 97% (95% CI 93.5 – 98.9) conducted the test properly. • 99.5% correctly identified the test result. • Participants correctly interpreted the result of 94.0% (95% CI 91.4 to 95.9) of 586 devices.
Vera 2019 (75)	UK Men attending sex on	Demonstration project	Feasibility & acceptability	To evaluate the acceptability and feasibility of using vending machines in a sex on premise venue (sauna) to distribute HIVST to men who have	<ul style="list-style-type: none"> • 265 testing kits were dispensed (number of men unknown). • Mean age 31 years (range 18–70). • 4% (n = 7) had never tested for HIV before and 11% (n = 22).had tested within the last 1–5 years.

1st author & year	Setting & sample	Data collection	Study type	Aim	Key findings
	premise venue			sex with men at high-risk of contracting HIV.	<ul style="list-style-type: none"> • Uptake of HIV tests was six times greater via the vending machine compared with testing conducted by community outreach workers in the same venue and study period. • HIVSTs perceived to lower barriers to testing, especially those related to stigma while increasing convenience. • Concerns about positive result with no support.
Witzel 2016 (15)	England 14 317 HIV negative / untested MSM	Cross-sectional online survey	Acceptability	To identify which groups of MSM in England are less likely to have tested for HIV and their preferred model for future tests.	<ul style="list-style-type: none"> • Younger men, older men and men who were not gay identified were least likely to have tested for HIV. • Groups less likely to test in line with guidelines were more likely to report wanting to access HIVST for their next test. • MSM who had never tested preferred self-administered testing options (HIVSS & HIVST) for their next test. • Higher educational attainment, migrancy, black ethnicity and being at higher of risk were associated with greater levels of HIV testing.

Key findings in **bold**

Although formative studies provide some insights into groups who might benefit from HIVST, these data have significant limitations. A key issue is that contact with the technology and discussions amongst peer groups will shape acceptability profoundly, so most of this evidence is only indicative of intervention potential at the outset of availability, not acknowledging how individuals will engage with the limitations of possible interventions. Finally, with the notable exception of Flowers et al. (28) and Vera et al. (68), both of which are mixed-methods investigations, all studies are quantitative and lack the depth of understanding needed to inform effective intervention development and to optimise service provision. Astonishingly little data exists about the values and preferences of MSM in Europe for HIVST interventions, a key component of service design and delivery (2).

The demonstration projects by Gibson et al. (2016) and Vera et al. (2019) are important building blocks in the HIVST literature, with some limitations. Gibson (et al. 2016) demonstrated that HIVST delivered online can reach those who do not test in line with national guidelines (69). A 19% follow-up rate in this study demonstrates the challenges of engaging with those who have received an HIVST following online delivery of the intervention to collect information on their results and provide support if necessary (69). This high attrition also makes it impossible to generalise the findings. Important data about experiential concerns around ease of use and acceptability were not collected, a particular concern given the test was an oral fluid kit designed for clinical use and adapted by the researchers for self-use. The accompanying information may therefore have been insufficient.

Vera et al. (2019) demonstrates that it is feasible to deliver HIVST through innovative mechanisms such as vending machines in public premises (68). This demonstration project however predominantly reached a group of MSM with less pronounced testing needs than Gibson et al., raising the possibility that these strategies may be sub-optimal when compared to online delivery if expanding testing to those less likely to test is a key objective. Furthermore, efficiency of service delivery is a potential issue with a small number of kits having been distributed in this demonstration project, although the intervention did outperform the community testing and counselling initiatives in the same venue (68).

Looking more broadly, MSM in many middle- and high-income settings are relatively well represented in literature around HIVST acceptability as well as research investigating values and preferences (studies that show the diversity in preferences around intervention design and characteristics). Emerging evidence amongst MSM from Peru (44, 76), the USA (62, 63), Vietnam (64) and Mexico (77) report that MSM find HIVST highly acceptable, with moderate acceptability observed in Hong Kong despite the availability of HIVST (45). These studies are heterogeneous in

their acceptability measures, variously using willingness to use, quantitative acceptability metrics and qualitative descriptions of acceptability.

A systematic review conducted by Figueroa, Johnson (32) among key populations (MSM, sex workers, trans people, people who use drugs and people in prisons) suggests that oral fluid self-tests are marginally preferred over finger stick or whole blood tests, although this tends to vary across country income settings and key populations (32). In a study in Vietnam, MSM and female sex workers (FSW) preferred oral fluid HIVSTs, while people who injected drugs preferred blood based kits (64). In work from the US conducted with an ethnically diverse group of high risk MSM, more frequent testers preferred blood based testing, whereas men who tested less frequently preferred oral fluid HIVSTs (78). MSM who prefer oral fluid testing in the literature tend to value painlessness (79) while those who value blood based testing generally feel it is more accurate (48, 79, 80).

A range of feasibility studies, demonstration projects and trials globally have provided data on the feasibility and acceptability of providing HIVST to different populations through an array of intervention designs. While the aims for each study vary, designs tend to fall into one of two categories: the first aims to detect longstanding prevalent infections, the second to increase frequency of testing in those at risk of acquiring HIV, particularly in risk groups with high incidence. Both types of study also tend to have cost containment as a goal as HIVST may be a useful diversionary tactic from “bricks and mortar” services, thus reducing demand on resources (2).

Feasibility and pilot HIVST studies provide some evidence that HIVST will perhaps detect undiagnosed prevalent infections in individuals who do not test in line with guidelines or have never tested, although it remains unclear if HIVST is more efficacious than other testing interventions to meet this aim. Projects in the US which focussed on reaching groups who have not previously tested or have difficulty accessing services seem to be successful in reaching MSM online (69, 81) and, to an extent, in sex on premises venues (51). For definitive evidence regarding the potential for HIVST to detect prevalent infections more quickly than other interventions we require RCTs powered to detect differences in rates of diagnosis.

Efforts to increase the frequency with which at-risk groups with high HIV incidence test are central to aspirations around the expansion of HIVST, and increased frequency of testing is a key benefit often repeated in values and preferences studies conducted with key populations. Non-RCT projects which have provided participants with a number of HIVSTs with instructions to test frequently have demonstrated that this intervention approach is feasible among transgender women in San Francisco (49), and MSM in Brazil and Peru (76).

Although these feasibility, demonstration and pilot studies provide valuable insights into basic elements of service delivery, there is a distinct lack of data on service uptake by demographic and behavioural groups with testing needs and documented utility for HIVST, such as MSM with lower educational qualifications, black MSM, those who are not gay identified, as well as both older and younger MSM (15, 82). These publications therefore provide relatively little insight into how HIVST might be a useful tool in responding to issues concerning health inequity or, conversely, the potential for HIVST to exacerbate existing inequalities. Although they have been conducted in a wide range of geographical locations with a range of populations, very few have been conducted in Europe and no RCTs have been conducted in the region. Sample sizes have also been very small in the quantitative studies. Qualitative work has thus far not had a prominent place in research initiatives providing HIVST, leading to significant gaps in our understanding of the experiences of individuals who have used the technology. This is especially important for widespread provision, which relies on intervention designs that meets the needs of a very wide variety of MSM. The absence of European evidence in this regard is especially problematic as the structures and accessibility of health systems in the European Region are vastly different to that of the US and Latin America, where much of this evidence originates.

Although mixed, RCT evidence related to HIVST provides some important insights. HIVST has increased testing uptake among MSM in all RCTS conducted (83-87). However, with the exception of Wang et al 2018 and Jamil et al 2017, most of these studies suffer from multiple sources of potential bias, including self-reported outcomes which were not validated by the study teams (83-88).

In terms of testing frequency in RCT evidence, in Seattle, MSM self-reported testing significantly more frequently when provided with multiple HIVSTs compared to standard of care (SoC) (5.3 tests compared with 3.6 over 15 months) (89). The study was too small (n=230), however, with too few reactive results (n=2) to show an effect on increasing HIV diagnosis or on linkage to care (83). These findings were repeated in an RCT among in MSM in Australia which showed increased testing frequency among the self-testing group that did not reduce attendance in STI clinics, indicating that men in this study used HIVST largely as a supplementary testing option. Two further US studies also showed increases in testing frequency (84, 85). Encouragingly, in Jamil et al 2017, frequency was increased in both those who tested annually or more often and those who did not.

A critical issue is that RCT evidence in regards to increasing rates of HIV diagnosis compared to other approaches through HIVST is not strong as studies have thus far been underpowered to assess rates of diagnosis compared to SoC. In addition, rates of reactive HIVSTs are an extremely challenging outcome to validate in the absence of surveillance databases that capture new infections. However

one recent RCT found more infections in the HIVST arm vs the SoC arm, a result which was statistically significant (HIVST = 12 of 1325 [0.9%] vs SoC = 2 of 1340 [0.1%]; $P < .007$) (84).

Linkage to care for confirmatory testing and linkage to care including early ART is necessary following a reactive result from a HIVST. There is very limited evidence from high-income settings of linkage rates after positive HIVST compared with other testing interventions, and that which does exist is not statistically significant (83, 86, 88).

1.4 An HIV Self-testing Public Health Intervention (SELPHI)

This PhD is embedded in the SELPHI study, the first HIVST RCT in the UK. SELPHI is also the first RCT globally which attempts to address both the ability of HIVST to detect undiagnosed prevalent HIV infections more effectively than current SoC though the offer of a baseline HIVST and also to reduce the time between HIV infection and diagnosis through the offer of repeated HIVST in men at higher risk of HIV infection. SELPHI launched in February 2017 and recruited 10,135 MSM and transgender people. The primary outcome was rates of HIV diagnosis as determined through confirmatory testing and linkage to care assessed through linkage with the UK national HIV surveillance database. This RCT will provide vital evidence for policy makers in high-income settings and those working with key populations on the efficacy and cost effectiveness of HIVST in increasing rates of HIV diagnosis. Intervention development for SELPHI has been underpinned by the Behaviour Change Wheel (BCW) system which includes the COM-B model of behaviour change (discussed further in section 2.2). This model emphasises that changes in capability, opportunity and motivation are required to support individuals in enacting and sustaining behaviour change (90, 91).

SELPHI is an online study with two randomisations: randomisation A occurred at baseline and 10,135 eligible MSM and transgender people were randomised to receive either one free HIV self-test (60% of participants) or none (SoC, 40% of participants). At 3 months 2,325 eligible participants drawn from those allocated to baseline HIVST in randomisation A (RA), who were at ongoing risk of HIV infection and who expressed an interest in receiving more HIVST kits were randomised through randomisation B (RB) to either a regular (3-monthly) offer of additional self-tests (50% of participants) or SoC (50%). See Table 2 for full eligibility criteria by randomisation.

Participants were recruited to SELPHI through geo-location socio-sexual networking applications (often referred to colloquially as 'hook up' apps) and social media. Most advertisement was paid, with some reliance on organic reach through community-based organisation (CBO) dissemination and media engagement. The first 1,000 participants were recruited during a soft-start phase (February to April 2017), during which a variety of advertisement approaches were tested. Following

analysis of data relating to this, SELPHI launched in earnest in July 2017. Recruitment was completed on 28th February 2018.

Table 2: Eligibility criteria by randomisation

Randomisation A	Randomisation B
MSM including cis & trans men, trans women	Allocation to baseline test in Randomisation A
Lifetime anal sex	Completed 3-month survey
Not previously diagnosed with HIV	Remains HIV negative
Aged ≥ 16	Expresses interest in further HIVST kits
Resident in England or Wales	CAI with ≥ 1 partner in preceding 3 months
Willing to provide name, date of birth and email address	Used HIVST kit
Consent to link survey responses to surveillance and clinic databases	
Not previously randomised in study	

When participants signed up online, they first provided informed consent, then completed a survey detailing eligibility criteria. They were then sent a second survey via email in which they were asked for additional demographic and behavioural information and other details required to send the HIVST kit and to subsequently link to the national HIV surveillance database to detect any future confirmed HIV diagnoses. Following randomisation, participants allocated to baseline testing (BT) were sent a kit through the post. After two weeks they received a survey asking whether the kit was used. At three months, a further survey was delivered to those in the BT and no baseline testing (nBT) groups; this asked for sexual behavioural information and determined eligibility for randomisation B. Those eligible were then randomised either to repeat offers of HIVST kits or SoC. Trial participants were matched with their clinical records through the HIV surveillance database held at Public Health England (PHE) through which endpoints were recorded. See Gabriel et al (92) for the full trial protocol.

2. Approaches and methods

My thesis informs SELPHI by generating key social science evidence before and during the trial. This provides a significant body of work suitable to inform self-test service provision and contribute more broadly to academic understandings of self-testing for HIV in MSM in England and Wales. My thesis includes several stages: it responds to pre-implementation questions regarding values and preferences of the intended beneficiaries as well as motivations for access and likely contexts of use. My attention then turns to questions of intervention feasibility and acceptability, specifically exploring the ease of use of the kit, preferences around intervention design and the real world use of HIVST among beneficiaries. This deepens the evidence base for others seeking to implement HIVST in similar settings. Finally, my thesis explores the contribution of HIVST to the lived

experiences of HIVST users, providing valuable data about the benefits and limitations of HIVST should it be made widely available, as well as potential for intervention adaptations. It also investigates the utility of the COM-B model of behaviour change (explored further in section 2.2) for conceptualising HIVST interventions.

This PhD aims to develop an understanding of the potential contribution of HIVST to the well-being of MSM in England & Wales.

The specific objectives are:

- i. To examine the values and preferences of MSM for HIVST interventions considering key domains of intervention design.
- ii. To explore the potential barriers and facilitators of HIVST for MSM using COM-B as a framework.
- iii. To understand how HIVST compliments existing testing strategies considered or adopted by MSM.
- iv. To assess the feasibility of recruiting MSM to the SELPHI pilot, and the acceptability of the HIVST intervention among those randomised to receive a kit.
- v. To explore the experience of utilising HIV self-tests and the implications for further intervention development and scale-up.
- vi. To explore how components of the SELPHI interventions impact on behaviour for, and are experienced by, RCT participants.
- vii. To examine the utility of COM-B as a useful model for understanding behaviour change in relation to the provision of HIVST.

This thesis has been embedded within a broader programme of work as part of a multi-institutional study. The team I have worked within is known internally as workstream one (WS1), which is largely separate from workstream two (WS2), the clinical trial group responsible for RCT delivery. WS1 contains all feasibility work for the trial and has had responsibility for all social science aspects of the programme grant. Within this team I have been given responsibility for the design, conduct and analysis of the studies we have undertaken to date, with guidance and support from my more senior colleagues. The aims and objectives used for each study have been produced by me with input from my wider team, and differ significantly from what was specified in the funding bid. This has provided me with the scope to form study questions relevant not only to the SELPHI RCT, but which also make a significant contribution to HIVST and the behaviour change literature more broadly. For each study used in this thesis I have created the data collection instruments, conducted the research, designed the analysis tools and carried out the analysis.

2.1 Thesis overview

This PhD, comprised of three studies presented over five results papers, employs a range of methods suitable for addressing specific questions relevant to the generation of high-quality evidence around the potential of HIVST in England and Wales. Section 2.2 describes my conceptual grounding and 2.3 outlines my theoretical basis for this pragmatic multi-method approach. Table 3 provides an overview of methods used in responding to each objective.

The first study used focus group discussions in taking a prospective approach to exploring HIVST acceptability; motivations and barriers; and values and preferences for HIVST among MSM in England. This formative inquiry has sought to overcome previous issues with prospective HIVST research by including the demonstration of kits, thereby providing some HIVST exposure during the discussion. This study also provides additional evidence on the ways in which the technology might be adopted by MSM based on normative understandings of HIV testing narratives. This study responds to objectives i, ii and iii and contributes papers 1 & 2 to my thesis.

The second study (which responds to objective iv and contributed towards paper 3 of my thesis) shifts to understanding implementation considerations for HIVST during the pilot phase of SELPHI. This study uses quantitative trial data alongside in-depth interviews which provide additional depth to the analysis. This study explores feasibility and acceptability of the intervention through evaluation of the recruitment strategy used for the pilot phase, investigating the proportions in receipt of the intervention who use the kit (and reasons for non-use), as well as acceptability of the intervention. This paper primarily uses quantitative longitudinal study data from three time-points with results from qualitative interviews undertaken during the pilot phase adding depth and context.

The final papers of my thesis respond to objectives v through vii and present the findings of an evaluative in-depth interview (IDI) study with SELPHI participants in which the outcomes related to HIVST are examined from the perspective of those in receipt of HIVST. In-depth interviews were the most appropriate method of data generation as they provide the opportunity to explore issues in greater depth with individuals, without necessarily generating normative understandings in the way that focus group discussions do. This has enabled the exploration of tensions within the data and the development of nuanced understandings of the potential of the SELPHI interventions and HIVST more broadly. This study has also allowed the testing of the behaviour change model used in intervention planning.

Table 3: Overview of thesis by objective and methods

Aim: to	Study	Objective	Methods	Paper
develop an understanding of the potential contribution of HIVST to the well-being of MSM in England & Wales.	Study 1: Formative	i. To examine the values and preferences of MSM for HIVST interventions considering key domains of intervention design.	Qualitative analysis of focus group discussions	1
		ii. To explore the potential barriers and facilitators of HIVST for MSM using COM-B as a framework.	Qualitative analysis of focus group discussions	1
		iii. To understand how HIVST compliments existing testing strategies considered or adopted by MSM.	Qualitative analysis of focus group discussions	2
	Study 2: Implementation	iv. To assess the feasibility of recruiting MSM to the SELPHI pilot, and the acceptability of the HIVST intervention among those randomised to receive a kit.	Quantitative analysis of RCT pilot data Qualitative analysis of in-depth interviews with trial participants	3
	Study 3: Evaluation	v. To explore the experience of utilising HIV self-tests and the implications for further intervention development and scale-up.	Qualitative analysis of in-depth interviews with trial participants	4
		vi. To explore how components of the SELPHI interventions impact on behaviour for, and are experienced by, RCT participants.	Qualitative analysis of in-depth interviews with trial participants	5
		vii. To examine the utility of COM-B as a useful model for understanding behaviour change in relation to the provision of HIVST.	Qualitative analysis of in-depth interviews with trial participants	5

2.2 Conceptual approach

2.2.1 Implementation Science

In addressing these objectives, this PhD is situated within the interdisciplinary field of implementation science (IS). IS can be described as: *the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services* (93, 94). It is an approach inherently concerned with the effective design and implementation of health interventions through robust theoretical development and the subsequent adoption of interventions into widespread practice (95, 96). It seeks to ensure high quality interventions are developed and evaluated so that they have optimal benefits for their individual recipients while also examining potential for other contexts (95).

This PhD generates a high-quality evidence base on self-testing and the potential innovations that can be adopted and implemented on a national scale. This evidence can also be used to inform implementation in other contexts. This PhD specifically addresses questions about intervention design, implementation, feasibility, acceptability, reach and adoption (95). In terms of intervention design and development, and in line with IS approaches, I focus on context, specific intervention components and the demographic and behavioural characteristics of individuals who are beneficiaries (95).

I take a hybrid approach to IS, drawing on the traditions that are most useful in meeting the overarching aim of this thesis. Nilsen (2015) describes three theoretical approaches to IS: describing and/or guiding the process of translating research into practice; understanding and/or explaining what influences implementation outcomes and evaluating implementation (97). My thesis primarily employs the second of these, using implementation theory to enhance understanding of critical issues relevant to HIVST (97). Doing so allows for the prioritisation of the most critical issues which can influence implementation, thereby increasing the appropriateness of interventions by documenting and responding to patient need (97).

In the synthesis stage of my thesis I employ a determinant framework to develop nuance and contextualise my results (97). Determinant framework approaches focus on the factors that can influence implementation and adoption, investigating barriers, facilitators and their interaction with qualities of end users (97, 98). These approaches recognise that implementation is a multidimensional phenomenon and that understanding influences on outcomes is a critical area of inquiry (97).

I use the Consolidated Framework for Implementation Research (CFIR) (95, 97), as a lens through which to synthesise many of the results generated in this thesis. This determinant framework posits that successful implementation and translation of interventions to new contexts is contingent on adequate attention being paid to five key domains (95, 97-99). The first domain, the intervention, contains all characteristics of the intervention which is being implemented, acknowledging that many interventions come into organisations as a poor fit (95). The second and third components, the inner and outer settings, provide recognition that context shapes intervention delivery, especially the structural, political, economic and social contexts through which intervention implementation proceeds (95). The fourth domain, the individuals involved in implementation, recognises that individuals in an organisation have agency to shape or to hinder delivery (95). The fifth domain refers to the process of implementation which is contingent on the organisation implementing the intervention (95).

CFIR has been used in a wide range of study designs, although it is most commonly used during and post implementation to investigate the experiences of those implementing an intervention (99, 100). Using this framework prospectively provides potential policy makers with additional insights into intervention implementation considerations identified in this thesis (100).

2.2.2 COM-B

The primary model informing this work is a systematically developed behaviour change model from IS, the BCW which includes the COM-B model. This system was chosen for this PhD because of its systematic development and clarity; the BCW and COM-B incorporate domains covered in pre-existing behaviour change models, but arguably in a more coherent way.

This system was developed by Michie and colleagues as a novel way of describing an array of issues to examine when seeking to improve the design of behaviour change interventions. It was developed under the premise that pre-existing models did not fully encompass the range of possible domains which could influence outcomes (91). In developing the BCW and COM-B, Michie and colleagues consolidated theorised behaviour change constructs, interventions and policy approaches from 19 frameworks to create a structured system with inter-related levels (91).

At its most basic, the COM-B model asserts that capability, opportunity and motivation interact to shape behaviour, which in turn also interacts with those three domains (see figure 1). Each of these

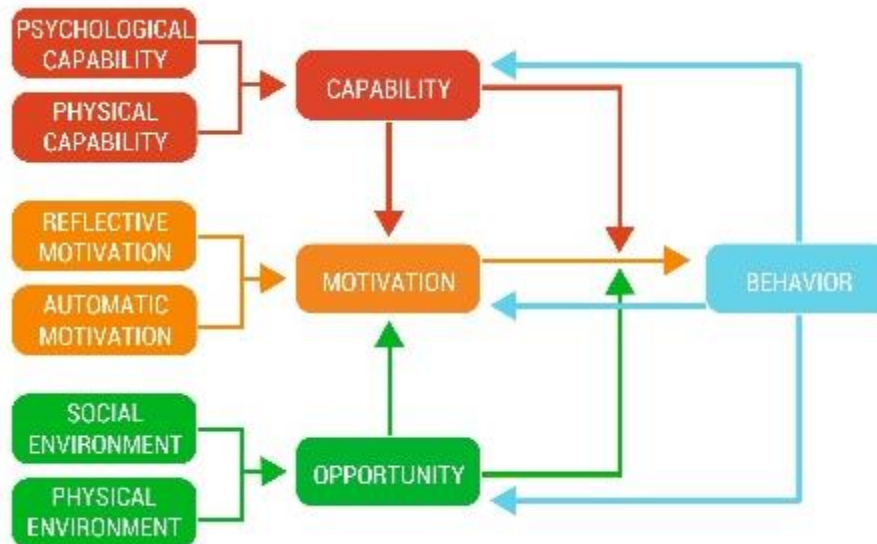


Figure 1: COM-B basic structure (Michie et al 2011).

domains is divided further into additional sub-domains to more comprehensively represent the ways in which behaviour is influenced at this level.

According to Michie et al; (91)

Capability is defined as the individual's psychological and physical capacity to engage in the activity concerned. It includes having the necessary knowledge and skills. Motivation is defined as all those brain processes that energize and direct behaviour, not just goals and conscious decision-making. It includes habitual processes, emotional responding, as well as analytical decision-making. Opportunity is defined as all the factors that lie outside the individual that make the behaviour possible or prompt it.

When used in developing interventions, one must consider which of these elements require modification in order to support behaviour change on the individual, community or population level (91, 101). For example, one might have the capability and motivation to change behaviour, but not the opportunity. Or, more realistically, there may be subtle modifications needed in more than one domain and supporting change in multiple areas may be required (91). The benefit of this structure is that it provides a simple and straightforward way to categorise influence on behaviour and is easy both to understand, and to apply.

The BCW (figure 2) elaborates on the basic model by providing an expanded framework for conceptualising the relationship between the pre-conditions of behaviour change, intervention functions and policy (91). The first level consists of the basic COM-B model (capability, opportunity and motivation). One level outwards are intervention categories that aim to address barriers or

required alterations in the first level. Finally, the outmost level is formed of policy approaches and categories that facilitate interventions. COM-B provides an articulation of both the intervention and policy areas which can be used to target each COM-B domain. Because the UK has a supportive policy environment represented by the HIVST technology being legalised in 2014 alongside associated regulation and supportive guidelines, and because SELPHI represents a form of service provision, for the constituent studies in my thesis I use only the intervention approaches (2).

The BCW and COM-B were chosen for use in this thesis for several reasons. It was indicated that COM-B would be used in formative research in the initial funding bid for the programme grant in which my work is embedded. I chose to continue using it partly for pragmatic reasons, leading to a more coherent body of work than would be the case if I switched between models. This has added depth and nuance by including a consistent lens through which these findings are viewed.

Further, the BCW and COM-B are especially useful because of their systematic development: the range of behaviour change constructs and theories represented within their production mean that they cover a wider range of influences on behaviour than many other models do. For example, the health belief model does not incorporate the role of some psychological processes such as habit and self-control (91). COM-B also has the benefit of being much simpler than TDF (90), increasing its utility through clarity.

The Theory of Planned Behaviour has a more elaborated concept of motivation and takes greater account of norms than COM-B making this an obvious choice for interventions seeking to modify behaviour which is heavily shaped by norms drawn from community and society (103, 104). This theory however has no space to theorise how a physical technology (such as an HIVST) can be provided within interventions, vastly limiting its utility in this context. It has also been much criticised for an overt focus on rationality, assuming that individuals will behave in specific ways in response to norms, ignoring differences across individuals and groups (104). Finally, the Information-Motivation-Behavioural Skills model could have been a promising approach given the need to develop capability in using HIVST and its wide application in HIV focused interventions (105); it too however suffers from a lack of conceptualisation around the potential of technology to shape behaviour.

The simplicity, organisation and clarity of the domains in the overall BCW system and their relationships to intervention functions mean that it is a useful model for planning interventions and theorising how intervention components can work together to produce behaviour change. The basic capability, opportunity & motivation structure provides flexibility within the model to consider a wide range of intervention processes and their impact on behaviour, as well as logical causal

mechanisms. The basic structure of COM-B allows for considering how the provision of a technology and the intervention components supporting that provision can work together to shape and encourage behaviour change. For example, the targeting of an intervention may seek to enhance motivation (either reflective, automatic or both), while the provision of a technology could alter both capability and opportunity, depending on the end user. This is a major benefit compared to other models, which often are only applicable to purely psychosocial interventions.

The BCW and COM-B do have some key weaknesses specific to this work. While the basic structure (figure 1) is very useful for considering interventions delivering novel technologies, the expanded wheel (figure 2) is arguably less attentive to this. Although Michie and colleagues state that the enablement intervention category in the intervention processes level refers to pharmacological and technological interventions, their approach lacks an understanding of the ways in which technologies work to produce behaviour change themselves. For example, the use of, or engagement with, a technology will logically produce certain behaviours as a result of engagement in that process, a discourse which is absent from the BCW and COM-B model. This is perhaps key to understanding behaviour change in an environment of increasing bio-medicalisation of risk, and medicalised approaches to self-management which increasingly rely of the adoption of novel technologies (106, 107).

Another important weakness related to this model is that the concept of ‘need’ is largely absent. Although motivation is described, the model itself does not acknowledge different types of need and the ways in which they are enacted. For example, in Bradshaw’s taxonomy of need, four types are described: normative need; felt need; expressed need and comparative need (108, 109). Normative

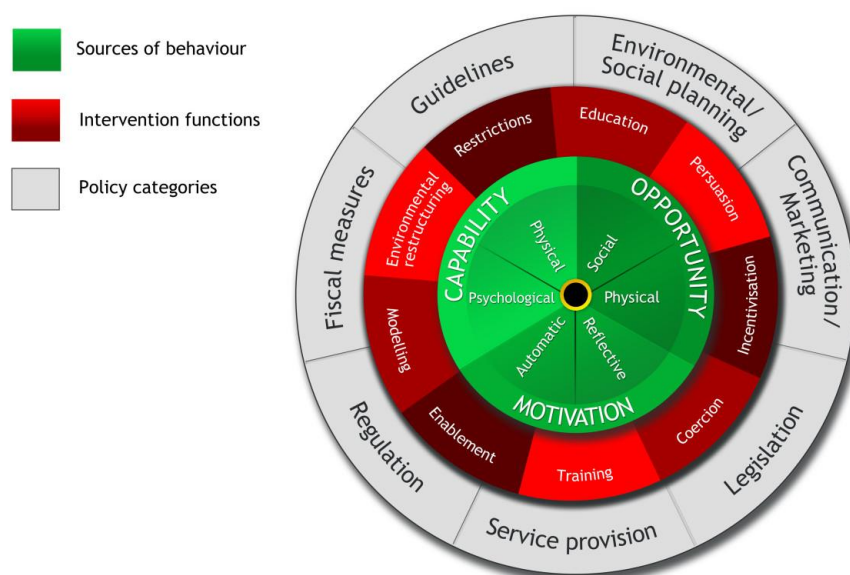


Figure 2: COM-B behaviour change wheel (Michie et al. 2011).

need is socially produced, felt need is a want or desire which has yet to be described. Expressed need is a felt need turned into action, and comparative need is generated through interactions with medical staff and health services (108, 109). The BCW and COM-B rely on felt need being converted to expressed need, with a small degree of acknowledgement of normative need. Comparative need is absent, despite it potentially being a major influence on health seeking behaviour.

The under representation of normative need is a symptom of a broader issue with COM-B which is that social influences on barriers, facilitators, and therefore behaviour are not given adequate attention. The production of these are social and structural and understanding their determinates are also central in addressing them. For example, participation in HIV prevention interventions (including testing) have become a highly normative activity for MSM and is often understood as a social obligation (19, 20, 110, 111). This process and this type of need are underrepresented in COM-B despite it being a primary driver in service access for many. It is for that reason that the final objective of my thesis is to examine the utility of COM-B as a model to understand behaviour change related to the intervention.

2.3 Multi-method approach

This thesis employs a multi-method approach to data generation, moving from one method to the next to develop a comprehensive understanding of the subject matter from a range of methodological perspectives. This allows for the capitalisation on strengths while minimising weaknesses of core data collection approaches (112). Rather than mixing methods for the purpose of triangulation, this multi-methodology focuses on theoretical integration of separate studies in order to address the overarching aim of my thesis (113). This involves using separate methods, with separate analyses and then integrating the new understandings gained as the final step (113, 114). Following this approach, I have focused on making pragmatic methodological decisions while rejecting what Bernstein calls the tyranny of the method (115, 116). Indeed, I selected each method used in my thesis to respond optimally to the objective it is addressing, rather than for the paradigm it is aligned with.

My thesis moves through several stages in a comprehensive data generation process. I begin with a prospective focus, interrogating important pre-implementation questions surrounding values and preferences as well as potential contexts of use. Following pilot intervention implementation, I investigate feasibility of intervention delivery and acceptability for those who have used HIVST. Finally, in a study grounded in interpretivism, the experiences of individuals are examined in greater depth to better elucidate how behaviour change has been facilitated for HIVST beneficiaries. This sequential approach to evidence generation is used often in development and implementation of new services and technologies in health care (117, 118).

Focus group discussions were the most appropriate choice for the first study in my thesis for several reasons. At the time this research began, little evidence existed to inform the development of an HIVST intervention in Europe. A major strength of focus group discussions is that they help to elicit normative understandings of community perspectives relating to a subject matter (119). This makes them especially useful for investigating new prevention technologies, their applications and potential reception (119).

The second study utilises longitudinal data drawn from the SELPHI trial with qualitative data from IDIs. This approach has the strength of measuring the aggregate experience of those in receipt of the intervention, while elaborating on and contextualising findings using participant's accounts of their own experience. This study is therefore led by the quantitative data with elaboration from qualitative sources, an approach called 'following a thread' (113, 120). This is especially well suited to acceptability and feasibility studies which can be measured in multiple ways and require a nuanced approach to generate useful understandings. Placing increased emphasis on quantitative data has the benefit of allowing a rigorous investigation into the ways in which acceptability and intervention uptake might vary across groups. Using qualitative data to add depth has the benefit of contextualising the reasons why this variation may occur and offer potential solutions to issues related to intervention delivery.

For the final study, in-depth interviews have been selected for data generation. This is the most appropriate approach as this work is concerned with the exploration of participants' understandings of their own experience in great depth, rather than the normative understandings which are elicited by focus group discussions. This approach enabled the collection of richer data and will help understand the broader influences on testing behaviour alongside accounts of experiences with HIVST. The focus on the broader influences of testing behaviour enables the testing of COM-B, using participants' own accounts of their experience and behaviour change journeys, without the influence of others. This allows for the examination of the ways in which HIVST can contribute to the well-being of MSM in England and Wales.

3. Results

My thesis has three main studies and therefore three sections of results. I outline these here before moving onto each section in turn.

The first study was a formative study of HIVST values and preferences investigated through focus group discussions with MSM in England. This formative section has two papers, one examining values and preferences and another elaborating on MSM's narratives of HIVST potential. I describe

how this formative study and others contributed to the SELPHI logic model, a key lens through which the intervention was subsequently viewed.

The second study in this thesis is an implementation study that interrogates the feasibility of delivery and acceptability of the intervention. This work is the lynchpin which changes focus from theoretical prospective questions regarding use to MSM's actual experiences.

Finally, my third study comprises two analyses of qualitative in-depth interviews with trial participants which provide important answers to key evaluative questions. Paper four in this section provides additional depth and nuance surrounding intervention acceptability, providing additional information regarding how interventions are experienced by their end users in order to support potential implementation. The fifth paper provides an analysis of how the SELPHI interventions performed when compared to our logic model, using an innovative testing typology as a lens through which to view divergent experiences.

3.1 Formative research

At the outset of the planning process for SELPHI, it was clear that there was little evidence that could support the design of an HIVST intervention, or strategies to deliver it optimally. My role in this early phase was to design a study which might help to answer some of these critical questions. Some of this was pre-specified in the funding bid but only at a very basic level, and development of final study design and methodology was left to me, supported by my colleagues.

I therefore looked to the literature which suggested acceptability would likely be high, that oral fluid testing might be preferred, and support would be a key issue (32, 121). There was however a lack of evidence regarding delivery mechanisms, preferences around instructions or contexts of likely use in a setting with a diverse array of existing testing interventions. In addition, little from comparable contexts was uncovered about how MSM might perceive HIVST in a context of diverse service provision, such as England and Wales.

In order to gain a better understanding of the groups who might benefit most from HIVST, I conducted an analysis of the 2014 Gay Men's Sex Survey (publication available in appendix 2). This indicated that those who test less frequently and not in line with UK guidelines (older men, younger men, those who were not gay identified) had stronger preferences for remote testing approaches including HIVST and HIVSS (15).

Using these data and taking the only available kits in the UK at that time, I designed a topic guide (appendix 3) and purposive sampling frame (appendix 4) to answer some of these critical questions.

This enabled the production of two papers which aided intervention development and made a significant contribution to the HIVST literature generally.

3.1.1 Paper 1: HIV self-testing among men who have sex with men (MSM) in the UK: a qualitative study of barriers and facilitators, intervention preferences and perceived impacts



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Student ID Number	1603113	Title	Mr
First Name(s)	T Charles		
Surname/Family Name	Witzel		
Thesis Title	HIV self-testing for men who have sex with men (MSM) in England and Wales: a multi-method study of self-testing intervention development and evaluation		
Primary Supervisor	Peter Weatherburn		

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SECTION E

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RESEARCH ARTICLE

HIV Self-Testing among Men Who Have Sex with Men (MSM) in the UK: A Qualitative Study of Barriers and Facilitators, Intervention Preferences and Perceived Impacts

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Data Availability Statement: Our data will not be publicly available. As a qualitative study there are inherent ethical concerns surrounding making data available as it can be more easily linked to research participants than in other types of research. In order to protect the confidentiality of our participants, we are therefore not making data available. We will consider sharing an anonymised data set on a case-by-case basis, requests for this should go to the corresponding author.

Abstract

Introduction

Innovative strategies, such as HIV self-testing (HIVST), could increase HIV testing rates and diagnosis. Evidence to inform the design of an HIVST intervention in the UK is scarce with very little European data on this topic. This study aims to understand values and preferences for HIVST interventions targeting MSM in the UK. We explore the acceptability of HIVST among MSM in the context of known barriers and facilitators to testing for HIV; assess preferences for, and the concerns about, HIVST.

Methods

Six focus group discussions (FGD) were conducted with 47 MSM in London, Manchester and Plymouth. HIVST as a concept was discussed and participants were asked to construct their ideal HIVST intervention. OraQuick™ and BioSure™ kits were then demonstrated and participants commented on procedure, design and instructions. FGDs were recorded and transcribed verbatim, then analysed thematically.

Results

Convenience and confidentiality of HIVST was seen to facilitate testing. Issues with domestic privacy problematised confidentiality. HIVST kits and instructions were thought to be unnecessarily complicated, and did not cater to the required range of abilities. The window period was the most important element of an HIVST, with strong preference for 4th generation testing. Kits which used a blood sample were more popular than those using saliva due to higher perceived accuracy although phobia of needles and/or blood meant some would

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Abbreviations: HIVST, HIV self-testing; HIVSS, HIV self-sampling; MSM, Men who have sex with men; FGD(s), Focus group discussion(s).

only access HIVST if a saliva sample option was available. A range of access options was important to maintain convenience and privacy. HIVST kits were assumed to increase frequency of testing, with concerns related to the dislocation of HIVST from sexual health care pathways and services.

Discussion

Utility of HIVST arises from relatively high levels of confidentiality and convenience. Until 4th generation assays are available HIVST will be seen as supplementary in a UK context.

Introduction

Reducing late HIV diagnosis is a UK public health priority which has led to the expansion of HIV testing outside clinical settings [1, 2]. Correspondingly, the volume of tests undertaken in the UK has increased dramatically, and the number of men who have sex with men (MSM) who have undiagnosed HIV has seen a steady decline over the past decade [1, 3].

HIV testing uptake and frequency remains sub-optimal however, with recent community surveys suggesting that approximately 25% of MSM have never tested for HIV and between 50–60% have not tested in the previous year [2, 4, 5]. An estimated 40% of MSM diagnosed with HIV in the UK are diagnosed late (defined as CD4 counts less than 350mm³), increasing the risk of HIV related morbidity and mortality [3].

Factors mediating MSM's testing decision making are complex. Significant barriers impeding access to testing include fears of the implications of receiving a positive result, stigma, and structural and health service factors [6, 7]. In an effort to address these, policy makers, health promoters and commissioners have made significant attempts to promote testing and have expanded the volume and variety of HIV testing services across the UK [1].

While the majority of HIV tests in the UK are conducted in genito-urinary medicine (GUM) clinics, the last 10 years has seen a substantial increase in other testing options [1]. Point of care (PoCT) (or rapid) testing (undertaken by another person such as a healthcare worker) is commonly offered in a wide variety of settings by community based organisations. England has a national HIV self-sampling (HIVSS) service, where an individual takes a sample which they then post back to the laboratory where it is processed and the patient is contacted with the result [8, 9].

Another approach is to offer HIV self-testing (HIVST) where the person takes a sample, conducts the test and reads the result themselves. Self-testing was legalised in the UK in April 2014, with the first kite-marked HIV self-testing kit released to the UK market in April 2015. This kit uses a whole blood sample and is marketed under the name BioSure™. HIVST has the potential advantage of increased confidentiality, privacy and convenience when compared to testing undertaken by a health professional, thus reducing key barriers for some individuals.

Evidence from outside Europe suggests that HIVST is acceptable to MSM both in high and low-income settings globally [10, 11, 12, 13, 14]. Data suggests that MSM appreciate the confidentiality and privacy afforded by HIVST but some feel the lack of counselling services as a routine part of the testing process is problematic [11]; the ease of use has also been raised as a potential issue [12, 15]. While very few studies have evaluated post-test linkage with counselling and support or with treatment outcomes [10] there is little evidence that HIVST leads to unintended harm [14] nor any other significant unintended outcomes [12].

While evidence emerges about the acceptability and likely feasibility of delivering HIVST interventions to key populations (see [14] for the most recent review), none arises from

England and very little from the rest of Europe [14]. Evidence to inform the design of an HIVST intervention for MSM in the UK is lacking. There is also a lack of evidence exploring how changes in the configuration of intervention components including delivery mechanisms and supportive strategies impact the acceptability of HIVST generally, an issue of particular relevance given that free HIV testing is readily available through a diverse array of other services.

This study aims to understand values and preferences for HIVST interventions targeting MSM in the UK. We explore the acceptability of HIVST among MSM in the context of known barriers and facilitators to testing for HIV and assess preferences for, and the concerns about, HIVST.

Our approach is embedded within implementation science, a field which seeks to translate and implement research evidence into policy and practice [16]. As such our results will be of particular interest to those seeking to understand the potential role of HIVST for MSM in the UK and other high resource settings (European and otherwise) with similar service provision (that is, good coverage of sexual health services for little or no cost).

Methods

Study design

This qualitative study sought to capture the perspectives of MSM in relation to HIV testing generally and HIVST specifically. Focus group discussions (FGDs) were selected in order to situate the perspectives of individual MSM in the context of group mediated normative understandings of HIV testing, such as those held within individuals' social networks.

