Research Paper

Impact and acceptability of HIV self-testing for trans men and trans women: A mixed-methods subgroup analysis of the SELPHI randomised controlled trial and process evaluation in England and Wales

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ABSTRACT

Background: Globally, trans people are disproportionately affected by HIV, but research on strategies to increase testing are limited. SELPHI is a randomised-controlled-trial (RCT) of 10,135 *cis* men, trans men, and trans women reporting lifetime anal intercourse with male partners (*cis* or trans), evaluating whether the offer of free HIV self-testing (HIVST) increases diagnosis. This subgroup analysis from the SELPHI RCT aims to describe key HIVST outcomes and HIVST acceptability for trans people.

Methods: SELPHI recruited using social networking and trans focused social media. Participants were randomised 60/40 to baseline HIVST (Biosure™) (BT) vs no baseline HIVST (nBT); and at 3-months (if completed the survey and reported recent CAI) 50/50 to 3-monthly HIVST (RT) vs no repeat HIVST (nRT). Outcomes were self-reported through online surveys. We conducted a qualitative study of semi-structured peer-led participant interviews (*n* = 20) exploring HIVST motivations and experiences. These were analysed using a framework approach.

Findings: SELPHI recruited and randomised 118 trans men and trans women (94 trans men, 24 trans women), of whom 20 (16 trans men, 4 trans women) underwent the second randomisation. Median age at baseline was 29 (IQR: 22, 37), 79% were white, 79% were UK born, 37% had degree level education, and 31% had never tested for HIV. 62% (*n* = 59) of trans men completed the 3-month survey, but survey completion by trans women in nBT was too low (1/11) for randomised comparison. In trans men HIV testing uptake by 3 months was significantly higher in BT (95% 36/38) vs nBT (29%, 6/21) (RR=3.32 (1.68, 6.55) *p*<0.001). Trans people randomised to RT reported 3 times higher rate of HIV testing compared to nRT during the two-year follow-up (IRR 3.66 (1.86, 8.01) *p*<0.0001). STI testing frequency (mean number of tests during each 13 week period/ 2-year follow-up) was not significantly different across interventions: RT (0.03) and nRT (0.01) (IRR=1.86 95%CI; 0.77, 5.15; *p* = 0.15). Social harms were rare. Acceptability was very high in BT: 97% (38/39) found instructions easy to understand, 97% (37/38) found the HIVST simple to use and 100% (39/39) reported good overall experience. In interviews, reported HIVST benefits included increased autonomy, privacy, convenience and avoidance of health care providers perceived to be discriminatory and services that increased dysphoria. Minor lancet and test processing issues were reported.

Interpretation: HIVST significantly increased testing uptake and frequency in trans men and trans people overall, although recruitment and retention of trans women was low. HIVST acceptability was high and indicates easy access to this novel technology may increase HIV testing access for this key population.

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Research in context

Evidence before this study

Trans people are a key population in the HIV response with pronounced HIV testing need. However few data exist on optimal approaches and interventions to support these groups.

The HIVST evidence base has evolved rapidly since 2012. A systematic mapping and reviewing exercise conducted to update the WHO HIV self-testing guidelines informs this study. Observational evidence from the US and Latin America suggests that HIVST is acceptable to trans women and may increase testing uptake by providing a private, convenient testing method which reduced the need to access clinics. The potential impact on incidence of harm is uncertain and is an important issue given the high levels of background violence faced by trans people.

The meta-analysis which underpins this research (see Witzel et al 2020) identified 10 randomised controlled trials (RCTs) evaluating HIVST amongst key populations, 2 of which included trans people. These two previous RCTs have not reported their trans participants (*n* = 72) separately from cisgender MSM, meaning that outcomes for this group are unknown.

Added value of this study

This study provides the first randomised comparison of HIVST outcomes for this population and includes the largest sample of trans people reported in HIVST RCT literature to date. This evidence demonstrates that HIVST is highly acceptable and can dramatically increase HIV testing uptake and frequency without negatively impacting on STI testing. Self-testing acceptability in this group was very high in both quantitative and qualitative enquiry.

This research also demonstrates the critical issues with service access faced by trans people in the UK which increases the acceptability and utility of remote HIV testing options.

Implications of all the available evidence

On the basis of this study and the other existing evidence reporting high acceptability, HIVST can be commissioned for trans men and trans women. Pilot and demonstration projects providing HIVST to these groups should monitor proactively for adverse events. In addition, the potential for HIVST to increase HIV diagnoses in this group is uncertain, as is the potential impact on linkage to care.

Sexual health services require investment in staff training as well as clinical processes and procedures to ensure they are able to provide appropriate care for trans people.

1. Introduction

Increasing uptake and frequency of HIV testing is a public health priority and is necessary to reduce HIV incidence globally. This is enshrined in the UNAIDS 95−95−95 targets whereby 95% of people living with HIV know their status, 95% of those are on ART and 95% on ART have virological suppression by 2030 [1]. Trans people and in particular trans women are a key population at increased risk of HIV acquisition, yet are severely underserved in the global response, including in HIV prevention and testing research [2,3]. There is also a lack of data on the sexual health needs of trans men and women in the UK, despite the fact that this group is more likely to be diagnosed with HIV late, less likely to attend sexual health clinics and less likely to test for HIV than cisgender men who have sex with men (MSM) [4−6].

Trans people globally face barriers to HIV testing and prevention services not experienced by other groups [7]. These barriers include services which are not culturally appropriate, health care provider hostility and lack of understanding, the risk of arrest and imprisonment and barriers surrounding trans visibility and associated vulnerability [5,7−10]. Trans women are also disproportionately represented in sex work, leading to additional sexual health needs which may be poorly met by existing services [11]. HIV testing rates among trans people in the UK are sub-optimal, with 49% of 500 trans participants reporting no lifetime HIV testing in a recent study [5].

