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Extended Research Article

An interactive digital behaviour change intervention to decrease incidence of sexually transmitted infections among users of STI self-sampling websites: a feasibility RCT

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Disclaimer: This article contains transcripts of interviews conducted in the course of the research and contains language which may offend some readers.

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Abstract

Background: Sexually transmitted infections such as chlamydia are common among young people. If left untreated, they can have serious health consequences. Condoms are recommended for prevention, but young people report often not using them for penetrative sex. Use of web-based sexually transmitted infection testing is increasing rapidly, but these services provide little support or advice on how to prevent future infections. 'Wrapped' is a web-based intervention that aims to support young users of web-based sexually transmitted infection testing to use condoms correctly every time they have penetrative sex, thus reducing future sexually transmitted infection incidence.

Objective: To assess whether and how it is possible to carry out a future randomised controlled trial of Wrapped.

Design: A two-arm, parallel-group feasibility randomised controlled trial, with nested qualitative study, in which Wrapped in addition to usual care is tested against usual care alone.

Setting: Participants were recruited from five English local authority areas through one web-based sexually transmitted infection testing service.

Participants: Young people aged 16–24 years with internet access and who were likely to have penetrative sex during the study.

Intervention: Wrapped interactive multimedia intervention. Control: Non-interactive web page with standard information on sexually transmitted infections and details about how to access condoms.

Main outcome measures: Proportion of sampling pool recruited and return of valid chlamydia self-sample at month (M)12. Other outcome measures: return of valid chlamydia self-sample at M3; completion of surveys at baseline, M3, M6 and M12; follow-up by demographic characteristics; and acceptability of intervention and measures.

Results: In total, 230 participants were recruited and randomised to the feasibility randomised controlled trial: 115 to the intervention group and 115 to the control. Of these, 173 (75.2%) self-reported the result of their first sexually transmitted infection test. This sub-sample ('restricted sample') best represents the true nature of the sample at full trial for which the baseline sexually transmitted infection test result is needed. Results which follow are therefore for this sample. Of the sampling pool, 1.5% were recruited. A valid chlamydia self-sample was returned by 75.7% at M12. Based on this information, 3574 participants, derived from a sampling pool of 238,266 service users, were estimated to be necessary to power a future full trial. Return of other follow-up measures was as follows: valid M3 chlamydia self-sample 75.1%, M3 survey 91.3%, M6 survey 90.8% and M12 survey 91.8%. Participants at M12 appeared to broadly represent individuals in the sampling pool with some limited exceptions: a tendency for over-representation of participants who were older (20–24 years), of black ethnicity, and in the least deprived quintile; and for under-representation of participants who were younger (16–19 years), of white ethnicity, and in deprivation quintile 3. There was no evidence of differential attrition by intervention group. Participants reported that trial processes and procedures were acceptable.

Limitations: Study advert was likely not visible to most eligible participants resulting in a low recruitment rate. Qualitative study sample lacked ethnic and gender diversity.

Conclusions: A full trial is feasible. Despite the low recruitment rate, there are sufficiently high numbers of young people accessing web-based sexually transmitted infection testing (585,000 per year based on most recent data) to achieve the required sample. Suggested strategies to address the potential for under- and over-representation of some demographic subgroups at M12 should be implemented.

Future work: A full definitive randomised controlled trial implementing learning from this study.

Study registration: This study is registered as Current Controlled Trials ISRCTN17478654.

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Supplementary material can be found on the NIHR Journals Library report page (https://doi.org/10.3310/LKOT7404).

Supplementary material has been provided by the authors to support the report and any files provided at submission will have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

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List of abbreviations

CONSORT	Consolidated Standards of Reporting Trials
COVID-19	coronavirus disease discovered in 2019
DMEC	Data Monitoring and Ethics Committee
ECDA	Ethics Committee with Delegated Authority
fRCT	feasibility randomised controlled trial
GBMSM	gay, bisexual or other men who have sex with men
HIV	human immunodeficiency virus
HRA	Health Research Authority
HRQL	health-related quality of life
ICS	integrated care system
ID	identifier
IMD	Index of Multiple Deprivation
KPI	key performance indicator
M	month
MRC	Medical Research Council
NCSP	National Chlamydia Screening Programme
NIHR	National Institute for Health and Care Research
PHIND	Public Health Intervention Development
PHR	Public Health Research
PPI	public and patient involvement
RCT	randomised controlled trial
REDCap	Research Electronic Data Capture
SMS	short message service (also known as 'text message')
SPSS	Statistical Package for the Social Sciences
SSC	Study Steering Committee
STI	sexually transmitted infection
URL	uniform resource locator

Plain language summary

Sexually transmitted infections such as chlamydia are common among young people. Without treatment, they can cause serious health problems including infertility. Condoms are recommended to prevent sexually transmitted infections, but young people often report not using them for penetrative sex. Face-to-face sexual health services are available for sexually transmitted infection testing, but more and more people are using sexually transmitted infection testing websites and demand for this service is rising rapidly. Young people most at risk of sexually transmitted infections are using these sites, but they do not offer much support or advice on how to prevent future infections.

Together with young people and health professionals, we developed a website called 'Wrapped'. Wrapped aims to reduce future sexually transmitted infection diagnoses among users of web-based sexually transmitted infection testing services by increasing their condom use. Users can order a free condom sample pack and carrier, access a free monthly condom-ordering service, and watch videos that demonstrate condom use, give tips on communicating about condoms and show real couples discussing and using condoms.

What we want to know is whether Wrapped works to reduce sexually transmitted infections. To find this out, we need to run a type of experiment called a randomised controlled trial. We conducted a feasibility study to see if it was possible to carry out this type of study. Uptake was low but given the large numbers of young people who use these sites, we estimate that this will still be high enough to run the randomised controlled trial. Over 12 months, a large number of young people completed all our surveys and used sexually transmitted infection self-sampling kits to provide us with the accurate information on whether they had a sexually transmitted infection. Young people liked Wrapped, said that it made them feel differently about condoms, and described taking part in the study as easy. We will now seek funding to run the required randomised controlled trial.

Scientific summary

Background

Young people are the group most affected by acute sexually transmitted infections (STIs). Untreated STIs can lead to serious consequences such as pelvic inflammatory disease and infertility. Condoms are recommended for the prevention of STIs, but young people report often not using them for penetrative sex. There has been rapid growth in the use of web-based STI-testing services over the last 5 years. Young people most at risk of STIs are using these sites, but they do not offer much support or advice on how to prevent future infections.

The Wrapped intervention was co-developed by researchers, young people and health professionals and aims to support young people to reduce STI diagnoses though increasing condom use. It is a multicomponent and interactive digital intervention developed for users of STI self-sampling websites aged 16–24 years. Content is tailored to the individual user. At first access, users self-identify their own barriers to condom use. As a result, between one to six different intervention components are displayed. The self-identified barriers reflect relevant behavioural determinants of condom use identified through existing meta-analyses. These include condom-use attitudes (particularly beliefs around pleasure, enjoyment and spontaneity), condom availability, and self-efficacy for condom use and communication.

While evidence indicates that behavioural interventions have modest favourable effects on condom use and STI incidence, few studies examining their effects have employed randomised controlled trials (RCTs). Furthermore, studies that have employed RCTs are often of poor quality. Wrapped is now ready to be definitively tested using a high-quality RCT to determine its cost-effectiveness. First, however, it was necessary to run a feasibility randomised controlled trial (fRCT) to assess whether and how it is possible to carry out this definitive RCT.

Objectives

The primary objectives were to estimate the following parameters for planning a definitive RCT:

1. The rate of recruitment of eligible participants.
2. The rate of participant follow-up for the definitive RCT primary outcome measure (chlamydia positivity at 12 months measured using biological samples).

Methods

First, a recruitment and retention strategy was co-developed with our public and patient involvement (PPI) group. This strategy was then implemented in a two-arm, 1 : 1 allocation, parallel-group randomised fRCT of Wrapped (intervention) plus usual care (basic information on STIs and condom use) compared to usual care alone (control). Participants were recruited from five English local authority areas through one web-based STI-testing service (Preventx). Young people aged 16–24 years with internet access and who were likely to have penetrative sex during the study were eligible to participate. Recruitment was through a study advert displayed to eligible individuals by Preventx on completion of ordering a self-sampling kit for chlamydia (the sampling pool). Following online completion of the baseline survey, participants were randomised by computer to the intervention or the control, with stratification across selected demographic characteristics. Engagement with the respective websites was tracked using Matomo analytics. Participants were requested to self-report the result of their initial test for chlamydia 10 days after randomisation. Further online surveys were sent at month (M)3, M6 and M12. Chlamydia self-sampling kits were also sent at M3 and M12. A nested qualitative study with trial participants was conducted to explore acceptability of the intervention and trial.