Study sites and health service features

Fieldwork occurred in London, Plymouth and Manchester. These cities were chosen as they have a variable prevalence of HIV and differ in their population density of MSM. They also vary substantially in the provision and diversity of gay venues and HIV and STI testing services.

London (population 8.5 million) is exceptionally well served by specialist GUM clinics and has a range of community based testing initiatives run by both the statutory and voluntary sectors [17]. Manchester (population 511 000) has less extensively developed services compared to London, although there is good coverage with health service and voluntary sector HIV and STI testing available [17]. Plymouth (population 235,000) is a relatively small city and a regional centre, and in contrast has markedly less choice in sexual health care with one main GUM clinic and some provision from a voluntary sector organisation, both of which draw service users from across the counties of Cornwall and Devon [17]. At the time of the research, Plymouth was the only location in England piloting free NHS-provided HIVST. This was a time limited service in which 1000 tests were available for distribution.

Study participants & recruitment

Gay, bisexual and other men who have sex with men (MSM) including trans men who were over the age of 18 and did not have diagnosed HIV were eligible for inclusion in this study.

Acknowledging differing patterns of testing across sub-groups, purposive quota sampling was used in order to ensure diversity regarding age, ethnicity, sexual orientation and past HIV testing experience including locations of previous HIV tests [2, 5]. In particular we emphasised including more men outside the ages of 26–39 years, as these men are less likely to test frequently [2, 4]. Further, we over-sampled ethnic minority men theorising that their barriers and motivators to testing may be different to men of White ethnicity. In our sampling strategy we

particularly focused on including larger numbers of participants who had utilised self-administered testing or sampling methods including HIVSS and HIVST.

Sampling proceeded iteratively, and as study recruitment unfolded, we made efforts to recruit those who had never tested and men at potentially higher risk of HIV transmission on the premise that they might have greater need for HIVST given the UK testing guidelines recommending quarterly testing for these groups [18], and the potential for HIVST to provide a gateway to testing for men who have never tested [11]. The first four focus groups (two in London, one in Plymouth and one in Manchester) were shaped by our purposive sampling, with one additional group conducted with men reporting at least two male partners with whom they had condomless anal intercourse in the preceding three months, and one final group of men who had never previously tested for HIV.

Participants were recruited through gay location based social networking applications (Scruff, Growlr and Grindr) as well as community based organisations in the three cities. Men interested in the research were directed to a web-pages detailing information on the study and collecting consent to be contacted. They then filled in a short survey providing demographic details (presented in Table 1) and, if eligible, their contact details. Participants were then selected and invited to participate in groups based on our sampling frame. In all, one hundred and ninety-six individuals completed our screening survey, forty-seven of whom were invited to and subsequently attended an FGD. Participants were compensated £40.

Data collection and analysis

FGDs were co-facilitated by the lead author and various members of Sigma Research, a research group at the London School of Hygiene and Tropical Medicine which focuses on the social, behavioural and policy aspects of HIV and sexual health. A topic guide was developed collaboratively within the research team and refined after the initial focus group. The topic guide was theoretically underpinned by the COM-B model of behaviour change which highlights how capability, opportunity and motivation impact on and interact with behaviour [19].

Table 1. Participant demographic details.

Demographic features	MSM recruited	
Age group	18–25 years	9
	26–39 years	21
	40+	17
Ethnicity	Asian	6
	Black	4
	White	37
	Mixed / other	0
Sexual orientation	Gay	38
	Bisexual	5
	Other (not gay or bi)	4
Recency of HIV testing	In last 12 months	30
	12+ months ago	9
	Never	8
Past HIV testing locations (multiple allowed)	GUM	30
	GP	6
	Community / PoCT	6
	Self-sampling	11
	Self-testing	4

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Our guide covered all three domains, including HIVST intervention specific details (opportunity and capability) and perceptions of HIVST in relation to other testing opportunities (motivation). During the section on intervention specific details, participants were asked to construct their ideal HIVST intervention choosing preferred options for sample type (blood vs saliva), window period (the time it takes for a test to detect an infection; 12 vs 4 weeks representing 2nd and 4th generation tests respectively), mode of instruction (written vs video), and access option (postal delivery or pick-up). Participants were handed cards with all options printed on separate pieces of paper, and asked to mark their preferred option between each pair. They then ranked importance of each domain (sample, window period, delivery and instructions) from 1 to 4.

OraQuick™ saliva-based and BioSure™ blood-based testing second generation HIV self-test kits were also demonstrated for participants who were asked to comment on procedure, design and instructions. The sensitivity and specificity of the tests was only commented on by facilitators if participants queried them.

FGDs were transcribed verbatim. All authors familiarised themselves with the transcripts and agreed a thematic coding framework through consensus. This framework took higher level codes such as barriers / facilitators, intervention preferences, and impacts; nested sub-themes described the most common understandings expressed by our participants. The data was initially coded at the higher level themes, then at sub-themes. Finally these sub-themes were coded iteratively where appropriate to derive more nuanced understandings of values and preferences. This analysis was conducted using QRS NVivo 10.

Ethical considerations

Ethical approval for the MSM focus groups was sought from, and granted by, the ethics board at London School of Hygiene & Tropical Medicine (reference 9893).

Results

Between July and November 2015, forty-seven MSM were recruited and attended a focus group. The sample was diverse, with a mean age of 36.1 years (range 20–64), more than 20% coming from Black and minority ethnic communities, 20% being not gay identified MSM and more than one third not following current UK HIV testing guidelines of annual tests for MSM [18]. We only asked men about condomless anal intercourse when recruiting to the higher-risk group so those data are unavailable for the majority of our sample, but in that group 9 men reported 2 or more anal sex partners with whom a condom was not used in the preceding 3 months. Location for past HIV tests was similarly varied, and more than 30% of our participants had accessed HIVSS or HIVST (see Table 1 for full demographic details).

Overall very few were outwardly opposed to HIVST with most describing it as highly acceptable, both as a general concept, and after specific discussion of the two test kits. We describe two key perceived benefits of HIVST—confidentiality and convenience—and two key potential drawbacks—concerns about the process and fear of the potential for a positive diagnosis with no immediate support. We also examine the key features of an ideal HIVST intervention and describe the perceived potential impact of widespread HIVST availability.

Perceived benefits of HIVST

The primary perceived benefit was that HIVST (and to a lesser extent HIVSS) was assumed to be exceptionally useful for individuals who were concerned about privacy and confidentiality when accessing testing face-to-face. HIVST was widely assumed to afford a level of privacy that made HIV testing more accessible to people who otherwise found it difficult.

I'm from up north and everybody knows everybody else. So people will see you go into that building [GUM clinic], and people will talk. Nothing is secret, but having the opportunity to have that sent away or getting it instantly over the counter eradicates all that embarrassment (28-year-old gay man, London).

Except among men who had never tested, the importance of privacy was usually articulated on behalf of 'other' populations of MSM, and not for the speaker themselves. HIVST was perceived to be potentially beneficial for those that were not yet "out" about their sexuality, such as relatively young men, those who also had relationships with women, men living in rural areas, and those from ethnic and cultural communities where disclosure of homosexual activity remained taboo.

My ex-partner was a Muslim and within his family, and all that, being gay is not allowed. But I think having a self-testing kit when he can do it at home in our home, I know he would appreciate that. I know he couldn't take it back to where he's from, but in my home he can. (51-year-old gay man, Manchester)

British Asian participants in particular identified HIVST as far preferable to accessing testing from GPs who were seen to have close links with family and community. The added privacy and confidentiality conferred by self-testing was also thought to be particularly important for individuals who lived outside major metropolitan areas or where there were concerns about being seen to use GUM clinics or asking for testing in primary care services.

HIVST was widely understood to be a technology used within the home. The confidentiality of the intervention was therefore somewhat undermined for participants who lived with family or other individuals with whom they were not open about their sexual activity.

The next most frequently cited benefit of HIVST was convenience, including the speed with which a test could be done and result obtained. The opportunity to test, when they had time, and wherever they were, was highly valued. This was true for individuals who lived in all areas of the country, but especially for those that struggled to access acceptable services because of long travel times, part-time clinic opening times, or appointments procedures.

Well for me it's an hour to drive here, and hour to go to Truro. Newquay is an option, and then that's only certain mornings of the week and then it's taking time off work to go, so it does get quite tricky. (41-year-old gay man, Plymouth)

Perceived drawbacks of HIVST

When considering HIVST, some participants had serious concerns about their capacity to perform a self-test. A few were averse to any possibility of self-administering a blood-based test and would only use a saliva-based HIVST, however more feared the process of self-testing, including the potential for errors in generating and interpreting the test outcome.

I am quite clumsy and I am not good with instructions and I do not like to be told what to do. So, I think, how can you trust that it you have done it right? How can you trust that you can interpret the results correctly? (25-year-old gay man, Manchester)

For some this performance anxiety was generalised—they simply had no experience of using a lancet or collecting a sample or interpreting a result, while for others the perceived volume and complexity of the written instructions was a major obstacle. Some specifically raised concerns about the high literacy level assumed by the instructions.

By far the most common cited barrier to using HIVST was the fear of having a reactive / positive result without any immediate personal support. These views were common across all groups but participants in the higher risk and never tested groups tended to express them more strongly.

... if you do self-test and the results are positive, there's the trauma as well of that, that person being by themselves having tested themselves and found out they're positive (62-year-old gay man, never tested group, London).

For some participants this could be mitigated by self-testing with a partner or friend/s, but for others having professional support available was crucial if there was any possibility of a positive/ reactive result. These men would either never use an HIVST or would only do so if they felt there was no chance of a positive result.

Intervention preferences

In the intervention preferences exercise, the window period and sample type emerged as the two most important elements, with access options and instructions typically being seen as of lesser importance (Table 2). Below we explore expressed preferences for self-test attributes. These are mapped onto the COM-B domains they impact (alongside other HIVST attributes) in Table 3. We also describe whether each element is a barrier, facilitator, or could be either depending on the individual.

In all our FGDs the window period was the most important element of a potential HIVST intervention, with 4th generation testing commonly understood to be the gold standard. There was a strong feeling that for HIVST to have widespread utility, it would require a similar window period to a clinic test.

I guess you don't want it to be "oh crap, things went a bit crazy last week and I'll get this now and do it and oh this is a negative" and find that actually it's much more like twelve weeks. . . I could imagine [using HIVST] but only if I could get a test [where the] window period was as good as a clinic test. (20-year-old queer man, London).

Indeed, for many the perceived benefits of HIVST (privacy, convenience, immediacy) were eroded by the fact that all available self-tests at the time of the research were 2nd generation when 4th generation tests were available for no cost in other settings, including self-sampling services.

Blood based sampling was believed to be more accurate than saliva and there was a preference for these samples. The exception to this was the minority of MSM who had aversion to blood or needles who stated they could not utilise HIVST unless a saliva option was available despite the perceived accuracy limitations.

Table 2. Intervention preferences exercise results.

Test attribute	Number of respondents ranking in position			
	1	2	3	4
Window period	17	12	5	2
Sample type	12	13	9	3
Access options	7	5	13	12
Instructions	2	7	9	19

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Table 3. HIVST attributes, components and relationship to COM-B domains.

HIVST attributes	COM-B domains	Barrier / facilitator
Choice	Opportunity	F
Confidentiality	Motivation, capability	E
Convenience	Motivation	F
Dislocation from care	Motivation	B
Intervention specific components	COM-B domains	Barrier / facilitator
Access options	Opportunity	F
Instructions	Capability	E
Sample type	Capability, motivation	E
Support	Motivation	B
Testing process	Capability	B
Window period	Motivation	E

Legend: B = Barrier; F = Facilitator; E = Either

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Postal delivery of kits was preferred over accessing through retail or healthcare settings as this option was seen to be exceptionally convenient. However, there was a high degree of concern that neither the BioSure™ nor OraQuick™ kits available at the time of the FGD would fit through standard letter boxes, potentially causing delivery problems. For an intervention to have widespread appeal, multiple access options were considered necessary.

Participants valued a range of mediums for instructions, with a slight preference for video. The test instructions were felt to make both tests seem significantly more complex to perform than they actually were. The nature of the packaging also led participants to be suspicious of the quality of the tests themselves because they were perceived to be over-produced and over-packaged.

The most favoured method of support was a telephone helpline ideally available 24 hours per day for individuals who test positive using HIVST and for those with a negative result who required additional support, particularly around risk reduction. This was seen as crucial to mitigate against the perceived potential for self-harm.

In the UK context, where HIV testing is free at a range of venues many participants reported being unwilling to pay for HIVST. Those who were willing to pay typically stated that they would pay the equivalent of travel costs to a clinic, plus a small amount of additional money for the convenience. This figure ranged from a low of £4 in London to £10 in Plymouth, probably reflecting the difference in accessibility of HIV testing in these cities.

Potential impact of HIVST

A wide range of potential impacts of HIVST were discussed. While increased frequency of testing was often cited as a benefit of HIVST, there were significant concerns about the impact of dislocating HIV testing from STI counselling and testing services and STI/HIV care pathways. We explore these below.

It was assumed that among those who would use HIVST, the intervention would facilitate more frequent testing. The highly convenient nature of the intervention, particularly in relation to potential long wait or travel times to clinics, as well as the reduced potential for embarrassment meant that providing HIVST was assumed to have the potential to dramatically increase the proportion of gay men that test every year, and the frequency with which they do so.

I don't think it's only the inconvenience, I take my health care quite seriously and don't want to have HIV and I'm not cavalier about it. On the other hand I don't think I've been tested for about two years where as if I could pick one up of supermarket shelf I'd probably have done that test about ten times. (38-year-old gay man, London)

However, participants tended to value time in GUM clinics, where staff were highly regarded for their role in educating and supporting patients about sexual risk management. While most pronounced in the higher risk group, concern existed for many that if individuals primarily tested through HIVST, this could lead to a de-skilling of themselves. This could be partially counteracted by providing enhanced sexual health information alongside HIVST, perhaps through a helpline or online.

I learn so much from when I go to get tested, there's always something new coming out or a trial or some sexual health information that I maybe didn't know and if someone's just carrying on their own doing it themselves. . . (26-year-old gay man, higher risk group, London).

A concern for several participants was the potential for an increase in STIs. These concerns typically came under one of two themes. The first was that widespread use of HIVST, if provided without other testing for bacterial STIs, could lead to increases in infections as individuals would not be accessing full screening. The second, less common but related theme, was that people using HIVST might test with sexual partners as a strategy to avoid use of condoms. The concern was that this could lead to an increase in either STIs, or that individuals with acute HIV infection might unwittingly transmit HIV to a sexual partner because of the window period.

People self-harming following a reactive result was the most common concern raised. This fear was projected onto 'others', with individuals rarely identifying themselves or anyone in their immediate social groups as being at risk of self-harm.

Some also raised concerns that HIVST could potentially lead to people not linking into HIV clinical care services following an HIV positive result, and the impact that this could have on disease progression for the individual as well as implications for onward transmission. This concern was also exclusively related to 'other' men, and not the speaker themselves or to individuals in their social networks.

Discussion

In our study of six FGD with 47 MSM in three UK cities, we found that HIVST was highly acceptable. MSM cited convenience and confidentiality as key benefits of the technology. Concerns about the testing process and in particular about the potential for a positive diagnosis using HIVST were commonly cited drawbacks. This is congruent with previous studies among MSM conducted largely in Australia, the USA and China (as well as emerging evidence from Scotland) indicating that HIVST is acceptable to MSM in a large part because of the associated privacy and ease of access, with concerns relating to support and capability in performing the tests [12, 14, 20].

Intervention potential

An important finding of this study is the degree to which the intervention components (window period, sample type, access options, instructions and support) impact upon the acceptability of HIVST to those who might find it useful.

Fourth generation testing was of very high importance. This is particularly true as, in relation to all other testing methods, HIVST is felt to facilitate immediate knowledge of one's HIV status, something undermined by a three-month window period. This poses potential questions as to the role of HIVST until 4th generation tests are available given the availability of 4th generation self-administered HIV testing methods through HIVSS services.

In contrast to much of the published literature [12, 14], we found a greater preference for blood based tests than for saliva sampling largely because participants felt that blood was a more accurate sample type. It is crucial to note however that for HIVST to have a wide appeal, a saliva option is also required otherwise those averse to needles or taking their own blood will be excluded.

It was clear that a range of access options were vital to ensure that the intervention was both confidential and convenient for a wide range of people with a diverse set of needs. The packaging and instructions of HIVST were also of importance to our participants, particularly given the high level of concern surrounding individuals' own capabilities to perform HIVST. The instructions were seen to over complicate the testing process and led to a high degree of confusion and anxiety. The format and intricacy of the instructions were in the main developed in order to gain CE marking (crucial for certain products for sale in the European Economic Area) indicating that this issue will likely persist.

Through understanding HIVST attributes and their relationship to COM-B domains, promotion of HIVST can capitalise on facilitators by ensuring that intervention components support men's values. Convenience and confidentiality in particular can be maintained by offering multiple access options while intelligent service design can make efforts to counteract significant barriers. Understanding and reducing barriers such as concerns around capability can be done through providing a range of instructions which should also enable motivational approaches to work more effectively.

Indeed, perhaps the greatest benefit of an HIVST intervention to commissioners and policy-makers is the opportunity provided by the potential flexibility of HIVSTs; they should be able to cater to a range of needs within a population through provision of different kit options regarding sample type, access points and instructions. By understanding how elements in HIVST interventions impact on individual's capability, opportunity, motivation and ultimately behaviour, service delivery can be tailored to suit the needs of particular groups, perhaps expanding testing to new sub-groups of MSM.

Context of implementation

HIVST was thought likely to provide opportunity and increase motivation for more frequent testing among MSM given its convenience, confidentiality and accessibility. Given the low level of willingness to pay, this is particularly true should HIVST be widely available at no cost. This is encouraging for policy makers and health practitioners who aspire to lessen the interval between tests for all MSM [2], and the time between infection and diagnosis for those acquiring HIV [21].

The opportunity to test away from clinical settings was problematic for some participants who feared the dislocation of HIV testing from STI screening and current care pathways. This underlines the central role that sexual health services play in the sexual health of MSM. The anxiety surrounding HIVST is heightened by the increasing focus on self-care and diagnosis on a remote basis with sexual health interventions increasingly being delivered in the community and remotely. These shifts are driven partly by public health policies aiming to increase the variety of testing options available [2, 22], by cuts to public health budgets [22] and as part of broader shifts in how care and responsibility for care is governed [23].

Consistent with other published research [24] we found that MSM were unlikely to utilise HIVST as their primary testing method. This was because of concern about the dislocation of testing from other services and preference for 4th generation HIV testing. Therefore, when designing interventions, HIVST should be considered a supplementary option which can increase the ability of individuals to test frequently while potentially diverting lower risk individuals from clinical services. For HIVST to be widely adopted, innovative strategies to embed HIVST within existing care pathways must be developed. In particular, it may be highly acceptable for HIVST to be delivered as part of an integrated package of care, include the provision of self-sampling kits for bacterial STIs and access to health advisor support if required. Using existing clinical services to manage the distribution of kits and provide care pathways may harness the widespread trust in GUM services and lend increased legitimacy to self-testing.

Strengths and limitations

This manuscript presents the results of a formative qualitative study investigating values and preferences of a potential HIVST intervention among MSM in the UK. While HIV testing preferences and behaviours within this group have been extensively studied and documented, this is the first UK research describing preferences for HIVST interventions. This data will be exceptionally useful when considered alongside emerging evidence from Scotland which reports HIVST is highly acceptable among MSM and stakeholders [20].

Our results should be interpreted with some caution. For one, only 4 of our sample of 47 had previously used HIVST, so our results largely relate to perceptions of a new intervention. To counter this concern we over-sampled individuals who had accessed HIVSS, but there remain key differences between these interventions, particularly surrounding support and care pathways. Concerns around impacts will therefore potentially be over-emphasised and more research is needed to understand how these are borne out when HIVST is more widely used.

Further, as a study which is qualitative in nature, these findings should be understood as indicative of the diversity of values and preferences and their meanings among MSM in the UK, rather than representative of the entire population. We delineate how the context of implementation should shape the design and delivery of future HIVST service development and its evaluation.

Author Contributions

Conceptualization: TCW PW AJR FMB.

Data curation: TCW.

Formal analysis: TCW.

Funding acquisition: AJR.

Investigation: TCW PW.

Methodology: TCW PW AJR FMB.

Project administration: PW.

Supervision: PW AJR FMB TR.

Visualization: TCW.

Writing – original draft: TCW PW.

Writing – review & editing: TCW AJR FMB PW TR.

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The first paper gives an in-depth overview of the likely dimensions of intervention acceptability and how specific decisions may shape uptake (e.g. home delivery and the implications for those with domestic privacy concerns). This data was less useful for exploring contexts of HIVST adoption, a potentially key consideration for the RCT and academia more generally.

During the focus groups it became clear that HIVST had a very specific relationship to norms around HIV testing, and that these would likely be highly relevant. I had used COM-B to guide the production of the topic guide and in initial coding, and these emerging results did not seem to fit well with what the model proposed. They also seemed to potentially threaten the central aspiration of HIVST as diagnosing incident and prevalent infections more quickly than other testing methods by expanding testing to new audiences (2).

In order to explore these data more fully, in the initial analysis I included the deductive codes risk, reassurance and norms, and coded data relevant to these very broadly. After initial coding I inductively coded data captured within these, generating the analysis presented here.

Attempts to interpret the data confirmed that COM-B could not speak to these results. The model did not serve as a convincing lens through which to view what I had observed. I therefore took the decision to look to social theory, especially to Rose and Novas' (2003) concept of biological citizenship (122) and Aronowitz (2009) and Lupton's (1995) ideas around the biomedicalisation of risk (123, 124). This allowed for an exploration of the narrative understandings of HIV testing among MSM and how HIVST may fit into these in the future.

Paper 2 of my thesis therefore moves to understanding intervention potential based on testing narratives amongst intended beneficiaries. Understanding this provides a critical evidence for RCT design and also for the academy more generally. This paper is of direct relevance to policy makers and commissioners in designing interventions which respond to the likely use of self-tests.

3.1.2 Paper 2: Risk, reassurance and routine: a qualitative study of narrative understandings of the potential for HIV self-testing among men who have sex with men in England



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Please note that a cover sheet must be completed for each research paper included within a thesis.

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Student ID Number	1603113	Title	Mr
First Name(s)	T Charles		
Surname/Family Name	Witzel		
Thesis Title	HIV self-testing for men who have sex with men (MSM) in England and Wales: a multi-method study of self-testing intervention development and evaluation		
Primary Supervisor	Peter Weatherburn		

If the Research Paper has previously been published please complete Section B, if not please move to Section C.

SECTION B – Paper already published

Where was the work published?	BMC Public Health		
When was the work published?	22/05/2017		
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SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I designed the study, data collection instruments and analysis tools. I recruited the sample, conducted data generation and conducted the analysis. I wrote the first draft of the paper and carried out revisions.
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SECTION E

Student Signature	
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RESEARCH ARTICLE

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Risk, reassurance and routine: a qualitative study of narrative understandings of the potential for HIV self-testing among men who have sex with men in England

T. Charles Witzel^{1*}, Peter Weatherburn¹, Alison J. Rodger², Adam H. Bourne¹ and Fiona M. Burns²

Abstract

Background: HIV testing has seen a rapid evolution over the last decade with multiple modalities now in use globally. In recent years HIV self-testing (HIVST) has been legalised in the UK paving the way for further expansion of testing. Interventions are delivered in particular social contexts which shape uptake. It is therefore important to understand how novel interventions are likely to be received by their intended users. This study aims to understand how HIVST compliments existing testing strategies considered or adopted by men who have sex with men (MSM). We do this by analysing normative discourses surrounding HIV testing and their perceptions of HIVST's potential future roles.

Methods: Six focus group discussions (FGDs) were conducted with 47 MSM in London, Manchester and Plymouth. One focus group included only MSM who reported higher risk behaviours and one with those who had never tested for HIV. Data were analysed through a thematic framework analysis.

Results: Three main narratives for testing for HIV were identified: (i) testing in response to a specific risk event; (ii) as reassurance when there was a small amount of doubt or anxiety related to HIV; and (iii) in response to social norms perpetuated through peers, HIV community groups and the medical establishment to test regularly for HIV. HIVST had limited utility for men when testing in response to specific risk events except in the case of significant structural barriers to other testing opportunities. HIVST was considered to have utility when seeking reassurance, and was thought to be very useful when testing to satisfy the needs and expectations of others around regular testing. There was some ambivalence about the incursion of a clinical intervention into the home.

Conclusions: HIVST following risk events will likely be limited to those for whom existing service provision is insufficient to meet immediate needs based on structural or personal barriers to testing. Obligations of biological citizenship are central to MSM's understanding of the utility of HIVST. In the context of discourses of biocitizenship, men perceive HIVST to have dual roles: firstly as a tool to manage (mild) anxiety around one's HIV status based on an acknowledgment of HIV vulnerability arising from being homosexually active. Secondly, HIVST is useful in complying with social norms and meeting the perceived demands of biomedicine.

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Background

HIV testing is essential for the diagnosis and treatment of HIV, and alongside widely available antiretroviral therapy (ART) has facilitated an enormous decrease in HIV related morbidity and mortality. The first HIV antibody test became available in 1985 [1], and for many years testing was only accessible in clinical settings with significant emphasis placed on pre and post-test counselling by trained healthcare workers. Throughout the 1980s and most of the 1990s, in the United Kingdom HIV testing was primarily used as a diagnostic tool and was not actively promoted in the name of HIV prevention, which in combination with lack of any effective treatment resulted in comparatively low rates of uptake [1].

As understanding of the public health benefits of reducing undiagnosed infection and, latterly, treatment as prevention (TasP) grew [2–7], testing underwent significant expansion. Policy change and the introduction of low-cost rapid diagnostic tests (RDTs) facilitated this. In 2008 the British HIV Association (BHIVA) UK guidelines recommended annual HIV testing among men who have sex with men (MSM) (or more frequently if at increased risk) [8]. More recently, the 2014 British Association for Sexual Health and HIV (BASHH) guidelines call for annual testing for MSM with 3-monthly HIV testing for MSM following ‘unprotected’ sexual contact (oral, genital or anal) with a new partner, following an STI diagnosis, or the use of drugs which might be a marker of risk behaviour [9]. RDTs meant testing could now be delivered in a variety of settings not just by clinical staff but also community health workers and volunteers.

Testing interventions in the UK proliferated both within and beyond clinical settings [10–14]. More recently testing has moved into the domestic and private spheres with the introduction of self-administered testing methods such as HIV self-sampling (HIVSS) and HIV self-testing (HIVST) [15, 16]. Individuals utilising HIVSS collect the sample themselves, then post it to a laboratory who processes it and returns a result. With HIVST, individuals perform an RDT themselves and interpret their own result. Currently available HIVSTs in the UK are all 2nd generation, meaning that the period between infection and a reactive result is around 12 weeks [17]. HIVST is simply the latest technological innovation, which further increases the volume and variety of ways in it is feasible to establish one’s current HIV status. HIVSS is provided by the statutory and voluntary sectors across much of England, while HIVST is currently only available commercially (notwithstanding sporadic public provision through pilot and demonstration projects).

Public health discourses around testing have also shifted, and increasing the frequency with which MSM

test has become a dominant focus of HIV prevention efforts. Indeed, recent campaigns (see Fig. 1 for an example) for groups most affected by HIV in the UK have moved on from focusing primarily on condom use to an almost exclusive focus on the promotion of HIV testing [18, 19].

While expansion of the volume and variety of testing opportunities has increased rates of HIV testing and reduced undiagnosed infections particularly in MSM [20], about half of MSM continue to test less frequently than advised in the BASHH and BHIVA guidelines and about 25% have not tested at all [21–24]. Six monthly testing uptake estimates for MSM at higher risk vary between 27 and 60% depending on the study [21, 22]. Meanwhile social norms emphasising frequent HIV testing among MSM have become pervasive, with conceptualisation of personal responsibility increasingly emphasising testing, rather than condom use alone [19, 25]. HIV testing is also the gateway to biomedical HIV prevention interventions, including pre (PrEP) and post-exposure prophylaxis (PEP) as well as TasP [4, 26, 27].

HIV testing discourses are both varied and dynamic. Commonly understood narratives around patient initiated HIV testing include: testing in response to a risk event; because of symptoms which may be indicative of



Fig. 1 HIV testing campaign in situ in London (Do it London, 2016)

infection; out of a feeling of responsibility to oneself or partners; or as part of health-seeking routines [25, 28]. Testing for HIV is embedded in particular cultural contexts and frameworks that can link HIV infection with deviance, promiscuity, shame and notions of immorality, making testing decisions particularly complex [29].

As HIV testing services continue to expand, HIVST may be utilised by commissioners as a low cost alternative, triaging patients unlikely to have HIV infection away from facility based testing. HIVST is also thought useful for increasing the frequency of testing for those who are most at risk and test insufficiently often [15, 27, 28]. It is crucial to understand, however, what role HIVST will play alongside the diverse array of HIV testing interventions available to and targeted at MSM in the UK. Further, HIV testing is often promoted and discussed by MSM in offline and online environments [18]. As interventions are delivered within particular social contexts, understanding normative discourses through narrative analysis in the groups which they target is an important component in understanding intervention potential upon implementation. This is particularly true in light of strong critiques of the responsabilisation of public health often put forward by sociologists concerned about the impact of the convergence of identity and the lived embodiment of a risk state among the 'most' at risk in society [29–31], a process if often referred to as biomedicalisation.

This study therefore aims to understand how HIVST compliments existing testing strategies considered or adopted by MSM. We do this by analysing MSM's narratives surrounding HIV testing and their accounts of HIVST's potential future roles. As a study grounded in implementation science, a field which seeks to translate research evidence into policy and practice [32], our results will be of interest to policy makers and commissioners who seek to understand the potential role HIVST will have in the sexual lives of MSM in high income settings. In particular, this manuscript focuses on the implications of these narratives for feasibility, potential intervention reach and equity concerns.

Methods

Full methods for this study are reported elsewhere [33]. Below we include an abridged version.

Study design

This qualitative descriptive study was conducted as part of the formative phase of SELPHI, a randomised controlled trial (RCT) taking place in England and Wales. To inform intervention design, our qualitative research sought to capture the perspectives of MSM in relation to HIV testing generally and HIVST specifically. Focus group discussions (FGDs) were utilised to situate the perspectives of individual MSM in the context of group

mediated norms, such as those held within individuals' social networks. This analysis was not planned when this study was conceptualised, instead, the emerging narratives proved to be useful for intervention design, thus warranting further analysis.

Study sites and health service features

Fieldwork occurred in London, Plymouth and Manchester. These cities were chosen as they have a variable prevalence of HIV and differ in their population density of MSM [20, 34]. They also vary substantially in the provision and diversity of gay venues and HIV and other sexually transmitted infection (STI) testing services. At the time of the study Plymouth and the surrounding counties of Devon and Cornwall were the only location in England where HIVST was available at no charge through an NHS pilot initiative.

Study participants & recruitment

MSM, including trans MSM, who were over the age of 18 and did not have diagnosed HIV were eligible for inclusion in this study.

Acknowledging differing patterns of and perspectives towards testing across sub-groups, purposive quota sampling was used to ensure diversity regarding age, ethnicity, sexual orientation and past HIV testing experience including locations of previous HIV tests. In particular, we sought to include more men outside the ages of 26–39, as these are less likely to test in line with BHIVA guidelines [21, 24]. Further, we over-sampled men from ethnic minority backgrounds theorising that their barriers and motivators to testing may be different to men of white ethnicity [21]. We also focused on including larger numbers of participants who had utilised self-administered testing or sampling methods including HIVSS and HIVST. See Table 1 for demographic and health service use details of focus group participants.

Sampling proceeded iteratively, and as study recruitment unfolded, we made efforts to recruit those who had never tested for HIV and men at potentially higher risk of HIV transmission (defined as 2 or more condomless anal intercourse (CAI) partners in the preceding 3 months). This was partly because data saturation was reached after only four general groups, and also on the premise that these individuals might have greater utility for HIVST given testing guidelines urging quarterly testing for MSM with multiple condomless sex partners [8, 9], and the potential for HIVST to provide a gateway to testing for men who have never previously tested [35]. The first four focus groups (two in London, one in Plymouth and one in Manchester) were shaped by our general purposive sampling quotas, with one additional group conducted with men at higher risk, and one final group exclusively for those never having tested for HIV.

Participants were recruited through gay, location-based sexual networking applications as well as community-

Table 1 Sample characteristics

Demographic characteristic		MSM recruited <i>n</i> = 47
Age group (range 18–64)	18–25 years	9
	26–39 years	21
	40+	17
Ethnicity	Black	4
	Asian	6
	White	37
	Other/Mixed	0
Sexual orientation	Gay	38
	Bisexual	5
	Other	4
Recency of HIV testing	Never tested	8
	Tested over 12 months ago	9
	Tested in preceding 12 months	30
Past use of HIV testing locations (multiple answers allowed)	Genitourinary medicine clinic	30
	General practice	6
	Community based testing	11
	Self-sampling	4
	Self-testing	

based organisations in the three cities. Men were directed to webpages detailing the study. They were invited to complete a short survey providing demographic details and, if eligible, their contact details. Participants were then selected and invited to groups based on our sampling frame. Participants were compensated £40.

Data collection and analysis

FGDs were co-facilitated by the lead author and members of Sigma Research.¹ A topic guide was developed collaboratively within the research team and refined after the initial focus group. The topic guide covered HIV testing behaviour, HIVST intervention specific details and perceptions of HIVST in relation to other testing opportunities. This analysis mainly focuses on the first section exploring how HIVST fits into health seeking frameworks. We began this section asking about the perceived barriers and facilitators to HIVST before moving on to hypothetical discussions about the likely situations in which individuals perceived it more or less appropriate to use HIVST. Finally, we asked about key influences on testing decision making, including risk, personal history and peer groups.

FGDs were transcribed verbatim. All authors familiarised themselves with the transcripts and agreed a thematic coding framework through consensus following the approach describe by Richie and Spencer [36]. This approach was chosen to reduce inherent bias in data analysis. This framework included higher-level codes such as risk, reassurance, and norms; within which nested sub-themes describing the most common

understandings expressed by participants. The data were coded deductively initially, then the sub-themes were coded inductively to derive more nuanced understandings of testing narratives. This analysis was conducted using QSR NVivo 10.

Ethical considerations

Ethical approval was granted by the London School of Hygiene & Tropical Medicine observational research ethics committee (reference 9893).

Reflexivity

This work is the product of a collaborative, multi-institutional, interdisciplinary effort conducted in the formative phase of the development of the SELPHI RCT. As such the team holds diverse perspectives on the potential role for health service and civil society in HIV prevention in high incidence groups. All authors believe that increasing the volume and variety of ways in which MSM can be empowered to learn their HIV status is productive so long as interventions are useful to MSM and meet their aspirations related to their sexual health.

Results

Our analysis identified three main narratives surrounding potential reasons to test for HIV: (i) testing in response to a specific risk event; (ii) as reassurance when there was a small amount of doubt or anxiety related to HIV; and (iii) in response to social norms perpetuated through peers, HIV community groups and the medical establishment to test regularly for HIV. During FGDs we did not ask our participants to describe their motivations or the anticipated motivations of others to seek HIV testing. Rather these narratives were volunteered within groups and explored further when appropriate. Here we describe each narrative about HIV testing generally in turn and then examine the utility of HIVST as a testing technology in response to each of these motivations.

Testing as a response to risk

The most cited reason to test for HIV was in response to a risk event, usually CAI outside a monogamous seroconcordant relationship. There was a perception that for many men, this was the only rationale for testing for HIV and without such a driver, individuals would not seek testing. The importance of testing for HIV following a risk event was universally acknowledged among our sample.

For those who had never tested, the most common narrative for not having done so was that they had used condoms consistently throughout their sexual careers and did not feel themselves to be at risk for HIV, and therefore felt HIV testing was not relevant for them.

Well, I haven't had an HIV test and I've got a partner for 40 years now, but I do have other people as well, but I always have safe sex. Maybe because they have safe sex, they don't think they have to test. (62-year-old gay man, never tested group).

HIVST was not perceived to be useful by the majority when seeking a test in response to a risk event or in the context of ongoing sexual risk. This was partly due to concerns raised by participants about longer window periods (reported in Witzel et al. [33]) and partly because of the lack of individual support in HIVST interventions. Many felt dislocation from clinical care and staff meant they would not want to self-test if they thought there was a realistic possibility that the result could be positive. Rather, in these narratives, support from doctors, nurses and health advisors was central to motivations to seek care.

[...] this sounds really stupid, but for me I'd probably test on a self-testing thing and I'd probably be alright, but I think if I knew something was... I'd go to the doctor, which doesn't make sense but it's just... yes, like if I did something really crazy and I thought "Oh damn that was bad," the next day I probably would go to the doctor, where generally [not testing in response to risk] a self-test would be okay and that's me being honest. (46-year-old gay man, tested last 3 months, London).

For some, this was to do with the desirability of having a more complete package of care including other STI tests which were of some (although lesser) concern. HIVST was presented as interrupting care in this context, and providing it to people following a risk event could be seen as contrary to public health objectives. For these men, it was not just the HIV test that provided comfort, it was also the care and support surrounding testing services and provision of information and advice around sexual health. This was particularly pronounced among the men in the higher risk group.

Probably I would still go to the clinic, because as [name redacted] said there's the other stuff that it doesn't actually test for and it's specifically looking for one virus or antibody and it's not looking for signs of syphilis or gonorrhoea or NSU or anything like that, so it would still be the same for me. I go to the doctor every 3 months, 4 months. (31-year-old gay man, tested in last 12 months, higher risk group, London).

The exception identified by men where HIVST was useful in response to risk was where significant structural barriers to accessing testing existed and the mounting stress made testing immediately crucial.

I think for me personally it would be more if I'd done something and I was concerned and I wanted to know quickly particularly if I tried to get an appointment at the local clinic and I had to wait a week or two to get a slot because they're quite busy but if I wanted to know really quickly then I'd prefer to get a test that way (33-year-old gay man, tested in last 3 months, London).

HIV testing as reassurance

Testing to gain reassurance of ones continuing HIV negative status was a common theme across our groups shaped by our general purposive sampling strategy as well as the higher risk group. While testing in response to risk was usually a response to a specific trigger event, testing as reassurance responded to recognition of an ongoing higher risk of HIV in the gay community. This need for reassurance about continued seronegativity was constantly reinforced by interaction with peers, with biomedicine and health promotion services. This was described in all FGDs, except for the group for those who had never tested.

For many men, being homosexually active brought a requirement to engage with the process of surveillance of one's HIV status. Social contacts were key in providing motivation and support for testing. Understanding and appreciation of belonging to a risk group was part of developing norms surrounding HIV testing, a distinctly social process which had a psychological impact.

None of my straight friends ever get tested, I don't think any of my female friends would know where to go to get tested at all and with my gay friends we'd text each other, and say: "It's negative, everything is clear" or: "I've got gonorrhoea. Guttled. Need to get an injection in my bum." Yeah, we talk about it. (26-year-old gay man, tested in last 12 months, higher risk group, London).

While individuals were often very confident of a negative result when testing, low levels of background anxiety surrounding HIV were strong motivators to test regularly. Among individuals who tested very frequently, ongoing reassurance was a key component of their decision to seek HIV testing.

Interviewer: ... but what's the point in testing when you are pretty sure you're negative?

Participant: I think it just reassures you even if there's a small degree of doubt, there's a very very low chance but there's still a chance and actually it's quite affirming - it's nice to have that reassurance. (36-year-old gay man, tested in last 3 months, London).

Risk of HIV in these narratives is viewed as a constant, and HIV testing is useful in managing and monitoring one's own risk and providing reassurance.

HIVST was perceived by many as useful to reassure oneself of a negative HIV status. This was particularly true for those who described a growing anxiety between tests despite the absence of a specific high-risk event. Self-testing for these men offered the opportunity to 'top-up' between other tests, and in the context of seeking reassurance from a self-test, the lack of support was perceived to be far less problematic.

I'm conflicted now, I think I think I came here feeling like I need comfort and I still feel like that but I also wonder if it was just small multi-pack cheap free casual testing... I wonder if that would be a nice thing for me actually because it would remove any of the building of the worrying about going to this place to get it done ... (29-year-old queer man, tested in last 12 months, higher risk group, London).

In terms of accuracy, HIVST was usually understood as a sub-optimal technology with longer window periods and less reliability when compared to point of care or laboratory testing available in other settings. For this reason, HIVST was sometimes seen as a gateway to more frequent testing for those who had a degree of anxiety and some participants assumed individuals would seek a confirmatory test whatever the result of the self-test.

Self-testing would be a brilliant thing because, yeah it's a bit like a pregnancy test. It might be wrong but it then might give people that kind of push to maybe go and then get tested again just reassure themselves... (26-year-old gay man, tested in last 12 months, Manchester).

HIV testing as routine – norms, peer groups and biomedicine

HIV testing was strongly viewed as normative behaviour by the majority of MSM in our groups, including those who had never previously tested. The norm was sufficiently pervasive that in our general FGDs, men who had never tested struggled with disclosing this during the FGD and most did not. In our group for men who had never tested these disclosures remained difficult, with some participants choosing not to discuss their untested status although all members knew they were in a group of MSM, none of which had ever tested for HIV.

Individuals identified key sources of influence as crucial to developing social norms relating to HIV testing and the frequency at which it should be done. Men cited friends and peers as the principal information source around testing methods, opportunities and novel interventions.