HIV self-testing (HIVST) is a relatively novel testing modality whereby people test themselves using a rapid diagnostic test, which involves taking their own sample, processing the test and reading their own result [12]. HIVST has been reported to reduce barriers relating to stigma, privacy and inconvenient healthcare services and can be delivered through a variety of mechanisms adapted to the needs of specific populations. This testing approach was first recommended by the World Health Organization in December 2016, with updated guidelines released in December 2019 [13,14]. However concerns remain regarding the potential of HIVST to lead to decreases in STI testing and increases in risk behaviour and also the potential for harms, such as coercion to test, negative impact on wellbeing or relationships, as well as intimate partner violence [12,15].

RCT evidence regarding HIVST for trans people is scarce. Small numbers of trans people (mostly trans women) (*n* = 72) have been included in two RCTs recruiting cisgender MSM; but their data were not reported separately [16,17,18]. Pilot and demonstration projects including trans women in the US show that HIVST is an acceptable and feasible method for delivering HIV testing both through clinic distribution and for onward distribution to their sexual partners [19,20]. No European evidence regarding trans people and HIVST exists, and there is a general lack of qualitative data for these groups.

It is critical to generate evidence for trans people specifically regarding the potential for HIVST to increase HIV testing uptake and frequency and to understand key dimensions of acceptability for trans people who access HIVST interventions. This subgroup analysis aims to describe key HIVST outcomes (HIV testing uptake/frequency, STI testing uptake/frequency, sero-status) and HIVST acceptability for trans people.

2. Methods

SELPHI (An HIV Self-Testing Public Health Intervention) is an RCT which recruited 10,135 MSM (*cis* and *trans*) and trans women who have anal sex with men. The study initially planned to include only MSM (*cis* and *trans*), but the SELPHI community advisory group recommended expanding the inclusion criteria to trans women provided a separate analysis of trans participants was conducted. The analysis we present here includes data on trans participants only.

In addition to the RCT data we also include a peer-led qualitative sub-study to elicit more depth and nuance surrounding the experiences of trans people concerning intervention usability and acceptability.

2.1. RCT methods

SELPHI is an online RCT with two randomisations and two interventions, the protocol has been published elsewhere [21] and is available in additional file 1. Participants were recruited through social media, and online geo-location social and sexual networking apps used predominantly by MSM but also trans women (Facebook, Grindr, Scruff and Growlr). SELPHI began recruitment in February 2017 through a predefined pilot phase, recruiting 10% of its overall sample [22]. Full recruitment began July 2017 and was completed in February 2018. Eligible participants were MSM (cis and trans) and

RANDOMISATION A - INCLUSION
- Men (including trans men) and trans women
- Has ever had anal sex with a man
- Is not known to be HIV Positive
- Aged ≥16 years old
- Resident in England or Wales
- Willing to provide name, date of birth, and a valid email address
- Gives consent to linkage with surveillance and clinic databases.
- Has not been previously randomised to the study

Randomisation A

No baseline self-test [nBT]

Free baseline self-test [BT]

Primary Outcome A
confirmed HIV diagnosis within 3 months of enrolment, with date defined as the date of the first confirmatory test at clinic

3-Month Survey*

RANDOMISATION B - INCLUSION
- Allocated to baseline self-test (BT) in randomisation A
- Has completed 3-month survey and;
    - reports using self-test sent at baseline
    - remains HIV negative
    - expresses interest in using HIV self-test kits in the future
    - is considered to be at high-risk for HIV infection. Defined as reporting condomless anal sex with ≥1 male partners in previous 3 months.

Randomisation B

No regular test offer [nRT]

Regular test offer [RT]

Primary Outcome B: confirmed HIV diagnosis between the date of this randomisation and study closure, with date defined as the date of the first confirmatory test at clinic.

* Surveys include Questions on Sexual behaviour and HIV testing

*Regular Survey**

Test reminders + *Regular survey**
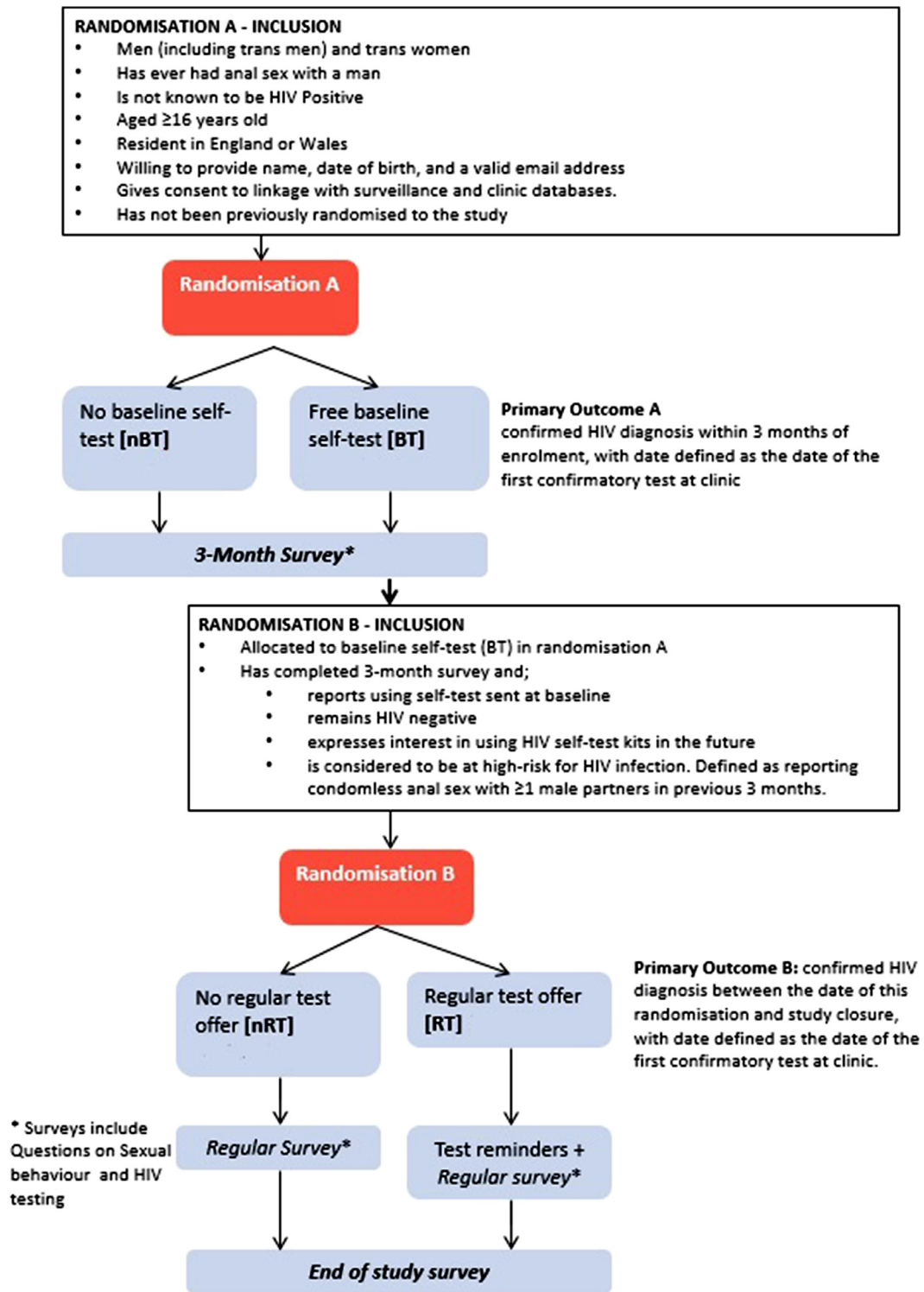
End of study survey