Results

A comprehensive recruitment and retention strategy was developed. This included a set of adverts to be displayed to potential participants, and details on the schedule of incentive payments, mode and frequency of all communications, and strategies for encouraging and maintaining engagement throughout the 12-month study period. This strategy was implemented in the fRCT.

In total, 230 participants were recruited and randomised to the fRCT as planned: 115 to the intervention group and 115 to the control. Of these, 173 (75.2%) self-reported the results of their first STI test. This sub-sample ('restricted sample') best represents the true nature of the sample at full trial, for which the baseline STI test result is needed. As such, the results which follow are for this sample only.

Of those in the sampling pool, 1.5% were successfully recruited (the estimate of recruitment applied to calculate the sample size required at full trial). Between the intervention and control groups, the distribution of participants across demographic characteristics [age, ethnicity, gender, sexual identity, Index of Multiple Deprivation (IMD) quintile and relationship status] at baseline appeared broadly balanced with some limited exceptions. The observed proportions suggested an imbalance across groups for bisexual participants (lower proportion in the intervention group) and across two age groups (20 years: lower proportion in the intervention group; 21 years: higher proportion in the intervention group), albeit the median age indicated balance. Also observed was a lower proportion of female participants and a higher proportion of male participants in the intervention group than in the control group.

Chlamydia positivity at baseline (4.6%) was lower than the national figures for internet test settings at that time (8.8%). Chlamydia positivity at M12 was 2.3%. A valid chlamydia self-sample was returned by 75.1% at M3 and 75.7% at M12 (latter is the primary outcome measure for a definitive RCT, and as such, the estimate of retention applied in the full trial sample size calculation). Return of surveys was as follows: M3 91.3%, M6 90.8% and M12 91.8%. All survey items that would be used in a definitive trial to evaluate primary and secondary outcomes had fully complete or near-complete data (latter defined as < 5% missing data).

On comparison of participants who returned a valid M12 self-sample to those in the sampling pool, the following observations were made: there appeared to be a lower proportion in IMD quintile 3 and a higher proportion in IMD quintile 5 (least deprived); a lower proportion of those in the younger age group (16–19 years) and a higher proportion of those in the older age group (20–24 years); and a lower proportion of people of white ethnicity and a higher proportion of people of black ethnicity. Fewer participants returned a valid chlamydia self-sample at M12 in the control group than the intervention group (85.7% intervention vs. 66.3% control), but there was no evidence that differential attrition was patterned by demographic characteristics. Data on costs associated with delivering the intervention and the control were successfully captured.

Information on recruitment and retention was used to estimate the required sample size for a future full trial. To detect a difference of 3.5% chlamydia positivity between the intervention and control groups (figure established following extensive consultation with sexual health commissioners and service managers), it was estimated that 2706 participants would be required (figure derived using G*Power). This figure was inflated to 3574 to allow for an estimated 75.7% retention (2706/0.757). On the basis of 1.5% recruitment, it was calculated that a sampling pool of 238,266 service users would be needed (3574/0.015). The number of Preventx service users varies annually, but in the most recent year for which data are available, 585,000 16- to 24-year-olds used the service to test for chlamydia.

For the full sample, 11 instances of an adverse event were reported across all surveys, 9 of which related to an unwanted disclosure that the participant was testing for a STI. Contamination was indicated for 43.3% of control group participants. On interrogation of data, and verification that technological measures to prevent this had operated as intended, it was concluded that the most likely explanation was that the item used to assess contamination was not reliable.

Of the 115 participants randomised to the intervention group, 68.7% successfully completed the registration process and accessed the Wrapped website. There was some limited evidence of higher intervention access among younger

participants and those in the least deprived quintile (IMD 5), and of lower access among those living in one of the more deprived quintiles (IMD 2). Users found the website useful and liked the design. Higher levels of engagement were observed for product-related components than for video-related components. Participants in the nested study reported that Wrapped had positively impacted their condom-use beliefs and behaviours. Trial processes and procedures were viewed as acceptable by participants with only minor amendments suggested.

Conclusion

Our research demonstrated the feasibility of delivering the Wrapped intervention and of conducting the full trial. Despite a low recruitment rate, there were estimated to be sufficiently high numbers of young people accessing web-based STI testing to achieve the required sample. Furthermore, this rate can likely be increased through alternative positioning of the study advert which would increase the speed of recruitment, thus reducing study costs. Nonetheless, introducing a stopping point in any future trial, at which recruitment rate and chlamydia positivity of the baseline sample are assessed and a continuation decision made, was considered prudent.

The slight imbalances across the intervention groups at baseline for some demographic characteristics do not present a concern for a future trial. This is likely a product of stratification using variables with broad sub-categories that did not account for finer groupings (e.g. for sexual identity, the sub-categories were 'heterosexual' and 'other'), and also as a result of selecting the restricted sub-sample post randomisation. A future trial would randomise on confirmation of the STI status at baseline, and the large number of participants involved means that we would expect balance to occur naturally, thus removing the need for stratification.

Evidence that the sampling pool was under- and over-represented at M12 across a limited number of demographic subgroups directs the team as to where additional efforts should be made to recruit and retain participants, particularly those aged 16–19 years and those from more deprived backgrounds. Given some limited evidence of disproportionate access to intervention materials, whether there are any systematic barriers to access should also be explored with a view to removing these. Additional recommendations to further enhance the robustness of the research were made. These include some refinements to the recruitment and retention strategy as agreed with the PPI group. Our independent Data Monitoring and Ethics Committee (DMEC) and Study Steering Committee (SSC) recommended progression to full trial.

Study registration

This study is registered as Current Controlled Trials ISRCTN17478654, IRAS: 20/EM/0275.

Funding

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Chapter 1 Introduction

Young people are the group most affected by acute sexually transmitted infections (STIs) such as chlamydia. In 2023, over 40% of the 401,800 diagnoses made in England were among those aged 15–24 years.[1] We know that the risk of STIs among young people is unequal. Diagnoses are higher among those who identify as black; live in areas of higher deprivation; and are gay, bisexual or identify as men who have sex with men (GBMSM).[1] Untreated STIs can lead to serious consequences such as pelvic inflammatory disease, ectopic pregnancy, infertility, stillbirth and increased risk of human immunodeficiency virus (HIV).[2] They have a significant impact on the quality of life and are associated with stigma, which can impact the willingness to seek care and contribute to onward spread.[2] Condoms are recommended for the prevention of STIs,[1] but young people report inconsistent use.[3] The National Institute for Health and Care Excellence (NICE) recommends that a range of settings are provided for STI testing, including web-based.[4] Web-based STI testing involves visiting a website to request a STI self-sampling kit (often free in the UK to under-25s). Kits are posted to users, allowing them to take a sample and return it to a laboratory for testing. Text messages communicate negative results and direct those with positive results to local services for treatment. Against a backdrop of rising demand for sexual health services, sustained budget cuts, and changes to service delivery resulting from the coronavirus disease discovered in 2019 (COVID-19) pandemic, there has been a rapid growth in the use of web-based STI-testing services over the last 5 years.[5] This is reflected in the National Chlamydia Screening Programme (NCSP) data, which show increases in use among 15- to 24-year-olds since 2017, rising to 43% of all testing in 2023.[1]

Evidence indicates that STI self-sampling websites are as effective as in-person services at reaching groups experiencing higher STI diagnosis rates; chlamydia positivity is comparable to that of other non-specialist services (which include sexual and reproductive health services, young people's services, and other outreach or community-based settings),[1] and they attract equivalent numbers of young people who identify as GBMSM and of black ethnicity compared to other in-person services combined.[6] Repeated use of internet testing services is however common, with chlamydia positivity remaining high for those that retest,[7] suggesting that testing online does not reliably translate into future individual prevention efforts. National STI management standards state that all people accessing STI testing should be provided with health promotion and prevention interventions, including encouragement of safer sex behaviour and condom use.[8] Most STI-testing websites do not however comply with this guidance.[9] Given the continued growth of the web-based STI-testing sector, this presents an important and currently missed opportunity to reduce the sexual health inequality experienced by young people through timely intervention.

The Wrapped intervention aims to support young people to use condoms correctly every time they have penetrative sex. It was co-created by researchers, health professionals and young people in 2016–17 with support from Medical Research Council (MRC) Public Health Intervention Development (PHIND) funding. Wrapped is a multicomponent and interactive digital intervention developed especially for users of web-based STI-testing services aged 16–24 years. Users' initial interaction is through selection of their salient barriers to condom use. These barriers reflect important behavioural determinants of condom use identified through existing meta-analyses,[10–13] namely condom-use attitudes (particularly beliefs around pleasure, enjoyment and spontaneity), condom availability, and self-efficacy for condom use and communication. Responses determine which combination of up to six different components they receive. Users therefore only receive components for which there is an expressed need, a strategy selected to optimise user engagement and cost-effectiveness.