Health promotion practitioners and individuals working in clinical services were also important in prompting men to test, to repeat testing frequently and in highlighting specific services. The gay media and the commercial scene were also vital in the dissemination of testing promotion messages, particularly in major metropolitan areas.

Especially since I moved to Manchester, coming from [city in Scotland] it's a bit, the gay scene is a lot smaller and its... I hadn't noticed any advertisement and measures about it when I was there and as soon as I got here it was all about. Everywhere "Test, Test, Test, Test, Test" everywhere. And I think it has been very very easy to get, to get done here and I have been here 3 years and I think I have been tested three or four times because its constantly everywhere like. So I would say it's quite positively done here to be honest. (40-year-old gay man, tested in the last 12 months, Manchester).

While there was an acknowledgement that not all were testing as frequently as might be considered ideal, it was clear that men valued regular testing and saw it as a normative behaviour for all homosexually active gay and bisexual men. Themes of responsibility were particularly pervasive in discourses about regular testing, even among those who were unclear what the 'ideal' frequency was. These obligations were sometimes viewed with ambivalence, particularly given perceptions about a lack of consistency in messages about how frequently they should test. However, the pervasive norm for regular testing was largely uncontested and widely advocated and accepted as a part of being a 'good gay man'.

One of the most common assumptions about HIVST was that it was exceptionally useful for meeting the expectations of peers (and biomedicine) surrounding routine HIV testing. Pervasive norms about frequently testing for HIV meant some participants felt that the requirement to test placed too high a burden on their time. For these men, HIVST was a way to meet social and biomedical expectations while minimising the opportunity cost to themselves.

Because you're supposed to test...I think in theory, it was meant to test – well, every 3 or 6 months, or every new sexual partner. So in theory HIV self-testing, I don't think most people really use it for that [following risk]. But then obviously in practice it's different, because a lot of people will just test if there's a reason to. So I guess if you're testing as often as you should be, then HIV self-testing perhaps will be useful to you, but I don't know about the other way. (42-year-old gay man, tested in last 12 months, Plymouth).

Self-testing was not always acceptable to men despite strong social norms around HIV testing. Instead, for men who were ambivalent or opposed, HIVST brought a clinical intervention into the home, clashing with other norms about what is appropriate in the domestic sphere.

[...]I would find it very difficult to envisage a situation in which I sat at home at my dining table with my cat looking at me with adoration whilst I identified my HIV status by sticking something here and then skewering my finger and then squeezing something in and looking at some colour chart. (51-year-old gay man, never tested group, London).

Discussion

In our focus group based study involving 47 MSM we found three main narratives surrounding motivations to test for HIV: i) in response to risk events, ii) as reassurance, and iii) testing to satisfy social and medical norms. HIVST had limited utility for men when testing in response to specific risk events except in the case of significant structural barriers. However, HIVST was considered to have utility when seeking reassurance, and was thought useful when testing to satisfy the needs and expectations of others around regular testing. There was some ambivalence about the incursion of a clinical intervention into the home. While health care professionals see HIV testing as a gateway to prevention strategies such as PrEP, TasP and TasP; this discourse was largely absent within FGDs perhaps indicating that these interventions are envisioned to take place within clinical services thus diminishing the potential of HIVST in these.

Based on the narratives we present, self-testing following risk events will likely be limited to those for whom existing service provision is insufficient to meet immediate needs based on structural or perhaps personal barriers to testing. Analysis of these narratives suggest that widespread adoption of HIVST in response to risk events is unlikely. Rather, men who are testing out of concern following CAI will likely continue accessing clinic based services, partly because of the much valued support from staff, partly because of the acknowledgement of the importance of STI testing and because of the longer window periods of current HIVSTs compared to clinic based POCT. The provision of self-sampling/testing kits for bacterial STIs alongside well developed and easily accessible pathways for men to access confirmatory testing for HIV and other STIs may go some way to countering this concern, potentially also providing a clear link between individuals who are self-testing and clinical services. This is in contrast with recent Scottish data which indicated that MSM were willing to use HIVST following a risk event, although which also reports similar concerns around support [37].

Early adopters of new prevention technologies are likely to have distinct motivations for accessing interventions, usually reflecting an unmet felt need [38]. These narratives are likely to be more indicative of how middle and late adopters will perceive the utility and potential of HIVST upon roll-out. It is essential to understand these because they will shape initial reception, as the potential of an intervention is understood primarily in specific cultural spaces rather than through individual clinical or health promotion interactions. These motivations will also likely change over time as MSM experience HIVST and incorporate the new opportunities it affords into their health seeking frameworks.

Obligations of citizenship are central to MSM's understanding of the utility of HIVST. Under notions of biological citizenship individuals are expected to take an active role in their health, including managing and monitoring risk. Good citizenship is demonstrated by MSM through complying with the testing behaviours which are expected of them. In doing so individuals organise around biomedical categorisations and develop programmes of self-care in collaboration with experts. Responsibility is demonstrated through these regimes, and compliance with these are central to belonging within these groups [31, 39]. This process has contributed to a reframing of biological or behavioural vulnerability into a socially lived health state similar to disease [30, 39]. This is particularly true for those deemed 'most' at risk by epidemiology and the allied public health sciences [29].

Testing imperatives disseminated through varied public health actors have led to increasing uncertainty amongst MSM about the stability and durability of one's HIV status even in the absence of significant risk. Consistent with an emerging body of literature [40–42], our findings suggest that HIV risk is being conceptualised as a health-state worthy of intervention in itself.

While notions of biological citizenship within this group have historically focused on maintaining condom use [43, 44], the emergent paradigm supplements (and in some cases replaces) these messages with those reinforcing obligations of monitoring [45, 46]. This has been constructed through the emphasis on testing regimes disseminated by biopolitical actors such as policy organisations, health promotion agencies and practitioners, epidemiology, clinical staff and MSM themselves. While much of the literature exploring this emerges from those investigating PrEP and PEP use in individuals at high risk of HIV infection [41, 42, 47], our research indicates that this is a wider process which also includes HIV testing norms and imperatives.

In the context of discourses of biological citizenship, men perceive HIVST to have dual roles: firstly as a tool to manage anxiety around one's HIV status based on an acknowledgment of HIV vulnerability arising from being

homosexually active. Secondly, HIVST is useful in complying with social norms and meeting the demands of biomedicine. In this context HIVST is not necessarily seen as problematic; the anxiety producing the need for re-testing is very real and HIVST has potential to reduce this. Similarly, the frequency with which MSM are expected to test represents a significant burden on time. HIVST allows men to meet these needs in a more efficient way, both for themselves and potentially for health services.

It is important to note that individuals interpret risk subjectively through their own cultural and personal frameworks which often are only partially based in biomedical understandings of the potential for HIV transmission. While men do not currently appear to perceive HIVST as particularly useful in testing following a specific risk event because of the relatively long window period with currently available HIVST and lack of clinical support, that does not necessarily mean that the technology will not facilitate increased testing or reduce the time from infection to diagnosis. These current dominant narratives do however pose a challenge to the notion that HIVST roll-out alone will reduce health inequalities by cost-effectively preventing onward HIV transmission by reaching significant numbers of high risk MSM who might not otherwise be testing frequently enough.

Understanding the importance of testing as anxiety reduction and as routine indicates that developing HIVST interventions integrated within existing services to formalise supplemental testing routines within a package of care could be feasible and highly acceptable. These interventions could emphasise support through clinic visits and remote portals, thus perhaps addressing some of the well-being concerns generated by anxiety brought about by biomedicalisation of risk. Such a package of care remains unlikely to address equity concerns, however, as it will by nature facilitate a more formalised and structured clinical relationship between already engaged patients and clinical staff. Indeed, based on the findings we present here, penetration of HIVST in the medium term (when it becomes widely available at no cost) will perhaps be partly limited to those who are already engaged in sexual health care, therefore not addressing health inequalities in the way envisioned by public health practitioners.

Finally, our findings indicate that self-testing extends the reach of risk governance from the clinic into the home and will probably reduce the time interval between tests for many MSM. Like many previous technological innovations, including RDTs and HIVSS, self-testing reduces the time burden to know one's HIV status, an increasingly vital demonstration that an individual is a 'good gay man'. Whether HIVST also reduces the time between infection and diagnosis across the population of gay men acquiring HIV remains to be seen.

Strengths and limitations

This manuscript presents the results of a formative qualitative study of narratives around HIV testing and HIVST among MSM in the UK. While HIV testing motivations within this group have been extensively studied and documented, this is the first UK research describing motivations for testing in the context of the possibility of HIVST. This data will be useful when considered alongside emerging evidence from Scotland which reports HIVST is highly acceptable among MSM and stakeholders and other data relating to this study [33, 37].

Our results should be interpreted with some caution. Only four of our sample of 47 had previously used HIVST, so our results largely relate to perceptions of a novel intervention. To counter this concern we over-sampled individuals who had accessed HIVSS, but there remain key differences between these interventions, particularly surrounding support and care pathways. Concerns around support will therefore potentially be over-emphasised and more research is needed to understand how these are borne out when HIVST is more widely used.

Further, it warrants emphasising that this is an analysis of narratives surrounding HIV testing motivations, and that these therefore are reflective of normative understandings explored by our participants. While useful for understanding HIVST intervention potential, it is also likely that the diversity of the population of UK MSM and their decision making will not be fully represented in these accounts.

Conclusions

In conclusion, MSM in our study typically did not identify HIVST as a useful intervention when testing in response to risk unless significant structural barriers to testing existed. When testing to seek reassurance or in response to the expectations of biomedicine around regular testing, HIVST was considered to have utility. There was some ambivalence about the incursion of a clinical intervention into the home.

Endnote

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Availability of data and materials

The datasets generated during and/or analysed during the current study are not publicly available due to their highly sensitive nature. Reasonable requests for access will be considered by the corresponding author.

Authors' contributions

Conceptualisation and critical direction provided by FB, AR, PW, & CW. Data generation completed by CW, PW & AR. Data analysis carried out by CW. CW, AB, AR, PW and FB revised drafts and provided critical input. All authors have provided final approval.

Competing interests

The authors declare they have no competing interests.

Consent for publication

Not applicable.

Ethics approval and consent to participate

Ethics approval was sought from, and granted by the observational research ethics committee at the London School of Hygiene and Tropical Medicine (ref: 9893). All participants provided written and verbal consent at the time of FGDs.

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The second paper of this thesis, *Risk, reassurance and routine: a qualitative study of narrative understandings of the potential for HIV self-testing among men who have sex with men in England*, provided insights into the potential contexts of HIVST use based on normative understandings of narratives around HIV testing more generally. Coupled with the findings of the first paper, it seemed likely that HIVST could be implemented and would be acceptable to a range of MSM, although questions remained regarding feasibility of delivery and acceptability for those who used HIVST, especially surrounding ease of use.

Sufficient information had been captured within these studies, and a further key informant interview study I conducted around the same time (the results of which are available in appendix 5) (125), to design the intervention for use in SELPHI. This was collaboratively developed with the clinical trials unit, with intervention components being selected based on their relationships with acceptability in the formative work, and because of pragmatic concerns related to trial design. The two-week follow-up was included as a response to concerns about lack of support identified in this formative research, as was signposting for Terence Higgins Trust (THT) direct, a voluntary sector run helpline covering the whole of the UK. These supportive concerns were related to care for self-testers with positive results and those with additional sexual health needs identified in this formative study.

In order to better illustrate pathways to impact in the two SELPHI interventions, I produced a logic model at this stage.

The logic model for SELPHI draw from the first two formative studies (the focus groups discussion study, the key informant interviews), as well as another study I led. This third study was a systematic literature map, which in itself was a collaborative project with the WHO, in which we began to capture emerging literature about HIVST acceptability, feasibility and RCT outcomes (protocol available in appendix 1, outputs available at HIVST.org) (31).

Focus group discussions, in-depth interviews and key results from the map provided themes which were mapped onto a framework informed by COM-B. Because SELPHI is an RCT situated within a supportive policy environment, the framework focused on producing behavioural alterations through the intervention functions specified in COM-B (Tables 4 and 5).

Contextual factors which I hypothesised to impact on intervention delivery included a cultural norm for regular testing; perceived issues with capability and concerns about supportive structures. The main testing barriers identified in formative work which HIVST could effectively respond to were motivation (reflective & automatic) and opportunity (physical & social). The intervention was

Table 4: COM-B intervention types (Michie et al 2011).

Interventions	Definition
Education	Increasing knowledge or understanding
Persuasion	Using communication to induce positive or negative feelings or stimulate action
Incentivisation	Creating expectation of reward
Coercion	Creating expectation of punishment or cost
Training	Imparting skills
Restriction	Using rules to reduce the opportunity to engage in the target behaviour (or to increase the target behaviour by reducing the opportunity to engage in competing behaviours)
Environmental restructuring	Changing the physical or social context
Modelling	Providing an example for people to aspire to or imitate
Enablement	Increasing means/reducing barriers to increase capability or opportunity ¹

Table 5: COM-B domains and intervention functions (Michie et al 2011)

Model of behaviour: sources	Education	Persuasion	Incentivisation	Coercion	Training	Restriction	Environmental restructuring	Modelling	Enablement
C-Ph					✓				✓
C-Ps	✓				✓				✓
M-Re	✓	✓	✓	✓					
M-Au		✓	✓	✓			✓	✓	✓
O-Ph						✓	✓		✓
O-So						✓	✓		✓

1. Physical capability can be achieved through physical skill development which is the focus of training or potentially through enabling interventions such as medication, surgery or prostheses.

2. Psychological capability can be achieved through imparting knowledge or understanding, training emotional, cognitive and/or behavioural skills or through enabling interventions such as medication.

3. Reflective motivation can be achieved through increasing knowledge and understanding, eliciting positive (or negative) feelings about behavioural target.

4. Automatic motivation can be achieved through associative learning that elicit positive (or negative) feelings and impulses and counter-impulses relating to the behavioural target, imitative learning, habit formation or direct influences on automatic motivational processes (e.g., via medication).

5. Physical and social opportunity can be achieved through environmental change.

conceptualised as inducing changes in these areas, while minimising concerns around capability (psychological & physical), which presented the primary barrier to intervention implementation.

The first intervention (intervention A (figure 3)) is linear, moving from targeted recruitment to a risk assessment represented by behavioural questions in a survey, then to receipt and use of the HIVST, and lastly a two-week follow-up survey. The advertisement was classified as a form of education and persuasion, seeking to enhance motivation (reflective). The risk assessment was a form of persuasion, enhancing motivation (reflective) by increasing feelings of vulnerability to HIV. Kit provision was a form of enablement increasing opportunity (physical). The two-week follow-up was a form of enablement, increasing motivation domains (reflective & automatic) (126, 127).

Intervention B (figure 4) includes all elements of A, with additional cyclical components consisting of a testing reminder and a linked risk assessment delivered every three months which triggers delivery of a new HIVST and another two-week follow-up survey. The testing reminder and linked risk assessment were forms of persuasion, targeting motivation (reflective & automatic).

The logic model (figure 5) articulates intermediate outcomes assumed to be precursors to achieving the trial outcomes. Each intermediate outcome relates to a documented deficit or need constraining testing within the target population and which intervention design has been attentive to as a key area which requires change. They are described as an outcome (e.g. increased motivation to establish HIV status) and a COM-B linked domain which required alteration to achieve this (e.g. motivation (automatic)).



Figure 3: Intervention A schema

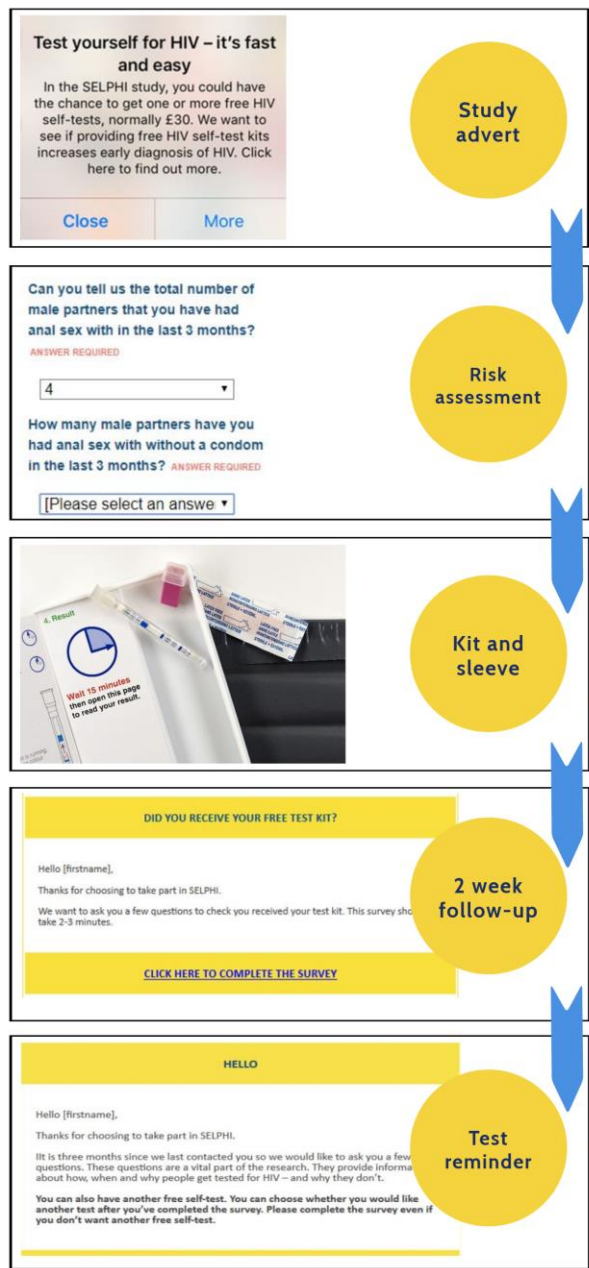


Figure 4: Intervention B schema

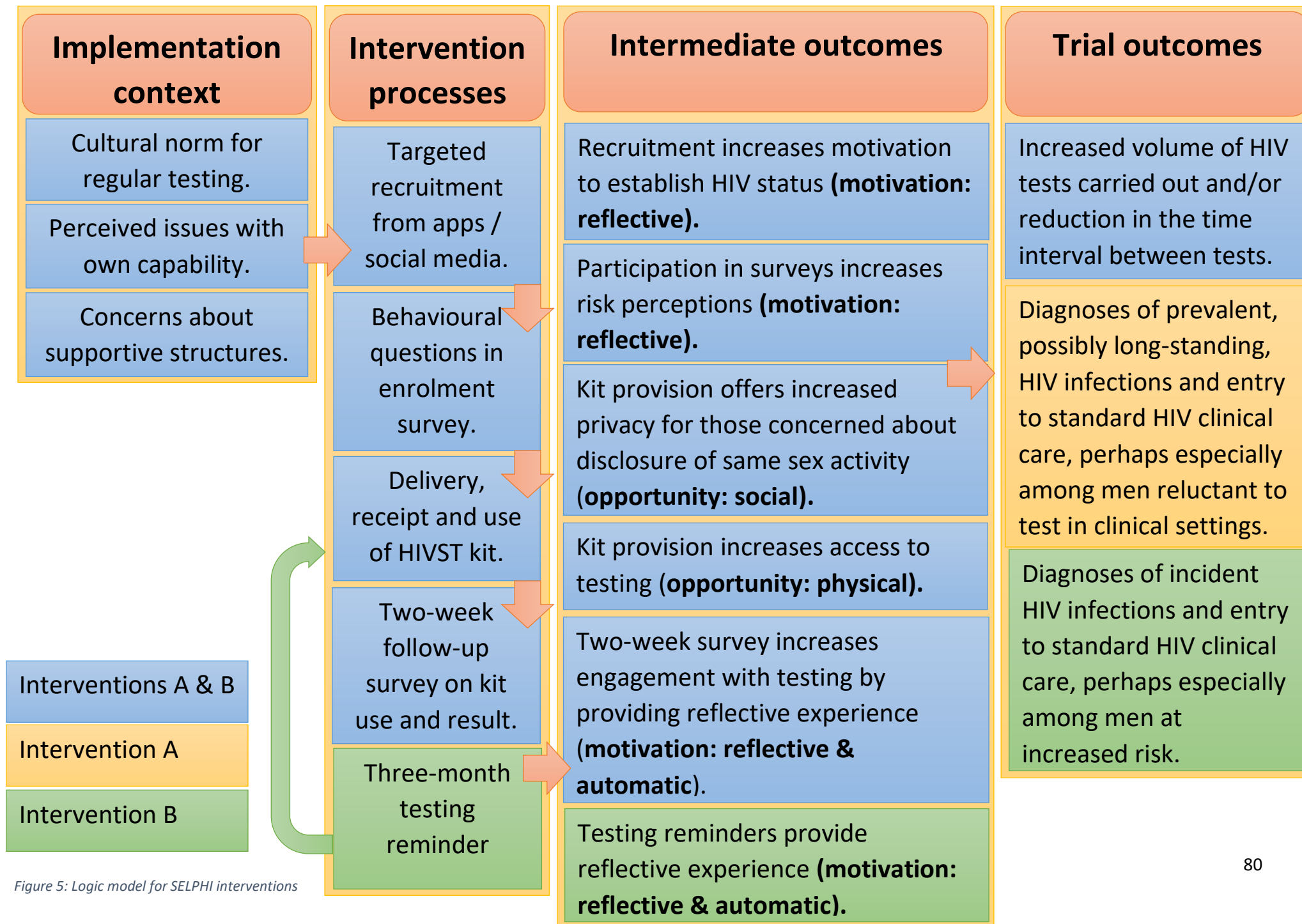


Figure 5: Logic model for SELPHI interventions

3.2 Implementation research

This phase of my thesis covers implementation research and contributes paper 3, the next in this inquiry.

Following the successful completion of the formative work, the intervention design and logic model articulation process, implementation proceeded as planned with a pilot of the RCT during which we recruited 10% of the overall 10,000 sample. I had a central role in planning this, with the majority of the intervention messages designed by me with input from our participant and public involvement representatives. I also designed the recruitment strategy with the trial manager, the emails which linked to the various surveys and much of the process evaluation questions in the survey itself. The published protocol which details these can be found at Gabriel et al 2018 (92).

Feasibility and acceptability of the intervention were still central considerations. Although pilot projects had delivered HIVST in the UK at this stage, it was still unclear how our specific intervention would be received. These pilot projects also reported relatively limited data, especially regarding usability, a central question given the capability issues I identified in formative work. In addition, there remained no European evidence from people who had used HIVST and capability concerns had emerged as a major barrier in the formative work.

Although quantitative driven questions regarding intervention experiences were included, we decided to conduct 15 interviews with a cross section of those randomised to receive a kit in order to assess how individuals responded to the technology (topic guide in appendix 6). I found a relatively high degree of homogeneity in qualitative accounts in this study. Data saturation was reached promptly with these early questions, and I decided to stop interviews after 10 participants. This enabled an analysis attentive to how to expand the topic guide to include other domains in a further qualitative enquiry (papers 4 & 5).

I proceeded with the analysis presented in the following chapter in order to identify any alterations that were required with the RCT before full implementation. This paper is useful for those seeking to engage MSM in online RCTs, and for those working in HIVST implementation.

3.2.1 Paper 3: Pilot phase of an internet-based RCT of HIVST targeting MSM and transgender people in England and Wales: advertising strategies and acceptability of the intervention



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RESEARCH PAPER COVER SHEET

Please note that a cover sheet must be completed for each research paper included within a thesis.

SECTION A – Student Details

Student ID Number	1603113	Title	Mr
First Name(s)	T Charles		
Surname/Family Name	Witzel		
Thesis Title	HIV self-testing for men who have sex with men (MSM) in England and Wales: a multi-method study of self-testing intervention development and evaluation		
Primary Supervisor	Peter Weatherburn		

If the Research Paper has previously been published please complete Section B, if not please move to Section C.

SECTION B – Paper already published

Where was the work published?	BMC Infectious Diseases		
When was the work published?	08/08/2019		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion			
Have you retained the copyright for the work?*	Yes	Was the work subject to academic peer review?	Yes

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SECTION C – Prepared for publication, but not yet published


Where is the work intended to be published?	
Please list the paper's authors in the intended authorship order:	


Stage of publication	Choose an item.
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SECTION D – Multi-authored work

<p>For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)</p>	<p>I had a significant role in designing and implementing the RCT pilot. I helped design the intervention, I produced the acceptability questions in RCT, designed the recruitment strategy and messaging. I designed the quantitative analysis which was carried out by the trial statistician. I designed the qualitative data collection instruments, as well as the analysis. I recruited participants, conducted the interviews and carried out the analysis. I wrote the paper and made revisions.</p>
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SECTION E

Student Signature	
Date	03/12/2019

Supervisor Signature	
Date	03/12/2019

RESEARCH ARTICLE

Open Access

Pilot phase of an internet-based RCT of HIVST targeting MSM and transgender people in England and Wales: advertising strategies and acceptability of the intervention



T. Charles Witzel^{1*}, Michelle M. Gabriel², Leanne McCabe², Peter Weatherburn¹, Mitzy Gafos^{2,3}, Andrew Speakman⁴, Roger Pebody⁵, Fiona M. Burns^{4,6}, Chris Bonell⁷, Fiona C. Lampe⁴, David T. Dunn², Denise Ward², Justin Harbottle⁸, Andrew N. Phillips⁴, Sheena McCormack² and Alison J. Rodger^{4,6}

Abstract

Background: The SELPHI study (An HIV Self-Testing Public Health Intervention) is an online randomised controlled trial (RCT) of HIV self-testing (HIVST). The aim of this study was to assess the feasibility of recruiting UK men who have sex with men (cis and trans) and trans women who have sex with men to the SELPHI pilot, and the acceptability of the HIVST intervention used among those randomised to receive a kit.

Methods: A mixed-methods approach to assessing trial feasibility and intervention acceptability was taken, using quantitative data from advertising sources and RCT surveys alongside qualitative data from a nested sub-study.

Results: Online recruitment and intervention delivery was feasible. The recruitment strategy led to the registration of 1370 participants of whom 76% (1035) successfully enrolled and were randomised 60/40 to baseline testing vs no baseline testing. Advertising platforms performed variably. Reported HIVST kit use increased from 83% at two weeks to 96% at three months. Acceptability was very high across all quantitative measures. Participants described the instructions as easy to use, and the testing process as simple. The support structures in SELPHI were felt to be adequate. Described emotional responses to HIVST varied.

Conclusions: Recruiting to a modest sized HIVST pilot RCT is feasible, and the recruitment, intervention and HIVST kit were acceptable. Research on support needs of individuals with reactive results is warranted.

Keywords: HIV self-testing, Men who have sex with men, Transgender people, Randomised controlled trial, Online service delivery, Implementation science, Process evaluation

Background

Late diagnosis of HIV infection and on-going HIV transmission in UK men who have sex with men (MSM) and transgender people are enduring public health challenges [1, 2]. Despite recent successes in reducing HIV incidence through combination prevention initiatives including expansion of

testing, many MSM continue to test sub-optimally and up to 25% have never tested [1, 3–5]. Few data exist on HIV testing among transgender people, although transgender women are disproportionately affected by HIV [6, 7] and evidence suggests innovative HIV prevention interventions are key to reducing incidence in this group [7].

HIV self-testing (HIVST) is a recent approach whereby an individual tests themselves and reads their own result using a rapid diagnostic test. There is an emerging evidence base suggesting that HIVST has the potential to improve access and overcome barriers to testing through

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reducing stigma and privacy concerns as well as increasing convenience and ameliorating geographical barriers in areas underserved by other HIV testing opportunities [8, 9]. It also provides flexibility in intervention design: components and delivery mechanisms can be adapted depending on the target population [8]. In 2016 the World Health Organization incorporated HIVST into its Consolidated Guidelines for HIV Testing Services with the recommendation that HIVST be provided as a supplementary option alongside existing services [10].

Evidence from UK studies conducted shortly after HIVST became commercially available in 2015 suggests that HIVST is acceptable, and that MSM have preferences for blood-based tests (due to perceptions of greater accuracy) and easy access to confirmatory testing [5, 11, 12]. However, a minority of MSM with aversion to blood reported being unwilling to use a blood-based kit [11]. Home delivery of an HIVST kit is a barrier for some with concerns around domestic privacy [11]. HIVST may be more appealing to groups who do not test in line with current guidelines, which recommend annual testing for all MSM, or more frequent testing if at increased risk [5]. Evidence also suggests that challenges relating to instructions and lack of familiarity with testing procedures may present barriers to use, particularly initially [11]. Little data exists on trans populations, although a study in San Francisco found HIVST was acceptable and feasible for trans women [13]. In addition, a small number of trans women have accessed England's national HIV self-sampling (HIVSS) service indicating that testing outside clinics may be preferable to some [2].

HIVSS, whereby a person takes their own sample and returns it to a lab that then processes it and provides a result, is the technology perhaps most analogous to HIVST. HIVSS has suffered from sub-optimal sample returns, with testing completion rates around 55% in service evaluations in the UK [14, 15]. Evidence suggests this relates to complicated sampling procedures which are not always feasible or acceptable to the target populations, including taking a sufficiently large blood sample to facilitate testing [16, 17]. If those accessing HIVST face similar barriers in performing tests this could threaten the aspiration of increasing testing uptake and frequency through the provision of this novel technology. Further, although the expansion of commercially available HIVST has seen moderate levels of uptake in the USA [18], HIVST may fulfil different roles for populations such as in the UK where HIV testing services are very well developed. This is especially true should HIVST also be provided at no cost, as with the vast majority of existing HIV testing models in the UK.

The SELPHI study (An HIV Self-Testing Public Health Intervention) is an online randomised controlled trial (RCT) being conducted between 2017 and 2020 which aims to assess whether HIVST can; (i) increase rates of

diagnosis in those with prevalent HIV infection and ii) reduce the time between infection and diagnosis for those at risk of incident infection. The primary outcomes are ascertained through linkage to the national HIV surveillance systems indicating confirmatory testing and linkage to care. SELPHI aimed to recruit 10,000 MSM (cis and trans) and trans women. Participants were recruited through advertising on geo-location social-sexual networking applications and Facebook. Initial baseline randomisation was to an offer of postal delivery of an HIVST kit accompanied with a follow-up survey or to no HIVST.

Intervention conceptualisation was underpinned by the COM-B model of behaviour change [19, 20]. COM-B is a systematically developed model which consolidates 19 pre-existing frameworks, positing that alterations in capability, opportunity and motivation are key to successful behaviour change interventions [20]. This model was chosen because of its simplicity and flexibility, and because of its use in HIV prevention interventions as well as interventions which include the provision of technologically assisted behaviour change [21–26]. The pilot phase of SELPHI ran from February to May 2017 and aimed for 1,000 recruits, from the overall target of 10,000.

Evidence on HIVST intervention implementation feasibility and acceptability in high income settings to date has focused on small scale demonstration studies distributing small numbers of kits with limited follow-up [27, 28]. The SELPHI pilot provides an opportunity to generate evidence about whether large-scale implementation of an online HIVST RCT is feasible in high-income settings. Usability of HIVST, defined as “the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use [29]”, can also be assessed. It is also vital to understand intervention acceptability among those who receive the intervention to inform practitioners, policy makers and commissioners. This study, which is grounded in implementation science, will be useful in a range of contexts with similar health system features and HIV epidemics.

The aim of this study is therefore to assess the feasibility of recruiting to an online HIVST RCT in which participants are randomised to receive a free kit or not, and the acceptability of the HIVST intervention used among those randomised to receive it. We consider key questions related to advertising performance, reach, uptake, kit usability and end user reception. We use a mixed methods approach examining the feasibility of recruitment, the motivations of SELPHI participants, and the usability and acceptability of the kit itself. Theoretically, this work is informed by COM-B, a behaviour change model which is often used to explore acceptability and to conceptualise intervention components and how they may work together to produce behaviour change [20, 22, 30, 31].

Methods

This mixed-methods study follows a data integration approach termed by Moran-Ellis et al. as following a thread [32]. As such key areas of inquiry were identified from quantitative RCT data; these were then used to guide the focus of the analysis of the in-depth interviews. This has allowed us to generate additional nuance in responding to questions about feasibility and acceptability.

RCT study procedures

The pilot was designed to test the RCT recruitment strategy and the procedures in place for the full online trial. The pilot also tested the likely acceptability of the intervention, especially the usability of the chosen HIVST kit, its delivery mechanisms and the support offered for its use. Full details of the RCT methods can be found in the published protocol [33].

Eligible participants were men (cis and trans) and trans women; reporting lifetime anal sex with a man; not known to be HIV positive; aged 16 years and older; resident in England or Wales; willing to provide name, date of birth, postal and email address; consent to linkage with surveillance and clinic databases and not previously enrolled to the study.

The recruitment strategy utilised adverts placed in geo-location social-sexual networking applications (apps) (Grindr, Growlr, Scruff & Hornet) as well as targeted Facebook advertising. Free advertisements were placed on the Facebook page of a transgender focused clinical service. Recruitment sources were chosen based on previous experience, and through consultation with voluntary sector organisations. Grindr was chosen as it has the largest market share in the UK, with Hornet targeting a similar group. Growlr caters to a largely older subgroup of MSM, while Scruff is ostensibly most used by hirsute MSM and their admirers. Some adverts targeted a national audience, while others took a city or regional approach. Messaging was devised drawing learning from earlier formative work [11, 34], and with participant and public involvement (PPI) representatives. Key themes regarding barriers and facilitators to recruitment were identified, and two members of the study team met with PPI co-chairs to develop specific advertising messages. Adverts focused on all COM-B domains: capability was addressed through promoting ease of HIVST use; opportunity was addressed through highlighting the HIVST kits were available at no cost; and motivation was enhanced through highlighting privacy and appealing to altruism to take part in a study. Some messages specifically highlighted trans eligibility. Advertisements appeared as sponsored posts, as direct inbox messages, as pop-up messages and as banners.

Participants were directed to a registration survey requiring informed consent and confirming eligibility, and

then to an enrolment survey via email. Ineligible participants (and those not randomised to HIVST) were offered additional information on HIV testing. The enrolment survey asked additional demographic and behavioural questions. Participants were randomised 60:40 to receive an HIVST kit (baseline test [BT]) or to no kit offer (no baseline test [nBT]). Kits were distributed by post, directly to the given address by the test manufacturer (BioSure™).

Two weeks after enrolment, participants randomised to receive the HIVST kit were emailed an online follow-up survey asking if the kit had been used (and if not, why not), what the test result was, and whether further care was accessed. Two reminders were sent.

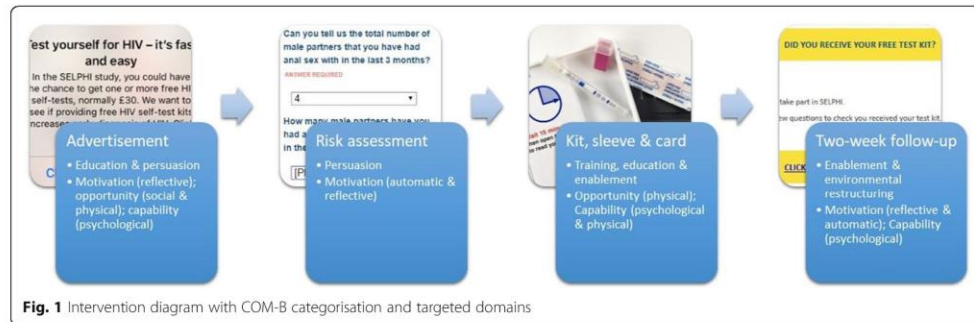
Three months after randomisation a survey was emailed to all participants asking for information on testing and risk behaviour in the intervening period. Two reminders were sent. Participants randomised to BT were also asked questions about their experiences with HIVST. They ranked on a 5-point scale their agreement with statements related to acceptability and usability of the kit: 1) the instructions were easy to use; 2) performing the test was simple; and 3) my overall experience was good.

Intervention development

The intervention being trialled was linear. The recruitment messages being tested were both part of the intervention and trial process, but in a scaled-up intervention delivering HIVST these would be adapted accordingly. A brief HIV risk assessment was conducted through behavioural questions in the enrolment survey. The kit and accompanying sleeve were then delivered and two weeks later a follow-up survey asked about kit use and the test result. Those who reported not receiving a kit had a new delivery arranged. These components (advertisement, risk assessment, kit and two-week follow-up) were defined as the intervention as all were theorised to increase engagement with HIV testing through COM-B channels.

Formative work was central to intervention development. Focus groups with MSM and key informant interviews identified specific barriers to uptake and use of the HIVST which the SELPHI intervention development was attentive to ameliorating, using COM-B. These efforts were also used in developing appropriate messaging for advertising. Figure 1 provides a visualisation of intervention components with a description of the intervention functions and the COM-B domains they seek to affect.

Anticipated concerns regarding ease of use, coded in COM-B as capability (physical), were addressed in advertisements (see Fig. 2 for examples). This combined intervention approaches described as persuasion and education in COM-B [20], enhancing motivation by minimising concerns regarding ease of use and highlighting privacy and convenience. Issues concerning lack of knowledge in using HIVST were also identified.



The COM-B model codes this as psychological capability; the behaviour change wheel then suggests intervention functions such as education, training and enablement might be useful [20]. This was alongside an observed preference for additional supportive information beyond what was provide in the original BioSure™ kit. This necessitated the development of a sleeve over the box holding the kit to provide support information (education), as well as behavioural support (enablement) which was highlighted in the two-week follow-up survey. The sleeve also provided signposting to a free telephone helpline and website for HIV and sexual health information (enablement).

In order to increase engagement with HIV testing generally, a risk assessment was included in the enrolment survey to provide a reflective experience examining personal risk. It was theorised that this approach (persuasion) can increase motivation (reflective and automatic) [20].

Formative research also identified issues with the instructions and packaging of an earlier iteration of the kit, both of which reduced motivation to access HIVST and capability when doing so. The kit instructions were reformatted by the manufacturer before implementation began, effectively addressing this issue. This intervention component is theorised as training (the imparting of skills) in the COM-B system [20].

The broader HIVST literature identifies support issues as a key concern in HIVST delivery, a concern also identified in our formative work [8, 11, 35]. This informed the provision of enhanced support information via our kit sleeve produced in collaboration with our community advisory group co-chairs (see Additional file 1). The two-week follow-up survey was also designed to counter this concern. If a participant reported a positive result here, they were directed to a page providing information on how to find their local HIV clinic. This same page was linked to from the three-month survey. Additional information about receiving a positive result was provided on the SELPHI website.

Data handling, generation & analysis

Data pertaining to advertising reach was recorded for all adverts, then pooled according to platform. The click conversion rate (proportion of those clicking on the advert who subsequently registered) was calculated. Eligible and ineligible registrations as well as the number of successful randomisations were tabulated. Registration conversion was calculated by deriving the proportion of eligible registrations who filled in the enrolment survey and were subsequently randomised.

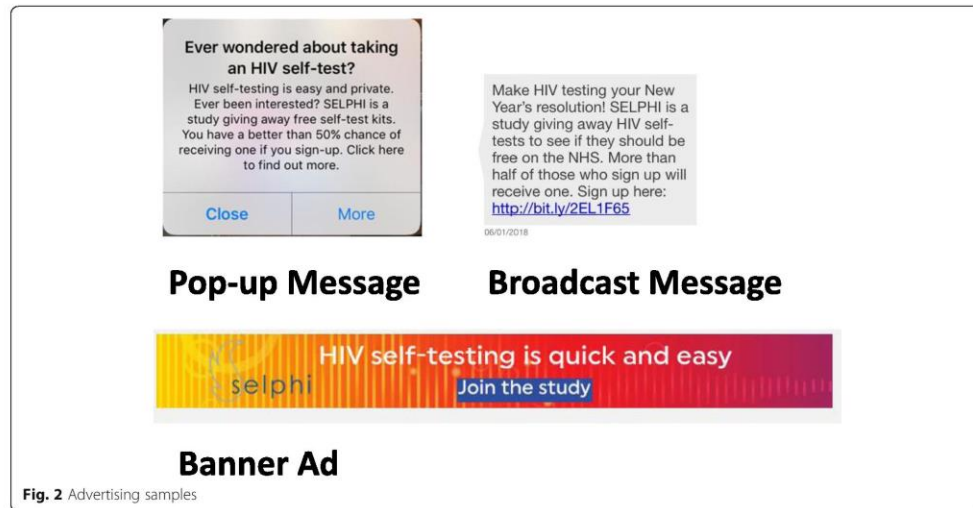
Baseline demographic and behavioural profiles were tabulated overall and by recruitment source. Variables considered were age (both continuous and 10 year bands), gender, sexual orientation, ethnicity (recoded from standard UK ethnicity codes into white, Asian, black & other), highest educational qualification (low: GCSEs and below; medium: A-levels or equivalent, higher education below degree level; high: degree or higher), HIV testing history (tested in preceding 12 months; tested more than 12 months ago; never tested), and condomless anal intercourse (CAI) in the preceding 3 months. Participant demographic and behavioural characteristics were compared between recruitment sources using chi-squared tests or a Kruskal-Wallis test for age.

Responses to the 2-week survey were summarised by proportion who completed the survey, proportion who received the kit, and the proportion who subsequently used the kit.

Kit use was summarised again from the 3-month survey alongside acceptability variables pertaining to instructions, simplicity of test performance and overall experience.

Qualitative data

A qualitative study was undertaken with 10 cis-gender MSM participants during the pilot in order to examine intervention acceptability in greater depth. Participants were sampled purposively from those randomised to



receive an HIVST kit. Sampling aimed to be diverse with regard to testing history: whether an individual had tested in the 12 months before joining SELPHI; not tested in the preceding 12 months; or never previously tested for HIV. Efforts were made to ensure sample diversity with regard to demographic features, especially education.