Fig. 1. RCT schema with eligibility criteria for both randomisations.

trans women not previously diagnosed with HIV and who reported lifetime anal sex with men (cis or trans).

In the first randomisation, eligible participants were randomised 60/40 to an offer of a baseline HIVST (BT) vs standard of care (no baseline testing (nBT)). In the second randomisation eligible participants were randomised 50/50 to offer of repeat HIVST (RT) vs standard of care (no repeat testing (nRT)). As the second randomisation sought to detect incident infections during the trial only those who

reported a negative HIVST result in BT were included. Fig. 1 presents a trial schema with eligibility for both randomisations.

The primary outcome of the trial was a confirmed HIV diagnosis; secondary outcomes included uptake and frequency of HIV testing, frequency of STI testing and harms experienced during SELPHI. Follow-up period for outcomes from randomisation A (HIV and STI testing uptake) was 3-months; for randomisation B outcomes (HIV and STI testing frequency) follow-up lasted 2

years. Harms follow-up was at 18-months and 2 years for randomisations A and B respectively.

2.1.1. RCT data collection procedures

RCT infrastructure was online. When registering for SELPHI, participants completed a survey confirming eligibility, giving consent to participate and for linkage to national HIV surveillance databases, and providing baseline demographic and behavioural details.

We used a two-stage gender question to identify trans participants. The first stage asked for gender identity (male, female, trans male, trans female, non-binary) while the second question asked assigned sex at birth (male, female, undetermined).

Following enrolment, additional surveys were delivered at two-weeks (BT participants only) and three-months (all participants). Those randomised to RT and nRT received three monthly surveys from the date of their second randomisation. BT and nBT participants received an end of study survey 18 months after enrolment; this was delivered to RT and nRT participants 24 months after enrolment. Three reminders were sent per survey.

Secondary outcomes were self-reported through these surveys. HIVST uptake and frequency for the intervention arms (BT and RT) were validated with delivery records kept by the trial team. Harms data were self-reported.

Data for the primary outcome were provided by data linkage with Public Health England's HIV surveillance databases.

2.1.2. Interventions

All kits distributed through SELPHI were BioSure™ 2nd generation blood based HIVSTs. Full descriptions of the interventions and theoretical underpinnings can be found in prior publications [19,23,24]. Here we present an abridged version.

2.1.2.1. BT.
Participants enrolled via an advert served on social media and apps. During registration a sexual behaviour risk assessment was delivered asking numbers of male partners and number of condomless anal intercourse (CAI) partners. Following randomisation to the BT arm, an HIVST kit was delivered via post directly from the manufacturer. This was accompanied by a sleeve detailing additional supportive information and signposting a helpline run by a community-based organisation (Terrence Higgins Trust). Two-weeks following kit delivery a short survey was delivered via email seeking to confirm kit receipt, use and outcome, this survey was considered part of the intervention. At three-months participants received a follow-up survey (considered part of trial infrastructure); those who were eligible were randomised a second time to RT or nRT.

2.1.2.2. nBT.
Participants randomised to nBT had a similar intervention pathway to those in BT. However, in terms of intervention, rather than receive a kit they were directed to an online widget into which they could enter their postcode and identify their nearest HIV testing opportunity. They did not receive the two-week follow-up component of the intervention but received a three-month survey with the same questions as in the BT questionnaire, except those about the HIVST kit.

2.1.2.3. RT.
Those who in BT were eligible were entered into a second randomisation. If randomised to RT they were sent a new kit, identical to that in BT and with the same supportive information. At two-weeks following kit delivery they received a result recording survey, considered part of the intervention. At three-months participants were emailed a testing reminder with a linked survey which prompted the choice to receive a further HIVST, beginning the cycle again. The risk assessment embedded within this survey was considered part of the intervention.

2.1.2.4. RT.
Those randomised to nRT were shown the widget identifying testing locations. They received three-monthly surveys which included the risk assessment.

2.1.3. Sample size determination

For the overall trial (including cis-MSM), sample size determination was based on the primary outcomes of confirmed HIV diagnosis for those with prevalent and incident infections [19]. Formal sample size determination was not determined for the trans sub-group prior to RCT implementation, largely because this element was exploratory and it was unclear how many trans participants we could recruit. Our sample size is comparable to early HIVST RCTs including only MSM [16,25].