Scores of behavioural interventions aiming to reduce sexual risk behaviour have been developed over recent decades. What this body of work tells us is that behavioural interventions have modest favourable effects on condom use and STI incidence, including for different populations and when delivered via face-to-face or digital methods.[14,15] There are a number of important qualifications to be made to this statement, however. A minority of studies examining the effect of these interventions use the most defensible design, that is, a randomised controlled trial (RCT).[16,17] This is important because other types of design have a tendency to overestimate effects and are not informative regarding causality. Furthermore, when RCTs are conducted they are often of poor quality. A meta-analysis of RCTs by Free *et al.*,[16] for example, included 139 trials of which only 4 were judged as scoring adequately on all four quality criteria (allocation sequence, allocation concealment, loss to follow-up and blinding of outcome assessment). Biological outcome measures are also rare; for example, only 15% of studies in the Free *et al.* review[16] and 13% of studies in a meta-analysis of

interactive computer-based interventions by Bailey *et al.*[17] were found to have used this type of measure. The length of follow-up for the primary outcome is also typically limited. In the meta-analysis by Bailey *et al.*,[17] for example, 5 of the 15 studies had a follow-up of < 2 weeks post intervention and the longest follow-up period was 6 months, achieved by only two studies. This limits conclusions that can be drawn about the long-term benefits of interventions on sexual health outcomes. In sum, despite the volume of work in this area, well-designed, high-quality trials are urgently required to provide reliable evidence on the effect of behaviour change interventions on sexual health outcomes. This is true for all types of interventions, including those delivered via digital methods.

Wrapped is now ready to be definitively tested using a RCT to determine its cost-effectiveness. To respond to previous criticisms of trials in this area and contribute reliable evidence concerning the effect of behaviour change interventions on sexual health outcomes, it is imperative that this future RCT uses procedures that minimise bias, has a long-term follow-up, and includes an objective, biological outcome. Because RCTs are complex and expensive, it was necessary to first run a feasibility randomised controlled trial (fRCT) to assess whether and how it might be possible to carry out this definitive trial.

In *Chapter 2* which follows, we describe the development of a recruitment and retention strategy to guide a future definitive trial. In *Chapter 3*, we describe a fRCT of Wrapped. Primary outcomes for judging the success of this fRCT were recruitment rate and completeness of chlamydia self-sampling test data at final follow-up. In *Chapter 4*, we describe our health economic assessment. In *Chapter 5*, we describe qualitative interviews to explore participants' experiences of the trial and their views and experiences of the intervention. In *Chapter 6*, we present our assessment of potential pathways for future implementation of Wrapped. Finally, in *Chapter 7*, we summarise the principal findings, the contribution of the work to existing evidence, the study strengths and limitations, and make recommendations for future research.

Chapter 2 Development of recruitment and retention strategy

Methods

Aim

To develop an evidence-based recruitment and retention strategy to guide a future RCT of Wrapped.

Design

Iterative development across five stages: (1) rapid review, (2) development of provisional strategies, (3) focus groups with young people, (4) confirmation of strategies for a fRCT, (5) delivery of strategies in the fRCT and (6) review and finalisation of strategies for a future RCT.

Public and patient involvement

Six users of an existing STI self-sampling service (Preventx) aged 20–24 years (two female, four male) supported development of the strategy, inputting into Stages 2 to 6. The group had initially supported development of the Wrapped fRCT funding application and wished to continue their involvement post award.

Ethical approval

Ethical approval granted on 4 February 2020 by the Health, Science, Engineering and Technology Ethics Committee with Delegated Authority (ECDA) at the University of Hertfordshire (reference LMS/SF/UH/04061).

Procedure

Stage 1: rapid review

The rapid review aimed to identify strategies used by existing digital RCTs that achieved relatively high recruitment and/or retention rates. Pubmed, Scopus, PsycArticles, CINAHL and Cochrane databases were searched in May 2020. Keywords were combined to identify studies that assessed a digital intervention (see *Report Supplementary Material 1* for the full search strategy). Articles were considered for eligibility if the study was a RCT, fRCT or a review of digital interventions, and reported recruitment and/or retention rates along with details on strategies that were used to support recruitment and retention. Protocol papers and conference proceedings were not eligible for inclusion.

Mendeley was used to eliminate duplicates and screen titles and abstracts for eligibility. Following initial screening, full-text articles were obtained and screened for eligibility. Data extraction for included articles was pre-defined as follows: study design, population, recruitment and retention rates, details of recruitment strategies, details of retention strategies and any qualitative feedback.

Data extracted from the included studies were organised into a single Excel spreadsheet, with one row per study. Columns contained information on recruitment outcome (rate or proportion of sampling pool recruited), retention outcome (percentage of participants completing the final data collection time point) and strategies used for recruitment and retention. Strategies were organised into categories (one column per category) as follows: value propositions (statements which communicate what individuals can gain from participation), engaging participants with the research (strategies used to develop and maintain participant engagement), timing and nature of survey invitations, value and implementation of financial incentives, reminders to complete activities, and actions to minimise non-response.

Stage 2: development of provisional strategies

The public and patient involvement (PPI) group first met online with the lead researcher (via Microsoft Teams) for a familiarisation session. This included discussion of the aims and design of this study and the role of the PPI group. The importance of maximising recruitment and retention in the context of trials was emphasised. A general discussion about recruitment and retention in research was initiated and members asked to begin thinking about what strategies might work, with consideration of the target population.

The intention was to follow-up this meeting with two face-to-face workshops to develop a set of provisional strategies. Due to the subsequent outbreak of COVID-19, it was however necessary to seek an alternative means of collaboration. To overcome challenges experienced in synchronising diaries and to maximise inclusion, the group agreed to work asynchronously on a shared workspace called Padlet (Padlet, San Francisco, CA, 2012), a cloud-based application which enables users to create, share and organise material together.

Two Padlets were shared in turn, the second building on the first. Five PPI members took part, with each Padlet made available for 1 week. Material was presented in columns, with members asked to work across the columns from left to right to complete each activity. The first column provided instructions on how to complete the activity. The remaining columns were themed around the categories of recruitment and retention strategies as identified in the rapid review. For the first Padlet, members were asked to provide their own suggestions for strategies against each category, before being told in a subsequent column(s) what strategies had been identified from the review. For these strategies, the group was encouraged to use the 'upvote' and 'downvote' facility to indicate those that they did and did not like and to post comments. For the value propositions category, PPI members were asked to upvote/downvote individual value propositions identified from the rapid review, make suggestions for additional value propositions, and to draft provisional adverts using a combination of these. Following completion of the first Padlet, the research team collated and refined the ideas generated across all categories and used these to create a second Padlet. This included drafting some further examples for adverts based on the feedback. This was then presented back to the group for a further round of voting. For the value propositions category, members were asked to vote on the new set of provisional adverts. For all remaining categories, members were encouraged to 'upvote' their preferred strategies. Those with the lowest ratings, or those that contained several negative comments, were discarded at this point and did not advance to stage 3.

Stage 3: focus groups with young people

Stage 3 consisted of data collection via focus groups. Participant groups consisted of (1) undergraduate psychology students, (2) young people in or leaving the care system and (3) members of a youth theatre organisation. Each recruiting organisation was asked to invite between six and eight young people aged 16–24 years to participate. All participants provided informed consent. Parental consent was additionally obtained for individuals under the age of 18 years.

All focus groups were conducted online via Microsoft Teams and were audio and video recorded. Focus groups lasted between 44 and 103 minutes (average 69 minutes). Two of the three groups were co-facilitated by a PPI member who was trained and supported by the team to perform this role. All recordings were transcribed verbatim, after which the original audio and visual recordings were destroyed. See *Appendix 1*, *Table 30* for focus group schedule.

Padlet was used to support the focus group discussions. A Padlet board was shared with participants which displayed the categories retained at the end of Stage 2, with some additional ideas and prompts added by the research team where further input was required. Discussions progressed through each category with participants encouraged to voice their opinions concerning the relative merits of each strategy. The potential for unintended negative effects of the various strategies was considered. Opinions on six provisional adverts developed during Stage 2 were also sought. After each category had been discussed, participants were asked to upvote strategies/adverts that they thought would be the most successful in maximising recruitment/retention and to provide any written comments if they wished to.

Data from the transcripts and the Padlet were subjected to content analysis using a directed, deductive approach.[19] Analysis was guided by the aim of determining which recruitment and retention strategies were likely to be the most and least successful. Analysis focused on each category in turn: value propositions (adverts), engaging participants with the research, timing and nature of survey invitations, value and implementation of financial incentives, reminders

to complete the activities, and actions to minimise non-response. An Excel spreadsheet was prepared in advance for each category. Spreadsheets contained tabs for each potential strategy/advert. Within each tab, columns were added to organise participant views in terms of whether the strategy/advert was considered likely to have an overall positive, negative or neutral impact on recruitment and retention with relevant quotes pasted in the rows of the corresponding columns. The total number of upvotes for each provisional strategy/advert was extracted from the Padlet and noted alongside the data.