A semi-structured interview topic guide was developed to explore questions from formative research [11, 34], including issues related to capability, HIVST potential, anticipated responses and acceptability and mapped onto COM-B. The guide covered HIV testing history, motivations for joining and experiences of the SELPHI RCT, questions related to using HIVST and emotional responses.

Interviews were conducted over the phone or through Skype, and participants were electronically given a £30 incentive. All interviews were audio recorded and transcribed.

A thematic framework was developed for analysis, fusing the approaches described by Braun and Clarke [36] and Richie and Spencer [37]. This inductive process involved familiarisation with the transcripts and drawing out emerging themes. These themes were arranged into groups, with higher-level themes emerging from sub-themes, both organised hierarchically, and again mapped onto COM-B to better elucidate how acceptability of intervention components related to the behaviour change domains. The framework was piloted on two transcripts, refined, and applied to all remaining transcripts. We draw data from across this framework and report themes by COM-B domain for simplicity of interpretation.

Ethical approval for the RCT and qualitative sub-study were provided by MRCCTU and LSHTM (refs: 11945 & 9233/001). SELPHI is registered with the ISRCTN (ref: ISRCTN20312003). All RCT participants provided online written consent. Qualitative sub-study participants provided verbal recorded consent at the time of interview.

Results

The recruitment strategy led to the registration of 1370 eligible participants through 13 advertisements across 5 platforms, of whom 76% (1035) subsequently enrolled and reached baseline randomisation. In this pilot, 631 participants were randomised to receive an HIVST kit (BT), while 404 were randomised to not receive a kit (nBT). Of those randomised to BT, 66% (415) completed the two-week follow-up survey and 64% (405) completed the first three-month survey. Overall 78% (494/631) completed at least one of these two surveys (2-weeks or 3-months).

Recruitment strategy performance

Click conversion was highly variable, from 8% in Grindr adverts to 20% in Facebook advertising. Registration conversion ranged from 71 to 80% (mean = 76%). Cost per randomised participant varied: Hornet was cheapest (£1.66) and Grindr most expensive (£7.16). Costs were stable through this phase, with no evidence in the pilot of diminishing returns. See Table 1 for full details.

Demographic features of sample including by recruitment source

Table 2 presents baseline demographics overall and by recruitment source. Figure 3 presents the geographic distribution of randomised participants with each dot representing a group of multiple randomised participant from a source, coded by colour. The recruitment strategy engaged a range of MSM, but less so trans women. Median age was 32.1 years (IQR 25.9, 41.6). Cis-gender MSM comprised the majority (99%) of the sample, as did participants of white ethnicity (89%, $n = 921$), and MSM who identified as gay (89%, $n = 757$). Most (60%, $n = 611$) were highly educated and reported CAI within the preceding 3 months (70% $n = 726$). Sixty-four percent of participants ($n = 652$) had tested for HIV in the preceding year and 14% ($n = 141$) had never previously tested. Of never tested participants, 82 (58%) reported one or more CAI partners in preceding 3 months. Table 2 presents full details of baseline demographics.

There were significant differences in age ($p < 0.001$) and gender ($p = 0.01$) across recruitment sources, with all other variables being similar. As anticipated, Growlr recruited older participants whereas Facebook recruited younger ones. Free advertising targeted towards trans people was most effective for reaching trans participants, although numbers were small. See Table 2.

Motivations of participants (qualitative sub-study)

Table 3 presents demographic characteristics of the qualitative sub-study. All participants were cis-MSM. When discussing their motivations for joining SELPHI, participants described three predominant motivations: i) to access HIV testing; ii) desire to use a novel technology; and iii) altruism.

Accessing testing

HIVST reduced specific HIV testing barriers, thereby facilitating uptake. This was especially true for those who had never tested, and those who had not tested within

the preceding twelve months. Opportunity barriers (e.g. convenience and ease of access) and motivational barriers (e.g. confidentiality and stigma) were ameliorated by HIVST.

Sometimes people ask you what you're coming in for, [...] if you say, 'oh I'm coming for an HIV [test]' they think you're gay, or they think you're disgusting, you don't use protection, or blah, blah, blah. But it's mainly about being labelled as something you're not. (23-year old bisexual man, never tested).

Desire to use a novel technology

Just under half of those interviewed reported being motivated to join SELPHI out of a desire to experience a novel technology or because they felt SELPHI was a new kind of study. HIVST was understood to be an evolution of HIV testing methods which was appealing to some:

It's an interesting one because it's obviously very new. So you kind of think, well it's really great. [...] You just think it's something that's interesting to try because it's new technology. (20-year old gay man, tested in last 2 years).

Altruism

Altruistic motivations were reported by just over half of participants with a range of testing histories. These were predominantly secondary motivations, helping support the decision to join a trial. Motivations were related to notions of good citizenship, desire to contribute to the gay community and to science more broadly.

I find it quite interesting actually that those kinds of services are targeted towards people through Facebook because you're kind of transpiring an audience of people who might benefit from that service. And I thought,

Table 1 Advertising source data

Recruitment source	Facebook	Growlr	Hornet	Grindr	Free/organic	Total
Number of campaigns	3	1	2	5	2	13
Advert clicks	1210	1193	Not available	6666	Not available	Not available
Registered & eligible	216	120	590	406	38	1370
Registered & ineligible	32	19	109	144	9	313
Click conversion ¹	20%	12%	Not available	8%	Not available	Not available
Randomised	173	96	433	308	27	1035
Registration conversion ²	80%	80%	73%	76%	71%	76%
Spend per randomisation	£3.70	£2.59	£1.66	£7.16	£0.00	£3.68

¹Click conversion: proportion of clicks leading to a registration

²Registration conversion: proportion of eligible registrations leading to a randomisation

Table 2 Participant demographics by advert source and overall

Recruitment sources	Facebook	Growlr	Hornet	Grindr	Free/organic	Total	<i>p</i> -values
Number of campaigns		1	2	5			
N	173	96	431	308	27	1035	
Median (IQR) age (years)	29.2 (24.6, 32.8)	44.8 (34.0, 51.2)	30.8 (24.7, 39.6)	35.0 (27.6, 45.4)	33.6 (29.2, 40.0)	32.1 (25.9, 41.6)	<i>p</i> < 0.001
16–25 years	57 (33%)	7 (7%)	130 (30%)	60 (19%)	5 (19%)	259 (25%)	
26–35 years	112 (65%)	23 (24%)	149 (35%)	102 (33%)	10 (37%)	396 (38%)	
36–45 years	2 (1%)	22 (23%)	93 (22%)	72 (23%)	6 (22%)	195 (19%)	
46 years or older	2 (1%)	44 (46%)	59 (14%)	74 (24%)	6 (22%)	185 (18%)	
Gender identity							<i>P</i> = 0.001
Cis man	171 (99%)	96 (100%)	430 (99%)	305 (99%)	23 (85%)	1025 (99%)	
Trans man	1 (1%)	0	1 (1%)	2 (1%)	3 (11%)	8 (1%)	
Trans woman	0	0	0	1 (< 1%)	1 (4%)	2 (< 1%)	
Sexual Identity	<i>N</i> = 153	<i>N</i> = 72	<i>N</i> = 361	<i>N</i> = 240	<i>N</i> = 25	<i>N</i> = 851	<i>p</i> = 0.23
Gay	143 (93%)	65 (90%)	322 (89%)	204 (85%)	23 (92%)	757 (89%)	
Bisexual	8 (5%)	5 (7%)	35 (10%)	30 (13%)	1 (4%)	79 (9%)	
Other	2 (1%)	2 (3%)	4 (1%)	6 (3%)	1 (4%)	15 (2%)	
Ethnicity							<i>p</i> = 0.52
White	153 (88%)	86 (90%)	394 (91%)	263 (85%)	25 (93%)	921 (89%)	
Asian	5 (3%)	2 (2%)	13 (3%)	10 (3%)	1 (4%)	31 (3%)	
Black	3 (2%)	3 (3%)	8 (2%)	12 (4%)	0	26 (3%)	
Other	12 (7%)	5 (5%)	16 (4%)	23 (7%)	1 (4%)	23 (7%)	
HEQ	<i>N</i> = 172	<i>N</i> = 95	<i>N</i> = 425	<i>N</i> = 307	<i>N</i> = 27	<i>N</i> = 1026	<i>P</i> = 0.31
High	114 (66%)	59 (62%)	244 (57%)	174 (57%)	20 (74%)	611 (60%)	
Medium	33 (19%)	16 (17%)	94 (22%)	65 (21%)	3 (11%)	211 (21%)	
Low	25 (15%)	20 (21%)	87 (20%)	68 (22%)	4 (14%)	204 (20%)	
HIV testing history	<i>N</i> = 173	<i>N</i> = 96	<i>N</i> = 426	<i>N</i> = 304	<i>N</i> = 27	<i>N</i> = 1026	<i>p</i> = 0.09
Last 12 months	120 (69%)	54 (56%)	280 (66%)	185 (61%)	13 (48%)	652 (64%)	
12 months+	39 (23%)	27 (28%)	85 (20%)	72 (24%)	10 (37%)	233 (23%)	
Never	14 (8%)	15 (16%)	61 (14%)	47 (15%)	4 (15%)	141 (14%)	
CAI last 3 months	124 (71%)	67 (70%)	308 (71%)	206 (67%)	21 (78%)	726 (70%)	<i>P</i> = 0.58

IQR interquartile range, CAI condomless anal intercourse, HEQ highest educational qualification

“Actually that’s quite smart” *because I’m in that audience. And so, I just thought, “Yeah, I will give it a try”* (34-year old gay man, tested in last 3 months).

Kit use at two weeks and three months

Of 631 who were randomised to BT, 66% (415) completed a two-week follow-up survey. At this point, 95% (394) reported having received their kit and 83% (328) of those had used it themselves. Reasons for not using the kit were mainly that participants were planning to use it in the future (97% *n* = 64) or that participants had tested elsewhere instead (3%).

At the three-month survey, completed by 64% of eligible participants, 97% (390/403) reported having received, of

which 96% (375/390) had used the kit. This indicates that although a significant minority delayed kit use, most did use the test kit by three months.

When results from both surveys were pooled, providing data for 78% of participants, 97% (477/494) received the kit and 90% (445/494) had used it. Assuming that all those participants that did not complete either of these surveys received the kit (137/ 631), but none used it, then the lowest possible estimate of kit use was 71% (445/631).

HIVST usability and acceptability

At three months, participants reported very high HIVST usability and acceptability. Of 375 who used the kit and completed the three-month survey, 98% (362/369) found

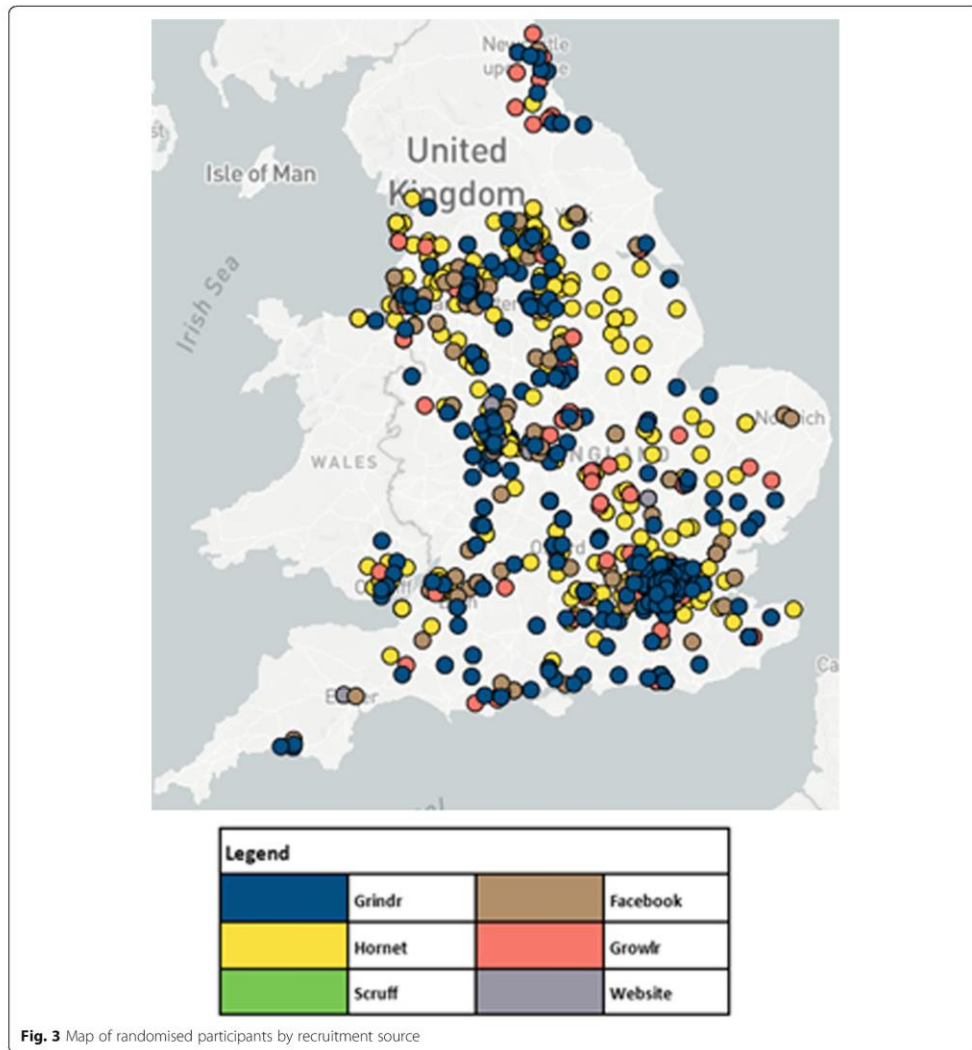


Fig. 3 Map of randomised participants by recruitment source

the instructions easy to understand, 97% (356/368) found the test kit simple to use and 97% (359/369) reported a good overall experience (Fig. 4).

All qualitative interview participants had used their kits to test themselves. Below we describe intervention acceptability as it relates to the main domains of COM-B: capability, opportunity and motivation.

Capability (physical & psychological)

Capability was the most pronounced of the three COM-B domains in our acceptability analysis, especially around test kit usability. Themes around physical capability tended to concern the instructions and using the lancet to take a blood sample. The inclusion of the two-week follow-up processes was a

Table 3 Qualitative sub-study sample

Demographic characteristics		Sample
Age	18–25 years	3
	26–40 years	6
	41+	1
Ethnicity	White	8
	Black	0
	Asian	1
	Other / Mixed	1
Sexual orientation	Gay	8
	Bisexual	1
	Other / undisclosed	1
Recency of HIV testing	< 12 months	2
	+ 12 months	6
	Never tested	2
HEQ	Low	3
	Medium	2
	High	5
Condomless anal intercourse preceding 3-months	0	1
	1	6
	2	2
	3–10	1

valued intervention element addressing psychological capability.

The instructions were generally felt to be easy to understand and interpret, although one participant felt they did not cater to a sufficiently diverse range of skills. The testing process was described as simple and the result was easy to interpret:

Very clear and it was quite obvious as well what goes where and how to do it. It was clear. The descriptions and the pictures were easy to follow (29 year-old man, undisclosed sexual orientation, tested in last 5 years).

Blood collection via the included lancet was a barrier for some. Those who had no previous experience of drawing blood with a lancet reported concerns about their capability to collect their own sample, although all felt with experience this would no longer be an issue.

I actually don't like getting my finger pricked [...] so I was most worried about the finger prick, [...] so for me that was the most difficult thing, and then I wasn't sure if I was getting enough blood [...] but once I pricked the finger and I collected the blood then it was pretty straightforward (31-year old gay man, tested last 4 weeks).

Capability (psychological) also emerged when discussing the support components of the intervention. Participants generally felt that the supporting information provided was adequate and did not diminish acceptability of the intervention.

What I think relieved me of most of the anxiety was actually the kit included a card saying, at the end, if you are diagnosed with HIV then not to worry, here's what you can do. A, B, C. And if you're not, great. A, B, C. And I think the steps on that card saying, if you are, step one, step two, step three, it helped to relieve some of the uncertainty of what might happen if the test came out positive. (16-year old gay man, not previously tested)

Opportunity (physical & social)

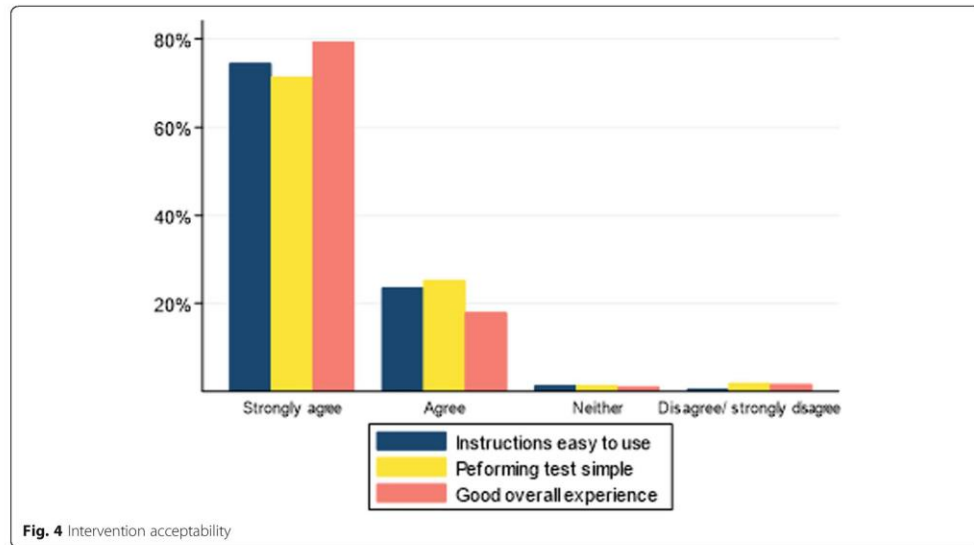
Themes related to acceptability of the entire intervention package were primarily related to opportunity (physical and social). For participants located in areas underserved by HIV testing opportunities, the kit ameliorated geographic barriers. Individuals who faced psychosocial barriers to testing felt HIVST gave them increased privacy around testing, enhancing the acceptability of the intervention.

I'm quite a private person. I like to keep certain aspects of my life to myself and sometimes people might be bothering you to talk about things where you think, "Well, I'm not there yet." [...] Whereas I can let that sink in and think, "Right, okay, now I'm ready to go and do whatever I need to do or talk to whoever I need to talk to." (34 year-old gay man, tested more than 12 months ago).

Motivation (reflective & automatic)

The dislocation of HIVST from care pathways affected acceptability through motivational channels. Despite high acceptability related to the follow-up provided, HIVST as a concept was perceived to be associated with increased anxiety relative to other testing opportunities. This was largely due to concerns about conducting a test alone, and the potential separation of initial "diagnosis" from established care pathways.

[...] I think slightly the kit at home [makes me more anxious]. It's almost because it's literally taken out of your hands when you go to an STI clinic. So you don't have to think about it as much. It's something done to you. (29-year-old gay man, tested within last 5 years)



One participant delayed using the kit due to anxiety and instead visited a GUM clinic, saving his HIVST for use at a later date.

The 15 min interval between conducting the test and reading the result was described as an exceptionally anxious time, especially for those who had tested due to risk.

I was feeling nervous actually because I was thinking what about if it does come back positive. That was quite like a bit of a head scratcher, waiting for the 15 minutes, and then when 15 minutes were up and I looked at the result and I was like, oh, you know it was negative so I thought right, but then I thought well yeah, maybe I shouldn't have worried that much, but you can't help it (23-year old bisexual man, not previously tested).

All participants described significant relief when reading a negative (non-reactive) result. A minority, who had more experience of HIV testing, felt that HIVST was associated with less anxiety than testing methods relying on laboratory-run tests due to the relative immediacy of results.

Discussion

Through this mixed methods study we assessed the feasibility of recruiting MSM and trans people to the pilot phase of the online SELPHI RCT and the acceptability of

HIVST, focusing mainly on the acceptability of the intervention and the usability of the kit.

Advertising performance varied according to platform by click and registration conversions and, crucially, cost. The pilot sample was predominantly white, well-educated, gay identified cis-MSM who reported CAI in the 3-months preceding and who had tested for HIV in the preceding 12-months. The pilot struggled to recruit significant numbers of trans people, particularly trans women. Our recruitment did however, reach a range of participants across demographic groups. Platforms recruited participants of a similar demographic and behavioural profile except when considering age and gender identity.

Sixty-six percent of participants completed the two-week follow-up, and 64% the three-month survey. Overall 78% of participants randomised to receive HIVST completed at least one of the two. Kit use was high, increasing from 86% at two-weeks to 96% at three months. The lowest possible estimate of kit use was 71%, assuming that all those not completing the follow-up surveys did not use their kits, which is unlikely. The kit was considered usable and the intervention was acceptable across the three dimensions interrogated (ease of use of instructions, test simple to perform and overall experience). Qualitative data provides nuance, with some participants reporting difficulty using the lancet. The relationship between HIVST and anxiety was ambiguous; individuals thought it could increase or ameliorate anxiety depending on previous HIV testing experience.

Our recruitment strategy was successful in reaching a group at risk of HIV who had not HIV tested previously, with 58% of never tested MSM reporting CAI in the 3-months preceding their enrolment. This is a key group with clear HIV prevention needs who should be a primary target for new testing interventions. The sample recruited in the pilot was comparable to previous convenience samples of MSM, as well as the ethnic make-up of the UK [38, 39]. This indicates that this type of recruitment strategy is capable of reaching a group broadly representative of UK MSM in terms of ethnicity. A group which is underrepresented when compared to national statistics is MSM of Asian ethnicity [39]. This could be due to specific privacy barriers to a postal delivery HIVST service experienced by this group, outlined in formative work [11]. Further, our sample reported similar levels of never testing (14%) to other convenience samples of UK MSM (other recent samples range between 8 and 25%), although more participants in the SELPHI pilot had tested in the preceding 12 months [38].

When compared to HIVSS return rates in the UK, participants in the pilot made use of their HIVST kits more frequently, lessening missed opportunities for testing. While with HIVSS only 55% of samples are returned for processing [14, 15], 95% reporting kit use at three months and at least 71% of kits were used overall. At this modest scale, HIVST appears to outperform HIVSS.

Acceptability and ease of use was very high, and indeed higher than in many other studies with MSM [8]. This is not without precedent, with similar levels of acceptability and reported ease of use observed in other settings [13, 40, 41]. These studies however provided oral fluid HIVSTs, which may have benefits in terms of simplicity (though have lower sensitivity and specificity) over kits which require self-collection of a whole blood sample [8, 42].

Qualitative accounts of acceptability focused on COM-B domains related to capability more than opportunity or motivation [20]. This could signify that when engaging with this novel testing technology, individuals are often doing so with questions about their own skills and capacity. These concerns may decrease with increased experience with HIVST. Indeed, using the lancet was described as difficult for many, although they managed to use it successfully despite this, and all expected this would improve with experience. An additional focus of enquiry for future study is the experience of those who have reactive tests (both confirmed as positive and subsequently confirmed negative) to better understand their experiences, support needs and any potential harms arising.

A number of changes to the trial design were made as a result of this pilot. The attrition between registration and

enrolment surveys (24% of participants overall) posed significant recruitment challenges. For the main roll-out of the RCT the language in the email linking the two surveys was made more motivational, specifically highlighting altruism. In addition, all messages used in the roll-out were designed to more clearly emphasise trans eligibility. In response to the increased costs generated by attrition and to take advantage of advertising efficiencies at larger scales, national rather than regional advertising campaigns were prioritised to increase recruitment volumes. Advertisement messages were also altered, with increasing use of motivational elements. In efforts to increase survey completion rates, the number of reminders was increased from 2 to 3, and delivery times were staggered at different times of the day to account for a variety of employment patterns. These changes were supported by a PPI engagement exercise with SELPHI participants.

Strengths and limitations

This is the first study in Europe to assess the feasibility of recruiting to an online HIVST RCT. A strength of this pilot is that the design perfectly mimics the full trial. Nevertheless, some limitations are noted. Recruited costs per participant should be treated with some caution. For one, the possibility of being randomised to the no baseline HIVST/SoC arm likely made costs per participant significantly higher than delivering free HIVST to all. In addition, recruitment costs in this pilot phase did not show evidence of diminishing returns per participant randomised, meaning that overall cost per participant could become much higher when recruiting larger numbers.

Test kit usability and intervention acceptability were extremely high when compared to other recent studies [8]. A possible explanation is the informed consent procedures in place provided a great deal of information about what a participant could expect from the study and the kit itself in a level of detail that a service might not include.

This pilot struggled to recruit large numbers of trans people compared with cis gender MSM. In addition, sexual practice among MSM is diverse. As only MSM who report lifetime anal sex were eligible for inclusion our sample may not be fully representative of the diversity in MSM sexual behaviour, as between 8 and 19% have never had anal sex [43–45]. This issue may be an especially pronounced for trans MSM and may have contributed to the low numbers of trans people recruited in this pilot phase.

Finally, while the qualitative data is illuminative, interview were conducted with a small group of participants. The data presented here should be understood as highlighting the diversity of facets of kit usability and intervention acceptability.

Conclusion

Recruiting to this online HIVST pilot RCT was feasible, the intervention was acceptable to participants, and the kit distributed had high reported usability. Kit use was high, outperforming previous HIVSS projects in the UK. This pilot led to a number of changes to the implementation of the RCT, including national advertising and enhancing efforts to boost trial retention. Further research investigating the experiences of trans people is necessary in order to optimise future intervention approaches for this group.

Additional files

Additional file 1: Kit sleeve design. (JPG 519 kb)

Abbreviations

Apps: Geospatial social/sexual networking application; CAI: Condomless anal intercourse; HIVSS: HIV self-sampling; HIVST: HIV self-testing; MSM: Men who have sex with men; PPI: Participant and public involvement; RCT: Randomised controlled trial; SoC: Standard of care

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Authors' contributions

Funding: AJR & ANP. Study design and conceptualisation: AJR; SMC; ANP; DTD; FCL; FMB; AS; MG1; PW; LMC; MG2; TCW. Qualitative data collection and analysis: TCW; PW; AJR; FMB. Statistical analyses: TCW; LMC. Interpretation: AJR; SMC; ANP; DTD; FCL; FMB; AS; MG1; PW; LMC; MG2; TCW; DW; JH; RP; CB. Manuscript drafting: TCW; PW; AJR. Manuscript editing: AJR; SMC; ANP; DTD; FCL; FMB; AS; MG1; PW; LMC; MG2; TCW; DW; JH; RP; CB. All authors have read and approved this manuscript.

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Availability of data and materials

RCT data will be locked and archived at the MRC Clinical Trials Unit. Requests for controlled access should be sent to mrctu.selphi@ucl.ac.uk. Qualitative data is not available due to its sensitive and potentially personally identifiable nature.

Ethics approval and consent to participate

Ethical approval for the RCT and qualitative sub-study were provided by UCL Research Ethics Committee (ref. 11945) and LSHTM Observational Research Ethics Committee (refs 9233/001). SELPHI was prospectively registered with the ISRCTN on 10/08/2016 (ref: ISRCTN20312003). All participants provided informed consent ahead of their involvement with the RCT and qualitative sub-study. Due to the remote nature of these studies, RCT consent was on-line written consent; sub-study consent was verbally recorded at the beginning of each interview.

Consent for publication

Not applicable.

Competing interests

All authors declare no competing interests.

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3.3 Evaluative phase

Following the analyses conducted for in paper 3, it was clear that HIVST implementation was feasible and that the intervention was acceptable and usable for a range of MSM. Full trial implementation proceeded as planned, and the RCT recruited its full sample of 10,135 MSM and trans people in 13 months. However, additional questions about HIVST experiences remained relevant for both the trial and for the HIVST literature more broadly.

Although it was clear the intervention was acceptable, the large sample recruited across England and Wales provided the opportunity to further investigate the dimensions of acceptability and qualitative outcomes for trial participants. While there were key issues emerging with the lancet and blood draw (outlined in paper 3), the experiences of a wider range of individuals was important to ensure no additional areas would pose a challenge to future use. Experiences of adverse events had not been captured, and we had no evidence regarding how people perceived repeated HIVST use, as provided in intervention B. This was felt to be a key piece of evidence supporting how HIVST could be implemented after SELPHI. This underlined the importance of a qualitative evaluative phase in which we could seek additional nuances regarding these key questions.

In order to do this, I expanded the topic guide used in the 10 initial interviews in the pilot phase to collect data on a broader range of topics (updated topic guide in appendix 7). Deeper understandings of experiences of using the kit was required, so I expanded focus in this second part of the study to look more closely at issues with the technology itself and included a kit demonstration to serve as a reminder of the testing process. In order to add context to many of the domains of enquiry which will be answered in the RCT, I included in-depth explorations of HIVST impact on STI testing, and looked closely at support needs and the experiences of those with a positive HIVST result. This topic guide exactly mirrored participants' accounts of their journeys through the SELPHI intervention, providing a rich dataset exploring key issues with each component in the sequence they first encountered them.

Recognising that local context will shape use, interviews were conducted in a range of geographical areas across both countries. Interviews were conducted face-to-face and remotely. For interviews outside London I used a mix of audio and video calling, with the latter being used for the kit demonstration section. I also travelled to Cardiff and Newcastle to conduct clusters of interviews face-to-face with MSM in those cities.

It was an aspiration of mine to test the coherence of the BCW and COM-B in relation to HIVST interventions, but at this stage it was not clear how I might do this. This analysis took shape largely by chance, as I outline later.

In total I conducted an additional 27 interviews during this phase of data generation. This sample was combined with the sample from the pilot for a total of 37 interviews in MSM who had received and used HIVST kits from across baseline (n=27) and repeat testing (n=10) arms.

3.4.1 Paper 4: HIV self-testing intervention experiences and kit usability: results from a qualitative study among men who have sex with men (MSM) in the SELPHI RCT in England and Wales



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Please note that a cover sheet must be completed for each research paper included within a thesis.

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Student ID Number	1603113	Title	Mr
First Name(s)	T Charles		
Surname/Family Name	Witzel		
Thesis Title	HIV self-testing for men who have sex with men (MSM) in England and Wales: a multi-method study of self-testing intervention development and evaluation		
Primary Supervisor	Peter Weatherburn		

If the Research Paper has previously been published please complete Section B, if not please move to Section C.

SECTION B – Paper already published

Where was the work published?	HIV Medicine		
When was the work published?	06/01/2019		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion			
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Where is the work intended to be published?	
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SECTION D – Multi-authored work


For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I designed the study, produced the sampling frame, produced the data collection instruments, recruited participants, conducted all interviews, carried out the analysis, wrote the results and made revisions.
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SECTION E

Student Signature	
Date	03/12/2019

Supervisor Signature	
Date	03/12/2019

HIV self-testing intervention experiences and kit usability: results from a qualitative study among men who have sex with men in the SELPHI (Self-Testing Public Health Intervention) randomized controlled trial in England and Wales

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Objectives

SELPHI (HIV Self-Testing Public Health Intervention) is the largest randomized controlled trial (RCT) of HIV self-testing (HIVST) in a high-income setting to date, and has recruited 10 000 men who have sex with men (cis- and transgender) and transgender women who have sex with men. This qualitative substudy aimed to explore how those utilizing self-tests experience HIVST and the implications for further intervention development and scale-up. This is the first qualitative study in Europe investigating experiences of HIVST among intervention users, and the first globally examining the experience of using blood-based HIVST.

Methods

Thirty-seven cisgender MSM SELPHI participants from across England and Wales were purposively recruited to the substudy, in which semi-structured interviews were used to explore testing history, HIVST experiences and intervention preferences. Interviews were audio-recorded, transcribed and analysed through a framework analysis.

Results

Men accessed the intervention because HIVST reduced barriers related to convenience, stigma and privacy concerns. Emotional responses had direct links to acceptability. Supportive intervention components increased engagement with testing and addressed supportive concerns. HIVST facilitated more frequent testing, with the potential to reduce sexually transmitted infection (STI) screening frequency. Substudy participants with an HIV-positive result ($n = 2$) linked to care promptly and reported very high acceptability. Minor adverse outcomes ($n = 2$; relationship discord and fainting) did not reduce acceptability. Ease of use difficulties were with the lancet and the test processing stage.

Conclusions

Intervention components shaped acceptability, particularly in relation to overcoming a perceived lack of support. The intervention was broadly acceptable and usable; participants expressed an unexpected degree of enthusiasm for HIVST, including those with HIV-positive results and individuals with minor adverse outcomes.

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Introduction

Reducing the prevalence of undiagnosed HIV infection is a key public health goal [1,2] enshrined in the Joint United Nations Programme on HIV/AIDS (UNAIDS) 90-90-90 targets; 90% of people with HIV infection diagnosed, 90% of people diagnosed on treatment and 90% of people on treatment achieving virological suppression [1]. The UK has been successful in this regard, with London the first city globally to achieve 95-95-95 [3]. While the HIV incidence in England is falling in gay men, expanding testing remains a priority, with prompt diagnoses and linkage into clinical services for those testing positive [4,5]. Despite the British HIV Association recommending annual testing for men who have sex with men (MSM) (or more frequently if at ongoing risk) [6], up to 25% of gay men and bisexual men have never tested and approximately half have not tested in line with these guidelines [7,8].

HIV self-testing (HIVST) is an approach whereby an individual uses a rapid diagnostic test and interprets their own result. HIVST has the potential to increase testing by providing convenience, privacy and accessibility [9,10]. The World Health Organization (WHO) recommends HIVST as a testing option [11].

HIV self-testing was legalized in the UK in 2014, with the first test coming to market in 2015 [10,12,13]. Widespread free public provision of HIVST has yet to occur in the UK. Pilot and demonstration projects have delivered a limited number of free tests, mainly to MSM and black African people [14–16].

Acceptability studies have focused on *potential* users of HIVST, with limited numbers of actual self-testers included in these formative studies [10,13,17]. Evidence of actual user experience from the UK and from Europe more broadly is limited [18].

SELPHI (HIV Self-Testing Public Health Intervention) is the largest randomized controlled trial (RCT) of HIVST in a high-income setting to date. SELPHI has recruited 10 000 MSM (both cisgender and transgender) and transgender women who have anal sex with men. SELPHI has two randomizations and two versions of the primary intervention. In randomization A, the 10 000 participants were allocated at a ratio of 60:40 to a single HIVST (intervention A) at baseline versus standard of care (SoC) (signposting to free testing services). In randomization B (which occurred 3 months post enrolment), eligible participants who had been allocated to HIVST in randomization A, remained HIV-negative and reported condomless

anal intercourse (CAI) in the preceding 3 months were randomized 50:50 to the offer of 3-monthly repeat HIVST with test reminders (intervention B) versus SoC. SELPHI has recruited from geolocation hook-up applications (apps) and from social media. All RCT data collection was online, and blood-based test kits (BioSure (UK) Ltd, Nazeing, UK) were delivered by post directly from the test manufacturer. To use the Biosure™ kit, users draw a blood sample using a capillary lancet, collect the sample in a test stick, push the test stick into a buffer pot, then wait 15 min before interpreting the result using included instructions. For the SELPHI protocol, see Gabriel *et al.* 2018 [19].

The interventions included multiple components which worked together to support uptake of HIVST, continued engagement with testing more broadly and linkage to care if positive (see Fig. 1). Intervention A began with targeted recruitment through adverts on apps and social media designed to increase motivation to test and reduce perceived capability barriers; then a baseline risk assessment (enrolment survey), which collected demographic and behavioural data prior to randomization A in which participants were allocated to being offered an HIVST kit or not. The HIVST kit was then delivered by post directly by the manufacturer. Following kit delivery a 2-week follow-up survey was sent via email which asked for confirmation of receipt and use of the kit, the result and provided linkage to care information for those with positive results. All those randomized to receive HIVST in intervention A were entered into randomization B (provided they met eligibility criteria outlined above) and were randomized to SoC or to intervention B, in which HIVST kits were offered 3-monthly for up to 2 years. They received a test reminder with an embedded risk assessment which was delivered every 3 months, with provision of a further test if desired with an additional follow-up survey 2 weeks afterwards (see Fig. 2). Both interventions were modelled on what would probably be provided in routine online provision of free kits [14,15,20].

This SELPHI substudy addresses critical questions surrounding intervention acceptability and kit usability. The substudy aimed to explore the experience of utilizing HIV self-tests and the implications for further intervention development and scale-up. The specific objectives were to understand motivations for accessing HIVST; to explore intervention acceptability; and to characterize experiences of kit use.



Fig. 1 The SELPHI (Self-Testing Public Health Intervention) intervention A.

Methods: This qualitative substudy involved 37 semi-structured interviews with cisgender MSM within the SELPHI RCT. The first 10 interviews took place in May 2017 during the pilot phase, with the remaining 27 conducted during the main trial between January and October 2018.

Interviews were conducted remotely ($n = 17$) or face to face ($n = 20$) depending on location, with a geographical spread of participants across England and Wales. We recruited 25 participants who received intervention A only, 10 who received intervention B and two who reported a positive result (both from intervention A). Purposive sampling ensured diversity in HIV testing experience, age, highest educational qualification (HEQ) and ethnicity. Potential participants who consented to in-depth interviews were approached by the lead author



Fig. 2 The SELPHI (Self-Testing Public Health Intervention) intervention B.

who provided details about the study and scheduled interviews. The face-to-face interviews were conducted in Cardiff and Newcastle to increase the diversity of experience of levels of gay community and social opportunity, as well as smaller scale HIV/STI service infrastructure. Participants provided written or verbal recorded consent and were compensated £30 for their involvement. Only cisgender MSM were included, as a study exclusively with transgender participants is ongoing [21,22].

The topic guide covered testing history, engagement with SELPHI, experience of the interventions and preferences for future HIVST interventions. It was piloted with two participants, refined, and used for a further eight

interviews. Following this, additional questions were added to explore intervention acceptability in greater depth, including a demonstration of the kit and a revisiting of the supportive components of the interventions.

Ethical approval was granted by University College London (UCL) (ref: 11945) and the London School of Hygiene and Tropical Medicine (LSHTM) (ref: 9233/001).

Interviews, all conducted by the lead author, were audio-recorded and transcribed verbatim. Data analysis followed a Framework approach [23,24]. Our framework drew from theorized key components of intervention acceptability from formative work, the wider literature and systematic reviews [10,17,25]. This framework was piloted, refined and applied to all transcripts by the lead author.

Results

The sample of 37 men was diverse with regard to age, education, previous HIV testing history, and number

Table 1 Participant demographic characteristics

Demographic characteristic	Number of participants
Age	
16–25 years	11
26–40 years	16
≥ 41 years	10
Ethnicity	
White	29
Black	3
Asian	2
Other/ mixed	3
Sexual orientation	
Gay	24
Bisexual	5
Don't use a term	1
Undisclosed	7
Recency of HIV testing	
Never tested	7
≥ 12 months	17
< 12 months	13
Highest educational qualification (HEQ)	
Low [†]	7
Medium [†]	11
High [‡]	19
Number of CAI partners in preceding 3 months	
0	12
1	14
2–3	7
4–10	4
> 10	0
HIVST outcome	
Positive	2
Negative	35
Intervention	
A	27
B	10

CAI, condomless anal intercourse; HIVST, HIV self-testing.

[†]GCEs and below.

[‡]A-levels or equivalent; higher education below degree level.

[‡]Degree or higher.

of CAI partners (Table 1). Thirty-five reported receiving a negative self-test result and two had received a positive result from their self-test. Here we outline two broad areas: experience of the HIVST intervention (focussed on acceptability), and experience of using the kit (usability).

Intervention experiences

This section relates to participant experiences of the overall intervention. First, we consider the appeal of the interventions, including initial motivations to access HIVST. Secondly, we discuss the acceptability of the psychosocial components embedded in the surveys, and then we discuss support structures, and finally outcomes.

Appeal, attraction and engagement

Study adverts were felt to be relevant, engaging and straightforward. These were praised for using simple language and for highlighting that the intervention was free, that the kit was simple to use and that the testing process was quick. For others, the adverts simply highlighted an attractive, more convenient testing opportunity. Those who did not report significant appeal based on the advert usually reported that the advert served as a prompt when they were considering testing anyway.

For those testing in response to a sexual risk event, HIVST provided a new way to access testing, overcoming personal barriers related to stigma and privacy concerns. This was most pronounced for those who had not previously tested, or those disengaged from testing services.

Yes, it was something new, it was giving me the ability to do it in private so I didn't have to go somewhere I might bump into somebody who knows me. You know clinics, there's a stigma there. And yes I think it was just the ease of it, the fact that I could do it at home in private on my own but I would get an answer, a yes or a no. (39 year-old gay man, not previously tested)

Neither of those who received a positive result had previously tested for HIV. They cited barriers related to stigma, geography and inconvenient clinic hours, but felt these issues were resolved by the opportunity to self-test.

For men testing for reassurance or as part of routine practice, HIVST offered an increase in convenience and a reduction in opportunity cost, overcoming barriers related to inconvenient clinical opening times, poor service quality and distance to services.

An important additional motivation to seek HIVST was curiosity about a new technology. This was often a primary motivator, particularly common among those who had recently tested via another method, but was also

reported as a secondary motivator for MSM who had not previously tested for HIV.

The appeal of HIVST was mediated by emotional responses. Self-testing was perceived as generating either more or less anxiety, relative to other testing methods, primarily based on testing history and motivation for testing. For some infrequent testers with concerns about health care professionals, the personal control provided by HIVST decreased anxiety by placing them at the centre of their decision-making.