2.1.4. Randomisation and allocation concealment

Both randomisations used random sequence generation by the survey provider, randomising individual participants.

Due to the nature of the intervention participants could not be blinded to their intervention condition. Chief investigators and the trial statistician were unblinded to participant allocation and trial outcomes to maintain participant safety and trial data validity. However all other SELPHI investigators were blinded.

2.1.5. Statistical methods

Our analysis plan for this sub-group mirrored that of the larger RCT within which it was contained. All analyses were complete case intention-to-treat.

Baseline demographic and behavioural variables were tabulated and assessed for balance using a rank-sum test or chi-squared test as appropriate.

Randomised comparisons and non-randomised acceptability analyses were summarised and tabulated. Data are reported by trans men, trans women and all trans participants (trans men and women combined). Randomised comparisons for the first randomisation were conducted using risk ratios. For the second randomisation, as all participants did not necessarily complete all surveys, follow-up time was estimated as 13 weeks for every survey completed (reflecting the time between each scheduled follow-up survey). The rate of testing using this follow-up time was then estimated and compared by calculating the incidence rate ratio using Poisson regression. For the primary outcome of HIV diagnosis, the data was linked with national HIV surveillance databases at Public Health England. Analyses were performed using Stata v16.0

2.2. Qualitative sub-study

We conducted a qualitative sub-study to explore dimensions of acceptability and generate a nuanced understanding of the potential of HIVST in addressing unmet testing need for trans people. We worked with a trans woman peer researcher who contributed to study design, data collection and analysis to engage trans participants and to develop additional insights. Interviews were conducted between April and October 2019. Methods for the qualitative sub-study are described below.

2.2.1. Recruitment and sampling

All 87 trans participants who provided consent to be contacted for qualitative interviews at enrolment for the RCT were considered eligible for this sub-study. Upon reaching 20 interviews we reviewed the data paying close attention to completeness of themes and negative cases. Through this process we assessed we had achieved thematic saturation and thus ended recruitment. We aimed to achieve diversity in the sub-study sample with regards to gender identity (oversampling trans women for this component because of their small numbers in the trial), RCT intervention allocation and age. One participant was not randomised when they joined SELPHI and

therefore are not included in the quantitative analysis but are included in the qualitative sub-study.

Participants were contacted by the peer researcher via email with the participant information sheet and were offered the choice between being interviewed by a trans woman (second author) or a cisgender gay man (first author).

2.2.2. Interviews and data analysis

The topic guide (available in additional file 2) was developed by first and second authors, adapting a previous topic guide used in a separate sub-study including cis-MSM [23,24]. This process focused on adapting questions and including new ones relevant to trans people.

The topic guide covered experiences of health care; mental health and gender identity services; previous HIV testing experiences; motivations for seeking HIVST; experiences of SELPHI trial infrastructure and potential intervention adaptations. Our analysis draws from the latter four of these.

Participants were interviewed over the phone and through video calling, with a minority ($n = 2$) interviewed in person. Interviews lasted between 45 and 90 min, were recorded and transcribed verbatim.

Analysis combined framework and thematic approaches [26,27]. Our framework drew from emerging themes identified during data generation, the wider literature around trans peoples' experiences of HIVST / sexual health services, theorised key components of intervention acceptability from formative and RCT acceptability work and systematic reviews [18,23,28-30]. The analysis framework can be found in additional file 3.

2.2.3. Registration, approval and ethics

SELPHI was prospectively registered with the ISRCTN (ref: ISRCTN20312003). Ethical approval was sought from and granted by the University College London (UCL) (ref: 11,945) and the London School of Hygiene and Tropical Medicine (LSHTM) (ref: 9233/001).

2.2.4. Role of funding

The funder had no role in study design; in the collection, analysis, and interpretation of data; in the writing of the report; or in the decision to submit the paper for publication.

3. Results

SELPHI recruited 118 trans participants. The majority ($n = 94$, 80%) were trans men, median age of 29, 79% ($n = 93$) white, 79% ($n = 93$) born in the UK, 37% ($n = 44$) highly educated and 31% ($n = 36$) had never previously tested for HIV. All 118 participants were included in the first randomisation, while 20 were also randomised in the second. There were no substantial imbalances across arms of baseline demographics. Table 1 presents baseline data. Fig. 2 presents a trial flow diagram with survey completion rates.

3.1. RCT outcomes

Below we present outcomes from both randomisations, as well as acceptability variables from the first SELPHI HIVST for trans men and trans people overall. Survey completion rates for trans women in nBT (1/11) and the total number of trans women randomised in RT or nRT ($n = 4$) were too low for randomised comparisons with this group. Table 2 presents comparisons for HIV and STI testing uptake and frequency and includes descriptive results for trans women.

3.1.1. HIV outcomes

No trans participants received a confirmed HIV diagnosis during the 2-year trial follow-up. HIV testing uptake at 3 months was significantly higher in BT (95%, 36/38) vs nBT (29%, 6/21) amongst trans men (RR=3.32; 1.68, 6.55, $p<0.001$) and in all trans participants (RR=3.43, 95%CI 1.72, 6.81, $p<0.001$). During the two-year follow-up

Table 1
Randomised trial baseline demographic details.