Stage 4: confirmation of strategies for the fRCT

Prior to the final PPI workshop, the votes and analysis from Stage 3 were examined by the research team to identify any strategies with mutual agreement from the PPI group and the focus groups; those with agreement were considered definitive and advanced directly to inclusion within the strategy. All other strategies were subjected to a final round of comment and voting by the PPI group via Padlet. In addition to presenting adverts to PPI members that had progressed from Stage 3, the research team decided to present the component parts of these to members, in recognition that some parts of the adverts may be liked but not others. These component parts, which typically included a call to action (e.g. 'we need your help!'), a description of the study, and mention of the financial (or other) incentive, were also voted on. As before, the PPI group were given a week to complete the Padlet in their own time. A total of three PPI members completed this activity.

The research team met to tally the Padlet votes and took all comments into consideration. In instances where the PPI group did not reach consensus, the research team made the final decision. Adverts that were considered too similar were removed. Some adverts had to be revised to conform with the Health Research Authority (HRA) Ethics Guidance, specifically that financial incentives should not be mentioned as the first line of a recruitment message (https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/hra-guidance-payments-incentives-research.pdf). Two new adverts were created based on component parts receiving the highest votes. Provisional strategies that were not technically feasible were removed. Following this process, the recruitment and retention strategy was finalised.

Stage 5: delivery of strategies in the fRCT

The recruitment and retention strategy was implemented in delivery of the fRCT (see *Chapter 3*).

Stage 6: review and finalisation of strategies for future RCT

On conclusion of the fRCT, a final Padlet was created and shared with the PPI group. This was used to update the PPI group on changes that were made to the recruitment and retention strategy during the trial and to seek reflection on these and any further changes that could be made with a view to plan a definitive RCT. Once again, members were given 1 week to complete the Padlet in their own time. This was followed up with a final meeting held online via Microsoft Teams in which the Padlet topics were discussed to elicit further feedback. Three members completed the Padlet and attended this final meeting.

Results

Stage 1: rapid review

The database search yielded 226 articles, of which 15 duplicates were removed. The remaining 211 articles were screened by title and abstract and 134 excluded. This left 77 full-text articles which were further screened for eligibility. A total of 36 articles, describing 26 studies, met the inclusion criteria and were included in the review. See *Report Supplementary Material 2* for PRISMA flow diagram and *Report Supplementary Material 3* for a summary of included articles. The following sub-sections summarise the findings by strategy category. Note: While the strategies were examined within the context of each study's reported recruitment and retention rates, no consistent pattern was observed, and therefore all strategies were considered to carry equal weight at this stage.

Value propositions

A total of seven studies referenced value propositions used to advertise the study. Value propositions used appealed to altruism, either as a petition to help others or to help with research. Value propositions also highlighted the benefits of taking part, such as financial incentives and improving personal health and well-being, and how taking part was easy,

or that there was a scarcity of available space to take part. Included articles advised collaboration with experts and/or the target population to create value propositions and using professional design and/or logos to indicate that messages were coming from an expert and/or a trusted source. *Table 31* in *Appendix 1* provides a summary, with examples where available, of the different types of value propositions identified.

Engaging participants with the research

A total of seven studies cited use of the following as strategies to maintain participant engagement:

- Continuity across all participant materials (such as logos, colours, fonts, templates and formatting)
- Personalising materials (i.e. addressing participants by name)
- Using clear, simple and brief communications
- Inclusion of social desirability statements in communications to encourage completion of measures
- E-mails to the intervention group to remind them to use the intervention
- Directly thanking participants for joining the study and/or their ongoing participation
- Newsletters to update participants on the progress of the study

Timing and nature of survey invitations

A total of 17 studies described using multiple modes to invite participants to complete surveys including e-mail, short message service (SMS, also known as 'text message') text message and letters sent through the post. These were all sent at the point at which completion was required. Some studies however also used a prompt ahead of the survey delivery, alerting participants that they would soon receive the invite.

Value and implementation of incentives

A total of 15 studies referenced the use of financial incentives as a strategy to motivate and sustain participation. Financial incentives were typically distributed upon completion of an activity. On occasions, a small incentive was additionally offered upfront before the activity was completed. Three studies offered financial rewards that increased in value throughout the duration of the trial. Prize draws were utilised by seven studies. One study detailed offering higher amounts of compensation if participants completed the measures quickly, but less if a researcher needed to call and ask them for their data over the phone.

Reminders to complete research activities

A total of 18 studies detailed the use of reminders sent by e-mail, SMS text message, telephone call or a letter sent through the post. Of these studies, 15 specified the number of reminders sent (range 1–6), the remaining 3 did not specify the amount. Six studies detailed how reminders were sent at varying intervals, ranging from 3 to 7 days; the remaining 12 studies did not specify how frequently reminders were sent.

Actions to minimise non-response

Five studies described taking additional steps beyond reminders to collect as much data as possible if/when participants failed to complete surveys or other data-collection measures:

- Asking participants to complete only the primary outcome measures instead of the full survey
- Telephone calls to offer participants support to complete the measures online or to ask them to complete with the researcher over the phone
- Resending postal measures (such as STI test kits)

Stage 2: development of provisional strategies

For an image of the Padlets from Stage 2, see *Report Supplementary Material 4* and *5*. The following sub-sections provide a summary of the outcomes from Stage 2. For further details, including illustrative quotes from PPI members, see *Appendix 1*, *Tables 32* and *33*.

Value propositions/adverts

In workshop 1, the PPI group created their own adverts that would attract people to sign up to the study and take part for the entire 12-month trial; eight adverts were drafted. Members felt that value propositions that appealed to the

values of altruism and prioritising sexual health should be used, but that those mentioning financial incentives would likely be most effective in recruiting to the trial.

In workshop 2, 12 potential adverts were presented to the PPI group: the 8 drafted by the members in workshop 1 and 4 drafted by the research team. The PPI group selected six adverts that they felt would be most successful in attracting participants to the study. See *Appendix 1*, *Table 32* for the 12 adverts voted on in the second workshop and which ones progressed to Stage 3 for further feedback by focus group participants.

Engaging participants with the research

Public and patient involvement members felt that it was important to convey to participants that their input was valued by the research team and that this in turn would promote retention. Suggested strategies to achieve this included personalising all communications to participants and including social desirability statements. It was also felt that using continuous, uniform branding on research materials and communications, as well as using clear, concise language, would increase the likelihood that participants would attend to and act on research communications. PPI members also suggested using WhatsApp, in addition to SMS and e-mail, which they thought could be effective for keeping in touch with participants; this idea however was not progressed as the research team had concerns regarding data security. The PPI group held mixed opinions on the idea of project newsletters to provide updates on the research as a whole: some felt that this would help participants to feel valued and involved in the study, thereby increasing retention, whereas others thought that participants might find it annoying. The consensus however was that using newsletters would be acceptable, providing that they were succinct, interesting, and friendly in tone. The PPI group endorsed the idea of sending participants birthday greetings as a further strategy for conveying the value of participation but thought that Christmas greetings would likely be identified as spam.

Timing and nature of survey invitations

The PPI group recommended SMS be used for survey delivery, but also felt that combining SMS and e-mail could work well (to respond to different preferences for mode of delivery). It was considered acceptable to send a prompt 3 days before the delivery of a research activity as long as it was brief in nature.

Implementation of financial incentives

In workshop 1, the PPI group provided feedback on different strategies for implementing financial incentives. (Note: The group was informed that incentives had to be in the form of vouchers; Amazon vouchers were chosen by the research team due to their universality and ease of digital distribution.) Offering increasing amounts was considered acceptable and effective for promoting long-term retention, but offering 'something for nothing' was rejected: the group thought vouchers should only be distributed upon completion of an activity. Sample voucher schedules were drafted based on this feedback and presented to the PPI group in workshop 2. Members voted and agreed on a schedule offering increasing amounts. Two schedules offering increasing amounts were progressed to Stage 3 for discussion with the focus groups. A schedule in which offering something for nothing was also worked up, so as to provide an example to refer to when discussing this strategy in Stage 3.

Reminders to complete activities

Reminders were deemed acceptable and useful by the PPI group. They felt that these should be concise, friendly, and reference both the financial incentive and how each participant's contribution makes a difference to the research. SMS was the preferred delivery method for reminders, but it was also considered acceptable to change to alternative modes of delivery (i.e. e-mail and telephone call) for non-responders. PPI members distinguished between reminders for surveys and test kits: additional reminders for test kits might be useful due to the extra effort required to complete them.

Actions to minimise non-response

Public and patient involvement members agreed that telephone calls to non-responsive participants were appropriate and potentially effective in increasing retention. While they felt that asking participants to complete the entire survey over the phone was unacceptable, asking a few brief items was considered acceptable. They advised that telephone calls should focus on checking in with the participants in terms of their well-being, given that unsolicited telephone calls which focused on non-response might make participants feel uncomfortable.