It [getting the result] felt the same as the other times with my doctor... my doctor telling me, except a lot more comfortable [...] because I then was the one... I'm now in control. And I suppose the same would've been if it had have been a positive result. I would have been the one in control of going to my doctor and saying, 'I've gone ahead and done this. It's come back like this and I need you to investigate'. (49 year-old man, undisclosed sexual orientation, tested in preceding 5 years)

Those with more routine experience of testing tended to describe self-testing as helpful for reducing anxiety by facilitating testing in a comfortable setting. For some with less HIV testing experience and men who had recent risk, HIVST amplified emotional responses because of the solitary nature of its use.

Risk, reflection and recognition

The supportive elements of the interventions (the behavioural questions in the survey, 2-week follow-up and testing reminders for those receiving multiple HIVST kits through intervention B) were generally praised for increasing engagement with testing. The follow-up after receiving a test provided a sense of connection to the trial, and an expectation that supportive action would be taken if a result was positive.

For participants receiving the offer of repeat HIVST, the testing reminders and risk assessments embedded in surveys provided an opportunity for reflection about recent sexual activity. This reflective experience was described either in neutral or positive terms; none felt it was not worthwhile or that it created significant discomfort.

Just made me think a bit harder of the past three months, what I'd been doing. It didn't make me feel anything like I shouldn't be asked this [...] it just made me think about all the movement I had in the last three months. (27-year-old gay man, tested in preceding 6 months)

Care, support and follow-up

This theme relates to the supportive structures within the intervention which facilitated uptake, including

accompanying information describing what to do in the event of a positive result and the 2-week follow-up survey.

The support structures were largely considered appropriate and in line with expectations. For those with concerns about the dislocation of testing from care, these structures helped to increase intervention acceptability.

I liked the fact that when I opened it, the first thing was the card that fell out and it was, kind of, like, one side was, 'If you're negative, great, continue to test, continue to use condoms, continue to have safe sex,' and then the other side was, 'If you're positive don't worry, we can help you,' etc. So that was quite comforting. (35-year-old gay man, tested more than 12 months ago)

Rather than source support through the intervention structures, most individuals with emotional support needs (regarding both positive and negative results) looked to their social networks, drawing on partners, family and friends. Both men who reported a positive result first spoke to a family member or friend who supported them in seeking confirmatory testing at a clinic.

Impacts, outcomes and expectations

Outcomes following testing varied, especially in relation to HIV testing history. Changes in testing behaviour appeared most pronounced among those with less testing experience. For these men, the interventions dramatically increased accessibility, facilitating testing when they would not have tested otherwise. This group also described reductions in barriers to other testing services, partly through an easing of anxiety facilitated by familiarity with testing and partly through increased engagement with services in general.

For many, HIVST increased testing frequency by facilitating testing between clinic visits. This was most pronounced amongst those receiving intervention B, but was described by individuals who received only a single test from intervention A.

Those who did not have well-established testing patterns felt that they were likely to entirely replace clinic HIV tests with self-tests as their needs were better met through this means of testing, thus potentially reducing STI testing frequency.

Well, [my behaviour since joining SELPHI] has already changed in a sense that I'm now getting tested every three months, [...] even if I don't receive one through you guys, I can buy it. (27-year-old bisexual man, tested in preceding 6 months)

Both men who received a positive result linked to care within 24 h. One had a very low CD4 count indicative of a long-established infection. Receiving positive results through self-testing did not diminish intervention acceptability, with both stating self-testing had 'saved their life.'

It's [HIVST] stopped me transmitting it to other people and saved my life. So yes, even though I got my bad news, it's been a very positive experience. I would recommend anybody do it, anybody who has got concerns, like I had, about going to clinics and stuff like that, get yourself a self-test. (49-year-old gay man, not previously tested, positive result)

Two participants reported negative outcomes related to the interventions. An individual who was receiving repeat self-tests shared a test with his partner whose family found it, prompting relationship discord. Another participant fainted on using the lancet to draw blood. These experiences did not diminish acceptability; both men stated they would be happy to use self-tests in the future.

Test kit usability

This section relates to men's experiences using the actual kit. First, we explore capability concerns and test errors, then the emotional impact of using the kit. Finally, we describe participant beliefs regarding sensitivity, specificity and accuracy.

Capability, cognition and ease of use

For individuals engaging with HIVST, questions around their own capacity to perform the test were commonplace. The majority used the written instructions provided, with a minority accessing online videos.

While most found using the test straightforward, issues with the lancet were common. A further area of concern for many was pressing on using the test stick into the pot containing the buffer solution. The information provided was felt not to be sufficiently clear, exacerbating confusion about how far to push the test stick in, and concern about breaking it.

This was the confusing part because this is a square and this is round. So I wasn't sure if this was supposed to go there. And looking at this just at first, you are not sure because, okay, this is round, this is a square. And it doesn't fit instinctively there. So this was where I was confused. This was the part that give me a lot of grief. (40-year-old gay man, tested in preceding 12 months)

One individual accidentally released the lancet early, but was able to draw blood by using the needle to prick himself. Two individuals were unable to complete their first test, both because of confusion with how to insert the test stick into the buffer pot. Both sourced a replacement kit from the study team.

Participants universally felt that, with increased experience, these issues would not recur. This was also confirmed by participants receiving repeat HIVST kits who reported that increased use enhanced confidence and competence.

Anxiety, relief and emotional engagement

The 15-min interval between completing testing steps and reading the result was nearly universally described as a period of heightened anxiety. This feature of the test provoked emotional responses beyond that experienced waiting for results through other testing opportunities (e.g. at sexual health clinics) for nearly all participants, even those who felt HIVST reduced anxiety overall.

The level of anxiety experienced varied according to testing history and the self-assessment of risk: those with more testing experience who were testing out of routine tended to be less anxious. For individuals testing following a risk event and for those without established routines (even if low risk), this wait generated profound feelings of vulnerability.

When I start doing the test, no [I didn't think it could be positive]. When I'd done the test and then I'm waiting I'm convinced I've got everything from Ebola to SARS to HIV. So then it's not until I actually get the result that I'm confident again. But there's always just that creeping panic that you could have something, because you don't know. (25-year-old gay man, tested in preceding 12 months)

Unsurprisingly, individuals with positive results described the experience as deeply upsetting, but also described the accompanying support information as being appropriate for their needs. Their emotional responses did not diminish intervention acceptability as both expressed great enthusiasm for HIVST.

Sensitivity, specificity and beliefs about accuracy

Participants with more testing experience sometimes had questions about HIVST accuracy. This concern was typically about completing the test as well as questions related to reliability of the technology. These concerns were usually dispelled through the support information or upon receiving a negative test result.

While the vast majority of those with negative results trusted that the test outcome was valid (with the exception of one who had made significant test errors), both men with positive results had significant doubts as to whether the result was correct. This was a primary motivator to seek confirmatory testing.

Honestly I was 50/50 on it [accuracy] because I don't know, I just thought shit, what if I have [HIV] [...] it's not 100% accurate and then I didn't know. I wanted to get a proper full-on test. I know this is a proper test as well, but I just wanted a doctor doing it. (21-year-old gay man, not previously tested, positive result)

Discussion

This study explored key dimensions of HIV self-test intervention acceptability and kit usability among 37 cisgender MSM drawn from a large HIVST RCT. Self-testing had different appeal depending on previous testing history and their motivations for accessing testing. In nearly all cases, HIVST reduced barriers to testing, which related to either stigma and privacy issues, or convenience and opportunity cost. Supportive intervention components increased testing engagement more broadly. The intervention support structures were adequate, although most support was drawn from social networks. The kit itself was well regarded, with few significant errors. Concerns regarding kit reliability typically resolved following a negative result, but persisted for those who tested positive. Both participants with positive results linked to care within 24 h.

Those without established testing routines and individuals with recent risk concerns found HIVST to induce anxiety, especially the 15-min interval between using the test and reading the result. This feature produced profound feelings of vulnerability, beyond what would be experienced while testing through a different method. For others, HIVST reduced anxiety relative to other models by putting them in control of the testing process. This underlines the central role of anxiety in HIV testing; anxiety may produce a key testing barrier for many regardless of their risk and testing history, although perhaps at different stages in the process depending on the testing technology and setting.

These findings underline the importance of intervention design in service delivery and the value of formative work with intended beneficiaries. Each component of both interventions (the advertisements, risk assessments, support components and the kit itself) had a specific relationship with acceptability, in most cases overcoming documented HIVST barriers such as lack of support [10,13,17,25].

This qualitative study demonstrates the potential for HIVST to increase testing frequency for frequent and infrequent testers, in line with existing RCT evidence [26,27]. Infrequent testers may access sexual health clinics less often, however, potentially reducing STI testing in this group, also consistent with existing evidence from the USA but contradicting an Australian study [26,27]. Offering bacterial STI self-sampling alongside HIVST may ameliorate this. The final RCT results will provide crucial evidence regarding this outcome.

Given that those new to testing frequently accessed the intervention in response to risk, it is especially important that clear information regarding test window periods is provided for those with less testing knowledge. The significant distrust of their results reported by both participants with a positive result underlines the importance of clear, supportive information providing an accessible pathway into clinical care no matter the geographical location.

Finally, minor adverse outcomes (fainting; relationship discord) were reported by two participants. Further research into potentially harmful outcomes is required to develop strategies to ameliorate these. This is particularly important given concerns about the potential for harm arising from HIVST despite the lack of evidence to date [10,12,28–30].

Strengths and limitations

To our knowledge, this is the first European study that has examined self-testing intervention acceptability solely among actual HIVST users and will be useful for those working with similar groups in similar health care settings. Nevertheless, some limitations are noted.

The majority of our participants reported negative results. Thus, the data pertaining to those with positive results cannot be considered representative of the experiences of others.

All participants chose to participate in an RCT that delivered an HIVST to an address (residential or otherwise) and that collected substantial amounts of personal data, and all of them consented to being interviewed. This sample, therefore, potentially does not include those with the greatest concerns surrounding disclosure of sensitive information about themselves, a group hypothesized to have a heightened need for HIVST [10,25].

Conclusions

This study explored how those using self-tests experience HIV self-testing and implications for intervention development and scale-up. Previous testing experience was

key in shaping intervention acceptability and test kit usability. Men were motivated to access the intervention because HIVST reduced specific HIV testing barriers related to convenience, stigma and privacy concerns. The intervention was acceptable, with participants expressing an unexpected degree of enthusiasm for self-testing, including those with positive results and individuals who experienced adverse events.

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Author contributions

RCT design: MMG, SMc, AJR, DTD, ANP, FCL, AS, MGaf, LM, FMB, TCW and PW. Patient and public involvement: RP. RCT implementation: MMG, SMc, AJR, DTD, YCM, ANP, FCL, AS, MGaf, LM, FMB, TCW, PW, DW and JH. Substudy design: TCW, PW, AJR, FMB, AB, SMc and CB. Data collection: TCW. Instrument design: TCW, PW, AB, FMB and AJR. Analysis: TCW. Drafting: TCW, AB and PW. Conceptual input: TCW, AB, PW, AJR, FMB, SMc, DTD, ANP, FCL, AS, MGaf, MMG, FMB, CB and RP. All authors have approved the final manuscript.

Ethical approval

Ethical approval for the RCT and qualitative substudy was provided by UCL and LSHTM (refs: 11945 and 9233/001). SELPHI was prospectively registered with the ISRCTN registry on 8 October 2016 (ref: ISRCTN20312003). All participants provided informed consent ahead of their involvement in the RCT and qualitative substudy.

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Following this analysis, which again found high intervention acceptability, it became clear that groups of participants had highly divergent experiences of the intervention. These first emerged when looking closely at the role of emotion in HIVST; groups of MSM had quite different emotional responses to the technology based on their testing histories and their motivations for engaging with SELPHI. I felt that these might be amenable to further exploration and perhaps a useful tool through which to gain an understanding of the way the intervention functioned for specific groups. I developed a typology of self-testers using these organising principles. How I would use this typology remained unclear at this stage.

After completing the 35th interview in this sample I was invited to present the SELPHI logic model at a symposia session at AIDS 2018. I instead proposed presenting a yet to be performed analysis, testing the logic model with the groups I had identified earlier as I was concerned the logic model presentation would be insufficiently engaging. This led me to conduct a preliminary version of the analysis presented in the next paper. While I initially thought it would be relatively inconsequential, the intervention experiences between the three different groups were so unique that I felt it was worth a more in-depth exploration. This also met an aspiration of the process evaluation embedded within SELPHI to identify differences in intervention reception and experience across participants.

The expanded analysis clarified that these data had the potential to expand the way we think about HIVST interventions specifically, but also the way that we think about COM-B and the contexts in which it is useful.

To my knowledge this is a relatively novel way of conducting a framework analysis, using the approach for a purpose it was not initially designed for. As such, the analysis approach is itself experimental. Never-the-less, the insights gleaned from it are unique in the literature and may have value for policy makers and practitioners seeking to design interventions.

3.4.2 Paper 5: Demonstrating pathways to impact: using a testing typology to understand intervention performance in an HIV self-testing RCT in England and Wales.



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RESEARCH PAPER COVER SHEET

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SECTION A – Student Details

Student ID Number	1603113	Title	Mr
First Name(s)	T Charles		
Surname/Family Name	Witzel		
Thesis Title	HIV self-testing for men who have sex with men (MSM) in England and Wales: a multi-method study of self-testing intervention development and evaluation		
Primary Supervisor	Peter Weatherburn		

If the Research Paper has previously been published please complete Section B, if not please move to Section C.

SECTION B – Paper already published

Where was the work published?			
When was the work published?			
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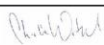
Where is the work intended to be published?	International Journal of Environmental Research and Public Health
Please list the paper's authors in the intended authorship order:	Witzel TC1; Weatherburn P1; Bourne A2; Rodger AJ3; Bonell C1; Gafos M4; Trelvelion R5; Speakman A3; Lampe FC3; Ward D6; Dunn DT6; Gabriel MM6; McCabe L6; Harbottle J7; Collaco-Moraes Y 6; Michie S8; Phillips AN3;


	McCormack S6; Burns FM3.
Stage of publication	Undergoing revision

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I designed the study, produced the sampling frame, produced the data collection instruments, recruited participants, conducted all interviews, designed the analysis, carried out the analysis, wrote the results and made revisions.
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SECTION E

Student Signature	
Date	03/12/2019

Supervisor Signature	
Date	03/12/2019



Article

Exploring Mechanisms of Action: Using a Testing Typology to Understand Intervention Performance in an HIV Self-Testing RCT in England and Wales

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Abstract: SELPHI involves two interventions: A provides one HIV self-testing (HIVST) kit; B offers 3-monthly repeat HIVST kits if participants report ongoing risk. A logic model underpinned by the Behaviour Change Wheel informed the design of the intervention. SELPHI recruited 10,135 cis-men and trans people in England and Wales, all reporting anal sex with a man. This paper explores how the interventions were experienced and the mechanisms of action leading to impact for different groups of trial participants. In-depth interviews with 37 cis-men who have sex with men (MSM) were used to inductively categorise participants based on sexual and HIV testing histories. Themes relating to intervention experiences and impacts were mapped onto SELPHI-hypothesised intermediate outcomes to consider intervention impacts. Three groups were identified: ‘inexperienced testers’ engaged with SELPHI to overcome motivational and social and physical opportunity testing barriers. For ‘pro self-testers’, testing frequency was constrained by psychological and social barriers and lack of opportunity. ‘Opportunistic adopters’ engaged in HIVST for novelty and convenience. Perceived impacts for inexperienced testers were most closely aligned with the logic model, but for opportunistic adopters there was little evidence of impact. Distinctive groups were discernible with divergent intervention experiences. Using COM-B as a model for understanding behaviour change in relation to HIVST, our results indicate how HIVST interventions could be adapted to respond to different needs based on the target population’s demographic and behavioural features.

Keywords: HIV testing; self-testing; men who have sex with men; COM-B; evaluation

1. Introduction

1.1. HIV Self-Testing in the UK

Early HIV diagnosis ensures improved treatment outcomes and a definitive body of literature demonstrates the impossibility of sexual transmission of HIV once an undetectable viral load has been achieved [1–5]. In response to this, HIV testing has undergone a rapid evolution over the last two decades, with increases in the variety of testing options offered in many settings [6,7]. Conceptualisations of HIV testing have shifted also; among men who have sex with men (MSM), testing can now be considered a normative behaviour, with strong pressure to test coming from other gay and bisexual men as well as from public health and voluntary sector organisations [8–10].

HIV self-testing (HIVST) is the latest in a long line of evolutions in HIV testing. Previously banned because of concerns surrounding potential harms, HIVST was legalised in the UK in April 2014, [11]. HIVST involves a person taking their own sample, processing their test, and interpreting their result. A positive result on an HIVST is the first step in a testing pathway; diagnosis requires undergoing further testing using a nationally recognised testing algorithm [4]. Free provision of HIVST has been patchy, with pilot and demonstration projects providing limited numbers of kits to specific risk groups in geographically defined areas [4,12].

1.2. SELPHI HIV Self-Testing RCT

SELPHI (An HIV Self-Testing Public Health Intervention) is the largest HIVST randomised controlled trial (RCT) in a high-income setting [13]. Between February 2017 and March 2018, SELPHI recruited 10,135 MSM (cisgender and transgender) and transgender women reporting anal intercourse with a man in their lifetime. SELPHI uses a one-off free HIVST intervention to assess whether an offer of HIVST can increase diagnosis rates of prevalent HIV infections, and an intervention comprised of a three-monthly offer of free HIVST to reduce the time between infection and diagnosis for incident infections [13]. Participants in SELPHI who receive HIVST kit(s) are provided with a BioSure™ HIVST, which uses a whole blood sample. Intervention acceptability and test kit usability for SELPHI participants has been reported elsewhere [14,15].

SELPHI used the Behaviour Change Wheel (BCW), which includes the COM-B model of behaviour as an organising principle in conceptualising intervention components, their functions, and outcomes associated with each [16]. COM-B posits that alterations in capability, opportunity, and motivation are key to successful behaviour change interventions, and services can target alterations in these domains through careful intervention design [16,17].

Each domain of capability, opportunity, and motivation is divided into two sub-domains. Capability refers to physical and psychological abilities, while physical opportunity refers to environmental aspects shaping behaviour, and social opportunity refers to cultural factors constraining or facilitating engagement [16]. Motivation is divided into reflective and automatic processes (e.g. planning vs. emotions and impulses) [16].

The BCW comprises two levels of intervention: policy changes (e.g. legislation, regulation, communications, and marketing) and interventions directed at the individuals themselves (e.g. enablement, modelling, restriction). Table 1 presents an overview of intervention types with definitions.

The BCW provides recommendations for which intervention types are useful in targeting each behavioural domain (see Table 2) [16]. It provides a template from which to create theoretically informed behaviour change interventions which respond to specific needs.

COM-B and the BCW have been criticised for over-simplifying understandings of sources of behaviour and individual responses, and for their potential to ignore variation in need [18]. This could lead to the development of interventions which are insufficiently attentive to diversity amongst their intended users. However, COM-B and the BCW are used effectively across a wide variety of health conditions including HIV [17,19–23].

Table 1. COM-B intervention types and definitions (reproduced from Michie et al., 2011, with permission).

Interventions	Definition
Education	Increasing knowledge or understanding
Persuasion	Using communication to induce positive or negative feelings or stimulate action
Incentivisation	Creating expectation of reward
Coercion	Creating expectation of punishment or cost
Training	Imparting skills
Restriction	Using rules to reduce the opportunity to engage in the target behaviour (or to increase the target behaviour by reducing the opportunity to engage in competing behaviours)
Environmental restructuring	Changing the physical or social context
Modelling	Providing an example for people to aspire to or imitate
Enablement	Increasing means/reducing barriers to increase capability or opportunity ¹

¹ Capability beyond education and training; opportunity beyond environmental restructuring.

Table 2. Relationship between COM-B domains and interventions (reproduced from Michie et al., 2011, with permission).

Model of behaviour: sources	Education	Persuasion	Incentivisation	Coercion	Training	Restriction	Environmental restructuring	Modelling	Enablement
C-Ph					√				√
C-Ps	√				√				√
M-Re	√	√	√	√					
M-Au		√	√	√			√	√	√
O-Ph						√	√		√
O-So						√	√		√

1.3. Understanding HIVST Interventions

Theorised to increase access for those with concerns related to privacy, convenience, and stigma, HIVST expands the locations in which an HIV test can be taken, and places increased emphasis on users' responsibility to respond to the technology in specific ways [24]. Thought to be especially useful for those with less HIV testing experience because of the reduction in healthcare barriers [11,25–27], little is known about the ways in which individuals, or indeed groups, respond to the technology and incorporate it into health-seeking behaviours [4]. The majority of HIVST acceptability studies focus on the accounts of potential users before intervention exposure, and therefore do not reflect lived experience.

Interventions do not perform in uniform ways across individuals or groups [28]. Understanding how and why interventions function is key to optimising delivery processes, enhancing the potential to facilitate behaviour change by tailoring interventions for heterogeneous populations [7,28].

For HIV testing specifically, Flowers and colleagues urge increased consideration of the technological, psychosocial, and sociocultural context of HIV testing [7]. Changes related to sexual career and a person's life-course are especially likely to affect how individuals seek and experience HIV testing interventions [7]. Those seeking HIV testing for the first time will likely have different needs than those who have more testing experience, factors to which intervention design should be attentive [7].

It is also important to better understand how interventions can be targeted based on group experiences to ensure optimal utility, especially from a life-course perspective. Self-testing provides the opportunity to design flexible interventions to meet a range of diverse needs, thus facilitating uptake in groups underserved by existing testing opportunities [7,11]. Further, it is important to understand how interventions impact on subsequent testing behaviour as this provides insights into the function they serve alongside a diverse set of other services.

1.4. SELPHI Logic Model

Likely pathways of impact from intervention delivery to the main trial outcomes are articulated through a COM-B informed logic model (Figure 1). An additional outcome of increasing the uptake of testing was also included, recognising the centrality of this aim to testing interventions. The logic model for SELPHI (Figure 1) draws from a systematic literature map, focus groups discussions (FGDs) with 47 MSM, and 17 key informant in-depth interviews (IDIs) [9,11,29,30]. As SELPHI is an RCT situated within a supportive policy environment, the framework focused on producing behavioural alterations through the intervention functions and their relationships with behaviour specified in COM-B (Tables 1 and 2).

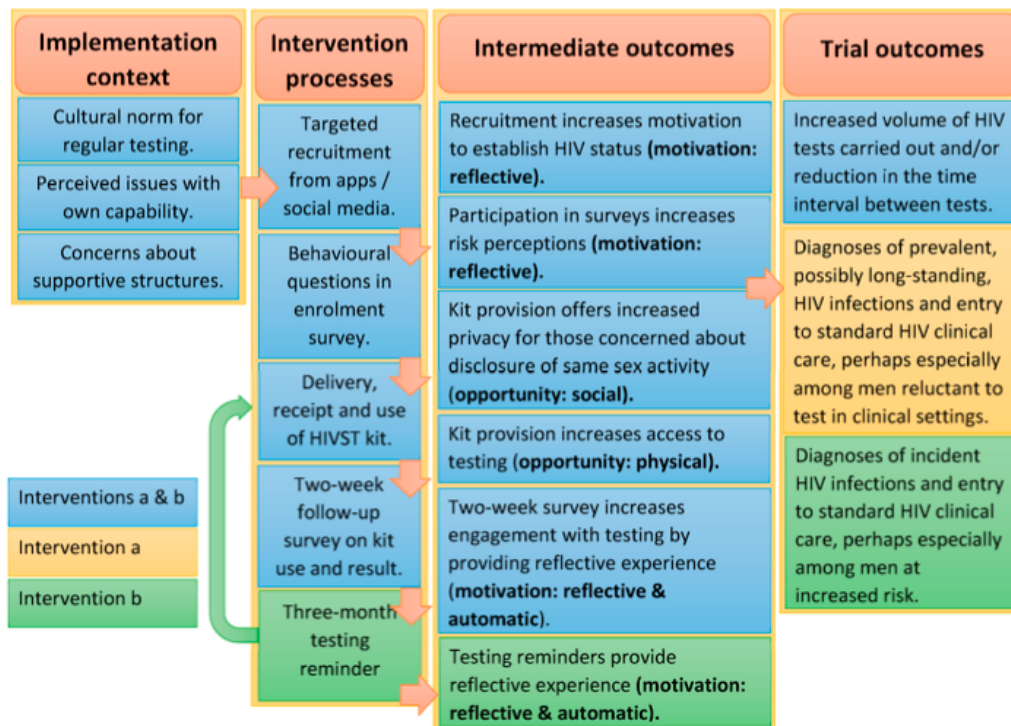


Figure 1. Logic model.

Contextual factors assumed to impact intervention delivery included a cultural norm for regular testing; perceived issues with capability and concerns about supportive structures.

The main testing barriers identified in formative work which HIVST could effectively respond to were motivation (reflective & automatic) and opportunity (physical & social). The intervention was designed to induce changes in these areas, while minimising concerns around capability (psychological & physical), which presented the primary barrier to intervention implementation. We sought to ameliorate capability issues through intervention design.

Intervention A (Figure 2) is linear, moving from targeted recruitment to a risk assessment represented by behavioural questions in a survey, then to the receipt and use of the HIVST, and lastly a two-week follow-up survey. The advertisement was classified as a form of education and persuasion,

seeking to enhance motivation (reflective). The risk assessment was a form of persuasion, enhancing motivation (reflective) by increasing feelings of vulnerability to HIV. Free kit provision was a form of enablement increasing opportunity (physical). The two-week follow-up was a form of enablement, increasing motivation (reflective & automatic). In the SELPHI pilot, participants reported the test kit was easy to use, that the instructions were simple and the support structures adequate for their needs [14,15], demonstrating that our efforts to ameliorate capability issues through intervention design were successful.

Intervention B (Figure 3) includes all elements of A, with additional cyclical components consisting of a testing reminder and a linked risk assessment delivered every three months which, should a kit be requested, triggers delivery of a new HIVST kit and another two-week follow-up survey. The testing reminder and linked risk assessment were forms of persuasion, targeting motivation.

The logic model articulates intermediate outcomes assumed to be precursors to achieving the trial outcomes. Each intermediate outcome relates to a documented deficit or need constraining testing within the target population and which intervention design has identified as a key area which requires change. They are described as an outcome (e.g. increased risk perception) and a COM-B-linked domain which required alteration to achieve this. None of the intermediate outcomes were related to capability concerns as a barrier to uptake as these had already been mitigated via the provision of enhanced support and through intervention messaging [14].



Figure 2. Intervention A.



Figure 3. Intervention B.

Understanding differences in experience in groups of individuals has long been a public health aspiration. Latent class analysis is a method often used in quantitative studies which seeks to create groups based on shared demographic and behavioural traits and uses these to investigate differences in outcomes [31,32]. We draw on the foundational principles of this approach and apply them to a qualitative analysis to examine how different groups of participants understand the utility of HIVST in the context of their testing behaviour. These findings can be used to guide commissioners and health promoters in how HIVST interventions might be adapted to better meet a range of needs and improve outcomes.

This paper aims to explore how the SELPHI interventions might be experienced by, and the pathways to impact on behaviour for, different groups of RCT participants. The specific objectives are: to develop a participant typology to identify commonalities in the intervention experience and how these vary according to sexual and testing behaviours; to describe how interventions can be designed to respond to these commonalities; and to examine the utility of COM-B as a model for understanding behaviour change in relation to HIVST.

2. Methods

2.1. Participants and Procedures

This study involved 37 in-depth semi-structured interviews with purposively sampled cis-gender MSM. The initial 10 interviews were conducted in May 2017, with a further 27 taking place between January and October 2018. Ethical approval was sought and granted from University College London [ref: 11945] and London School of Hygiene & Tropical Medicine [ref: 9233/001].

Interviews were conducted face-to-face ($n = 20$) and remotely ($n = 17$). Purposive sampling was used to ensure a diversity of participants, based primarily on testing history and then on geographical location, highest educational qualifications, age, and ethnicity. Interviews were conducted in Cardiff, Newcastle, and London, ensuring participation from men in areas with variable health service development and differences in the prominence of gay scenes. Two interviews were conducted with participants who had a positive result from HIVST.

A topic guide for interviews was developed drawing from earlier formative work, the logic model, and the broader HIVST literature [9,11,26,33]. The first iteration covered testing history, engagement with SELPHI, intervention experiences, and preferences for future HIVST development. After piloting, this was refined. Following the first ten interviews the topic guide was expanded to provide additional focus on the HIVST intervention being used in the RCT. Questions about trial infrastructure and intervention processes were added; participants were asked to revisit the adverts they were recruited from and the surveys they filled out and take time reviewing components of the kit. Interviews were audio recorded and transcribed verbatim.

2.2. Analytic Procedures

A deductive framework approach to data analysis was chosen to focus on specific elements of the intervention and because of the need to compare these across participants [34]. Key domains of enquiry were extracted from the topic guide, the interviews, and the broader HIVST literature and organised around broad themes. This analysis draws from a section of this framework which focuses on intervention function. Each intervention component and the intermediate outcomes, assumed to be a result of these, had their own code to which data were assigned by the first author. COM-B domains were mapped onto the framework to ensure it captured relevant emerging data. The analysis remained attentive to the emergence of new issues and lines of enquiry, especially around the groupings of participants. The framework itself was refined twice: once after two interviews in the pilot phase, and again following the addition of new questions in the second phase of data collection.

During analysis it emerged that participants were clustered qualitatively into three main groups based on their life-course, HIV testing history, and engagement with HIVST. We solidified this into a typology of participants based on prior testing and orientation to SELPHI, and then looked to see whether accounts of intervention experiences and perceived intermediate impacts differed among the groups identified in the typology, and how these aligned with constructs from the logic model. This was then qualitatively assessed for strength and clarity of feeling expressed by intermediate outcome for each of the groups. These themes relating to intervention functions by participant groups were reviewed by TCW, PW, AJR, and FMB to ensure coherence of interpretation and agreement with assessments related to strength of evidence.

3. Results

The SELPHI interventions were experienced variably by the groups identified in our analysis. In this section, we first outline the groups and their defining characteristics, before describing each intervention component and associated intermediate outcomes. The differences in intermediate outcomes across groups are then presented.

3.1. A Testing Typology

In our analysis, we found three main groups who had distinct experiences of intervention performance: inexperienced testers (n = 14), pro self-testers (n = 11), and opportunistic adopters (n = 12). These groups were classified primarily based on their testing history and motivations for engaging with HIVST. These groups represent individuals at different stages of their life-course and sexual careers; they are therefore fluid and exist on a spectrum. Although diversity of experience existed within these groups, their shared characteristics meant that the interventions functioned in differing ways for these three groups. These distinct experiences are useful for understanding how intervention components varied in their utility and the potential for future intervention optimisation. Table 3 presents our sample demographics.

Table 3. Sample demographics.

Ethnicity	White	29
	Black	3
	Asian	2
	Other/mixed	3
Sexual orientation	Gay	24
	Bisexual	5
	Don't use a term	1
	Undisclosed	7
Recency of HIV testing	Never tested	7
	12 months +	17
	<12 months	13
Highest education qualification	Low ¹	7
	Medium ²	11
	High ³	19
Condomless anal intercourse partners in preceding three months	0	12
	1	14
	2–3	7
	4–10	4
	10+	0
Test outcome	Positive	2
	Negative	35
Intervention	Intervention A	27
	Intervention B	10

¹ GCSEs and below. ² A-levels or equivalent, higher education below degree level. ³ Degree or higher.

3.1.1. Inexperienced Testers

This group's defining characteristic is their estrangement from testing services. Inexperienced testers had either never previously tested or had not tested in quite some time. These men were usually at the beginning of their sexual careers, but also included those who had been sexually active for many years but had never routinely tested for HIV. All were below the age of 25 or over the age of 40. This group often had profound issues relating to stigma, shame, internalised homophobia, and traditional conceptualisations of masculinity. HIVST facilitated engagement with testing due to the reduction in barriers which had previously prevented them from testing. Barriers for this group clustered around the COM-B domains motivation (reflective & automatic); opportunity (social & physical) and capability (psychological). These barriers included psychological and social barriers such as stigma, perceived lack of privacy, and low self-efficacy regarding clinic access, as well as structural barriers such as geographic isolation from existing testing services. Some inexperienced testers viewed testing as a normative behaviour, but these views were much less strongly held than in the other groups. If they

tested at all, individuals in this group usually tested in response to risk, with a small minority testing for reassurance. None tested out of routine.

3.1.2. Pro Self-Testers

Men in this group had an established testing routine but tested sub-optimally based on guidelines or less than their own preferences because of barriers to accessing services. Generally speaking, these men could be understood to be at an intermediate point of their sexual careers. They may have been sexually active for some time but often retained barriers to living very open lives related to stigma, shame, conceptualisations of masculinity, and homophobia. They were spread across all age groups. These barriers related to the COM-B domains of opportunity (social & physical) and capability (psychological). Barriers to testing services faced by this group included stigma, privacy concerns, and perceptions that services were inaccessible or inappropriate. This group experienced a tension between norms to test balanced against their personal barriers to access which constrained their testing behaviour, sometimes leading to feelings of guilt, shame or of being stigmatised. HIVST helped to resolve these barriers and facilitate testing uptake thereby alleviating negative feelings about not testing. HIVST was the preferred testing option and they used HIVST when testing in response to risk, for reassurance and out of routine.

3.1.3. Opportunistic Adopters

The final group in our analysis were already very engaged with testing services where their needs were generally well met. This group had no discernible COM-B barriers, except for some minor issues with physical opportunity related directly to accessibility of clinics based on opening or waiting times. Opportunistic adopters tended to test at least annually, but often much more frequently. Men in this group were, on the whole, comfortable with their sexual orientation, led quite open lives, and had access to services which met their needs in an appropriate way. These men were all over 25 years of age. Although HIVST uptake was facilitated by increased convenience; they had no obvious deficits to which HIVST responds. They used self-testing largely out of novelty, as a replacement for a routine test or to gain reassurance.

3.2. Intervention Components and Behavioural Influences

We found key differences in the way the intervention functioned for each group. Inexperienced testers' experiences matched most closely with the hypotheses in our logic model. Pro self-testers experiences diverged, especially around elements designed to enhance motivation (automatic & reflective). Opportunistic adopters diverged further, with significantly different experiences when compared to inexperienced testers. Figure 4 presents differences across groups of SELPHI participants by assumed intermediate outcome.

3.2.1. Recruitment and Testing Motivation

The SELPHI logic model assumed that the adverts used to recruit participants would increase motivation to test. These adverts were a form of education and persuasion targeting reflective motivation. Evidence relating to this intermediate outcome was mixed; while strong evidence supporting this hypothesis was found for inexperienced testers, evidence was moderate for the other two groups.

For inexperienced testers, the messages used in advertising functioned largely as expected, producing the assumed outcome. They increased motivation by highlighting a convenient, free testing opportunity, and provided a reflective experience where individuals could consider the process of testing and the benefits it could bring.

Deep down, I knew that it was something that I should do anyway. And it was free. And I knew that not all people would get it. But it was free if I was selected. And it just seemed

like I'd no excuse, really, to turn it down. It's free. It would be in private. I wouldn't have to go to the clinic. And I'd get a little bit of peace of mind if it came back negative. (23-year-old man, undisclosed sexual orientation, not previously tested, inexperienced tester).

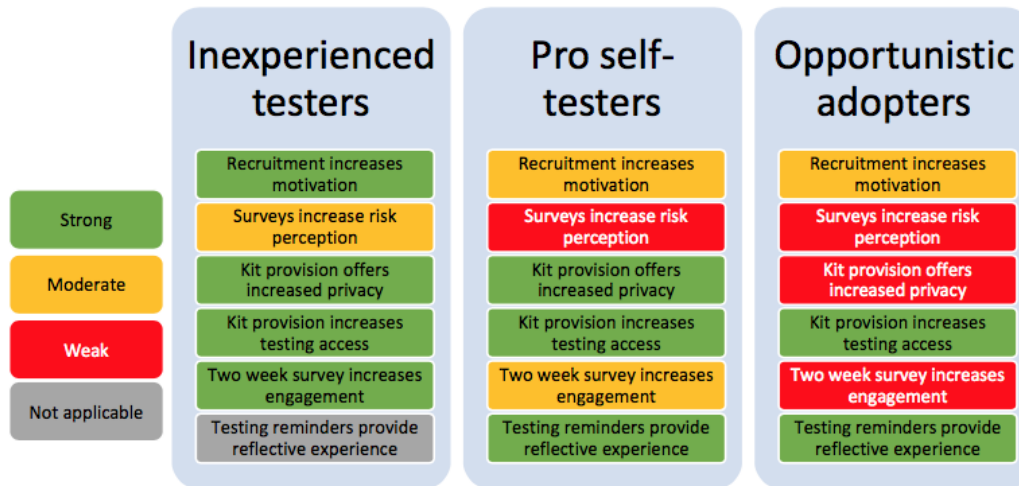


Figure 4. Outcomes and evidence strength by group.

Pro self-testers had more mixed response to the recruitment element. For some the SELPHI adverts were profoundly motivational and functioned as expected, while for others these simply came at an appropriate time.

For me, it was timing. It was just a case of like, ‘okay, it’s been a year’; I knew I had had some ... maybe not the cleverest of sexual encounters a couple of months beforehand, and it literally landed at the right time in my thought processes so I was like ‘yep, we’ve got that whole World AIDS Day thing coming up again, and this is probably about the right time to get tested again’. (29-year-old gay man, tested in last 12 months, pro self-tester)

Opportunistic adopters rarely identified the adverts as increasing motivation to establish their HIV status, largely because their motivation was already high, and they did not have a COM-B barrier to address in this regard. The majority stated that the adverts came while considering or planning their next test. For the minority who found this element motivational, the source was the novelty of HIVST.

3.2.2. Surveys and Risk Perception

The SELPHI logic model assumed that participating in surveys pertaining to risk behaviour would increase risk perception, and these were considered part of the intervention itself. These surveys were considered a form of persuasion, working through reflective motivation pathways in the COM-B model. Overall, this intervention component had the weakest evidence across all MSM. Some inexperienced testers and a minority of pro self-testers felt the surveys functioned as assumed, while opportunistic adopters felt they did not.

Most inexperienced testers anticipated that the types of questions asked in the risk assessment would form part of the intervention. Although some found answering these personally uncomfortable because they highlighted sexual risk, others externalised this feeling to ‘others’ who might find this element of the intervention challenging. This externalisation was also present for a small number of pro self-testers, although this group on the whole did not report this intervention component increased motivation.

Some of the questions [...] I felt might make some people worry, maybe [...] The ones relating to having sex without protection. Also, having sex whilst taking drugs as well. That

was another one. And I thought, 'oh, okay, well, that's half of gaydom'. (49-year-old man, undisclosed sexual orientation, tested in last 12 months, pro self-tester).

Opportunistic adopters universally felt the questions were unproblematic and expected. Experience was a key component of this lack of intervention impact: this group identified being asked similar things routinely while accessing other testing services. This was also related to length of time openly identifying as gay or bisexual and a feeling of self-acceptance and acceptance of ones' own risk behaviour.

It doesn't make me feel any different about myself. Because I have been actively gay for 20 years now. Maybe or definitely, in my early years, that would make me feel uncomfortable that I was promiscuous, so to speak. But having been active for 20 years now, it's not something that bothers me anymore. (40-year-old gay man, tested in last 12 months, opportunistic adopter)

3.2.3. Kit Provision and Privacy to Test

The provision of the HIVST was assumed to increase social opportunity by providing additional privacy for testing. This intervention approach is termed enablement in the BCW. Evidence for this intermediate outcome was generally strong overall, with inexperienced testers and pro self-testers identifying the intervention as performing in this way. For opportunistic adopters, however, there was weak evidence for this outcome.

Inexperienced testers and pro self-testers often primarily engaged with SELPHI because of the reduced psychosocial barriers to clinic access including stigma, shame, and a lack of privacy. Unsurprisingly, for these two groups the increased privacy offered by HIVST was incredibly valuable, dramatically increasing social opportunity. For some this was related strongly to keeping their sexual identity private or hidden while also accessing services, while for others this was out of a preference for privacy and control while also meeting norms around HIV testing.

The SELPHI thing actually appealed to me that I could be totally anonymous. [...] I'll say the shame and embarrassment. And I'll put it that way because I'm in the closet and probably prefer to remain that way. So, it is the difficulty of taking that step [accessing a clinic]. [...] (55-year-old bisexual man, not previously tested, inexperienced tester)

Opportunistic adopters did not have privacy concerns when accessing services, partly because strong social norms supporting HIV testing did not conflict with desires for privacy or anonymity.

3.2.4. Kit Provision Increases HIV Testing Access

Providing HIVSTs at no cost was assumed to increase physical opportunity by reducing testing barriers related to inconvenient or geographically removed HIV testing services. Again, this is classified as enablement in the BCW system. This was the only assumed intermediate outcome on which there was positive evidence across the three groups. How important this was to each of the groups differed, however.

Inexperienced testers identified the increases in physical opportunity as being helpful in facilitating testing. This was not necessarily the area in which they had the most pronounced need as the privacy offered by HIVST was more important. Rather, this was secondary or incidental.

I started having sex with other men more frequently. And, at that point, I started to consider [testing for HIV]. And that was around the time when... about a month or so after that when, I think, the SELPHI thing came up on Grindr. And that's when I thought, mmm, self-testing seemed like a better idea, I thought. (23-year-old man, undisclosed sexual orientation, not previously tested, inexperienced tester)

For the majority of pro self-testers, although this was important, it was also secondary to the increased privacy provided by the intervention which was the main benefit. For some however, their

predominant testing barriers were related to inconvenient or geographically removed HIV testing services. For these men, HIVST met their needs in terms of providing a physical opportunity.