Demographic detail	Trans men $N = 94$	Trans women $N = 24$	All $N = 118$
Included in Randomisation B	16 (17%)	4 (17%)	20 (17%)
Median (IQR) age (years)	28 (21, 36)	33 (26, 38)	29 (22, 37)
Age category			
16−25 years	37 (40%)	6 (25%)	43 (36%)
26−40 years	39 (41%)	14 (58%)	53 (45%)
41+ years	18 (19%)	4 (17%)	22 (19%)
Born in the UK	76 (81%)	17 (71%)	93 (79%)
Ethnicity			
White	77 (82%)	16 (67%)	93 (79%)
Asian	4 (4%)	5 (21%)	9 (8%)
Black	2 (2%)	0	2 (2%)
Mixed	6 (6%)	1 (4%)	7 (6%)
Other/Don't know/Not disclosed	5 (5%)	2 (8%)	7 (6%)
Highest educational qualification			
Low[1]	22 (23%)	12 (50%)	34 (29%)
Medium[2]	31 (33%)	8 (33%)	39 (33%)
High[3]	40 (43%)	4 (17%)	44 (37%)
Sexual orientation			
Gay	34 (36%)	3 (13%)	37 (31%)
Bisexual	31 (32%)	9 (38%)	40 (34%)
Straight	1 (1%)	4 (17%)	5 (4%)
Other	6 (6%)	2 (8%)	8 (7%)
No term/Not disclosed	22 (23%)	6 (25%)	28 (24%)
Partner numbers (3 months)			
0	23 (24%)	3 (13%)	26 (22%)
1	32 (34%)	9 (38%)	41 (35%)
2−4	23 (24%)	8 (33%)	31 (26%)
5+	16 (17%)	4 (17%)	20 (17%)
Previous HIV test			
Never	27 (29%)	9 (38%)	36 (31%)
<12 months	47 (50%)	9 (38%)	56 (47%)
>12 month	20 (21%)	5 (21%)	25 (21%)

[1] GCSEs and below.
[2] A-levels and further education below degree level.
[3] Degree+.

period trans men randomised to RT reported 3 times the rate of HIV testing compared to nRT (IRR 2.98 95%CI 1.50, 6.56; $p = 0.0002$), as did trans people overall (IRR 3.66 95%CI 1.86, 8.01; $p<0.0001$).

3.1.2. STI outcomes

STI testing in the 3 months after enrolment was similar for trans men across BT (29%, 11/38) vs nBT (29% 6/21) (RR=1.01 95%CI; 0.44, 2.35; $p = 0.98$) and for trans people overall: BT (26%, 12/46) vs nBT (27% (6/22)) (RR=0.96; 95% CI 0.41, 2.12; $p = 0.92$). Over the two-year follow-up frequency (mean number of STIs tests per 13 week period) did not differ significantly for trans men RT (0.02) and nRT (0.02) (IRR 1.20 95%CI 0.46, 3.49; $p = 0.69$) and was not significantly different for trans people overall RT (0.03) and nRT (0.01) (IRR=1.86 95%CI; 0.77, 5.15; $p = 0.15$).

3.1.3. Harm

No participants in either arm reported negative impacts on well-being or relationships in exit surveys. No false positive test results were reported. No participants reported they were pressured or persuaded to test when they did not want to. However 2 participants in the repeat testing arm (one trans man and one trans woman) reported pressuring or persuading someone else to test when they did not want to.

3.2. Acceptability

HIVST was highly acceptable for trans men and women in the baseline testing arm: 97% (38/39) found instructions easy to understand, 97% (37/38) found the test simple to use and 100% (39/39) reported a good overall experience.
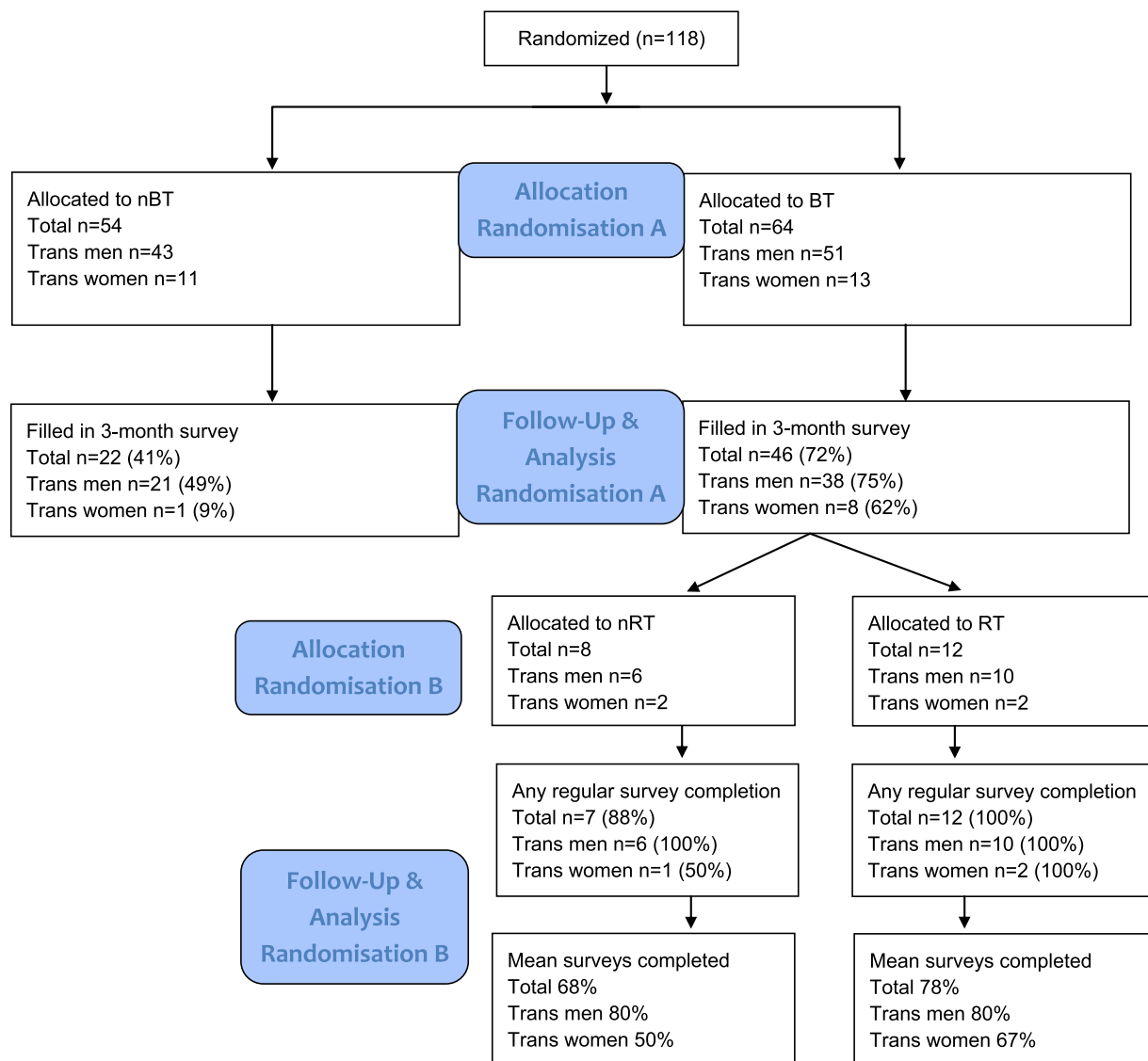
Fig. 2. SELPHI trans sub-analysis flow diagram.