Stage 3: focus groups with young people

A total of 15 young people took part. See *Table 1* for demographic characteristics of the sample.

For an image of one of the Padlets from Stage 3, see *Report Supplementary Material 6*. A summary of the findings is presented below. See *Appendix 1*, *Tables 34* and *36*, for further details including illustrative quotes.

Value propositions/adverts

Participants discussed the six potential adverts carried through from Stage 2, focusing on the key elements that they thought would make it successful. These included that people should be able to read and understand them quickly and easily; that any financial incentive was likely to be the most important driver of participation and should be prominent within recruitment adverts; that altruistic factors would likely also encourage participation; that adverts should convey that participation was valued; and that adverts should communicate what the expectation of participants was, striking the balance between informing people about the level of commitment required but also that participation was straightforward. For more details, see *Table 34* in *Appendix 1*. Two focus group participants also suggested additional provisional adverts, emphasising financial incentives and altruism (see *Appendix 1*, *Table 35*). Based on the feedback from participants about which value propositions they thought should be emphasised, two further adverts were drafted by the research team to take forward into Stage 4.

Engaging participants with the research

The tone of messaging was considered as important as the information being conveyed. It was suggested that participants should be addressed by name in any communications and that the message should be signed off with the names of the researchers, rather than just providing the name of the study. All messages should have instantly

TABLE 1 Demographic characteristics of focus group participants

Characteristic	Undergraduate psychology students (*n* = 8)	Young people associated with care system (*n* = 2)	Youth theatre organisation (*n* = 5)	Total (*n* = 15)
	n	*N*	*N*	*n*
Age (range and mean)				
	19–22 (20.4)	22 (22)	18–22 (19.8)	18–22 (20.4)
Ethnicity (n)				
White English/Welsh/Scottish/ Northern Irish/British, Irish	3	2	2	7
Any other white background	2	0	1	3
African	1	0	0	1
Any other black/African/Caribbean background	1	0	0	1
Pakistani	1	0	0	1
White and Black Caribbean	0	0	1	1
Any other mixed/multiple ethnic background	0	0	1	1
Gender				
Female	8	1	4	13
Male	0	1	1	2

recognisable branding, not look scripted, and contain playfully worded subject lines that encourage the message to be acted on. Any instructions should be clear and use plain language. Social desirability statements to complete the study were considered useful so long as they were sincerely worded and felt encouraging, not demoralising.

In terms of maintaining engagement over the 12-month trial, focus group participants felt that the study should convey to participants the impact that their involvement was having and that their participation was valued. They agreed that newsletters were one way of doing this. Although some focus group participants thought that sending a happy birthday message to participants might make them feel valued, others thought it was over-familiar.

Timing and nature of survey invitations

E-mail was the preferred method for sending survey invites, with SMS text messages being used as prompts (i.e. to notify of forthcoming research activities). Overall, it was felt that the number of separate communications should be minimised to prevent participants feeling bombarded. It was felt that invites and prompts should contain two elements: a call to action and mention of the financial incentive for that specific activity. Participants also suggested that invites include the estimated time required to complete the survey. Sending prompts by SMS text message prior to test kit arrival was thought to be useful, especially if it served to assure participants that it would arrive in discrete packaging. While two of the three focus groups had a consensus of opinion that prompts for surveys could be useful, one of the groups questioned the utility of this: the concern being that without a direct call to action it could lead to participants ignoring messages, resulting in attrition.

Value and implementation of financial incentives

One of the most important elements for maintaining engagement throughout the trial was thought to be financial incentives; offering increasing amounts over the course of the trial was preferred, although agreement on a particular voucher distribution schedule across the activities was not achieved. The two schedules offering increasing amounts were progressed to Stage 4, whereas the schedule offering something for nothing was not.

Reminders to complete activities

Focus group participants were in favour of reminders sent via SMS, emphasising the need for reminders to be friendly and encouraging, and to mention the financial incentive of completing the research activity. Some participants felt that including a completion deadline would motivate trial participants to complete the activity.

Actions to minimise non-response

Focus group participants agreed that non-responsive participants should be sent an e-mail asking if they were okay, with the aim being to further highlight the benefits of completing, such as the financial incentive, rather than making them feel guilty. Participants also felt that if there is still no response, it would be acceptable to send a letter in the post to confirm that the individual's e-mail and/or phone number was still valid, but some did not like the idea of phone calls to participants (too intrusive).

Stage 4: confirmation of strategies for the feasibility randomised controlled trial

The following sections outline the finalised strategies for the fRCT as developed by the PPI group in collaboration with the research team. See *Appendix 1*, *Tables 37–39* for further details including the result of voting and illustrative participant quotes. For an image of the Padlet from Stage 4, see *Report Supplementary Material 7*.

Value propositions/adverts

The PPI group voted on: potential adverts created by both the focus groups and by the research team based on analysis from Stage 3 (see *Appendix 1*, *Table 37* for adverts and voting outcomes). The four adverts with the highest number of votes were finalised for use. The PPI group also voted on the individual component parts of these adverts (see *Appendix 1*, *Table 38* for component parts and voting outcomes), the outcomes of which were then used by the research team to create two new adverts for use. The list below presents the final set of selected adverts:

1. Help us make a positive change to young people's sexual health: make a difference by joining our study and get paid for your time.
2. Take part in a study to improve sexual health and earn up to £65 in vouchers, find out how you can make a difference today.

3. Your views are important: join our study to help improve sexual health for young people while being paid!
4. Make a difference to improve sexual health for young people – join our study and earn up to £65 in vouchers for your time.
5. Want to make a difference to young people's sexual health? Take part in our study and get paid for your time.*
6. We need your help! Take part in a study to improve young people's sexual health and earn up to £65 in vouchers for your time.*

*Created from value proposition segments.

Engaging participants with the research

- All communications to be sent at 5:00 p.m. as participants more likely to be responsive at this time, but not prioritise any particular day of the week.
- Use e-mail as the primary mode of communication.
- All communication to be signed off using names of the research team but should not include any photos of the team as this could make participants feel uncomfortable.
- The tone of all communications should be balanced between being relaxed and fun but professional, and reference current events (e.g. holiday period).
- Avoid sending communications over Christmas holiday period as it could result in lower response rates.
- Send newsletters by e-mail as a standalone communication (i.e. do not combine with other communications such as reminders) and include an opt-out feature if possible.
- Do not send birthday greetings – potential to be annoying and perceived as overly familiar.

The following strategies had mutual agreement from Stages 2 and 3 and as such were not presented to the PPI group for further voting:

- All communications with participants should:◦ Have an explicit purpose
  - Address participants by name
  - Be brief and clear, easy to read and with no jargon
  - Contain social desirability statements that are encouraging not shaming

- Newsletters should be sent quarterly.

Timing and nature of survey invitations

- Use e-mail for survey invites.
- Use prompts for test kits only – use this as an opportunity to check if the postal address is accurate and reassure that kit will arrive in discrete packaging.
  Note: The PPI group divided on whether prompts should be used. Research team made a decision to include for test kits only.

The following strategy had mutual agreement from Stages 2 and 3 and was not voted on:

- Text messages should be used to send prompts.

Value and implementation of financial incentives

- Provide vouchers of increasing value over the trial period as follows:
  Month (M) 0 (joining the study) £5
  M3 kit £10
  M3 survey £5

M6 survey £10
M12 kit £20
M12 survey £15

- Provide higher amount for test kits than surveys.

Reminders to complete activities

- Send a maximum of three reminders for test kits and surveys.
- Send first test kit reminder 3 days after expected arrival of the test kit at participant's address and all remaining reminders 10 days apart.
  Note: The PPI group advised all reminders sent 10 days apart. The research team decided to send the first one after 3 days to encourage timely completion.
- Emphasise the financial incentives of completion.

The following strategy had mutual agreement from Stages 2 and 3 and was not voted on:

- Text messages should be used to send reminders.

Actions to minimise non-response

The following strategies had mutual agreement from Stages 2 and 3 and were not voted on:

- Non-responders should be e-mailed; the tone of the e-mails should be friendly and supportive, should clearly outline the research activity that is outstanding and how to complete it, and mention the financial incentives.
- Non-responders should not be called: this could feel confrontational. Instead, a letter sent via post to check if their contact details were correct would be acceptable.

Stage 5: delivery of strategies in the feasibility randomised controlled trial

A small number of changes were made to the recruitment and retention strategy during the fRCT, either to enable the potential merit of alternative strategies to be assessed or in response to unexpected challenges. These are outlined in *Table 2*.