But when I had seen it, and doing it at home I thought it was a great idea, because you're at home, you can sit and get your result there and then, you can take it from there, and go and get support if you needed to. (30-year-old gay man, tested in last three months, pro self-tester)

For opportunistic adopters, the increased convenience was the main element of the intervention that functioned as assumed for this group. Increased convenience, and therefore physical opportunity, was the primary intermediate outcome experienced by these men.

So, I think for me, whenever I found out about this I was like, 'Okay, well that makes my life a lot easier,' because I work long hours and I have quite an unpredictable job. So, trying to maybe get time off and having that time off assured so that I can go to an appointment is quite difficult, so this study was very helpful. (27-year old gay man, tested in last three months, opportunistic adopter)

3.2.5. Two-Week Survey and Testing Engagement

Our logic model assumed that the two-week follow-up survey (which we envisage would remain an integral part of the intervention if rolled-out) increased engagement with HIV testing generally through reflective and automatic motivation channels while also providing support. Overall, this intermediate outcome had the most inconsistent evidence across all groups and accounts diverged dramatically. Although more inexperienced testers felt that this element was supportive and provided a reflective experience, for pro self-testers this was inconsistent. For opportunistic adopters this was rarely the case.

Inexperienced testers were more likely than the two other groups to identify the two-week follow-up as providing support and being a reflective experience. For these participants, it was an important part of the intervention which provided a degree of connection to the study team which was valued. This feeling of connection itself provided a prompt to reflect on trial involvement and intervention experiences.

I've done the test and then there was nothing for a while, and then you get the survey back and you feel, 'Oh yes, they are still thinking about me. I am still part of this study, I still feel included.' Whereas I think if it'd just been left and there was nothing you have thought, 'Well, okay, I've got a free test out of it but what's the point?' (35-year-old gay man, tested in last 12 months, inexperienced tester)

Neither of the inexperienced testers who received a positive result noticed the delivery of, or filled in, the survey, so could not comment on its value.

Pro self-testers on the whole thought the provision of the two-week survey was a positive element, and some valued the support, anticipating that some people would receive a positive result. For the majority however, this element did not provide a reflective experience and did not increase personal engagement with testing. This is perhaps a function of strong testing norms, but also high psychological and social barriers to testing in this group which create ambivalence around testing. One participant who expressed significant ambivalence about the survey said:

Interviewer: So, if you were getting the test from the NHS, you wouldn't necessarily want to fill out one of those surveys?

Participant: I wouldn't want to, but I think it would be good practice to. If you were going to distribute self-tests, it would be good to use a follow-up. If in my situation now, if I wasn't studying it, if it was just a routine thing and it was negative, I probably wouldn't fill it out,

it'd go into the junk box. But I still think it's probably a good thing to do. (32-year-old gay man, tested in last 12 months, pro self-tester).

Opportunistic adopters nearly universally felt that the two-week survey was part of a trial process rather than a supportive structure. It was not a helpful component of the intervention for them, although there was some acknowledgment that as a reflective experience it could be helpful for others.

I took it as a study. I felt like I was trialling something, I didn't have any expectations of what it would be. Nothing stood out to me, but again, with my sexual health and dealing with sexual health services, there is a resilience or comfortability of having to share information, if that makes sense? (25-year-old gay man, tested in last 12 months, opportunistic adopter)

3.2.6. Testing Reminders and Reflection

Testing reminders with a linked risk assessment were assumed to provide a reflective experience for those receiving repeat offers of HIVST kits in intervention B, thus enhancing motivation to test. Because of the cyclical, repeated nature of the intervention, inexperienced testers either transitioned to being pro self-testers or opportunistic adopters.

In intervention B, testing reminders were acknowledged by all to function as assumed by providing a prompt to consider sexual behaviour and HIV risk in the intervening three months. This had multiple effects: it normalised HIV testing, increased risk perception, provided a prompt to reflect on past testing, and increased motivation to test again.

Just made me think a bit harder of the past three months, what I'd been doing, yeah. It didn't make me feel anything like I shouldn't be asked this or this and that, yeah, it was just a questionnaire and it just made me think about all the movement I had in the last three months [...] (27-year-old bisexual man, tested in last six months, pro self-tester)

4. Discussion

This qualitative study investigating intervention performance with 37 cis-gender MSM participants in the SELPHI RCT identified three main participant groups, defined by their testing history and engagement with HIVST, who had distinct intervention experiences and intermediate outcomes.

Inexperienced testers largely had not been previously tested, or were disengaged from testing because of profound barriers to service access. Pro self-testers had a testing history, and sometimes had a routine, but their frequency of testing was constrained by many of the same barriers as inexperienced testers. HIVST resolved many of these barriers for both groups, leading to expectations of increased testing frequency. Opportunistic adopters were very well served by existing services and had a routine involving frequent testing. For this group, HIVST uptake was facilitated by the novelty of the technology, or because of increased convenience.

Intervention performance across these groups was highly variable. For inexperienced testers, intermediate outcomes were closest to the six assumptions in the logic model. Divergence began for pro self-testers and was most pronounced for opportunistic adopters. Divergence was found to be related to the pre-existing needs of the groups and their corresponding testing barriers. Inexperienced testers had the most pronounced needs and therefore the most favourable outcomes, whereas for opportunistic adopters who had less needs (mainly related to physical opportunity), the intervention components assumed to impact on the other domains had little relevance. The exception to this was testing reminders, which impacted all groups in a similar way increasing reflective motivation.

4.1. Strength and Limitations

This is the first systematic study of the relationships between intervention components and their influences on uptake of HIVST. Some limitations are noted. Our sample was derived entirely from an RCT which had substantial informed consent procedures, providing a level of detail about the kit and

trial processes beyond what would be provided in standard free HIVST provision. Those who engaged may be more likely to have altruism as a primary motivator indicating that this group may not be reflective of those who have need for HIVST [14]. In addition, a requirement of participation was to provide a mailing address and consent for the study team to link to clinic records and monitoring data held by the government. This may have dissuaded those with the highest privacy barriers from participating, a group with pronounced utility for HIVST [11,26,33].

The sample was relatively small ($n = 37$). Conducting additional interviews with larger numbers of participants may have led to a refinement of groups with larger amounts of data. In addition, as HIVST becomes more mainstream over time and more gain self-testing experience, these groups may also shift. This should therefore be viewed as indicative of a broad typology of MSM that are potential beneficiaries of HIVST prior to widespread free availability in the UK.

Our results will be applicable to other culturally similar settings with comparable health services. They may not effectively translate to very different contexts such as the USA and Southern Africa where motivations to use HIVST will vary along with intervention approaches.

Finally, our analysis relies on participants accurately reflecting on their thoughts and feelings during intervention engagement some time afterwards, potentially not fully reflecting their experiences.

4.2. COM-B, HIVST, and Challenges for the Model

Our analysis poses some challenges for the application of COM-B as an overarching framework. We required a more nuanced framework of motivation to analyse the influence of social norms drawn from peers, community, and society and the way that they might shape engagement with interventions. Indeed, although aspects of social norms are captured in motivation, the centrality of these to behaviour is perhaps not fully accounted for in the existing model. This is a challenge for understanding the experiences of opportunistic adopters especially; many had engaged because of strong norms to test frequently and because they had a routine to do so—a well-documented phenomena and one which HIVST has been hypothesised to respond to among MSM in high income settings [8,9].

This is a critical issue for HIV prevention research where norms are central to uptake of precautionary behaviours and shape use of condoms, testing and biomedical prevention technologies [8–10,35–37]. The model should pay additional attention to the impact on motivations of strong social norms arising from peers, service providers, and the wider community [18,38,39].

4.3. Considerations for Future HIVST Intervention Development

Life course relating to sexual experience and acceptance of sexual identity clearly have a significant impact on how the SELPHI intervention was experienced. This demonstrates the potential for intervention optimisation available for those seeking to implement HIVST. Advertising can be designed for those with most utility for HIVST: inexperienced testers and pro self-testers, targeting key influences revealed by our COM-B analysis. A brief risk assessment, sexual history, and testing history could then be taken, with an automated process streaming service users into specific intervention types based on their characteristics, preferences and histories. The two-week results survey can be conceptualised as playing a dual role of maintaining engagement in testing for those with negative results, while also offering support for those with positive self-tests. Enhanced interventions providing additional support could then be provided for inexperienced testers and pro self-testers with lower level support provided for those with more testing experience. This could make interventions more acceptable and more efficient by providing a more personalised HIVST service.

It is important to note that men did not have static positions within these categorisations. For some, engagement with the intervention facilitated a movement from one group to another. This was especially true for inexperienced testers who tended to move to being pro self-testers or opportunistic adopters following intervention exposure. Intervention design should therefore be attentive to shifts within individuals who use HIVST, especially if longer-term provision will allow repeat testing. HIVST

service provision should also be attentive to the potentially transformative properties of self-testing, especially for those who face barriers to accessing other testing services.

The SELPHI logic model can be refined as a result of this analysis, clarifying behavioural influences and their implications for the interventions. Doing so will also enable the inclusion of an additional level of assumed outcomes between intermediate and ultimate (trial) outcomes clarifying the likely pathways to these.

5. Conclusions

This study demonstrates the profoundly different experiences MSM can have when engaging with HIV testing interventions. Clearly, adaptations can be made to better meet the needs of individuals based on needs related to their testing history, life course, and sexual careers. Further, we provide a critique of COM-B, demonstrating limitations in its application when considering engagement in some groups for which a more elaborated theory or model of motivation is required.

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4. Discussion

In this section I first discuss my own position in relation to the topic matter before moving on to the ways in which the aim and objectives of this thesis have been met. I then discuss potential logic model adaptations which could be made to facilitate future intervention implementation. Following, I propose a framework for HIVST implementation in the UK before discussing the merits of COM-B as illuminated by this research. Finally, I address the strengths and limitations of this thesis before my concluding comments.

4.1 Reflexivity

I have a long history with HIVST. When I initially relocated from Brighton to London in 2011 following my first degree I was employed at a large HIV voluntary sector organisation. During that time I specialised in supporting MSM newly diagnosed with HIV. Although I had a strong background in HIV health promotion, I learned much about HIV treatment and transmission. I began to find attending sexual health clinics as a gay man extremely cumbersome; the support available was not what I needed or what I valued in a clinical interaction.

Rather than attend clinic appointments, I began to use Insti point of care HIV RDTs to test myself at home. I continued testing regularly this way until I enrolled in the PROUD study and started receiving regular HIV tests through clinic visits.

For me, HIVST was a useful way to manage my HIV risk, and to make decisions about my health without needing input from other healthcare providers. Never-the-less I remained sceptical about the introduction of self-testing; my needs were related to having too much information and I worried about men like the ones I saw regularly during my years of self-testing who struggled with their diagnoses, oftentimes in isolation.

I can identify these concerns in my earlier works included in this thesis. The interpretation of these data is more cautious than I would likely be now, although they are an accurate reflection of what I found and the time period in which they were collected. If I were to repeat the formative study, I would have likely been more attentive to the voices in the data who were very supportive of HIVST implementation, especially for MSM who would use HIVST to test in response to risk because of significant barriers to healthcare settings described in paper 2. Although a minority in the focus group discussions, these men did have pronounced utility for HIVST which I could have more fully described.

My perspective and conviction that HIVST is an exceptionally useful tool for many MSM comes from the implementation and evaluation studies. I interviewed many individuals for whom HIVST had a profound impact on their lives. Because of my role in establishing the RCT and in assisting with

implementation, I was often quite touched during these interviews. Although I have made every effort to be objective about self-testing in the interpretation of these data, especially in highlighting issues with the technology, it is likely that my shift in perspective about the utility of HIVST is evident during the shift from formative to implementation and evaluative research.

4.2 Meeting thesis aims and objectives

4.2.1 Aim: To develop an understanding of the potential contribution of HIVST to the well-being of MSM in England & Wales.

The overarching aim of this thesis is to develop an understanding of the potential contribution of HIVST to the well-being of MSM in England & Wales. Based on the constituent studies in my thesis HIVST clearly has a potentially significant contribution in this regard, especially when considering intervention adaptations that can be used to broaden testing access for the various groups I identify.

In this section I describe how I have met each objective of this thesis, which collectively contribute to meeting the overarching aim.

4.2.2 Objective i. To examine the values and preferences of MSM for HIVST interventions considering key domains of intervention design.

The first objective of this thesis is met in the first paper *HIV Self-Testing among Men Who Have Sex with Men (MSM) in the UK: A Qualitative Study of Barriers and Facilitators, Intervention Preferences and Perceived Impacts* study which begins this body of work. For the purpose of this objective, the key domains of intervention design are test type (including test generation and sampling approach), delivery method, instructions and support tools.

This paper clearly demonstrates the range of preferences relating to HIVST designs and kit types that exist amongst MSM in England, and the reasons underpinning them. Perhaps most importantly, a strong preference for 4th generation testing was found, as tests with this window period most closely match what is routinely available in clinical settings and has the shortest time between initial infection and detection. This is despite the current lack of availability of a 4th gen HIVST, perhaps constraining potential intervention implementation, and possibly relegating the technology to use when no significant recent risk is perceived for many.

The importance of sample type in decision making is also demonstrated in this publication. Although a preference for blood based testing was observed because of higher perceived accuracy, a significant minority had a strong preference for oral fluid testing because of their aversion to drawing and collecting a blood sample. This is broadly in line with existing evidence from this time (32, 47).

MSM tended to prefer HIVST interventions which delivered kits through the postal system. These were perceived to be exceptionally convenient for most and were generally unproblematic, providing packaging was discreet and the kit could fit through a standard letterbox. There was a minority of MSM who would not access such an intervention however, mainly due to domestic privacy concerns. This formative research indicated that this would likely be especially problematic for younger MSM who may live in their family home, shared accommodation or with carers, as well as Asian MSM who were described by other Asian MSM in our study as more likely to be living with female partners or in extended family groups.

Instructions that were simple to understand and relied on small volumes of text were preferred. In this study the kits which were shown to participants were disliked as their relatively opaque instructions gave the impression that the tests were significantly more challenging to perform than they were. Video instructions were also valued.

In terms of support, interventions which provided helplines were felt to be essential in order to mitigate against potential harm and to support correct use. Further results drawn from papers 3 and 4 demonstrate the importance and value of follow-up systems embedded in the intervention, especially those that record results through follow-up approaches and can signpost to care if necessary. This type of support tool mimics what has been implemented with MSM in the UK and in other high-income settings (128-130).

This first paper demonstrated the variability in preferences for HIVST interventions and illuminates a core benefit of the approach: HIVST interventions can be tailored to the preferences of the groups being targeted by service delivery. Doing so allows for more responsive interventions enabling wider uptake than one intervention approach might facilitate, especially when compared to clinical interventions which may be constrained by clinic spaces and priorities, with the needs of beneficiaries often being secondary considerations. This illustrates the contribution HIVST can have to the well-being of MSM in England and Wales by providing an additional, flexible intervention which better meets need across heterogeneous groups.

4.2.3 Objective ii. To explore the potential barriers and facilitators of HIVST for MSM using COM-B as a framework.

The first paper from the initial formative study also addresses the second objective of my thesis. This publication explores the primary barriers and facilitators that potential intervention beneficiaries face when considering uptake, described using COM-B. Capability, both physical and psychological, were largely associated with barriers such as difficulty performing the test. Opportunity and motivation had both associated facilitators and barriers.

When considering potential HIVST interventions, concerns around capability (physical) were a significant issue for MSM. This was due to the instructions in the existing kits in the first formative study, but also because of concerns regarding their own abilities in operating an RDT properly, and the potential risks associated with failure, such as an incorrect result. This is in line with existing literature, although perhaps more pronounced (62, 80).

Capability (psychological) was typically seen to be reduced by the dislocation of testing from care pathways, because of concerns around the implications of receiving a positive result alone, the potential for social harm and the perceived likelihood that HIVST would reduce STI screening. However, this domain was enhanced for those with significant privacy concerns (largely those who tested sub-optimally) by the added confidentiality provided by HIVST interventions, giving beneficiaries a level of privacy not typically provided in clinic based interventions. This could however be partially eroded depending on delivery mode as discussed previously.

Opportunity (physical) was shown to be enhanced by the provision of HIVST through increased choice offered by the potential of HIVST interventions, and the range of alterations that could be made for individual target groups. Strong testing norms (as illuminated in the second paper of this thesis), provide a facilitator to HIVST uptake, working through opportunity (social).

Motivation (automatic) was enhanced through the additional convenience associated with HIVST; reduced opportunity cost provided a strong incentive to access a novel intervention. Participants' motivation was also reduced however by the potential for HIVST to reduce STI testing frequency, posing a danger to both self and community by potentially increased incidence of STIs, underlining the importance of developing strategies to respond to this concern.

Motivation (reflective) was reduced by concerns about HIVST's dislocation from established care pathways, providing a barrier to uptake. This is a well documented concern with HIVST (32, 40, 52, 75). Reflective motivation could also be influenced by sample type, window period and support tools provided; different options could pose either a barrier or facilitator to uptake depending on intervention design and the preferences of the end user.

Individuals planning and implementing testing interventions need to take into account a variety of barriers and facilitators specific to HIVST. This provides a good starting point in terms of evidence elucidating what these are, how they might be operationalised and the COM-B channels through which they function. This demonstrates the barriers that must be overcome and facilitators harnessed to enable appropriate service provision of HIVST thus potentially enhancing the well-

being of MSM in England and Wales. To my knowledge this is the first inquiry into HIVST that uses COM-B in this way.

4.2.4 Objective iii. To understand how HIVST compliments existing testing strategies considered or adopted by MSM.

This objective is met through the second paper from the formative focus group discussion study. This manuscript explores the normative understandings of the predominant testing motivations for MSM, providing insights into the ways HIVST may be received upon implementation. This is a significant contribution to the academic literature as prior to this research it was unclear the role that self-testing may fill and what considerations implementation had to be attentive to.

This study found three clear motivations for accessing testing: in response to risk; for reassurance, and out of routine. Testing in response to risk was a normative practice, and was understood universally as a primary testing motivation. Given issues regarding a perceived lack of support for a potentially reactive result, HIVST was not thought to be useful for testing in this context except where significant barriers to clinic access existed.

Testing for reassurance was a major theme, especially for those in the general focus group discussions and those with MSM at higher risk of HIV acquisition. When considering testing in response to this motivation, MSM were seeking confirmation of a continued HIV negative result, rather than because they felt there was a possibility of infection. Never-the-less, the anxiety driving these testing motivations was significant and could be challenging to manage. HIV testing was felt to be a form of self-monitoring and risk management in this context. In these narratives, HIVST was perceived as a useful self-management tool, 'topping-up' between clinic run tests and providing reassurance of a negative status.

Frequent HIV testing was strongly viewed as a normative behaviour for many MSM in this study, reflecting wider research (20). These norms were a palimpsest with layers drawn primarily from friends and peers, with health promotion practitioners, those working in clinical services and public health agencies contributing to their increasing emphasis and reinforcement over years. Testing norms were so widely held that MSM who had never tested for HIV struggled to disclose this in focus group discussions. HIVST was felt to be exceptionally useful in narratives surrounding testing in response to biomedical norms disseminated through friends and peers, as the technology allowed individuals to meet these expectations with limited effort. However, for some, self-testing transgressed other norms by bringing HIV testing into the home.

These results indicate ways in which HIVST complements existing testing strategies adopted and considered by MSM, illuminating the likely reception the intervention will receive and its position

alongside other services. Based on these narratives, self-testing will likely be confined to testing when not perceived to be at significant risk of a positive results, except for when major barriers to clinic access exist. Implementers can therefore consider the various needs of different populations; those who test in response to risk will likely maintain their clinical barriers whatever the result and supportive structures clearly must consider this issue in intervention development. This demonstrates the potential of HIVST to contribute to the well-being of MSM in England and Wales by reducing opportunity costs when testing for reassurance and out of routine, and by providing a testing mechanism for those who seek testing in response to sexual risk, but who have significant barriers to clinic access. Although motivations and testing norms around HIV testing generally are well understood in the literature (20, 131), this is the first publication that explores this in such depth in the context of HIVST.

4.2.5 Objective iv. To assess the feasibility of recruiting MSM to the SELPHI pilot, and the acceptability of the HIVST intervention used among those randomised to receive a kit.

This objective is addressed through paper 3 of this thesis, drawn from the study that provides a link from formative to implementation research. Recruiting MSM to the pilot was demonstrated to be feasible, and the intervention highly acceptable among those who received it. This provides the first European data about usability of HIVST amongst end users, providing a vital piece of evidence to support implementation efforts.

In this study I demonstrate the feasibility of recruiting a broadly representative sample of MSM to the RCT pilot using a range of platforms, as outlined in the comparison with other convenience and probability based samples (126). In contrast with Vera et al 2019 (68), this publication demonstrates HIVST can reach significant numbers of MSM who do not test in line with national guidelines. In contrast to Gibson et al 2016, this study had much higher retention with vastly more participants completing the two-week and three-month surveys (69).

These results also highlight the need to design interventions which require minimal steps between them. In the pilot phase, 25% of participants did not link through from the recruitment to enrolment surveys, leading to attrition at this stage likely due to the demands of trial processes. For interventions distributing free kits very widely in a routine setting, simplicity of access should be a key goal.

I found that HIVST outperforms HIVSS tests on test completion when comparing our results to self-sampling service evaluations. In total, 95% of those who filled in the three month survey in the pilot, far outperforming the 55% return rates of HIVSS (126).

Test kit usability was extremely high in this study, with the vast majority reporting good or very good experiences, higher than in many other studies. This was not expected given the capability concerns identified in the formative work (27), although extensive efforts went into addressing these before the pilot phase of the RCT. Never-the-less, elements of the kit such as the lancet and the buffer pot, both sources of usability problems, could not be changed leading to concerns that capability issues may persist.

The findings of this usability analysis are further nuanced by the qualitative data, which demonstrates that despite very high usability, capability issues did indeed remain especially in relation the use of the spring loaded lancet to draw blood, a step which was felt to be challenging by some. The instructions were perceived to be easy to understand, perhaps reflecting increased simplicity introduced following a kit redesign by the manufacturer which also reduced the size of the box so that the kit could fit through a standard letterbox. Opportunity was enhanced by the provision of a free HIVST, ameliorating barriers pertaining to inconvenient clinics, and psychosocial barriers such as privacy and stigma. Motivation (reflective & automatic) was negatively affected by increased anxiety associated with the intervention as a whole, and the 15-minute waiting period for results.

This significant contribution clearly demonstrates that intervention delivery is feasible, and the kit usable. Some issues surrounding capability remain, although they are less pronounced than might have been predicted following the formative work. Self-testing clearly ameliorates barriers to testing access, but poses its own challenges with regard to a potential increase in anxiety amongst some end users. This demonstrates that HIVST contributes to the well-being of some MSM in England and Wales by providing a convenient, highly acceptable HIV testing method which leads to increased test completion when compared to HIVSS, thus lessening missed testing opportunities and potentially reducing undiagnosed HIV.

4.2.6 Objective v. To explore the experience of utilising HIV self-tests and the implications for further intervention development and scale-up.

The fifth objective of my thesis is met by the fourth paper which itself is drawn from a study investigating intervention experiences among cis-gender MSM in the SELPHI RCT, the third constituent study of this thesis. In this publication I use in-depth interviews to explore the experiences of 37 MSM who participated in SELPHI. This is the first purely qualitative evidence investigating HIVST experiences of use from Europe. This study provides important insights into the experiences of different groups of MSM, based primarily on previous testing history and makes a significant contribution to the literature, especially in relation to the role of emotional responses in HIVST acceptability and uptake.

MSM were motivated to access the intervention because of a reduction of barriers related to stigma from clinic staff and attendees, as well as simultaneous increases in privacy and in convenience. HIVST was conceived of as generating either more or less anxiety than other services based primarily on testing history and motivation for testing; individuals who were less testing experienced and those testing in response to risk reported increases in anxiety relative to other testing methods. There was a significant minority, however, who felt HIVST reduced anxiety associated with other testing services by placing them at the centre of their decision making around their health.

In this paper I also described how the supportive components of the intervention worked to facilitate increased engagement with testing more broadly by providing a series of reflective experiences throughout the intervention process. This provided a sense of involvement with and connection to the trial, and facilitated increases in motivation to test generally.

Although the support structures were felt to be adequate and in line with expectations, most in this study sought support (regarding positive and negative results) from wider social groups. This includes both of the participants with positive results who initially told a friend or a family member before seeking care. This underlines that HIVST is a socially embedded testing technology, expanding healthcare into the private realm.

Capability concerns were again a significant theme within this analysis. Although most completed the test without errors, several participants had difficulty with both the blood draw and test processing stage. Two broke their first HIVST test stick while attempting to use it, underlining the role of enhanced supportive information and instructions accompanying these tests.

The 15-minute waiting period between the test processing stage and result interpretation stage were described universally as an exceptionally anxious period. In this period of vulnerability individuals had intense reflection on their potential risks, often concerns which were not grounded in reality as many had no significant risk of which to speak.

I describe important qualitative outcomes relevant to implementation. Firstly, individuals who had higher barriers to clinic access based on stigma, privacy concerns or geographic issues tended to describe HIVST as facilitating increased testing frequency, but with the potential to reduce STI screening by reducing incentives to access clinical services. Secondly, minor adverse outcomes (n=2; fainting, relationship discord) were also reported by two individuals, a key finding given that I did not sample based on this criteria and the adverse outcomes were discovered spontaneously. Although these did not affect intervention acceptability, intervention development should be attentive to concerns regarding potential adverse outcomes. Finally, both individuals who had positive HIVST

results linked to confirmatory care within 24 hours and described very high intervention acceptability, crediting the technology with saving their lives.

Clearly this study illustrates a variety of considerations for intervention development and scale up. The role of emotion in HIVST needs to be accounted for in developing interventions which provide reassurance where possible. This could be done through a variety of mechanisms, including enhanced access to counselling, reassuring messaging about HIV treatment, prompts to discuss difficulties with family members and other social contacts as appropriate, and linkages to other types of support both online and face-to-face. Capability concerns continue to be an issue for those operating the tests, underlining the need for clear instructions and more prominent linkage to alternative forms of instruction such as videos. Bacterial STI self-sampling for STIs should also be considered for inclusion in self-testing packages of care in order to counteract concerns regarding reduced uptake of STI testing.

This provides strong evidence that HIVST can improve the well-being of MSM in England and Wales by providing a highly acceptable testing intervention which addresses previously identified issues surrounding care pathways and, to an extent, capability issues while increasing choice and facilitating more frequent testing among some MSM who test sub optimally. The potential of HIVST to place those with concerns about healthcare access at the centre of their decision making around testing is a significant benefit, perhaps transforming how these men access services.

4.2.7 Objective vi. To explore how components of the SELPHI interventions impact on behaviour for, and are experienced by, RCT participants.

The sixth objective of my thesis is met in the fifth paper included. This is drawn from the third study investigating intervention acceptability and experiences of cis-gender MSM in the SELPHI RCT. This study uses an innovative method to investigate the experiences of distinct groups of MSM identified in the data. During analysis it was clear to me that there were three distinct groups with profoundly differing intervention experiences. I formalised these into an inductive typology based largely on HIV testing history and engagement with SELPHI. I then used these as the lynchpin for a framework analysis investigating to what degree the assumed intermediate outcomes related to specific intervention components were experienced by these groups, and to investigate reasons for variations within these. This analysis demonstrated the mechanisms through which HIVST can contribute to well-being among MSM in England and Wales.

The three groups identified were 'inexperienced testers'; 'pro self-testers' and 'opportunistic adopters.' Inexperienced testers were those who had little or no testing history and did not test out of routine; they were typically early in their sexual or testing careers and tended not to be very open

about their sexual orientation or practice. They had high psychosocial barriers to testing relating to the COM-B domains of motivation (reflective & automatic), opportunity (social & physical) and capability (psychological). These barriers included lack of risk perception, shame, fear of stigma, privacy concerns and low self-efficacy when considering testing in a clinic. Some also had concerns related to the COM-B domain of opportunity (physical) (e.g. inconvenient clinics). HIVST ameliorated many of these concerns, facilitating testing uptake.

Pro self-testers were often at an intermediate point in the sexual careers and sometimes lived partly hidden lives in terms of their sexual orientation. Men in this group had many of the same psychosocial concerns related to opportunity (social & physical) and capability (psychological). This group tended to have a testing history and were somewhat motivated to access testing, but their frequency was constrained by the high barriers to clinic access they faced. HIVST was the most preferred testing method for this group as it ameliorated many of their psychosocial and opportunity (physical) concerns, facilitating increased testing frequency.

Opportunistic adopters were men who are well served by existing testing opportunities with few distinct COM-B barriers, except for some minor issues with opportunity (physical). Some in this group used HIVST because of increased convenience, but the majority engaged with the intervention out of novelty and to respond to social norms around testing.

Assumed intermediate outcomes were highly variable across groups. Figure 6 provides an overview of the differences in these based on strength of qualitative evidence. The intermediate outcomes assumed in the SELPHI logic model were most closely matched for the first group amongst whom there was typically strong evidence of intermediate intervention outcomes. For men in this group, HIVST engaged them in testing more generally through a variety of intervention components. The adverts increased motivation (automatic), and kit provision strongly enhanced opportunity (social) by providing an additional, private testing method while also increasing opportunity (physical). The two-week survey increased motivation (reflective) by providing a reflective experience which increased engagement with testing generally. There was some evidence that the risk assessment embedded in the intervention increased risk perception through motivation (automatic) channels, but this was partial.

For pro self-testers, evidence began to diverge. Kit provision did increase privacy and therefore opportunity (social), as well as physical accessibility, and the testing reminder increased engagement with testing through motivation (reflective) channels. There was however only partial evidence

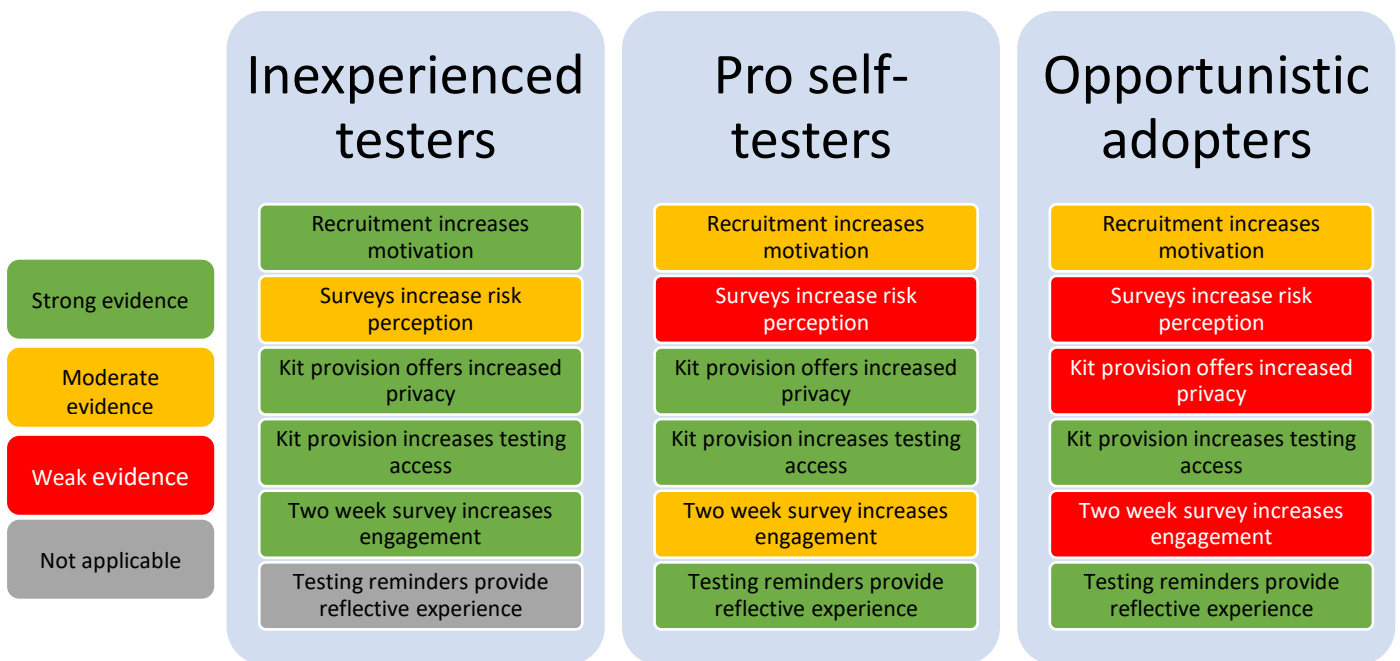


Figure 6: Testing typology and participant outcomes

regarding the adverts and two-week survey increasing motivation, as this group was already largely motivated to test. There was weak evidence that the surveys increased risk perception.

Opportunistic adopters had the highest divergence in experience from the logic model. For this group the provision of the test increased convenience through opportunity (physical) channels and the testing reminder increased engagement with testing. However, there was less evidence regarding increases in testing motivation relating to the adverts and weak evidence on the rest of the assumed outcomes.

This demonstrates the clear differences various groups of MSM have when engaging in the HIVST intervention provided by SELPHI. Clearly experience is highly variable across groups, and largely related to the COM-B domains individuals have barriers around. These findings allow a close examination of intervention functions which facilitates a reimagining and redesigning of HIVST interventions to better meet the needs of heterogeneous groups of MSM, facilitating responsive interventions which can contribute to increases in well-being by improving interventions, their targeting and their delivery. This study is not only methodologically unique, no other research in the existing literature investigates HIVST experiences in this way amongst intervention beneficiaries.

4.2.8 Objective vii. To examine the utility of COM-B as a useful model for understanding behaviour change in relation to the provision of HIVST.

This objective is also met in the fifth paper of my thesis. Using a novel application of framework analysis has enabled me to demonstrate the ways the intervention functioned for groups with distinct differences in COM-B deficits. This illuminates the utility of COM-B as a model for

understanding behaviour change in relation to HIVST provision, and the challenges in using it for this purpose.

As it is currently articulated, COM-B makes no differentiation about the utility and impact of intervention components for those with pronounced needs for an intervention versus those who engage for other reasons (91). Clearly, for those who engaged with the SELPHI intervention, assumed outcomes from our logic model were only achieved in those who had distinct deficits in these areas. Further, it seems that the strength of outcome experienced may have been related to the level of barrier. This demonstrates that interventions only function as intended for those who have specific areas of need which the interventions respond to. Interventions are often designed for those with the highest deficits, potentially involving components which beneficiaries find irrelevant at best, or cumbersome and annoying at worst. It also shows that in COM-B the intervention functions described only enact changes in the individual under certain conditions. This is a significant departure for how COM-B is thought about as currently it is presented as a monolith: all things in it are presented as true in all circumstances.

This paper therefore illustrates that although COM-B can be useful for conceptualising interventions and how they function, it does not take adequate account of the implications of delivering interventions to those who do not have the hypothesised COM-B deficits. The potential for frustrating beneficiaries and providing components they do not value may have the converse impact of reducing acceptability through needless components. It does however illustrate the importance of designing flexible interventions which account for a range of needs. Harnessing this knowledge for HIVST and other multi-component interventions delivering new prevention technologies can contribute to the well-being of MSM by providing flexible, acceptable interventions which better meet their needs.

4.3 Logic model adaptations

Over time, as I have developed this evidence base on HIVST, my thinking on how interventions work for individuals has evolved from my initial logic model theorising. This has necessitated adaptations in the SELPHI logic model to reflect the understandings that have emerged from the third, fourth and fifth paper of my thesis. Specifically, I suggest an additional level of outcomes and expanded detail on context. Instead of moving from intervention processes to intermediate outcomes and then on to trial outcomes, I have shifted what I previously conceived of as intermediate outcomes to the immediate level, and have developed a range of intermediate outcomes which occur before, and facilitate, trial outcomes which have been renamed long-term outcomes. I also more clearly specify the groups who are likely to experience these outcomes based on their COM-B deficits. I included additional detail on context, reflecting the structural and political changes that have occurred over

this research period and which influence the intervention. Figure 7 presents the updated logic model.

4.3.1 Context

Strong cultural norms for HIV testing support HIVST uptake, with constraints drawn from perceived issues with capability and a lack of supportive structures. It is also clear that well-documented healthcare rationalisation and the closure of sexual health services will create barriers to existing services which will also increase HIVST adoption. This should not be seen as a positive development, but is clearly important in considering intervention uptake as it could potentially change the context of use for those who access the intervention. Indeed, there may be increased engagement from groups who have an HIV testing routine and are testing in response to risk, whose first preference would be to access a bricks and mortar service but who face new structural barriers to access. In addition, increased focus on self-management in healthcare may shift norms around testing, overcoming issues related to the incursion of HIV testing into the domestic sphere (58).

4.3.2 Immediate outcomes

These outcomes have been brought forward from the intermediate outcome level acknowledging that these occur almost immediately at the point of contact with the intervention components. It is clear that these are not evenly distributed amongst those accessing the interventions: for those who are new to testing or have high psychosocial barriers to testing access, the intervention performs most closely to the assumptions specified in the logic model. For those with more testing experience and limited barriers to access, many of the intervention functions have little impact. I have removed that the risk assessment increases motivation to test as evidence in this regard was non-existent in most groups and scant even in inexperienced testers.

4.3.3 Intermediate outcomes

I have developed additional hypothesised intermediate outcomes which are necessary pre-conditions to achieving the trial outcomes and which follow from the immediate outcomes. These reflect the changes in how I conceptualise the ways in which HIVST interventions function, drawing learning from across the 5 constituent papers of my thesis.

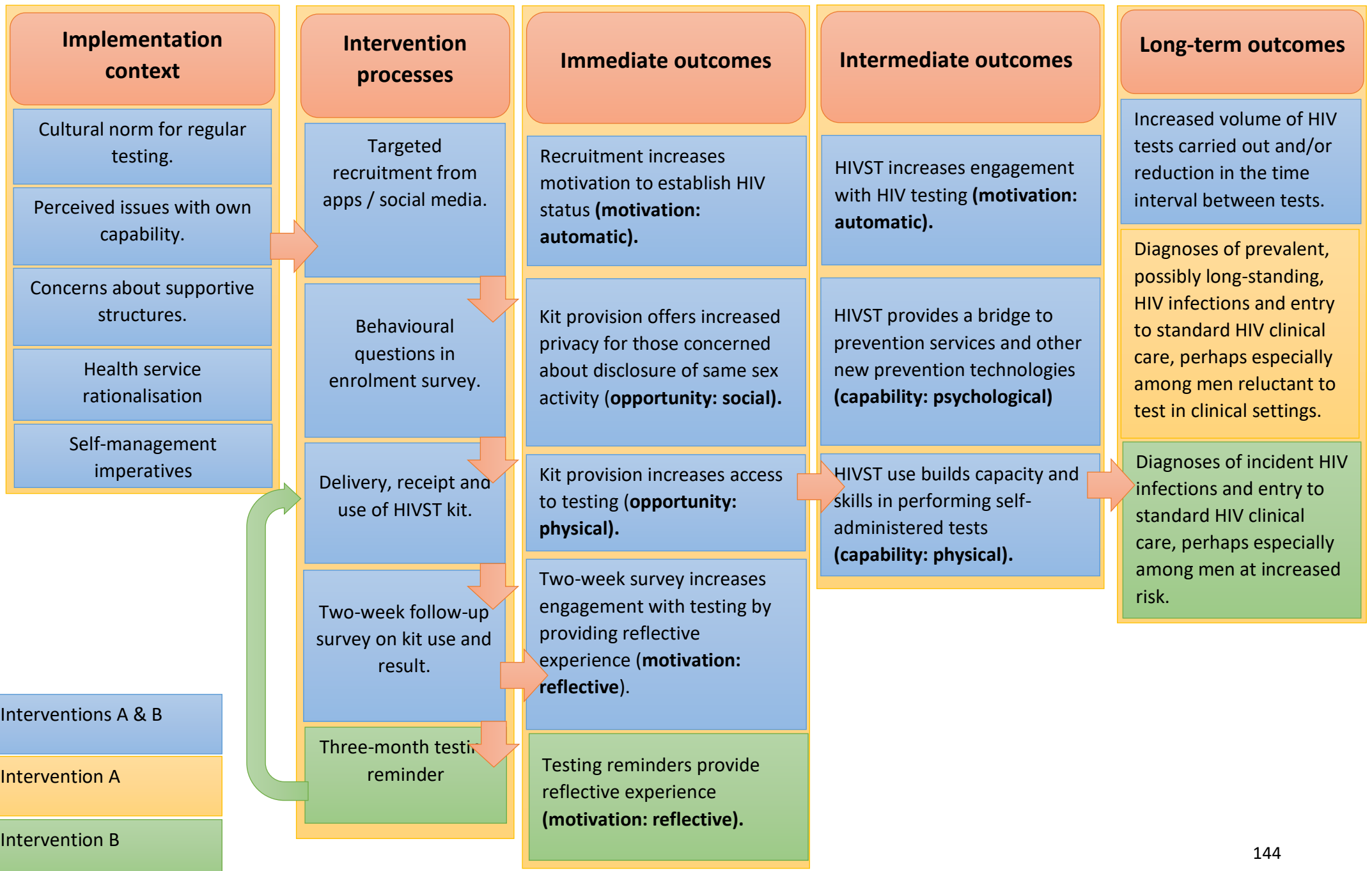


Figure 7: Updated logic model

These are: 1) HIVST increases engagement with HIV testing more broadly (motivation: automatic); 2) HIVST provide a bridge to clinical services including HIV and STI testing, as well as to other new prevention technologies (capability: psychological); 3) HIVST use builds confidence and skills in performing self-administered HIV tests (capability: physical).