Table 2
Intervention outcomes.

Randomisation A outcomes	BT% (n)	nBT% (n)	RR (95% CI)	P value
HIV testing uptake (3 months)				
All	93% (43/46)	27% (6/22)	3.43 (1.72, 6.81)	<0.0001
Trans men	95% (36/38)	29% (6/21)	3.32 (1.68, 6.55)	<0.0001
Trans women	88% (7/8)	0 (0/1)	N/A	N/A
STI testing uptake (3 months)				
All	26% (12/46)	27% (6/22)	0.96 (0.41, 2.21)	0.92
Trans men	29% (11/38)	29% (6/21)	1.01 (0.44, 2.35)	0.98
Trans women	13% (1/8)	0 (0/1)	N/A	N/A
Randomisation B outcomes	RT Incidence rate	nRT Incidence rate	IRR (95% CI)	P value
HIV testing frequency (2 years)	**All *N* = 7**	**All *N* = 12**		
	Trans men *N* = 6	**Trans men *N* = 10**		
All	0.07	0.02	3.66 (1.86, 8.01)	<0.0001
Trans men	0.07	0.02	2.98 (1.50, 6.56)	0.0002
STI testing frequency (2 years)				
All	0.03	0.01	1.86 (0.77, 5.15)	0.15
Trans men	0.02	0.02	1.20 (0.46, 3.49)	0.69

Note: estimates could not be generated for trans women due to the very small sample size. In Randomisation B, one trans women reported always taking a HIV test (RT), and two reported never taking a HIV test in follow-up (one nRT, one RT). CI: confidence interval; IRR: incidence rate ratio; RR: risk ratio.

3.3. Qualitative results

We interviewed a diverse sample of participants (*n* = 20) from all trial arms. Below we present results of our qualitative analysis, focusing on barriers and facilitators to HIV testing services which shaped HIVST engagement; intervention experiences and RCT infrastructure acceptability. Table 3 provides demographic data from qualitative sub-study sample.

3.3.1. Motivations and barriers to HIV testing services

A number of barriers to accessing sexual health and community HIV testing services were described. These barriers were the primary motivation for HIVST uptake through the trial, profoundly shaping acceptability as HIVST allowed for the bypassing of clinical services for HIV testing. Many barriers and facilitators described are common across key population groups when considering standard HIV testing services (e.g. inconvenient clinic opening hours, HIV stigma, physical distance, fear of a positive result) [31]. Here we describe barriers and facilitators specific to trans men and trans women. These clustered around three primary areas: (i) skills, empathy and cultural competence; (ii) systems, processes and clinic design and (iii) gender identity, dysphoria and reticence.

3.3.1.1. Skills, empathy and cultural competence. significant problems with clinic personnel were reported by those who had previously accessed clinic-based HIV testing, contributing to substantial HIVST acceptability. Experiences of overt discrimination from health care professionals were rare, more commonly personnel lacked the necessary skills, empathy and cultural competence to meet the needs of trans people.

A trans man reported being misgendered and having his sexual orientation doubted while being denied post-exposure prophylaxis (PEP) at a London sexual health clinic following condomless intercourse with a cis-MSM:

Table 3
Qualitative sub-study demographic details

	Demographic characteristics	Participant numbers
		N=20
Age	16 - 25 years	7 (35%)
	26 - 40 years	6 (30%)
	41+	7 (35%)
Gender	Trans women	7 (35%)
	Trans man	12 (60%)
	Non-binary	1 (5%)
Ethnicity	White	16 (80%)
	Black	2 (10%)
	Latin American	1 (5%)
	Asian	-
	Other / mixed	-
	Undisclosed	1 (5%)
Sexual orientation	Heterosexual	2 (10%)
	Gay	7 (35%)
	Bisexual	6 (30%)
	Don't use a term	1 (5%)
	Undisclosed	4 (20%)
Highest educational qualification	Low[1]	7 (35%)
	Medium[2]	3 (15%)
	High[3]	9 (45%)
	Undisclosed	1 (5%)
Randomisation	RT	4 (25%)
	BT	10 (50%)
	nBT	5 (25%)
	Not randomised	1 (5%)

[1] GCSEs and below
[2] A-levels and further education below degree level
[3] Degree+

I'm not the most masculine-looking person in the world, I have to admit. But I did have a little bit of facial hair. And not to be glib but I have got body hair. And one said, "I wouldn't worry about it 'cause he's probably heterosexual." And that was just quite frustrating. 'Cause I'd started the transition [...] I'd been on testosterone for several years. [...] It's like I wasn't trans, [the way] he was talking about it. And so [he felt] I wasn't particularly at risk of anything. (28-year old trans man, baseline testing arm)

These types of experiences were very common, with staff often misgendering trans people, treating them as a burden, erasing their sexual orientation and/or gender identity and disregarding their perceptions of risk. Conversely, positive experiences usually focused on affirming interactions with clinical staff, largely (but not wholly) in services specifically designed for trans people. The potential for avoidance of any clinical staff or facilities felt to be hostile or not trans competent, led to substantial enthusiasm for HIVST.