Stage 6: review and finalisation of strategies for future randomised controlled trial

The PPI group reflected on all above changes (see *Table 2*) and felt that they were acceptable. With regards to the phone calls, members felt that provided they were handled discreetly it was appropriate to call a participant who had not completed an activity. The PPI group understood why it had not been possible to tailor the content of messages or to alter their timing; the group highlighted however that participants should not receive communications at unsociable hours. Changes to voucher amounts were also considered acceptable, with members reporting that higher amounts would likely result in higher recruitment, but that if £65 was ultimately effective there was no need to increase it to £100. The PPI group recommended budgeting accordingly for a future trial and keeping in mind that changes might need to be made to accommodate any increases in amount.

The findings of the fRCT were also discussed with the PPI group. The *Recommendations for future research* section of the discussion reflects the consensus opinion of the PPI group and the research team.

TABLE 2 Changes made to the recruitment and retention strategy during the fRCT

Original strategy	Change	Reasoning
Do not make phone calls to non-responders to encourage completion of research activities	Phone calls were made to participants who had not returned their survey or test kit following all automated reminders. These were done discreetly by telling the participant at the start of the phone call that it was the research team and asking if they were free to talk for 2 minutes. The calls focused on checking if the participant had received their survey or test kit and resolving any issues they experienced (such as the test kit not arriving)	PPI members and focus group participants felt that some participants may find phone calls too direct and that this would have a negative knock-on effect in terms of dropout. However, the research team felt that participants who had not acted on the reminders were at risk of dropout anyway and therefore there was nothing to lose. The feasibility study provided an opportunity to test this
Messaging to participants to refer to seasonal events (Christmas, summer, etc.) to give a current, more personal feel and be delivered at 5:00 p.m. (when young people expected to be most available to respond/act)	Not implemented	The limitations of our data collection software (REDCap) meant that this was not possible
Data collection to cease over Christmas and New Year (due to the concern that this could affect completion)	Not implemented for surveys Postage of chlamydia self-sampling kits was suspended for a 2-week period	The limitations of our data collection software (REDCap) meant that delaying scheduled survey invites was not possible
A maximum total of £65 to be received for completing research activities	Increased to £85 and then to £100. Amount per activity increased and also incentivisation for self-reporting baseline STI test result and visiting intervention and control material added	Changes made to increase recruitment and completion of research activities

REDCap, Research Electronic Data Capture.

Chapter 3 Feasibility randomised controlled trial

See *Appendix 2* for completed Consolidated Standards of Reporting Trials (CONSORT) 2010 checklist for reporting of pilot or feasibility trials. Also see our protocol paper[20] for a detailed description of planned methods.

Methods

Aim

The aim of the fRCT was to assess whether and how it would be possible to carry out a future definitive RCT of the Wrapped intervention.

Design

A two-arm, 1 : 1 allocation, parallel-group randomised feasibility RCT of Wrapped (intervention) plus usual care (basic information on STIs and condom use) compared to usual care alone (control).

Objectives

The primary objectives of the fRCT were to estimate the following parameters for planning a definitive RCT:

1. The rate of recruitment of eligible participants
2. The rate of participant follow-up for the definitive RCT primary outcome measure (chlamydia positivity at 12 months measured using biological samples)

The secondary objectives for the fRCT were as follows:

3 Estimating the rate of participant follow-up for the definitive RCT secondary outcome measure chlamydia cumulative incidence
4 Identifying whether the level of deprivation of the final sample is representative of online STI self-sampling users
5 Identifying whether differential retention occurs across groups (gender, ethnicity, sexual identity, deprivation, randomised groups, chlamydia diagnosis at baseline)
6 Estimating chlamydia positivity at 12 months in the intervention and control groups (to support sample size calculation for the definitive RCT)
7 Estimating the rate of attrition at 3 months, 6 months and 12 months, and ways of minimising this
8 Determining the feasibility and participant acceptability of all primary and secondary outcome measures (including health economic)
9 Identifying which recruitment message(s) results in the highest rate of recruitment
10 Identifying and removing intervention 'friction points' to minimise attrition and maximise future intervention dose
11 Identifying costs and resource use associated with the intervention for healthcare services and users (to inform the design of a future definitive RCT with economic evaluation)
12 Measuring contamination of intervention effect in the control group
13 Identifying possible adverse effects of the intervention, for example, participants' inadvertent disclosure that they are sexually active and/or testing for a STI, initiation or increase in the consumption of pornography

Deviation from protocol

The above list of objectives is an amended version. With agreement of our Data Monitoring and Ethics Committee (DMEC) and Study Steering Committee (SSC) (see *Ethical approval and research governance*), and approval of the National Institute for Health and Care Research (NIHR) and National Health Service (NHS) research ethics, a correction was made to the second primary objective (June 2022) to read 'chlamydia positivity' instead of 'cumulative incidence of chlamydia'. New secondary objective also added: 'Estimating the rate of participant follow-up for the definitive RCT secondary outcome measure chlamydia cumulative incidence'.

Ethical approval and research governance

Protocol for the fRCT was approved on 16 November 2020 by NHS East Midlands – Leicester Central Research Ethics Committee (reference 20/EM/0275), registered with the ISRCTN (ISRCTN17478654) and later published.[20] An independent SSC and DMEC provided oversight and ensured adherence to standards of best practice. Research sponsorship provided by the University of Hertfordshire. Trial management and statistical oversight by Brighton and Sussex Clinical Trials Unit.

Public and patient involvement

The Wrapped PPI group (as described in *Chapter 2*) also supported delivery of the fRCT. Their roles included working with the research team to draft the participant information and consent statements to ensure that they were clear and easy to understand, and to iteratively test the surveys prior to use to maximise content validity, readability, clarity and comprehensiveness. Two members of the PPI group also supported monitoring of the fRCT by serving as members of the SSC.

Study population and setting

The study population included young people requesting a test for chlamydia via a web-based STI self-sampling service, namely Freetest.me or SH.UK (both operated by Preventx Ltd). Preventx provides a STI self-sampling service to 70 local authority areas across England (free at the point of use for most young people). Users residing in one of the five geographical areas (selected to represent English demography) were invited to participate, namely East Sussex, Kingston-Upon-Thames, Northamptonshire, Somerset and Warwickshire.

Eligibility criteria

People aged 16–24 years living in one of the above five geographical recruitment areas were eligible. People who satisfied these requirements were ineligible if they had no internet access or reported having sexual preferences which meant that they were unlikely to have penetrative sex (penis in vagina or anus) over the course of the study period.

Participant timeline

Participation was for a period of 12 months. See *Table 3* for an overview of participant activities and timing.

To recompense for the time spent completing activities, participants received payment in the form of vouchers – see *Appendix 3*, *Table 40* for the schedule of payments (refer to first wave).

Recruitment and randomisation procedure

The study advert was placed on the 'thank you' page of freetest.me/SH.UK viewed by users following an order of a chlamydia self-sampling kit (see *Report Supplementary Material 8* – example advert). Every 2 weeks, the advert changed (see *Chapter 2*, *Stage 4: Confirmation of strategies for the fRCT* for the finalised set of adverts). A hyperlink took users to the study web page (located on REDCap, secure data capture and management platform hosted on University of

TABLE 3 Participant activities across the duration of the study

Activity	M0	M3	M6	M12
Read participant information	✓			
Complete consent	✓			
Complete survey	✓	✓	✓	✓
Self-report chlamydia test result	✓			
Complete chlamydia self-sample		✓		✓

Hertfordshire server)[22,23] for participant information, eligibility assessment and consent. Each individual's freetest.me/SH.UK order number was appended to the hyperlink uniform resource locator (URL) and captured by REDCap. All participants were required to provide informed consent before joining the study. Randomisation of participants to trial groups (1 : 1 allocation) was managed within REDCap on completion of the baseline (M0) survey. Stratification across groups, using randomly permuted blocks (ethnicity, sexual identity, deprivation), was performed to balance participants across the trial arms (see *Appendix 3*, *Table 41* for groupings). Participants and those assessing outcomes were blind to allocation. Prior to randomisation, manual checks were performed to ascertain that each individual was unique by cross-checking identifying information (name, e-mail address, postal address, mobile phone number, freetest.me order number) with participants already in sample. Checks were also made to ensure that the baseline survey was answered with reasonable care (i.e. no evidence of random responding or completion under the expected minimum time). Those not meeting these criteria were not randomised.

Challenges with recruitment and deviation from protocol

Initial per protocol recruitment was planned from four areas offering freetest.me: Bromley, East Sussex, Somerset and Warwickshire. Just prior to starting recruitment, Bromley changed their STI self-sampling provider. Recruitment from the three existing areas was initiated while a replacement area was sought. At week 7, recruitment from East Sussex and Somerset was paused to enable service migration from freetest.me to SH.UK (unplanned migration in response to COVID-19). At week 13, recruitment began from a new replacement site, Kingston-Upon-Thames. At week 17, recruitment was resumed via East Sussex and Somerset. At week 28, recruitment began via a further replacement site Northamptonshire. To address slow recruitment, an amendment to the protocol was sought from the NIHR and NHS research ethics committee to increase total e-voucher payment from £65 to £85 (commenced week 8) and again to £100 (commenced week 11). See *Appendix 3*, *Table 40* for revised schedule of payment (refer to second and third waves).