Given the transformation observed for inexperienced testers in the 5th paper of the thesis, it is clear that HIVST interventions can fulfil the dual role of engaging individuals with both HIV testing more broadly and with other clinical services. This is enacted through several processes. Firstly, barriers related to fear regarding the outcome of a positive test are reduced by those without testing history and who use an HIVST and receive a negative result, eliminating a key barrier to service access. Secondly, familiarity with the process of testing, coupled with the supportive elements of the intervention, increase engagement with testing through a series of reflective experiences which occur at different times throughout the intervention journey. Finally, by reducing barriers to testing generally, barriers to other services are also reduced through increased comfort and feelings of capability in service access.

Another important intermediate outcome is that HIVST exposure increases capability for those who access the intervention. Despite this area being a major concern for those engaging, having used a self-test makes it much more straightforward to operate one in the future. Although individuals had concerns about operating the HIVST and some issues with the lancet and test processing stage, as reported in papers 3 and 4, all felt these would become less problematic over time. Paper 4 provides the clearest evidence of this; both participants who broke their kits were able to source replacements and complete the test properly.

4.3.4 Long-term outcomes

In this logic model I have renamed the final section from trial outcomes to long-term outcomes, illustrating that these outcomes are important for public health more widely, rather than just for SELPHI. I have included that HIVST contributes to the well-being of MSM through improving service access and sexual health as illustrated by the constituent studies of this thesis

4.4 Intervention implementation: a recommendation and a framework

On the basis of these findings, I recommend the implementation of free online HIVST in England and Wales to support the well-being of MSM and to provide an additional testing option alongside a diverse array of service provision. In order for HIVST to fulfil its potential in meeting the needs of groups least likely to test and to widely increase testing engagement, the flexibility offered by the technology must be harnessed in intervention design. For example, HIVST could be provided through

a national programme, perhaps providing specific intervention adaptations in regions and to specific sub-populations with unique needs.

In this section, drawing on the constituent studies of my thesis and the wider published literature, I explore potential adaptations to increase the reach, uptake and effective use of self-tests, especially among underserved groups. I also describe the key concerns which implementation must be attentive to. I draw on the first four of the five broad categories identified in CFIR (first explained in section 2.2) to illustrate the main areas of concern in service delivery, mainly the intervention, the outer and inner settings and individual characteristics (95). I do not focus on process of implementation as this is beyond the scope of this thesis and is dependent on how the intervention is commissioned and who is responsible for service delivery (95).

4.4.1 Core components

In CFIR, the intervention is divided into two parts: core components and the adaptable periphery (95). Core components refer to elements of an intervention which cannot be changed and must play a central role in intervention delivery (95). This section describes considerations relevant to the core components of HIVST, mainly, the RDT being used.

Currently no self-tests are available globally which use 4th generation assays which provide the shortest window period possible with an RDT, reducing this from 6 weeks to 4 (2). Given the preferences for the shortest possible window periods and high sensitivity observed in formative work, it is imperative that these are developed in the future in order to more widely meet the needs of MSM. These are technically possible; currently 4th generation RDTs exist which could be adapted for self-use as has been the case with other tests. This adaptation may have the advantage of expanding self-testing to individuals testing following a risk event who are also comfortable accessing clinics as identified in the formative papers of my thesis (27, 58).

Although blood sampling is preferred by many MSM in England and Wales due to its advantages in terms of sensitivity, a significant minority of MSM will not access self-testing while only blood-based tests exist. Thus, oral fluid self-testing should be considered as a supplementary option to support men in testing more frequently and comfortably. Additional attention will be required in implementing these as they have more limited utility for MSM on PrEP as the detection of seroconversion can be blunted due to the antibody detection assay used and lower sensitivity, potentially leading to missed infections (132).

4.4.2 Adaptable periphery

This section described the elements of interventions that can be adapted depending on the needs of the target population drawing on data from the constituent studies of my thesis. The elements

discussed here are presented in table 6, which described the potential intervention approaches, their target audience and the COM-B domains associated.

Capability issues remain a primary barrier to HIVST uptake which is critical to resolve. While manufacturer provided kit instructions are sufficient for many MSM, clearly significant capability concerns remain, as demonstrated by papers 3 and 4 in this thesis. For some, these can be resolved in straightforward ways such as providing supplementary information with the kit, or very clearly signposting to freely available videos explaining the testing process and how to interpret the result. For those with significant capability challenges (e.g. those with lower educational attainment, non-English speakers), this will likely be insufficient. Acknowledging the privacy barrier posed to this approach, these men may benefit from in person demonstrations from peer support workers or healthcare providers depending on the service delivery model. It is also critical that interventions are designed so that end users can easily source replacement kits when efforts to conduct an HIVST fail.

Delivery mode for self-tests is an important consideration to increase accessibility widely by improving opportunity (physical & social). For the potential of self-testing to be realised, interventions must take into account a range of needs related to this issue. This is especially true given the high value many place on privacy in HIVST interventions (2, 27, 32, 82). In order to counter domestic privacy concerns, distribution mechanisms whereby individuals can access kits themselves without having them sent to their home or another address are required (27). These can be through healthcare services such as pharmacies or clinics, or, recognising other potential privacy concerns, through automated systems such as click-and-collect functions or through vending machines. As previously discussed, the latter has been successfully trialled in Brighton and could potentially be expanded to other locations with high densities of MSM and other affected groups (75). It is important to note that this demonstration project reached low numbers of MSM who were testing sub optimally, perhaps reflecting its location in a sex on premise venue both reaching a group at potentially increased risk who were already testing frequently, but also in a location posing additional psychosocial barriers to access. Never-the-less this approach may help boost equity in HIV testing interventions if placed appropriately, especially by providing a testing opportunity to Asian MSM, and younger MSM who are perhaps more likely to have concerns related to domestic privacy (27).

Targeted outreach has been used in other settings to reach MSM at higher risk of HIV acquisition and could be an approach which helps increase social acceptability of self-tests and provides outreach workers with the ability to address capability concerns (51).

Table 6: Intervention adaptations, target audiences and COM-B domain

Intervention component	Possible adaptations	Target audience	COM-B domain
Test generation	4 th generation assay	All MSM	Motivation (automatic)
Sample type	Blood	Most MSM	Motivation (automatic)
	Saliva	MSM with aversion to blood draw	Capability (physical)
Instructions	Providers' written instructions	Most MSM	Capability (physical)
	Enhanced written instructions	MSM with minor capability needs	Capability (physical)
	Video	Most MSM	Capability (physical)
	Demonstration	MSM with pronounced capability needs	Capability (physical)
Delivery mode	Postal	Most MSM	Opportunity (physical)
	Click-and-collect	MSM with domestic privacy issues	Opportunity (physical)
	Vending machine	MSM with high privacy barriers	Opportunity (social); capability (psychological)
	Pharmacy & clinic	MSM with capability or support needs	Opportunity (physical & social), Capability (physical)
	Outreach	MSM at higher risk	Opportunity (physical), capability (physical & social)
	Partner delivered	MSM at higher risk	Opportunity (physical), capability (social)
Support	Passive reporting and follow-up	MSM with lower level needs	Motivation (automatic)
	Help line	All MSM	Motivation (automatic)
	Active follow-up	MSM testing for the first time	Capability (physical & psychological)
	Online counselling	MSM with high level needs	Capability (physical & psychological)
Demand generation	Advertisements	All MSM	Motivation (automatic), capability (social), opportunity (physical & social)
	Risk assessments	MSM who test infrequently	Motivation (reflective)
	Testing reminders	MSM who test sub optimally	Motivation (automatic), opportunity (social)
Accompaniments	Bacterial STI self-sampling	MSM who test at clinics infrequently	Motivation (automatic), capability (psychological)
	Syphilis self-testing	MSM who test at clinics infrequently	Motivation (automatic), capability (psychological)

An option which has been used widely in other settings is to design interventions whereby individuals distribute HIVSTs to their sexual partners. This approach has the advantage of potentially reaching individuals with the highest levels of concern around privacy and healthcare access, while also potentially exposing those distributing kits to unintended outcomes such as harm and relationship breakdown (133-135).

Clearly varying levels of support regarding using an HIVST and in dealing with the psychological consequences of testing are required by different groups of MSM. For perhaps the majority, basic levels of support will be adequate for their needs. A minimum standard of support should be established, and include a results recording follow-up system and a telephone helpline for those requiring it. Interventions could then provide active follow-up for those reporting positive results. For groups with higher needs (e.g. first-time testers, younger MSM, people with specific learning disabilities, individuals with identified language issues) an optional active follow-up system could be provided with a healthcare worker contacting individuals identified either through an algorithm selecting candidates based on demographic and behavioural characteristics, or through an opt-in process. This system would require permission from the end user and could potentially help manage or reduce any harms which might occur. Kits have also been developed in the US which include a Bluetooth beacon which activates upon opening prompting a counsellor to contact the user, with an RCT demonstrating feasibility of service delivery (88, 136). This could be an option provided to the same groups as active follow-up could target. Both options would require permission from the end user and clear information about the provision of this, lest these intervention types negate benefits of privacy and confidentiality associated with HIVST.

Demand generation initiatives will be required to draw people to the intervention, working through motivation channels and through increasing opportunity (social). This will also be helpful in increasing uptake as HIVST use spreads from the first groups who access it (innovators, early adopters, early majority) into those who pick up the intervention in later phases (late majority and laggards) (59). Clearly, as demonstrated by the third paper in my thesis and in other pilot and demonstration projects (69, 128, 129), online advertisement is likely to be the cornerstone of self-testing interventions in England and Wales. Other demand generation initiatives can also be considered, such as automated testing reminders, especially for those who report markers of risk such as CAI. Broader social marketing initiatives, such as those funded by the statutory sector, could incorporate information about HIVST, ideally highlighting facilitators (e.g. convenience, privacy), minimising capability barriers while potentially harnessing narratives around uptake including testing out of routine (27, 58, 126). Finally, HIVST could be included in broader longitudinal e-health

promotion interventions, providing kits to individuals taking part in them as an additional option rather than forming the cornerstone of an intervention (137).

In order to counter the well documented concern about lack of STI testing in HIVST interventions (2, 27), STI self-sampling kits should be provided boosting acceptability through motivational and capability channels. Dual HIV and syphilis STs are currently being developed and may be a key development, broadening the utility of self-testing to cover additional STIs.

4.4.3 Outer setting

In CFIR, the outer setting is defined as the economic, social and political context that affects implementation (95). Generally this is used as a lens through which to view an organisation's position inasmuch as it affects a pathway to implementation. For the purpose of this thesis I use it to refer to the broader economic, political and social contexts of service delivery.

Although few data exist about cost savings with HIVST, the technology has often been promoted as a low cost intervention which could potentially be useful for diverting patients from bricks and mortar services. HIVST has emerged at a time of austerity, healthcare rationalisation and the associated widespread closure of GUM clinics. This may lead to commissioners relying on HIVST as a cost saving mechanism, as has been the case with HIVSS. Although this supports intervention implementation, it fails to consider that HIVST is, for many, a supplementary testing technology and that it is vital for existing services to be maintained to meet the wide variety of needs of heterogeneous groups of MSM (15, 58). Implementing organisations must be attentive to this, and resist pressure to rationalise services in favour of self-testing.

This temptation for commissioners to replace clinics with remote approaches such as HIVST programmes is perhaps the largest threat to successful implementation. As demonstrated in my thesis, HIVST interventions are a supplementary testing option for many MSM who highly value interactions with healthcare professionals. Deprioritising clinical interactions has the potential to reduce HIV and STI testing amongst many MSM, while also potentially leading to an increase in STIs. Service provision must be attentive to these potential issues.

Current public health priorities also align with widespread implementation. The drive to reduce new HIV infections through expansion of testing through the test and treat agenda clearly supports the widespread introduction of HIVST, especially given the potential to reach those who test less often and increase their testing frequency. HIVSTs wider ability to engage MSM in testing, as demonstrated in the fifth paper of my thesis, should be highlighted as a key benefit for the intervention.

Culturally, among MSM, strong norms around HIV testing support HIVST implementation. This is demonstrated in my thesis by the potential contribution of HIVST to the well-being of MSM through its role in testing for reassurance.

4.4.4 Inner setting

In CFIR, the inner setting refers to the structural, political and cultural contexts through which implementation will proceed (95). For HIVST this mainly means the structural context of potential implementing organisations, and the features and priorities of organisations likely to deliver HIVST.

Structurally, implementation is not necessarily supported by current priorities and attitudes.

Currently, Public Health England (PHE) commissions the national HIVSS service on behalf of participating local authorities in England. This approach was used partly because it retains links with the service user to the organisation facilitating follow-up for false positives (a significant issue with the technology) (138), and linkage to care for true positives. This approach also has the benefit of contributing to surveillance data. For HIVST to be implemented by PHE, a culture shift is required. Because HIVST relies on the service user to seek care themselves, potentially with limited support from healthcare professionals, PHE may be reluctant to adopt the technology over concerns of sub-optimal linkage to care when compared to HIVSS approaches. It is vital for HIVST to be implemented that patient autonomy is respected and the choice not to seek immediate care following a positive result using an HIVST is understood as a socially situated decision grounded in rational decision making for some people. The emphasis on capturing all potential positives within surveillance must also be relaxed to support the technology. Given that HIVST is likely to outperform HIVSS at scale this will mean potentially increasing rates of diagnosis on the whole, while also possibly losing some individuals at the first step of the care pathway. In this scenario HIVST will still contribute to an overall increase in well-being for MSM in England and Wales however by perhaps diagnosing more HIV and reducing service provision barriers.

The features and priorities of implementing organisations are likely to be supportive; two of the four main demonstration projects have been provided by the voluntary sector, namely the Terrence Higgins Trust and SH:24 (128, 129). Both of these organisations have experience in developing systems to provide a basic level of support and would likely be capable of providing the intervention alterations which might be required to increase acceptability and reach.

4.4.5 Individuals involved

The fourth domain in CFIR is individuals involved in the implementation process. For implementing organisations themselves, delivering HIVST is not a significant departure from the work they

currently do. However my previous formative research with key informants in England suggests that some may be resistant, especially those in clinical settings (125).

A robust evidence base should help assuage concerns, however additional motivators may need to be put in place to gain buy-in from these groups. Although beyond the scope of my thesis to discuss these in-depth, these could include small local needs assessments informing adaptations and increasing buy-in, the development of interventions responsive to local needs and a robust evidence base demonstrating the benefits of HIVST among their client groups and the potential to expand testing.

4.5 Critiquing COM-B

The analyses presented in my thesis make a significant contribution to recasting how COM-B can be used in practice by expanding our understandings of the impact of intervention exposure for those without pronounced needs while clearly illustrating one of its key weaknesses: the absence of a robust concept of need which may lead to improper conception and design of interventions.

Although COM-B helps illustrate the role of HIVST in meeting the needs of inexperienced testers and pro self-testers, the results surrounding opportunistic adopters encourage broader thought on how the model can be used.

Although need is partly captured in motivation (automatic) and opportunity (social), the model does not provide sufficient consideration for those who have needs which are based on normative practices drawn from the sociocultural tapestry in which they are embedded. The second paper in my thesis clearly demonstrates the impact of norms drawn from peers, doctors, public health and the voluntary sector in testing narratives (58). This publication underlines the centrality of these in decision making processes for MSM. These concepts are further explored in the final paper of my thesis which shows that for many MSM (in this analysis pro self-testers and opportunistic adopters) norms are one of the primary drivers to test for HIV, even when significant psychosocial barriers constrain testing. Need is clearly derived from these norms for a significant number of MSM, a phenomena known as biocitizenship (58, 122).

While COM-B includes some elements of need such as felt need, it is not adequately attentive to issues surrounding normative need (need derived from norms) or comparative need (that which is derived from interactions with healthcare professionals) (108, 109), which are key drivers to testing uptake (58). Indeed, COM-B has a tendency to reduce complex social and psychological process in an attempt to control patient variation while prioritising needs identified by healthcare professionals (139). This perhaps contributes to the issue identified in paper 5, whereby intervention components

have little impact on individuals who take-up interventions due to needs not captured in the model which are therefore not addressed in intervention development based on COM-B.

Although these elements can be retroactively identified and interventions adapted in response, using only COM-B in planning interventions can cause these important issues to be overlooked and can lead to interventions which are primarily attentive to the priorities of healthcare professionals and those implementing the interventions. It also has an important impact on how interventions are conceptualised and what their role is assumed to be; it seems that for many MSM with established testing routines HIVST may not be primarily useful for identifying prevalent and incident infections more rapidly. Rather its utility may lie in its ability to meet normative and comparative need more quickly in MSM well served by existing testing interventions. A reliance on COM-B may obscure this role by thinking of the intervention as meeting a specified biomedical outcome important to those planning and delivering interventions and with all intervention components working towards that, rather than outcomes also important to MSM themselves. Using social theory relating to concepts of biological citizenships and biomedicalisation of risk early in intervention development has enabled some of these issues to be identified and clear, coherent explanations for variations in experience to be identified in a way that reliance solely on COM-B would not allow.

COM-B should therefore be used with a degree of caution, especially in designing interventions which respond to highly normative behaviour. In these contexts it may be preferable to draw from a range of theories, likely beyond behaviour change models, which contribute to a more in-depth understanding of the potential uses of a technology in heterogeneous groups. This will enable understandings of use to move beyond individualistic concerns and encourage deeper thought about natural variation in patient behaviour, especially that which is related to normative and comparative need.

A recasting of COM-B in this way requires something of a paradigm shift for those working in implementation science. Disciplines tend to favour tools which come from their own traditions and histories. Clearly in certain contexts the constraints of these produce limitations to how knowledge can be usefully produced and applied in real world contexts, potentially threatening successful implementation. While COM-B has been useful in gaining much of these understandings, without further input from social theory the understandings developed in my thesis would have been partial. The analysis from formative work has been central in interpretation and demonstrating why COM-B on its own would have been insufficient for these purposes.

4.6 Strengths and limitations

My thesis has several strengths alongside some limitations. Much of the first formative, implementation and evaluative evidence pertaining to HIVST in the UK is included in this work, as my thesis has been embedded within a pioneering programme of research. As such many of the findings are novel and have much relevance for policy makers and commissioners more broadly.

Embedding this thesis within a broader package of work has allowed for a programmatic approach not possible in many other projects. The movement from pre-implementation formative work to piloting and implementation research to evaluative work has allowed for a broader examination of HIVST in a variety of contexts. Further, this has enabled a tracking of emerging understandings of the technology, beginning at a relative unknown stage and moving towards normalisation and adoption.

From a methodological perspective, rejecting the tyranny of the method (116) and disentangling my research from any particular paradigm and instead focusing on the method most appropriate for each question I sought to answer has given this work the strength of responding very specifically to individual challenges which emerged over the research process. This pragmatic approach has likely increased the rigour and utility of these findings, while also allowing for an examination of COM-B.

While my thesis provides a great deal of formative evidence supporting the implementation of HIVST, it should be treated with some caution. The research included in the formative papers were conducted before HIVST was widely available and it is likely that values and preferences related to interventions will have changed as an increasing number of people have been exposed to HIVST. These papers should therefore be used as a guide alongside local understandings and the wider literature.

Concerns about capability are a clear theme running through this thesis. It is likely that these will shift over time, potentially diminishing as individuals gain more knowledge and skills as demonstrated in papers 3 and 4. Countering these is clearly an important priority during early implementation but it must be acknowledged that the landscape will change over time and as HIVST becomes mainstream.

4.7 Recommendations for future research

The self-testing evidence base will inevitably continue to develop from this point. On the basis of this body of work I am in a position to make key recommendations for areas of inquiry. Firstly, HIVST may have the potential to either exacerbate or reduce testing inequalities based on ethnic identity, depending on intervention design. More research is required to inform the development and implementation of HIVST programmes that meet the needs of black and minority ethnic MSM, a key group in the HIV response (12, 30, 140).

Secondly, questions regarding the potential of HIVST to contribute to harm require additional inquiry, especially given two adverse events were spontaneously discovered during qualitative interviews. The development of this evidence base should be treated as a critical priority in order to develop additional supportive interventions which respond to these issues.

5. Conclusion

My thesis is an exploration of key formative, implementation and evaluative questions surrounding HIVST in England and Wales. This multi-method enquiry provides a substantial evidence base upon which commissioning decisions for self-testing can be made. I demonstrate that HIVST adaptations can impact on acceptability for sub-groups of MSM depending on their personal circumstances. I also provide evidence surrounding the potential context of use, based on narrative understandings of self-testing. The feasibility and acceptability of HIVST is explored in a great deal of depth, as is the functioning of the SELPHI interventions. Finally, the utility of COM-B is explored in the context of HIVST, results which may have direct relevance to other new prevention technologies.

Clearly, throughout this work, I have demonstrated the significant contribution that HIVST can make to the well-being of MSM in England & Wales. Self-testing for HIV serves divergent roles for different groups; my most significant contribution to the literature is perhaps the exploration of these and demonstrating the ways in which this innovative testing approach can meet MSM's testing aspirations and support their sexual health.

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PROTOCOL

Open Access



Consolidating emerging evidence surrounding HIVST and HIVSS: a rapid systematic mapping protocol

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Abstract

Background: HIV self-testing (HIVST) is becoming popular with policy makers and commissioners globally, with a key aim of expanding access through reducing barriers to testing for individuals at risk of HIV infection. HIV self-sampling (HIVSS) was available previously to self-testing but was confined mainly to the USA and the UK. It remains to be seen whether the momentum behind HIVST will also energise efforts to expand HIVSS. Recent years have seen a rapid growth in the type of evidence related to these interventions as well as several systematic reviews. The vast majority of this evidence relates to acceptability as well as values and preferences, although new types of evidence are emerging. This systematic map aims to consolidate all emerging evidence related to HIVST and HIVSS to respond to this rapidly changing area.

Methods: We will systematically search databases and the abstracts of five conferences from 2006 to the present date, with monthly-automated database searches. Searches will combine key terms relating to HIV (e.g. HIV, AIDS, human immune-deficiency syndrome) with terms related to self-testing (e.g. home-test, self-test, mail-test, home dried blood spot test). Abstracts will be reviewed against inclusion criteria in duplicate. Data will be manually extracted through a standard form and then entered to an open access relational map (HIVST.org). When new and sufficient evidence emerges which addresses existing knowledge gaps, we will complete a review on a relevant topic.

Discussion: This innovative approach will allow rapid cataloguing, documenting and dissemination of new evidence and key findings as they emerge into the public domain.

Systematic review registration: This protocol has not been registered with PROSPERO as they do not register systematic maps.

Background

HIV self-testing (HIVST) as an intervention and a potential HIV prevention tool is gaining popularity amongst policy makers globally, as well as amongst key populations affected by HIV. While previously HIVST was uncommon and generally confined to individuals working in healthcare settings informally testing themselves [1], changes in attitudes towards HIV infection brought about by the availability of highly effective HIV treatment have led many countries to introduce legal

and policy changes to allow HIVST kits to be licensed and distributed formally [2].

In some settings, HIV self-sampling (HIVSS) gained popularity before HIVST became available [2]. HIVSS was approved in the USA by the Food and Drug Administration in 1996 in response to a desire amongst clinicians and service providers for greater patient autonomy in healthcare. HIVSS harnesses the convenient and private nature of HIVST while also providing support in the form of a laboratory to process the sample and a trained counsellor who could provide results in an effort to counter some of the concerns around self-harm, adverse events and issues with user error [2].

The development of and wide availability of low-cost rapid diagnostic tests (RDTs) have also made it possible to

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expand testing within and beyond facilities by using community-based approaches, which are increasingly used in HIV testing in low-, middle- and high-income settings [3, 4]. The wider availability and lower cost of anti-retroviral therapy (ART) alongside evidence indicating that early diagnosis and immediate treatment initiation improve patient health outcomes, and enable HIV-positive patients to achieve virological suppression which can then prevent onwards transmission, have strengthened the policy argument for the expansion of testing [5–7].

HIVST in particular is now considered to have an important role as part of the expansion of standard HIV testing services and is congruent with widespread shifts in western health systems which increasingly emphasise patient self-management and autonomy [8].

The last 5 years have seen a rapid emergence of published data and corresponding reviews synthesising evidence around HIVSS and HIVST [9–13]. Reflecting the distribution of evidence at the time, the first and most far ranging of these reviews [10] relied substantially on relatively few papers, mainly from the USA.

Since 2013, there has been an increasing flow of evidence about self-sampling and self-testing from a wider range of countries including Australia [14–16], Brazil [17], China [18, 19], the USA [20–22], the UK [23–26], Malawi [27–30] and Lesotho [31]. There remain very little European implementation-based evidence and evidence related to patient experience of HIVST. Aside from exploratory surveys and recent reviews [9–13, 32] in which the majority of included data on the perceptions of values and preferences around HIVST arise from studies of gay, bisexual or other men who have sex with men (MSM), almost exclusively in industrialised countries (and still disproportionately from the USA as well as Australia), there has also been a wide range of opinion pieces broadly supportive of HIVST [2, 33–35].

The vast majority of this research, and hence the focus of all the reviews, has been the acceptability of HIVST, HIVSS and the values and preferences that inform the responses of key populations (MSM, transgender people, sex workers and injection drug users) to these emerging technologies. There can be little doubt that many individuals find the notion of HIVST to be acceptable and that it is feasible to deliver HIVST services in a range of settings in high-income countries. To quote the most recent, [13], “in general, MSM were interested in HIVST because of its convenient and private nature. However, they had concerns about the lack of counselling, possible user error and accuracy” (of test results).

Recognising that the limited evidence base had already been repeatedly reviewed, we will undertake a systematic mapping exercise to formalise the literature searching process behind HIVST.org, an online centre for public health research, documentation and policies regarding

HIV self-testing. A redesign of this website will create a searchable relational database where all literature on HIVSS and HIVST globally can be consolidated.

Systematic mapping is a process of collecting, collating and describing the parameters of the existing literature on a particular topic [36]. This systematic map will focus on HIV testing modalities. This tool will offer policy makers, practitioners and researchers an explicit and transparent means of identifying narrower policy and practice-relevant review questions. It also enables the contextualisation of in-depth systematic literature reviews within the broader literature and identification of gaps in the evidence base. Systematic mapping was originally developed by the EPPI-Centre at the Social Science Research Unit, then part of the Institute of Education at the University of London [37].

Aims and objectives

Aim

The aim of this paper is to consolidate emerging evidence related to HIVST and HIVSS.

Objectives

- To monitor and catalogue changes in published evidence as it emerges
- To collate evidence describing social and contextual factors shaping HIV testing practices, especially barriers to testing, perceptions of the acceptability of self-testing and self-sampling relative to other testing approaches and associated issues including management of psychological effects and subsequent pathways to care
- To document impacts from the expansion of HIVST as the technology continues to gain popularity

Methods

The Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) were used to prepare this protocol [see Additional file 1].

Search strategy

Published studies will be captured through a variety of standard searches which were trialled and refined throughout January 2016. Going forward searches will be automated to provide updates on the first of every month. This will enable us to capture all new articles published in that month and monitor changes in the published literature in real time. Searches will cover from January 1, 2006, to the present date, reflecting changes in the nature of HIV infection following widespread availability of anti-retroviral therapy and the emerging imperative to expand HIV testing [34, 37].

Databases included in this search are MEDLINE, Embase, Global Health, Social Policy and Practice, PsycINFO, Health Management Information Consortium, EBSCO CINAHL Plus, Cochrane Library and Web of Science. Searches will combine key terms relating to HIV (HIV, AIDS, human immune-deficiency syndrome, etc.) with terms related to self-testing (home-test, self-test, mail-test, home dried blood spot test, etc.). Five HIV conference databases (British HIV/AIDS Association, Conference on Retroviruses and Opportunistic Infections, European AIDS Society Conference, International AIDS Society and US National HIV Prevention Conference) will be systematically searched from January 2006 to the present date and then searched again annually as they become available. Additional grey literature search was not conducted. For full outline of database search strategy, see Additional file 2.

Inclusion criteria

This systematic map will include peer-reviewed publications from a wide range of disciplines within social science and public health including epidemiology, sociology, anthropology, health economics and clinical practice. All study designs will be included. Examples include trials, observational data, economic evaluation and systematic reviews. Trials will include RCTs, cohort and other large-scale studies as well as smaller scale implementation, feasibility and demonstration projects. Observational studies will encompass quantitative epidemiological studies and cross-sectional studies of all types including qualitative, quantitative and mixed methods studies. Diagnostic accuracy studies will be coded as observational studies. Modelling will be included under the tag of economic evaluation. Systematic reviews and meta-analyses will be included.

Comments, reviews that are not systematic, opinion pieces and letters to the editor will be excluded (Table 1).

Table 1 Study codes and designs

Study types	Designs
Trials	RCTs and cohort studies Implementation, feasibility and demonstration projects
Observational studies	Epidemiological studies Cross-sectional studies (qualitative, quantitative and mixed methods) Diagnostic accuracy studies
Modelling	Economic evaluation Epidemiological modelling
Systematic reviews	Meta-analyses, meta-syntheses and meta-ethnography

Studies written in English and published after January 1, 2006, will be eligible for inclusion in this map. Grey literature beyond conference papers and abstracts will not be included as this map focuses on academic outputs which have been through peer-review processes.

Screening

Eppi-Reviewer 4 will be used as a reference reviewing and management software for the duration of the project. Using this software, the titles and abstracts of studies only will be screened in duplicate against inclusion criteria by researchers from the study team and coded as EITHER eligible for inclusion OR ineligible, or THEY will be put forward for A second opinion. If it is not possible to ascertain whether a study is eligible based on title and abstract, it will be coded as requiring a second opinion and the full text will be obtained. Results from both researchers will be reconciled. Where disagreements exist, these will be resolved by full-text screening by both researchers. If disagreement persists, a third member of the study team will undertake a full-text review and provide an opinion.

Data extraction and relational mapping

Evidence related to HIVST and HIVSS will be input into HIVST.org, a resource which consolidates and maps evidence and policy globally. Following further development, HIVST.org will become a public facing, open access relational database for policy makers, practitioners and academics to search for up to date information on HIVST. Results will be displayed on a map and through a searchable database. This will be completed through the following steps:

Studies which are eligible for inclusion will be coded by study design, population, year of publication, HIVST type and approach in EPPI-Reviewer 4. Following this coding, all studies will undergo a data extraction process, whereby key data are extracted and input into a Google document spreadsheet with pre-defined fields which link with those of a publicly available systematic map. This will be conducted by either a member of Sigma Research or a team member at the HIV Unit at the WHO. Data extraction will be done from full text where available, with abstract utilised when manuscripts cannot be sourced. Data extracted will include region, target population, aims, date of research, research methodology, study design, sample size, key results and summary of findings. Extraction for each study will be conducted by one member of the team only. See Additional file 3 for data extraction template.

The Google document spreadsheet will then be uploaded into the relational map. The externally facing map will have filterability as a database from the public facing end, with broad meta-level tags for study design

as well as more specific tags for population, setting, HIVST type and key themes to allow for easy retrieval of results. This will enable identification of studies by key theme and easy comparison and interpretation of results. The Google document spreadsheet which the data is input through will have greater filtering capability, but these will only be available to the study team.

Quality appraisal

During the systematic mapping process, we do not plan to undertake a formal quality appraisal of studies. The key purpose of such a process is to explore the existence and characteristics of the evidence base of a topic rather than to make judgements about the quality of studies themselves [24]. When systematic reviews are conducted using the results of our systematic map, then quality appraisal will be completed as relevant to the review type and nature of the evidence base.

Outcomes

A key outcome of this systematic map will be the ongoing population of HIVST.org with results. Further, when sufficient evidence that is significantly different from the already published reviews emerges, then a systematic review can be completed from the subset of literature that is relevant to that specific research question.

It remains to be seen when sufficient evidence will emerge concerning use and effectiveness of HIVST (and HIVSS), but the systematic mapping exercise will facilitate the refining of additional or alternate questions for a systematic review. The suitability of conducting a further review will be assessed qualitatively through identifying emerging trends in the published literature and in conjunction with experts at the WHO. Having pre-completed, screening processes will allow for a timelier compilation of a systematic review when it is relevant to undertake one.

The precise approach taken for systematic reviewing (i.e. full meta-analysis, meta-summary, meta-ethnography, etc.) will be determined by what is most appropriate given the research question selected and the scope and quality of the pertinent evidence base.

Discussion

This open access rapid systematic map will enable easy access to up-to-date information for policy makers, practitioners, academics and others with an interest in HIVST. It will also formalise a current WHO endeavour and provide a greater degree of rigour to HIVST.org. Further, having searches and filtering already completed will allow for a more rapid completion of a systematic review on a relevant topic when the necessary data emerges.

Strengths and limitations

The approach outlined in this protocol has key strengths and limitations.

The ability to rapidly capture and characterise emerging literature which can then be used for a variety of application for academics and policy makers is a key strength. The transparent process through which this is completed provides intellectual rigour. This approach also allows for easy contextualisation of results from individual studies amongst the diverse evidence base of HIVST and HIVSS.

The major limitation of this type of review is that quality of evidence is not assessed. This rapid systematic mapping therefore gives all results equal weight in terms of prominence, and lower quality studies are not distinguished from those conducted with more rigour. It is therefore up to the audience to critically appraise the evidence base themselves.

Additional files

Additional file 1: PRISMA checklist. (PDF 130 kb)

Additional file 2: Search strategy. Searches updated after peer review. (DOCX 19 kb)

Additional file 3: Data extraction template. Template to be used to extract data and upload to map. (XLSX 9 kb)

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Availability of data and materials

All relevant data is included.

Authors' contributions

Conceptualisation and critical direction were provided by AR, PW, CJ and CF. Searches were designed by LSHTM library with input from CW and CF. CW, AR and PW drafted the manuscript. CW, CJ, CF and FB revised and provided critical input. CF and CJ provided data collection instruments. All authors have provided final approval.

Competing interests

The authors declare they have no competing interests.

Consent for publication

Not applicable.

Ethics approval and consent to participate

Not applicable.

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BMJ Open HIV testing history and preferences for future tests among gay men, bisexual men and other MSM in England: results from a cross-sectional study

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ABSTRACT

Objectives: The British HIV Association's (BHIVA) testing guidelines recommend men who have sex with men (MSM) test annually or more frequently if ongoing risk is present. We identify which groups of MSM in England are less likely to have tested for HIV and their preferences for future tests by testing model, in order to inform health promotion programmes.

Methods: Data come from the Gay Men's Sex Survey 2014, a cross-sectional survey of MSM, aged 16 years or older and living in the UK. Only men who did not have diagnosed HIV and were living in England were included in this analysis. We used logistic regression models to understand how social determinants of health were associated with not testing for HIV in the past 12 months, and never having tested. We then cross-tabulated preferred testing location by demographic characteristics.

Results: Younger men, older men and men who were not gay identified were least likely to have tested for HIV. Higher educational attainment, migrancy, Black ethnicity and being at higher of risk were associated with greater levels of HIV testing. Men who were less likely to have tested for HIV preferred a wider range of options for future HIV testing.

Conclusions: If the BHIVA's HIV testing policy of 2008 was used to guide testing priorities among MSM focus would be on increasing the rate of annual testing among MSM at less risk of HIV (ie, younger men, older men and non-gay identified MSM). Instead the promotion of more frequent testing among the groups most at risk of infection should be prioritised in order to reduce the time between infection and diagnosis.

BACKGROUND

Both globally and in the UK, HIV prevention is moving towards a test and treat model. This approach evolved from the recognition that the majority of new HIV infections among men who have sex with men (MSM) are passed from those who are unaware of their infection, and that treating HIV-positive individuals early drastically reduces their infectivity.^{1 2} Sexual health promotion now

Strengths and limitations of this study

- This study identifies which groups of men who have sex with men (MSM) in England are less likely to have tested for HIV ever and in the preceding 12 months and their service preferences for future tests.
- This study provides a robust critique of The British HIV Association's (BHIVA) 2008 HIV testing guidelines which recommend annual or more frequent testing for all MSM.
- While the gay identified men in our study are broadly representative of probability-based samples of MSM in the UK, there is a greater divergence in the non-gay identified MSM, which may lead us to overestimate testing among these men.
- HIV self-testing was not available at the time of this research was conducted, and HIV self-sampling was often advertised as self-testing in England. Participants may therefore have been confused by the difference between these options.

has a major focus on reducing the time between infection and diagnosis through increasing rates of testing, as well as providing earlier HIV treatment to those found to be positive.^{1 2} Essentially this approach emphasises reducing the amount of undiagnosed HIV within the population in order to reduce community viral load (and therefore onward transmission) while also preventing illness in individuals who have HIV.³ The British HIV Association (BHIVA) and Public Health England (PHE) now recommend that all MSM in the UK test for HIV at least annually and 'and every 3 months if having unprotected sex with new or casual partners'.⁴ While rates of HIV testing among this group have increased dramatically in the last decade, PHE estimates that currently 14% of UK MSM with HIV infection have yet to be diagnosed.⁴

Factors mediating MSM's decisions to test are complex and varied. Significant barriers to encouraging MSM to test for HIV exist, particularly in relation to psychosocial needs and negative emotional responses to testing.⁵ In the UK, policymakers have focused on creating demand for testing services through demand side interventions including policy and health promotion interventions addressing some of these factors, and by encouraging regular testing through national campaigns.⁶ Efforts to boost supply have also been central in attempts to increase the rate and frequency of testing among MSM. Models of delivery for HIV testing have also evolved with a key aim of reducing barriers to testing among most at-risk populations (for a comprehensive discussion on barriers to HIV testing, see ref. 7). While hospital-based outpatient HIV testing remains the norm, public health provision has focused increasingly on providing a wider range of settings for HIV testing. Initial expansion focused on opt-out as opposed to opt-in protocols in clinics, and providing HIV testing services within the community^{8,9} and, more recently, providing opportunities for self-administered testing methods including self-sampling and self-testing.¹⁰

It is unclear however which groups of MSM are most likely to access HIV testing and why. In addition, it is not known which groups favour which types of testing and what mix of testing services might achieve higher rates of HIV testing.

In this paper, we present analyses of the Gay Men's Sex Survey (GMSS) 2014, the 17th in a series of national sexual health needs assessments for gay, bisexual and other MSM. Our aim is to identify which groups of MSM in England are less likely to have tested for HIV and their preferred model for future tests. We do this by identifying demographic and behavioural characteristics associated with never having tested for HIV and not testing in the preceding 12 months, and by identifying preferences for future HIV testing among respondents based on demographic and behavioural characteristics. We focus on English MSM only as England has a separate health infrastructure to the rest of the UK leading to a restriction of interventions by region.¹¹

METHODS

GMSS received a favourable ethical opinion from the Observational Research Ethics Committee at the London School of Hygiene and Tropical Medicine (reference number 7658) on 17 June 2014.

The survey recruited men who reported attraction to other men who were aged 16 or older and living in England between August and November of 2014. Recruitment occurred through advertising on internet dating services (websites and geolocation social networking apps), social media and, to a lesser extent, voluntary sector organisations. The survey could only be completed online in English.

Demographic and behavioural characteristics treated as independent variables included age, sexual identity,

ethnicity, highest educational qualification, migrancy and having had two or more non-steady sexual partners with whom a condom was not used for anal sex (2+NSSPNC). Age was recorded as a continuous variable and then recoded into 10-year bands beginning at under 20 and ending at 60 or over. Sexual identity was categorised as gay or homosexual, bisexual, straight or heterosexual, queer, 'any other term', and 'I don't usually use a term'. Ethnicity was recoded from standard UK ethnicity codes into four categories to avoid issues with having many categories with small numbers of observations: respondents were classified as Black, White, Asian and other. Responses to highest educational qualification were stratified into 'high', 'medium' and 'low'. Those with no qualifications or those with no post-16 education were classed as having low educational qualifications, while those educated to degree level were classed as having high educational qualification. The remaining men were classed as having a medium level of education (including men with A levels or equivalent and the majority of those with vocational or trade qualifications). A migrancy variable was created using responses to a question asking if the respondent was born in the UK. Those who indicated that they were not were classed as migrants. We created the variable 2+NSSPNC by stacking a variable indicating any casual partners into one where men identified the number of non-steady sex partners they had condomless anal sex with.

Respondents were asked if they had ever received an HIV test result. The options were 'no, I have never received an HIV test result', 'yes, I've tested positive' and 'yes, my last test was negative'. Respondents that had ever received an HIV test result were asked when they received their last negative HIV test, divided into time bands ranging from within the past 24 hours to more than 5 years ago. These data were recoded to 'tested for HIV in the last year' and 'not tested for HIV in the last year'. For our variable reporting having tested in the preceding 6 months, the data were recoded as appropriate following the same method.

Respondents were also asked where they would most like to test for HIV in the future. This dependent variable was recoded from initial values into general practitioner/family doctor, a doctor in a private practice, at a hospital or genitourinary medicine (GUM) clinic, at a community HIV testing service (including in a bar/pub, club or sauna, or mobile medical unit), self-sampling kit (taking own sample and sending off for result), self-testing kit (taking a sample and finding out a result on the spot), other and 'I will not want to test for HIV in the future'.