3.3.1.2. Systems, processes and clinic design. With the exception of services created and run for and by trans people, existing systems within sexual health services were usually not designed with the needs of trans people in mind. These services, which often advertised as being LGBT inclusive, were felt only to cater to cis-MSM. This was especially true when considering clinic pathways which emphasised the male/female sex binary rather than gender identity. Experiences of encountering clinics which did not have established processes for trans patients was common.

They don't have in their system that I am a trans woman. So they always. think that I'm a [cis] woman. Because I don't have vagina yet, so they always give me the test for vagina. So I have to go always to the reception desk to tell them, sorry, but I don't have vagina yet. (42-year-old trans woman, repeat testing)

These issues with clinic processes centred around record keeping systems and pathways that relied on biological conceptualisations of sex rather than social understandings of gender. There were also significant issues with systems which did not represent the diversity in anatomy represented in trans men and trans women, coming both from hormone treatment and gender affirming procedures. Inflexibility in systems was common; staff were often required to take ad hoc approaches to providing care to trans patients.

It was only now that I live as a man, and that I have a half and half body if you like, so I'm a man with a vagina, so their system [doesn't account for that], in the end I think they had to draw things on, use one [file] and draw it onto the other. We used the female one and then drew things on that [...] of course, my vagina doesn't look like that, because it's changed since I've been taking testosterone. (52-year-old trans man, repeat testing)

SELPHI was felt to be more appropriately trans inclusive, with HIVST providing a discreet testing method which was embedded within systems which were designed for participants from a range of genders.

3.3.1.3. Gender identity, dysphoria and reticence. Personal concerns specific to gender identity were a major barrier to accessing clinics. These ranged from worries that gender affirming treatments could be withheld should an individual have a positive HIV diagnosis, to concerns about experiencing gender dysphoria when describing body parts.

Like I have very, very bad chest dysphoria, and bottom dysphoria didn't bother me so much. But the idea of going and getting tested

and like having to talk about it so explicitly [...] induced a little bit of dysphoria. (20-year-old trans man, no baseline testing)

Gender dysphoria and concerns about discussing one's own body were described as being pronounced in the early stages of transition, a time when often individuals were also navigating changes in sexual orientation, desire and practice. HIVST provided a sense of privacy and autonomy, which ameliorated testing barriers.

3.3.2. Intervention acceptability

This section describes intervention acceptability and kit use experiences. It focuses on initial engagement with SELPHI, capability concerns, support and behaviour changes.

3.3.2.1. Appeal, attraction and engagement.
HIVST was felt to be a useful, new technology which provided personal control over the HIV testing process; a highly valued trait. The RCT adverts were described as informative and helpful in highlighting benefits of self-testing. Those who were recruited through adverts which focused solely on HIVST facilitators and were therefore not specifically trans inclusive assumed they would not be eligible and were surprised when they attempted to sign up that trans men and women were included in the RCT.

3.3.2.1. Capability, cognition and ease of use.
The HIVST kits were almost universally described as straightforward to operate and the instructions as easy to understand. There were some minor issues with the lancet and test processing stage (e.g. difficulty using the lancet, errors in correctly inserting test stick into the pot containing reagent), although none reported they could not complete a test. Those receiving repeat testing described any capability issues as resolving by the second test.

3.3.2.2. Care, support and follow-up.
Emotional support following testing was drawn primarily from social networks for those requiring it, largely from friends, family and trans peers. A number of participants reported testing with others present, primarily to help with test processing but also for emotional support. For those who were socially isolated, support was mostly drawn from online sources with message boards and closed Facebook groups identified as a key site of engagement for health information.

3.3.2.2. Impacts, outcomes and expectations.
Increased HIV testing frequency for those receiving repeat HIVST was commonly reported. This was perhaps due to low levels of prior testing, itself partly because of a general lack of norms emphasising the need for frequent testing. Two participants reported having less sex following HIVST, but did not attribute it to the technology. Already low uptake of STI testing for many participants meant that most did not feel accessing HIVST would reduce their STI testing frequency.

3.3.3. RCT infrastructure acceptability

Here we describe data related to the process evaluation questions in the RCT, specifically investigating the functioning of trial infrastructure and acceptability of the questions in surveys.

Few issues with RCT function were reported; on the whole experiences matched expectations of being involved in research. Registration, enrolment and follow-up surveys arrived as expected. Kits were delivered promptly and undamaged. For one participant the randomisation process failed and they were left waiting for a kit which never arrived.

The number, timing and frequency of surveys was on the whole described as appropriate and in line with expectations, although one participant reported finding surveys annoying and cumbersome. Questions asked in surveys were largely felt to be fair, balanced and appropriate for the trans population.

The two-stage gender question used was universally popular and praised for providing a range of options and for the ability to accurately capture data. One participant however expressed desire to select more than one gender option to better reflect their identity and lived experience.

While most found the sexual behaviour questions to be appropriate and relevant, two trans male participants felt questions about anal sex with men were not relevant to them as it did not reflect the range of sexual practices trans men are likely to engage in or the anatomy of trans men.

4. Discussion

SELPHI recruited a modest if diverse sample of 118 trans people who have sex with men. The majority (80%) were trans men, most were white and born in the UK. Just over a third were educated to degree level and 31% had never previously tested for HIV. Uptake and testing frequency were significantly higher in intervention arms than nBT and nRT arms, with no adverse impacts on STI testing uptake or frequency. The test kit was perceived to be highly acceptable, easy to use, and the vast majority reported a good overall experience.

Previous studies have investigated the experiences of trans people with HIVST in other (non-European) settings; this work adds weight to the conclusion that HIVST is highly acceptable to this group in a range of settings [18,20,32]. We also demonstrate significant unmet testing need; 31% of trans men and women had not previously tested for HIV, this is more than double the 15% of MSM (cis and trans combined) from the wider trial who had not previously tested [33].