Measures

Survey completion (months 0, 3, 6 and 12)

All survey completion was via REDCap. Baseline (M0) survey collected information on: contact details (name, postal address, e-mail address, mobile phone number), demographic characteristics (age, sex, gender identity, ethnicity, sexual identity), recent STI diagnosis/treatment, sexual well-being, condom use, condom-use intentions, multilevel behavioural determinants targeted by the intervention, health-related quality of life [using the EuroQol-5 Dimensions, five-level version (EQ-5D-5L) and the Short Form questionnaire-12 items (SF-12)],[24,25] and public sector resource use. Except for contact details and demographic characteristics, all items were repeated within surveys at 3 months (M3), 6 months (M6) and 12 months (M12). An additional item on adverse events was included within all follow-up surveys. The M3 survey included items to collect information on participants' engagement with the intervention. The M12 survey included items to identify evidence of contamination between arms and to assess use of Wrapped products (intervention group participants only).

Completion of the M0 survey was scheduled for immediately after consent was provided. All other survey completion was triggered by e-mail. Participants not completing a survey were sent up to three reminders (delivered by SMS text message). If no response was received, one e-mail and then one telephone call was made to prompt completion. During the telephone call, participants were given the option to verbally respond to a reduced set of survey questions. If there was no response to the telephone call, a paper-based version of the survey was posted out with a stamped addressed return envelope. Alongside was a letter informing participants that as an alternative to completing the paper-based survey, they could access the online version using a Quick Response code provided or by searching for the link already sent to them via e-mail. Those not providing any data 20 days after the initial survey was sent out were classed as non-responders. Surveys continued to be sent to non-responders at subsequent time points unless a participant asked to be withdrawn from the study.

Chlamydia testing (months 0, 3 and 12)

Ten days after randomisation, participants were sent an SMS text message with a link to a single-item survey (on REDCap) to self-report the result of their baseline chlamydia test (the test requested by participant from Preventx immediately prior to study sign-up). Participants were asked to record the result, and any treatment received if

applicable. The option to record that the self-sampling kit or result was 'not yet received' or 'not yet returned' was also available. This could be selected up to two times which triggered a repeat of the SMS text message 10 days later. A single SMS text message reminder was sent to participants who did not respond. Those not providing these data 4 weeks after the first SMS contact was made were classed as non-responders.

Chlamydia infection at M3 and M12 was measured using self-sampling kits sent to participants directly by the research team. One week before posting out the kits, participants were sent an SMS text message to confirm their postal address. Kits contained the usual user instructions to collect a sample and return by Freepost to Preventx for processing. Participants were sent up to three SMS text message reminders to complete and return a self-sample. If the self-sample was still not returned after this point, one e-mail and one phone call were used to prompt return. Those not returning their kit 30 days after posting out were classed as a non-responder. Non-responders were sent test kits at subsequent time points unless they asked to be withdrawn from the study. Participants with a positive test result at M0, M3 or M12 received one item within SMS survey 2 weeks post result to record whether infection had been treated. If treatment was incomplete, or the participants did not respond, they were sent one reminder SMS to obtain this information. Each local NHS trust was informed of any positive cases (for participants residing in their local authority area) so that appropriate treatment and follow-up could be provided.

Intervention access, content and tracking

Participants were directed to the intervention content by a hyperlink sent in an e-mail (e-mail triggered by completion of randomisation). All participants were free to interact as much or as little with the respective materials (participants assigned to the intervention condition were required to register and to login on repeat visits). An e-mail reminder to access the content was sent to participants who had not accessed the material after 2 weeks.

Wrapped website

See *Table 4* for an overview of Wrapped. Also see logic model (see *Report Supplementary Material 9*) for theoretical rationale, and the development paper[26] for a detailed description of intervention content reported in line with Template for Intervention Description and Replication (TIDieR) guidance.

Comparator website

Basic information on STIs and condom use (akin to that provided by NHS choices; www.nhs.uk/live-well/sexual-health/#have-safer-sex) was presented via a Wordpress website created for this study. Wrapped branding was used on the site to create an equivalent intervention 'experience'. Identical information was duplicated within the Wrapped website.

TABLE 4 Overview of Wrapped content and tailoring

Component	Description	Tailoring
Sample pack	Box containing 12 condoms, two sachets of lube and condom-application instructions. Single order. Posted to user.	For everyone: to enable users to test out different types of condoms/lubes and identify preferred fit/feel
Condom ordering	A free discrete condom postal service. Bundles of 6 or 12 condoms plus up to three sachets of lube. Maximum one order per month.	For users who report finding it hard to access/afford condoms
Condom carrying	Choice of two small wallet designs with a discrete, hidden compartment for condoms/lube. Single order. Posted to user.	For users who do not routinely carry condoms
Condom demo	Video of step-by-step instructions on how to correctly put on a condom, giving tips on how to do this in a way that is enjoyable/pleasurable for self and partner. Unlimited access.	For users who are not confident putting on condoms or who find that condoms interrupt the flow of sex
Discussing condoms	A series of videos in which young people discuss talking to partners about condom use. Unlimited access.	For users who find condom use difficult to discuss
Real life	Videos of three real couples (two straight, one gay) discussing and demonstrating condom use. Unlimited access.	For those who report associating condom use with reduced pleasure or enjoyment (available to 18 + years only)

Analytics data

Use of intervention and control materials was tracked using Matomo analytics package. A unique study identifier (ID) for each participant was appended to intervention URL to enable individual-level use to be measured.

Sample size

At least 60 participants per arm are recommended to estimate proportions with good precision.[27] This was inflated to allow for estimated 25% non-return of initial chlamydia self-test sample (based on freetest.me statistics; 60/0.75 = 80) and a further estimated 30% dropout by 12 months (80/0.7 = 114 per arm).

Progression criteria

1. Proportion of Preventx users recruited to the feasibility trial is sufficient to obtain the sample size required for the definitive RCT.
2. 60% of participants (those randomised) followed up for the definitive RCT primary outcome measure at 12 months.
3. Index of Multiple Deprivation quintile distribution for the final sample comparable to that of individuals in the sampling pool (freetest.me/SH.UK users in the partner local authority areas).
4. Adverse events are judged as sufficiently infrequent and/or serious to cause concern.

Progression decision to be determined by the DMEC and SSC based on achievement of the criteria or convincing evidence that any one criterion was amenable to sufficient improvement.

Deviation from protocol

The above criteria are an amended version. The amendment was made in June 2022 with agreement of the DMEC/SSC and with approval of NIHR and NHS research ethics. Criterion 1 was amended to enable the target recruitment rate to be determined at study end. Criterion 2 was amended on the advice of the DMEC/SSC that 80% was too ambitious. Criterion 3 was amended as Preventx was only able to provide data on IMD quintile (as opposed to index of multiple deprivation [IMD] score) for the sampling pool. Criterion 4 was amended as the DMEC/SSC requested that the wording reflects the subjective nature of this assessment. See *Appendix 4* for original criteria and further details on rationale for the changes.

Analysis

Planned descriptive analyses are presented below in line with each research objective (RO).

Primary outcome measures

- Percentage of participants recruited to the feasibility RCT (assessed as the number of participants randomised) out of those in the sampling pool (those shown the study advert via freetest.me/SH.UK) (RO 1).
- Percentage of participants with valid primary outcome measure (chlamydia positivity measured using biological samples) at 12 months (RO 2).

Secondary outcome measures

- Percentage of participants with outcome data required to measure cumulative incidence of chlamydia (measured using M3 and M12 chlamydia self-sample, and the relevant item within M3, M6 and M12 surveys) (RO 3).
- Distribution of IMD quintile among those in sampling pool compared to that of the final sample (RO 4).
- Percentage of participants with valid primary outcome measure at 12 months by group (gender, ethnicity, sexual identity, deprivation, randomised groups, chlamydia diagnosis at baseline) (RO 5).
- Percentage of participants with a positive chlamydia test result at 12 months in the intervention and control groups (RO 6).
- Attrition curves comparing the percentage of participants in the trial at M3, M6 and M12 plotted for the intervention and control arms (dropout attrition) (RO 7).

- Percentage completion of survey items required to measure primary and secondary outcomes at main trial (including self-report of chlamydia result at baseline, results from biological samples, demographic information, self-report of condom use, and data needed for cost-effectiveness and cost–utility analyses) (RO 8).
- Percentage of participants randomised as a direct result of each of the different adverts employed (RO 9).
- Percentage of participants in the two arms that do not achieve pre-determined intervention 'goals', and the bounce rate for home and content pages (RO 10).
- See *Chapter 4* for planned health economic analysis (RO 11).
- Percentage of participants in the control group who report (at M12) any exposure to Wrapped (RO 12).
- Percentage of participants who report (at M12) having experienced an adverse event during the study (RO 13).