Analysis

First, we examined associations between demographic characteristics and HIV testing history. We used logistic regression models to understand how demographic and behavioural variables were associated with the dependent variables of not having tested for HIV in the past 12 months and never having tested for HIV. We

regressed both of our dependent variables on each of age, sexual orientation, ethnicity, highest educational attainment, migrancy and 2+NSSPNC. We chose reference categories with the aim of understanding key equity dimensions of access to healthcare, particularly in relation to men with lower educational qualifications and barriers to accessibility which may vary across cultural groups.⁴⁻⁷ Our risk variable was chosen as we theorised that having two or more non-steady sexual partners with whom condoms are not used for anal sex was indicative of likelihood of ongoing risk. After entering each demographic characteristic into a bivariate logistic regression, we included all characteristics in one model for each dependent variable using block entry. For each logistic regression model, we report ORs (unadjusted or adjusted) and Wald tests for overall model significance.

Second, we calculated χ^2 tests on 2+NSSPNC and testing in the preceding 6 months.

Third, we calculated χ^2 tests on preferred testing location by comparing MSM who had last tested negative with MSM who had never received an HIV test.

Fourth, we cross-tabulated preferred testing location by demographic characteristics. We did not use inferential testing because of the multiplicity of categories.

Missing data across all variables was <5% of observations. We decided this level of missing data was acceptable for a community-based cross-sectional survey and did not make attempts to use corrective statistical mechanisms.

All analyses were undertaken in Statacorp Stata V.13.

RESULTS

The survey recruited 15 704 MSM in England of whom 14 317 (86%) had not been diagnosed with HIV. Of these, 14 235 (99%) had indicated whether or not they had received a previous HIV-negative test result and data on whether or not they had tested in the past 12 months were available for 14 194 (99%) men. See figure 1 for exclusion flow chart.

Having never tested

In the sample of men who had not received a positive HIV test, 73.9% had received a negative HIV test, while 26.1% had never tested for HIV.

Findings from univariate models are in table 1. Compared with men in their 20s, men below the age of 20 were more likely to have never tested for HIV whereas men in their 30s and 40s were significantly less likely to have never tested for HIV. Men in their 50s were not significantly different from men in their 20s, whereas men in their 60s were more likely to not have received an HIV test. Men who identified as queer were not statistically different from men who identified as gay in odds of never having tested for HIV, but compared with men who identified as gay, men in every other sexual orientation category were significantly more likely to have never received an HIV

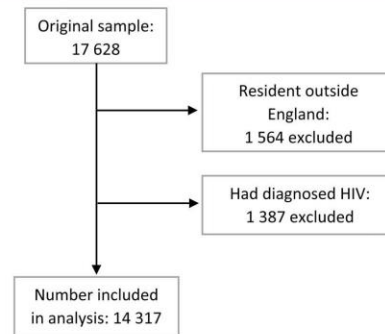


Figure 1 Participant exclusion flow chart.

test. White men were most likely to not have received an HIV test, though Asian men were not significantly different. Compared with men with high levels of education, men with low and medium levels were more likely to have never received an HIV test. Men born in the UK were more likely to have never received an HIV test compared with migrants. Other than migrants, men who reported condomless anal intercourse with two or more casual partners were least likely to have never tested for HIV.

Findings from multivariate models (table 2) were similar in magnitude, direction and significance to findings in univariate models. However, men in their 50s were now less likely to have received an HIV test, and men aged 60 and above were not significantly different, as compared with men in their 20s. Finally, in multivariate models, men reporting condomless anal intercourse with two or more casual partners were least likely to have never tested for HIV.

Testing in the past 12 months

Of the analysis sample, 53.7% of men had received a negative HIV test result in the 12 months prior to completing the survey.

Findings from univariate models are in table 1. Compared with men in their 20s, men in their 30s were not significantly different in their odds of having tested in the past 12 months; however, men both younger than 20 and aged 40 and above were more likely to not have received an HIV test in the past 12 months. Compared with men who identified as gay, men who described their orientation as bisexual or straight or who described not using a term were significantly more likely to have not tested in the past 12 months, but men who identified as queer or with any other term were not significantly different from gay men. All groups of non-white men were less likely to not have tested in the past 12 months, and all groups of men who did not have high education qualifications were more likely to not have tested in the past 12 months. Men who had migrated to the UK were less likely to have not received an HIV test in the past 12 months. Men who reported

Table 1 Not ever testing and not testing in the preceding 12 months by demographic variables: univariate analyses

Variable	Percent of sample (n)	Never tested for HIV		Not tested in the past 12 months	
		Percent	OR (95% CI)	Percent	OR (95% CI)
Age					
Under 20	8.4 (1181)	65.4	5.16 (4.52 to 5.91)	67.5	2.91 (2.55 to 3.32)
20s	37.6 (5314)	25.7	Ref	41.6	Ref
30s	22.4 (3169)	15.6	0.50 (0.45 to 0.56)	39.9	0.91 (0.85 to 1.02)
40s	16.8 (2368)	18.1	0.61 (0.54 to 0.68)	47.5	1.27 (1.15 to 1.40)
50s	9.8 (1383)	25.6	0.94 (0.82 to 1.07)	52.9	1.57 (1.40 to 1.77)
60+	5.0 (710)	30.4	1.19 (1.01 to 1.42)	57.6	1.90 (1.62 to 2.23)
Wald test (χ^2 , df, p value)			1098.37, 5, p<0.001		376.81, 5, p<0.001
Orientation					
Gay	83.7 (11 738)	23.2	Ref	44.2	Ref
Bisexual	10.6 (1483)	44.2	2.62 (2.35 to 2.93)	59.1	1.83 (1.64 to 2.04)
Straight	0.4 (59)	69.5	7.55 (4.33 to 13.16)	83.1	6.20 (3.14 to 12.24)
Queer	1.4 (189)	18.5	0.75 (0.52 to 1.09)	38.1	0.78 (0.58 to 1.05)
Any other term	0.4 (60)	40.0	2.21 (1.32 to 3.71)	51.7	1.35 (0.81 to 2.25)
Don't use a term	3.5 (495)	37.6	1.99 (1.65 to 2.4)	55.6	1.58 (1.32 to 1.90)
Wald test (χ^2 , df, p value)			370.98, 5, p<0.001		175.91, 5, p<0.001
Ethnicity					
White	92.6 (13 117)	26.6	Ref	47.2	Ref
Black	2.1 (295)	20.3	0.70 (0.53 to 0.94)	31.5	0.51 (0.40 to 0.66)
Asian	3.6 (513)	24.1	0.88 (0.72 to 1.08)	37.8	0.68 (0.57 to 0.81)
Other	1.7 (234)	16.2	0.54 (0.35 to 0.38)	29.9	0.48 (0.36 to 0.63)
Wald test (χ^2 , df, p value)			20.79, 3, p<0.001		72.49, 3, p<0.0001
Education					
Low	18.0 (2509)	35.2	2.51 (2.27 to 2.78)	55.6	1.86 (1.70 to 2.04)
Medium	34.0 (4728)	32.0	2.11 (1.93 to 2.3)	49.4	1.45 (1.34 to 1.56)
High	48.0 (6691)	18.3	Ref	40.3	Ref
Wald test (χ^2 , df, p value)			431.19, 2, p<0.001		204.34, 2, p<0.001
Migrancy					
Yes	19.5 (2713)	15.8	0.47 (0.42 to 0.52)	35.1	0.57 (0.52 to 0.62)
No	80.5 (11 201)	28.7	Ref	48.9	Ref
Wald test (χ^2 , df, p value)			186.07, 1, p<0.0001		170.00, 1, p<0.001
2+NSSPNC					
Yes	17.4 (2415)	16.3	0.50 (0.44 to 0.56)	27.3	0.37 (0.33 to 0.40)
No	82.6 (11 462)	28.2	Ref	50.4	Ref
Wald test (χ^2 , df, p value)			155.02, 1, p<0.001		442.08, 1, p<0.001

2+NSSPNC in the preceding 12 months were least likely to have not tested for HIV in that time period. Findings from multivariate models (see table 2) were similar to findings from univariate models.

Higher risk men and testing recency

Men who reported 2+NSSPNC in the preceding 12 months reported testing more frequently than those who did not. Of these men, 59.5% had tested in the preceding 6 months, compared with 33.8% of men who reported lower risk. The OR reporting the likelihood of men at higher risk having not tested in the preceding 6 months was 0.35 and was statistically significant (table 3 for results).

Preferences for future tests

Men who had never tested had significantly divergent preferences for future tests when compared with men

who had received a negative test result (table 4). For this group, self-administered testing options (HIV self-testing and HIV self-sampling combined) were the most popular, followed by GUM and testing in general practice. These men had the lowest reported interest in testing in GUM settings of all groups included in this analysis. This is in contrast with the preferred testing locations of men who had previously tested with the majority preferring GUM clinics, followed by self-administered testing options and then preferring community-based testing services. Very few men stated that they had no intention of testing for HIV in the future indicating that even among those who have never done so, testing for HIV is acceptable.

When examining testing preferences by demographic and behavioural characteristics (table 5), these general patterns continued, with groups associated with lower levels of testing reporting preference for a greater diversity of testing services outside of GUM than groups who

Table 2 Not ever testing and not testing in the preceding 12 months by demographic variables: multivariate analyses

Variable	Adjusted OR (never tested)	Adjusted OR (12 months)
Age		
Under 20	4.15 (3.59 to 4.80)	2.47 (2.13 to 2.85)
20s	Ref	Ref
30s	0.55 (0.49 to 0.62)	1.02 (0.93 to 1.12)
40s	0.56 (0.49 to 0.62)	1.26 (1.13 to 1.40)
50s	0.79 (0.68 to 0.91)	1.46 (1.29 to 1.67)
60+	0.91 (0.75 to 1.11)	1.67 (1.40 to 1.99)
Orientation		
Gay	Ref	Ref
Bisexual	2.72 (2.40 to 3.08)	1.73 (1.54 to 1.95)
Straight	8.82 (4.81 to 16.20)	6.18 (2.98 to 12.83)
Queer	0.78 (0.52 to 1.19)	0.87 (0.64 to 1.19)
Any other term	2.25 (1.26 to 4.04)	1.55 (0.88 to 2.72)
Don't use a term	1.98 (1.61 to 2.42)	1.55 (1.28 to 1.89)
Ethnicity		
White	Ref	Ref
Black	0.61 (0.43 to 0.85)	0.48 (0.36 to 0.64)
Asian	1.16 (0.92 to 1.07)	0.78 (0.63 to 0.96)
Other	0.72 (0.48 to 1.08)	0.58 (0.42 to 0.79)
Education		
Low	1.92 (1.72 to 2.17)	1.53 (1.38 to 1.70)
Medium	1.48 (1.34 to 1.63)	1.26 (1.16 to 1.37)
High	Ref	Ref
Migrancy		
Yes	0.62 (0.54 to 0.71)	0.65 (0.59 to 0.72)
No	Ref	Ref
2+NSSPNC		
Yes	0.47 (0.42 to 0.53)	0.36 (0.32 to 0.40)
No	Ref	Ref
Wald test (χ^2 , df, p value)	1716.89, 17, p<0.001	1105.27, 17, p<0.001

were more likely to have tested who tended to report a greater preference for GUM. The exception to this is community-based testing, which was more popular among groups more likely to have tested previously.

DISCUSSION

The BHIVA testing guidelines for the UK state that all MSM should test at least annually or more frequently if there is ongoing risk.¹² Our results clearly demonstrate that UK testing guidelines are not being uniformly followed by men in different life stages. These findings report levels of HIV testing broadly congruent with the similarly opportunistically recruited Scottish Bar Survey,¹³ and substantially higher rates than among MSM in the third National Survey of Sexual Attitudes and Lifestyles, a general population probability survey in which 51.6% of MSM reported ever testing for HIV.¹⁴

Our results describe which groups of MSM in the England are less likely to be following the BHIVA guidelines. In multivariate models, we found that men under

Table 3 Men reporting 2+NSSPNC testing in the preceding 6 months

Six months	2+NSSPNC	<2NSSPNC
Yes	59.5% (1425)	33.8% (3851)
No	40.5% (972)	66.2% (7536)
OR 0.35 (0.32 to 0.38)	$\chi^2=535.46$	p<0.001

the age of 20 were less likely than men between the ages of 20 and 30 to have tested in the preceding 12 months. As age increased the number of men who had never tested declined, but so too did testing frequency after a peak when men were in their 20s and 30s. This suggests a strong age trend whereby men are, in part, aware of their own HIV testing needs and responding to them by testing more frequently when most sexually active (between the ages of 20 and 40) with frequency declining later. This is congruent with other evidence which suggests strong age trends in HIV testing patterns among MSM in Europe, North America and Australia.^{13 15–18} However, despite regular testing fitting into the life courses of many MSM, a significant proportion (over 25%) of MSM over the age of 50 have never tested for HIV, indicating that throughout life many MSM are choosing not to ever test for HIV.

Bisexual men were significantly less likely than gay men to have tested. Straight identified MSM were the least likely to test. In total 83% of MSM who identified as straight (n=59) had not tested for HIV in the past 12 months and nearly 70% had never received an HIV test result. There are therefore clear associations between sexual identity and rates of HIV testing within this sample, and our results indicate that either these men (correctly or incorrectly) do not believe themselves to be at risk of HIV infection, or that their needs are not being adequately addressed through existing service provision. These patterns have been observed in several other European countries.^{14–17 19}

Also consistent with existing evidence^{15 16} is our finding that men with lower levels of education were less likely to test for HIV. As this association weakened in adjusted ORs, these data are suggestive of a clustering of other demographic influences on likelihood to test around men with medium and low levels of education. These results did however retain significance indicating that there is an important educational component to decision-making around HIV testing and perhaps in access to services. This underscores the importance of psychosocial barriers to testing among this population, barriers on which expansion of testing in itself cannot overcome.²⁰

The men in our sample who were most likely to have tested for HIV were men who reported having two non-steady partners with whom they did not use condoms for anal sex in the preceding 12 months. In this group, only 16.2% had never received a test result, the lowest

Table 4 Preferences for future HIV test by HIV testing history

Most preferred next test	Percent of those who have never tested (n=3723)	Percent of those who have ever tested (n=10 512)	χ^2 , p value
General practice	21.6 (803)	8.8 (920)	424.50, 0.001
Private practice	5.9 (220)	2.4 (254)	104.20, 0.001
GUM clinic	30.7 (1143)	56.3 (5915)	718.00, 0.001
Community test	7.8 (292)	10.3 (1086)	19.47, 0.001
HIV self-sample	12.0 (446)	8.1 (856)	48.70, 0.001
HIV self-test	20.2 (750)	12.7 (1332)	123.00, 0.001
Other means to test	0.9 (32)	1.2 (125)	2.74, 0.098
Will not test	1.0 (37)	0.2 (24)	37.76, 0.001

DF = 1 for all models.

proportion bar migrants and men of 'other' ethnicity. Only 27.3% had not tested in the preceding 12 months, the lowest of any group in our sample. However, 40.5% had not tested in the preceding 6 months, indicating that a significant proportion of these men are likely falling short of BHIVA guidelines to test every 3 months in the presence of ongoing risk.

GUM settings remain the most popular future testing setting for MSM in England, for all groups except those who had never tested. Those who have never tested have a preference for a wider range of testing options than those who had tested before. However, regardless of testing history, men valued a range of settings indicating that while expanding access through providing a wider variety of ways to test is worthwhile, no one testing method is likely to lead to a surge in uptake of HIV testing.

Importantly, community-based rapid HIV testing services were most popular with the demographic groups who were most likely to have ever tested (and to a lesser degree among men reporting higher risk), indicating that expanding access to these services is unlikely to be efficient if policy goals include meeting the testing needs of men that would not otherwise be testing.

Sale of HIV self-testing kits was made legal in the UK from 1 April 2014 but no CE-marked product was available in the market when this survey took place. Despite this, and the relatively widespread availability of HIV self-sampling, self-testing was more popular than self-sampling across all subgroups, with more pronounced preferences for self-testing in those who had not tested in the last year. Further research is required as to whether self-sampling will maintain a position in the HIV testing landscape when self-testing becomes more widespread.

In light of our findings, the value of the current HIV testing guidelines can be called into question, particularly the guidance to test annually. If commissioners, clinicians and providers are to use these guidelines alone to inform testing interventions, the priority will be to raise the proportion of gay men, bisexual men and other MSM that have ever tested and encourage them to test at least annually. Focus will fall on the relatively young and old; men with lower levels of educational

attainment; and those who are not gay identified. This goal could be achieved by increasing focus on providing a wide range of testing opportunities to better meet the diverse preferences of this population. This however could only have limited impact on the more intractable psychosocial barriers to testing, including stigma and fear of a positive result.^{5 20}

Further, the groups who would likely be targeted by this strategy are not reflective of those most likely to have undiagnosed HIV, and this focus would therefore deliver significant diminishing returns per infection detected from a resources perspective. A perhaps more impactful approach would instead focus on the behavioural element of the policy and prioritise reducing the average time between HIV infection and diagnosis with an aim to reduce community viral load. This is congruent with modelling evidence suggesting testing high activity MSM once or twice per year would yield similar results to testing all MSM with the same frequency.²¹ This approach would require increasingly targeted interventions and more nuanced information around testing in response to risk, while simultaneously maintaining and expanding the services these groups most value. This would instead direct focus to increasing the frequency of testing among men at higher risk through ongoing condomless anal intercourse with multiple partners, while simultaneously raising the rate of annual testing among both Black and White identified men^{5,22} and men between the ages of 20 and 44.⁴ These groups of MSM are most likely to have HIV in England, and are also among the most likely to test.^{4 22} In this scenario, GUM would remain a crucial piece of this service mix, with increases in investment in self-administered testing methods, which may also serve to triage lower risk MSM to less expensive (per unit cost) testing options. These approaches will likely require more focus on the psychosocial barriers to testing and a greater degree of individual engagement in the provision of nuanced and in-depth interventions that acknowledge men's own values and aspirations around sex and understand the social contexts in which testing decisions are made.

Table 5 Demographic details and preferred setting for next HIV test in proportions (in percentages)

Subgroups	GP	PP	GUM	Com test	HIVSS	HIVST	Other	Will not
All men	12.1	3.3	49.6	9.7	9.2	14.6	1.1	0.4
Age								
<20s	17.1	7.4	42.9	6.1	9.8	15.4	0.9	0.4
20s	13.1	3.5	49.7	6.3	10.6	15.8	0.8	0.2
30s	10.2	2.4	51.8	10.3	8.9	15.0	1.2	0.3
40s	10.4	2.9	50.3	12.5	7.5	14.8	1.2	0.6
50s	11.8	2.4	47.9	17.5	6.9	10.8	1.9	0.9
60+	11.4	2.5	51.4	14.1	8.2	9.3	1.8	1.3
Orientation								
Gay	11.9	3.0	51.0	9.5	8.8	14.4	1.1	0.4
Bisexual	14.2	4.9	43.3	9.6	10.6	15.8	1.2	0.4
Straight	13.6	6.8	39.0	10.2	3.4	23.7	1.7	1.7
Queer	10.6	1.6	48.7	21.7	7.4	9.5	0.5	0.0
Any other term	20.0	0	35.0	13.3	16.7	11.7	1.7	1.7
Don't define	11.5	4.9	41.4	8.5	12.3	19.8	0.6	1.0
Ethnicity								
White	12.5	3.2	49.2	9.6	9.2	14.8	1.0	0.4
Black	6.1	4.7	51.0	7.4	12.8	14.5	2.7	0.7
Asian	7.8	5.0	52.7	13.0	6.8	12.8	1.4	0.4
Other	5.1	4.2	61.1	11.5	6.4	10.3	1.3	0.0
Education								
Low	15.8	4.6	47.0	8.3	9.0	13.4	1.4	0.5
Medium	14.3	3.2	47.1	8.5	10.4	15.4	0.7	0.4
High	9.0	3.0	52.3	11.1	8.4	14.6	1.2	0.4
Migrancy								
Yes	8.9	3.7	54.8	11.0	7.1	12.9	1.4	0.3
No	12.8	3.2	48.4	9.4	9.6	15.1	1.0	0.5
2+NSSPNC								
Yes	7.6	2.7	55.4	10.1	7.3	15.8	0.9	0.3
No	13.1	3.4	48.5	9.4	9.6	14.4	1.0	0.5

GP, general practitioner; PP, private practice, GUM, genitourinary medicine centre; Com test, community testing; HIVSS, HIV self-sampling; HIVST, HIV self-testing.

Limitations

Our results should be interpreted with some caution. For one, while our participants who are gay identified are largely representative of the gay population in the UK, there is greater divergence between convenience and probability samples of other non-gay identified MSM in our sample and others (see ref. 23 for a full discussion). Furthermore, in convenience samples of MSM in the UK reported HIV testing tends to be higher than in probability-based samples, indicating that we may overestimate the level of testing in the population as a whole but in particular among non-gay identified MSM. This indicates that the true differences in testing between gay and non-gay identified MSM may be more pronounced than the ones we present.

Another limitation is that for most men, HIV self-testing was an entirely hypothetical testing option at the time of this research. This is in contrast to the many other options for HIV testing which men could (and did) use. HIV self-sampling is also often advertised as 'HIV self-testing' in England, so it is possible that some of our respondents were confused about the difference between these two options.

Finally, because we had low levels of missing data, we did not make attempts to control it. It is possible that those with the highest barriers to testing could be less likely to answer questions relating to HIV testing in research such as GMSS.

CONCLUSIONS

HIV testing policy in England is guided by BHIVA testing guidelines from 2008 which emphasises annual testing for all MSM (regardless of sexual behaviour) and more frequently for those at increased risk. Our results indicate that younger men, older men and those who are not gay identified were the least likely to test for HIV. If we were to use these policies to guide service development, our focus would be on increasing the proportion of MSM who had had an HIV test every year, irrespective of their sexual risk and precautionary behaviours. This however would not focus on the MSM most at risk of HIV and could potentially lead to increasing screening costs per infection detected. Instead, we feel the promotion of more frequent testing among the groups most at risk of infection should be prioritised,

effectively reducing the time interval between tests to reduce the time between infection and diagnosis.

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Appendix 3: Focus group discussions topic guide

PANTHEON: A STUDY ABOUT HIV SELF TESTING



Focus Group topic guide

Date	Focus group number	Venue	Staff Present

Advance Preparation

Arrange tables and chairs - prepare refreshments.

Set up and check the TWO digital recorders.

Organise focus group materials – hand-outs for ranking exercises.

Organise focus group materials – HIV-ST kits.

Notepad, pen, list of attendees, copy of focus group outline for facilitators.

Arrange chart paper and markers.

Make sure watch/clock is in sight.

Distribute consent forms as men arrive – ensure they are signed and collected before start.

Opening talk

Introduction of facilitators and Sigma Research

Rules - Share as much or as little information as you are comfortable with

Rules – reinforce confidentiality of the group

Rules - respect for other's opinions / we want everyone to contribute

Describe the reason for audio recording and later destruction (3 months hence)

Encourage participants to talk one at a time for recordings' sake.

Group will take about 90 minutes and will finish at [time] at the latest.

Ask participants to turn off (or at least mute) mobile phones

Invite queries..

Ice breaker – 10 minutes

So, to kick off I'd like us to all introduce ourselves. As you do so, I'm really interested to hear about what kind of messages you get about HIV testing from health care organisations or from health professionals. Now that could be your GP, from a charity or from advertising campaigns. If you've noticed that these messages have changed over time I'd be really interested in hearing your thoughts on that too.

Part 1: How HIV-ST fits into health seeking frameworks– 25 minutes

Now I'd like to talk about HIV self-testing. It is different from what is known as HIV self-sampling. With self-sampling you take your own sample and send it to a lab. Self-testing is when you take your own sample, process it yourself, and then read your own result. Just to reiterate, it's a test that you get your results very quickly with, and that you are able to do without anyone else present.

So, let's brainstorm first about what the key benefits of HIV self-testing are.

Why might someone want to test themselves for HIV? *[Ensure that opportunity and motivation are covered, particularly in relation to social and physical opportunity]*

And now the key drawbacks.

What do you think are the things that might stop someone from testing themselves for HIV?
[Ensure that barriers in relation to opportunity and motivation are explored]

**Now I'm wondering if there are particular situations that are more or less appropriate for HIV-ST?
Is there a time when you think someone would be more likely to use this approach?**

Are there other times where a different approach would be better?

**And how do you think people would make these decisions? Are they in any way informed by risk?
Is there a way that we could support these decision making processes?**

I'm also curious about how individual's peer groups might influence their decision making. Do you think that peers have a big impact on HIV testing decisions? And could they have an influence on self-testing decision making processes?

Com-b Domains: Opportunity – social & physical; Motivation – automatic and reflective.

Outputs: Discussion notes to be recorded on flipchart and photographed after the FGD.

Part 2: intervention specific details – 25 minutes

So now I'd like to talk about what HIV self-testing might look like in practice. This will involve a couple of activities, a bit of discussion and then I'll open up some different self-tests for you to look at.

Firstly, I'm wondering what you think is the most important or effective way to get people interested in HIV self-testing.

What kind of promotion of self-testing would be appropriate?

Is there anything that would be **totally inappropriate**?

Com-b domains: education, persuasion and enablement.

HIV self-testing kits are currently only available if you pay for them yourselves. I'm curious, with all the different HIV testing options available to you, **would you be willing to pay for a kit? And how much ££?**

Com-b domains: incentivisation

Does anyone know how much an HIV self-testing kit currently costs?

If these were free to you as part of a clinical trial, how often do you think you would test yourself?

And when would you test yourself? Every few weeks or months, or between partners? If you had an unlimited supply, what would make you test?

Now I'd like to do some quick exercises where **first we chose between two different options, then order the importance of these options in relation to each other**. HIV self-testing kits can have many different features. Some of the differences are around sample type (blood spot or saliva) and length of the window period. The packaging can be really different as can the price. Some are easier to use than others. Some have videos that show you how to use them, while others rely more on written instructions.

[Action: Hand out cards with 5x testing features, ask participants to choose between them on the following questions and explain their choices. After they have chosen perform a ranking exercise putting the categories in order of importance – may not be consensus so keep careful notes]

What do you think is the most important feature of an HIV self-testing kit?

Test features:

Sample type (blood vs. saliva).

Window period (12 weeks vs. 4 weeks).

Directions (video vs. written) and ease of use.

How they are accessed or delivered to you (posted to your address vs. pick-up / physical distribution).

Com-B domains: enablement, training

Now that we've discussed these options, let's look at some actual kits and I'll talk you through their features. [Action: open up two Biosure and one Ora-quick kit. Explain the features of both of them, collect feedback on kits themselves].

What are the advantages and disadvantages of both kits?

Outputs: Photographs of results of ranking activities; discussion notes to be recorded on flipchart and photographed after the FGD.

Part 3: support, positive results and adverse events 10-15 minutes

What I'd like to talk about now is what kind of support might be useful for people who have tested themselves for HIV.

First off, let's talk about people who have self-tested HIV negative.

What do you think their support needs might be?

What types of issues come up for men who receive a negative HIV test result?

Now let's think about the same for those who have a positive result.

What kind of support do you think they will need?

What types of issues come up for men who receive a positive HIV test result?

The other thing that sometimes gets talked about alongside HIV self-testing is what kind of harm could come from letting people test themselves for HIV.

Can you think of any specific difficulties that people are likely to face in using HIV self-tests?

There are a lot of ways that support could be provided to people who have tested themselves for HIV. **Three options are online support, support through the telephone (perhaps on a helpline), and printed information. What support do you think would be the most useful and why?**

Outputs: Flipchart results.

Part 4: HIV-ST verses other testing models – 20-25 minutes

There are a lot of different ways to test for HIV, and these different ways all have particular advantages and disadvantages. Now that we're coming to the end of the focus group I'd like to do an activity comparing some different testing approaches. First I'll walk you through what they are, and I'll explain what I'd like us to do.

Quick descriptions

GUM - One of the most popular ways is to test in a GUM clinic. Most of the time you can get your result right there and then, although sometimes you have to wait a week or two.

GP – Some people like to test at their GP.

Community based testing – In the last few years there has been a lot of emphasis on testing for HIV in community venues like bars, saunas and in vans.

Self-sampling – Recently there have been programmes where people are sent a self-sampling kit in the post. The person takes their own sample and sends it back to a lab. The lab then processes this and contacts the person to give their result (usually by phone).

Self-testing – self-testing is similar to self-sampling but in this approach people actually process the sample themselves and interpret their own results.

Activity

I've made cards with all of these services on them and am interested **in hearing from you what you think about key benefits and drawbacks of these approaches, particularly in relation to each other.**

[Following each ranking activity ensure results are discussed].

First off, let's take a really wide view and talk about **accessibility**. Ranking these in order, which are the most and least **accessible** testing service.

Moving on, we're interested in **confidentiality**. Would you please rank these services in order of most to least confidential?

Another related issue that often gets discussed around HIV testing is **fear**. Assuming that you had decided to go for an HIV test this week, which of these services would make you the most or least fearful and why?

Com-B domains covered: Capability- psychological and physical. Opportunity- physical.

Outputs: Results of ranking activities to be photographed or recorded verbally.

That's great- I think we've got a really good idea of these key areas of HIV testing.

Anything else you want to tell us about HIV self-testing?

Thanks for coming!

Appendix 4: Focus group discussions sampling frame

Demographic characteristics		Minimum	Maximum
Age	18 - 25 years	11 men	24 men
	26 - 40 years	11 men	24 men
	40+	8 men	16 men
Ethnicity	Black	4 men	
	Asian	4 men	
	White	11 men	
	Other / Mixed		
Sexual orientation	Gay	23 men	
	Bisexual	4 men	
	Don't use a term / other (not gay or bisexual)	4 men	
Recency of HIV testing	Never tested	8 men	16 men
	12 months +	11 men	32 men
	< 12 months	11 men	26 men
Previous HIV testing locations (not necessarily last HIV test location)	GUM	18 men	35 men
	GP	4 men	8 men
	Community / PoCT	4 men	8 men
	Self-Sampling	4 men	15 men
	Self-testing*	2 men	8 men

What are the perspectives of key informants on the implementation of HIV self-testing (HIVST) in England? A qualitative study of barriers, facilitators and anticipated impacts.



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Introduction

HIV self-testing (HIVST) is a new approach, enabling individuals to test themselves for HIV in a location and at a time of their choosing using a rapid diagnostic test (1-3). The first HIVST came to market in the UK in 2015 and since then there have been a variety of implementation projects (4-6).

HIVST has the potential to increase uptake and frequency of HIV testing for those most at risk (3). Most recently, SELPHI, an online randomised controlled trial (RCT) delivering an HIVST intervention, has begun enrolling men who have sex with men (MSM) and transgender people in England and Wales.

Study aims: To understand the perspectives of key informants on the implementation of HIVST.

Methods

In order to inform development of an HIVST intervention for use in the SELPHI RCT, 17 in-depth interviews were conducted with key informants (KIs) including clinical staff in NHS HIV and sexually transmitted infection (STI) services, voluntary sector service providers and HIV testing commissioners from across England. Table 1 describes our sample.

- Data collected between April and December 2016
- Interviews were face-to-face and over the telephone.
- Audio recorded and transcribed verbatim.
- Thematic framework analysis (7).

Results

Increasing patient choice

HIVST was valued for increasing choice in accessing HIV testing. Specifically, those who directly provided HIV testing services acknowledged that the remote nature of the technology might increase accessibility for some, potentially expanding testing to new audiences currently experiencing structural barriers.

I think the big benefit to self-testing is the ability for people to access tests, one, in the setting that they choose to, so a choice is always good; and two also to reach people in more rural communities and places where they don't have as good a service to engage with [...] (Service delivery, voluntary sector, North of England).

Local context & client group

Careful attention to intervention design was identified as important, as local context and client group shaped anticipated patient responses to HIVST. Several KIs expressed concern that a national HIVST intervention could be of limited utility if developed with insufficient attention to local needs. When considering intervention components, a KI involved in community outreach programmes in public sex environments stated:

Whether it's easy to say groups or whether it's about circumstances, because there are going to be some people who can't have a test delivered to their home, or even take a test home. [...] If you look at the MSM community [in the South West of England], the large majority of MSMs have a partner or a wife or children, and lead a heterosexual lifestyle, so may not want to even think about bringing any kind of testing kit into their home. (Service delivery, voluntary sector, South West England).

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Table 1: KI interviews sample characteristics

Sector	Role	Numbers
Voluntary	Service delivery	3
	Strategic	4
Commissioning	Local	1
	National	1
Clinical	Clinician	4
	Health advisor	2
	Nurse	2

Integration & pathways to care

It was widely perceived that HIVST should be delivered through integrated approaches that provide direct pathways into additional services and HIV care. While some felt HIVST should be delivered through clinics alongside other STI tests, others felt that the most important element was the development of multiple pathways which responded to patient need. Flexibility was highly valued.

I think if you can set up a variety of potential openings and opportunities and routes into engagement, whether that's community clinics or different healthcare settings and services, then people will gravitate to the one that's most suitable for them, either logistically or geographically or psychologically. So I think it's multi-pronged, really. (Clinician, North West of England)

Anticipated impacts

A range of impacts were predicted by KIs. The primary concerns centred on dislocation of HIV testing from supportive structures thereby leading to an increase in bacterial STIs through reduced opportunities for prevention and STI detection. Clinical staff specifically were concerned about a potential for increased self-harm. Some felt these impacts would occur in a very small group, while others believed they would be widespread consequences of service delivery. Conversely, this dislocation offered the potential for empowerment for some patients and was valued for increasing autonomy, and potentially increasing accessibility.

I think the benefits [of HIVST] are that it increases that nation's self-care and agency. For me, people have the right to know what's going on for them. They should be able to do that in any way that technology allows. Obviously, there are people who just want to have tests and don't want to tell anybody. (Strategic role, voluntary sector, North West England).

Discussion

In this qualitative in-depth study with 17 KIs, a number of key themes emerged providing conditional support for HIVST implementation. HIVST interventions should be responsive to context, taking into account both local and national needs. The flexibility of HIVST interventions to provide a variety of entry points into further STI testing and into HIV care may be a key benefit of a wider-roll out. Innovative approaches in this regard should be investigated. Concerns centred on negative impacts of dislocating HIV testing from supportive structures. Our results indicate that innovative service delivery designs which address these concerns while harnessing the benefits of flexibility may be key to KI buy-in for HIVST implementation and improved patient outcomes.

Appendix 6: Pilot interview topic guide

1. Introductions

- Researcher, Sigma, LSHTM
- This is an interview to hear your thoughts on HIVST. You've been invited because of your involvement with the Selphi trial, and specifically because you've been offered repeat tests. I'll ask you some specific questions about yourself, some questions about your history and some questions about your thoughts and experiences of HIVST. Feel free to answer them however you see fit. There are no right or wrong answers etc.

2. Ethics

- We would like to record the interview so we don't miss any of what you say.
- Explain how we will use and protect the data
- Do you have any questions?
- Are you happy to proceed?

3. HIV testing history

- When was your first HIV test?
- Can you remember what prompted you to seek testing the first time you went?
- What was the experience like? Where did you go? How did you choose to test that way?
- What kind of support were you provided with?
(*Prompt: Was this what you wanted? Can you think of anything else that would have been helpful for you in that situation?*)

4. HIV testing patterns

- How often do you test for HIV typically? Do you always get an STI screen when you test for HIV?
(*Prompt: Do you have a usual clinic that you go to? How did you choose that clinic?*)
- Can you think of how you have formed your testing patterns?
- What has influenced your thoughts on testing?

5. Seeking HIVST

- When did you first hear about HIVST?
- What were your initial thoughts?
- How did you hear about the SELFI study? What made you decide to take part?
- How did you find the process of signing up? Was there anything difficult?
- Did delivery of the kits go well?

6. Experience of HIVST

- Thinking back to when you took your first self-test, what was going through your mind?
(*Prompt: did you think there was a possibility of a positive result?*)
- Did you decide to take the test by yourself or was there someone with you?
- What were your impressions of the kit? Did you watch any of the videos online?

- (*Prompt*: what did you think of the instructions? Did the kit look easy to use?)
- What was your experience of using the test kit like?
(*Prompt*: Do you think you made any mistakes?)
 - Describe your experience of reading the result?
 - Did you trust the result that your test gave you?
(*Prompt*: Did you seek support from anywhere?)
 - Have the emails prompting you to think about testing again been helpful to you?
 - How have these experiences changed as you've used more kits over time? Are your emotional reactions the same?

Appendix 7: Updated topic guide

Topic guide one-to-one interviews

1. Introductions

- Researcher, Sigma, LSHTM
- This is an interview to hear your thoughts on HIVST. You've been invited because of your involvement with the SELPHI study. I'll ask you some specific questions about yourself, and some questions about your history. Feel free to answer them however you see fit. There are no right or wrong answers etc.

2. Ethics

- We would like to record the interview so we don't miss any of what you say.
- Explain how we will use and protect the data
- Do you have any questions?
- Are you happy to proceed?

3. HIV testing history

- Have you tested for HIV before?

If no

- Have you considered HIV testing before?
- What has stopped you?
- Have you ever tested for STIs?
- Have you ever considered testing but not gone?
- Can you tell me about the last time you heard about HIV testing? From whom? Where? What was the message?
- What did it make you think? Was this different to other messages/images about HIV testing that you've seen in the past? How?

If yes

- Can you tell me about the first time you tested for HIV?
- Can you remember what prompted you to seek testing the first time you went?
- What was the experience like? Where did you go? How did you choose to test that way?
- What kind of support were you provided with? Was this what you wanted?
- Can you think of anything else that would have been helpful for you in that situation?
- How about the last time you tested before SELPHI? Can you tell me a bit more about that?
- Where did you go? How did you make that decision? What kind of support did you get?

4. HIV testing patterns (If previously tested)

- What is usually your motivation to test? Do you have conversations about HIV testing with your friends? Are you ever prompted to test by discussions you have with others? Do your friends support each other around HIV testing?
- How often do you test for HIV typically? Do you always get an STI screen when you test?
(*prompt: Do you have a testing routine? Do you think this is common with your friends? Do*

doctors ever prompt you to test?)

- What challenges have you faced when taking a test or thinking about testing? Are there things that have stopped you from testing? Or that make testing more difficult?
- Has there been anything that has made testing easier for you?
- Can you think of how you have formed your testing patterns?
- What or who has influenced your thoughts on testing?
- The last time you had a risk, did you consider going for an HIV test? Describe your decision making process around that? Where did you go? What role does risk play for you generally in testing for HIV?
- (if not answered) what kind of risk would prompt you to look for an HIV test?
- Has there ever been a time you tested when you were genuinely concerned you may be HIV positive? What made you think that? How did you test and what led you to choose that method? Is that the same thing you would do now?

5. Initial engagement with HIVST & SELPHI

- When did you first hear about HIVST?
- What were your initial thoughts?
- How did you hear about the SELPHI study? What made you decide to take part?
- Do you remember the advert for the study that you saw? Anything stick in your mind from that?
- **[Show study advert]** Here's the advert you were recruited from. What do you think about it? Is there anything you find appealing or not about it? Was it motivational in any way?
- How did you find the process of signing up? Was there anything difficult? Anything that you didn't understand?
- **[Show registration and enrolment surveys]** Here are the surveys that you filled out at the time. What jumps out in your mind about these?
- Do you have any thoughts on why I might be curious about what these questions made you think?
- Were there any of these questions unclear when you completed the surveys? Any that you didn't feel comfortable answering?
- How long did it take for your kit to arrive?

6. Experience of HIVST & trial infrastructure

- **[Show kit with accompanying sleeve]** This is the same version of the test we sent you. Can you remember what your first impressions of it were? (Make sure sleeve and kit itself are covered in conversation)
- Thinking back to when you first took the self-test, what was going through your mind? Tell me everything you can about the first time you used HIVST (*Prompt: Where were you? did you think there was a possibility of a positive result?*).
- Did you decide to take the test by yourself or was there someone with you?
- Did you read the instructions? How many times?
(*Prompt: if not answered: What did you make of them? Did you watch any of the videos online? Did the kit look easy to use?*)
- How was your overall experience of using the test kit?

(Prompt: Do you think you made any mistakes? Was it difficult to use the lancet?)

- Describe your experience of reading the result.
- What did you do immediately after you took the test?
- How did you feel after using HIVST? Did you trust the result that your test gave you?
- Did you seek support from anywhere?
- Have you talked to anyone about HIVST? Did you tell anyone you had taken a self-test? What did you tell them about the experience? What do you think they thought about it?
- Do you remember receiving a follow-up survey about two weeks after you took the test? What were your impressions?
- **[Show copy of email and two week survey]** This is what it would have looked like. Can you think about how you reacted to this? (prompt: did you recognise this as a form of support?)
- **[Show copy of email and three month survey]** Do you remember receiving this survey? What was your initial reaction to the email? Did you fill the survey out?

7. Experiences of randomisation B (if randomised to RT)

- So you were randomised to receive repeat testing at your three month point.
- How have you felt about the offer of repeat testing? Has it been useful? How many tests have you had through SELPHI now? Have you used all the tests that have been offered? (if not used) what has influenced you to not take a test?
- Are you also accessing other testing options?
- **[Show copy of email and three month survey]** Have these emails been useful in prompting you for more testing?
- Have there been changes to the way you think about testing through this process?

8. After HIVST

- What are your thoughts on using an oral fluid test rather than blood?
- What do you understand by the term 'window period'?
- Have you thought about having an STI screen as well?
- On reflection, is there any additional support you would want with an HIVST?
- Do you think your behaviour will change in any way following the experience of using HIVST?
- Would you use HIVST again if it was available to you? Would you use it alongside other services or instead?
- Is there someone or a group of people you think HIVST is particularly good for? Anyone that it is not suitable for?