Qualitative data suggest the primary driver of HIVST uptake for trans people was issues with inaccessible and inappropriate clinical services which created pronounced barriers to accessing testing and care. These barriers, which arose de novo in this research, clustered around the themes of skills, empathy and cultural competence; systems, processes and clinic design as well as gender identity, dysphoria and reticence. The primacy of these issues suggest generic HIV testing services are neither accessible nor appropriately tailored for trans people in England and Wales, including those services that advertise as LGBT inclusive. These findings are consistent with research from the UK and other settings [5,7-10]. It should be noted that services designed specifically for trans people were very highly valued.

These data also demonstrate the HIVST intervention was attractive, easy to use and included sufficient follow-up relative to need. Generally, participants recognised that SELPHI was designed primarily for cis-MSM but felt the amount it was tailored to trans men and trans women was adequate. Trial infrastructure was largely felt to be appropriate. However a minority (*n* = 2) reported concerns with the trial focus on anal intercourse as they felt this did not necessarily reflect the diversity in sexual practice for trans MSM specifically.

As trans people face barriers to HIV services and poor HIV health outcomes [8,34], services delivering HIVST to trans people in the UK should be implemented to support this group. Tailored and targeted HIVST interventions are likely to be acceptable and feasible to deliver. Evidence suggests HIVST does not lead to unintended negative outcomes in this group, especially around decreases in STI testing rates (although these were low in all arms). In addition, we found little evidence of increased harms in the HIVST groups. Additional consideration needs to be included in order to increase engagement with trans people more widely. Indeed, including additional delivery mechanisms may be helpful in increasing uptake across a wider group of trans people, especially if delivered alongside services which provide gender affirming care, and through mechanisms which increase convenience (e.g. through click-and-collect systems). A further avenue of exploration includes peer HIVST initiatives, potentially

utilising secondary peer distribution models of HIVST delivery, as well as the provision of STI self-sampling alongside HIVST in a way which recognises the diversity of need within the trans population.

This is the first study of HIVST among trans people in Europe, and the first RCT to report HIVST data of trans people separately from cis-MSM [16,17]. Never-the-less some limitations are noted.

Recruiting trans men and trans women was extremely challenging. This was partly due to the lower proportion of trans people using geo-location sexual networking apps than cis-MSM, an issue we sought to ameliorate through increased use of social media and trans specific recruitment. Because there are no reliable estimates of the demographic make-up of the trans community in the UK it is unclear whether our sample is representative. However, given the very low number of trans women who participated this sample is almost certainly more heavily weighted towards trans MSM.

We also only recruited participants who identified as trans men or trans women, not those who identified as non-binary which is perhaps the most significant limitation in this work and which remains a critical research gap. In addition, people identifying as women rather than trans women would not reach the next survey question before they would have the opportunity to answer 'sex at birth', potentially inadvertently excluding some trans women. Future work with trans people should provide gender options which include both cis and trans people in both male and female categories alongside suitable non-binary categories. This approach, with a follow-on assigned sex at birth question, is more affirming of trans identities.

Although 67% of trans men completed the 3-month survey, and retention of this group was adequate in randomisation B, retention of trans women was an issue especially in the nBT and nRT arms. This means that randomised analyses could not be completed for this group. These analyses therefore reflect only the experiences of trans men and trans people overall.

In addition, although uptake of HIVST was validated in BT and RT arms, HIV testing in nBT and nRT were self-reported, as were STI testing outcomes across all arms. This may have introduced recall bias or social desirability bias, perhaps overestimating rates of HIV and STI testing.

Using condomless anal intercourse as an inclusion criteria for the overall trial and for the second randomisation may have restricted access to the trial for trans people who do not have anal sex and instead have other types of penetrative sex with HIV risk. This issue may be especially pronounced for trans men who may be at risk of HIV from receptive genital sex [35,36]. Future efforts must ensure that eligibility questions are trans inclusive and reflect the diversity of sexual practice (and associated HIV risks) in these groups.

The landscape of sexual health provision has changed in England and Wales since RCT recruitment. Firstly, austerity and health service rationalisation has led to the closure of many sexual health clinics. Secondly, the COVID-19 crisis has led to increased difficulties in service access, some potentially enduring. It is therefore likely that motivations to access HIVST for all groups, trans people included, will now be increasingly driven by lack of choice.

Engaging a peer researcher in the qualitative study design, data collection and analysis is a key strength of this work, leading to rich, nuanced data elaborating on RCT findings.

In this modest sized RCT, HIVST increased uptake testing and frequency among trans men and trans people overall, without leading to adverse events. We did not identify any HIV infections in this group, potentially because of small numbers participating. Trans people face significant barriers to HIV testing services, which HIVST substantially ameliorates. The SELPHI intervention was highly acceptable and valued for providing a simple kit and good overall experience. Recruitment was challenging; future research and implementation activities should be attentive to developing innovative ways to engage trans people with HIVST interventions that are specifically tailored to their needs. Peer led approaches are critical to achieving this.

Declaration of Competing Interest

Author contributions

Conceptualisation: SMc, DD, AJR, ANP, TCW, PW, FMB. Funding: AJR, ANP. RCT Design: AJR, SMc, DD, MGaf, MGab, FCL, ANP, PW. RCT implementation: TCW, MGab, DW, LM, JH. RCT analysis design: TCW, LM. RCT analysis: LM (checked by TCW). Qualitative sub-study design: TCW, TW, AJR, FMB, PW. Instrument design: TCW, TW. Qualitative sub-study data collection: TCW, TW. Qualitative analysis: TCW (checked by TW). Drafting: TCW, AJR, TW, LM. Critical input: All authors.

Data sharing

Quantitative RCT data sharing requests can be made to the SELPHI trial management group via the corresponding author. Due to the sensitive and personally identifiable nature, data from the qualitative sub-study will not be made available, although reasonable requests will be considered.

The SELPHI protocol is available at Gabriel MM, Dunn DT, Speakman A, McCabe L, Ward D, Witzel TC, et al. Protocol, rationale and design of SELPHI: a randomised controlled trial assessing whether offering free HIV self-testing kits via the internet increases the rate of HIV diagnosis. BMC Infectious Diseases. 2018;18(531).

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Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.eclinm.2020.100700.

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