Deviation from protocol

In June 2022, with agreement of DMEC/SSC, and with approval of NIHR and NHS research ethics, it was agreed that all quantitative analysis should be performed and reported for the full sample (n = 230) and a 'restricted sample' where relevant (with comparisons made to examine whether these groups differed across any important demographic characteristics or fRCT outcomes). The full sample is defined as all randomised participants. The restricted sample is defined as randomised participants who report both (a) baseline chlamydia test result, and (b) if positive, whether the full course of prescribed antibiotics was taken (indicating that the individual was infection free). The decision to present data on both samples was made with the acknowledgement that participants at full trial would be required to meet these additional criteria (and therefore that the restricted sample provides a better approximation of the nature of the sample at full trial). The rationale for requiring these additional criteria to be applied at full trial was that data on baseline chlamydia positivity (primary outcome) would be needed to ensure a balance across groups, and that the number randomised and infection free at baseline would be needed to calculate chlamydia cumulative incidence (secondary outcome).

Results

Data were downloaded from REDCap and analysis performed using International Business Machines (IBM) Corporation Statistical Package for the Social Sciences (SPSS) 28 (SPSS Statistics for Windows, IBM Corp., Armonk, NY, 2022).

Recruitment took place over 31 weeks between 22 March and 18 October 2021. The study advert was displayed to individuals residing in the selected local authority areas. As outlined in *Challenges with recruitment and deviation from planned protocol*, the number of participating local authority areas varied throughout the recruitment period from one to five. In total, 11,413 individuals were presented with the study advert (either on freetest.me or SH.UK) over the recruitment period. How many of these clicked on the link and visited the project page is unknown as Preventx was unable to supply this data. Four hundred and eighty-eight of those shown the advert completed the eligibility questions. Of these, 36 (7.4%) did not meet the inclusion criteria and 12 (2.6%) reported that they were unable to commit to the study. Two hundred and ninety-four individuals went on to provide consent. Of these, 247 (84.0%) completed the baseline survey. Prior to randomisation, manual checks were performed to establish that each respondent was unique and had completed the baseline survey with sufficient care. Seventeen individuals were excluded at this point, leaving 230 available for randomisation. Recruitment stopped once the target of 230 participants was reached. In total, 115 participants were allocated to the intervention and 115 to the control (*Figure 1*).

Withdrawals

Three participants withdrew from the study, two in the intervention arm and one in the control arm. None of these individuals requested that data they had provided up to that point be withdrawn. One of these participants self-reported the STI test result at baseline (negative result) and requested withdrawal 7 months after randomisation. Another self-reported the STI test result at baseline (negative result), returned the M3 and M6 surveys, and requested to be withdrawn 7 months after randomisation. The third participant withdrew 8 months after randomisation having provided no data other than at the M0 survey. All three participants requested withdrawal via e-mail in response to receiving a non-responder e-mail or voicemail message. In line with the study ethics protocol, participants were not asked to provide a reason for their decision, but one participant volunteered that, 'it's not something I can be a part of at this time'.

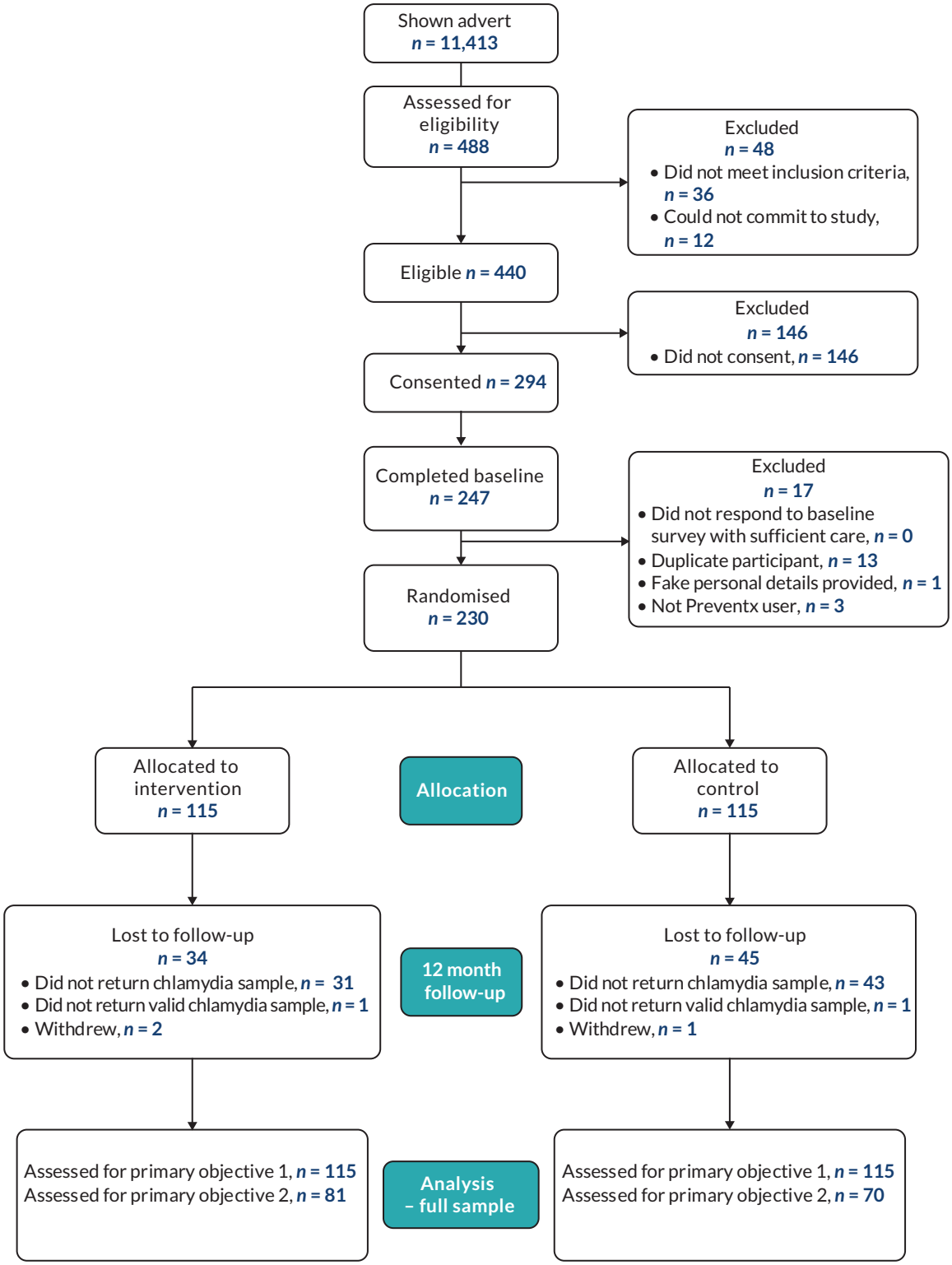

FIGURE 1 Participant flow diagram. Reproduced from Newby *et al.*[21] This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) license, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: https://creativecommons.org/licenses/by/4.0/. The figure above includes minor additions and formatting changes.

Reasons for losses to follow-up

Most losses to follow-up at the M3, M6 or M12 surveys were due to non-completion. Some contact problems were however experienced. One M6 survey was lost to follow-up due to an e-mail bounce back; this participant was sent a letter by post asking for an alternative e-mail address, but no reply was received. Surveys that remained incomplete following a series of e-mail prompts triggered postage of a paper copy. Two M12 surveys were known to be lost to follow-up due to incorrect postal address (these surveys were posted back to the research team by the occupants stating that the participant no longer lived at that address). Unlike with the paper surveys, chlamydia self-sampling kits were not posted out with a return address (deliberate strategy to ensure discrete delivery) and consequently there were no returns. The number of STI results that were lost to follow-up at M3 and M12 due to incorrect postal address is therefore unknown. Finally, five chlamydia self-sampling kits returned by participants for testing were identified as invalid at M3 (one due to degraded sample and four due to incomplete information submitted with the sample), and two at M12 (one due to degraded sample and one due to incomplete information submitted with the sample).

Demographics of the sample

The demographic characteristics of participants at baseline (full sample) are presented in *Table 5*. At randomisation, participants were stratified according to self-reported deprivation, ethnicity and sexual identity. See *Appendix 3*,

TABLE 5 Demographic characteristics overall and by trial arm at baseline for full sample

Characteristic	Intervention (*n* = 115) *n* (%)	Control (*n* = 115) *n* (%)	Total (*n* = 230) *n* (%)
Age			
16	1 (0.9)	2 (1.7)	3 (1.3)
17	2 (1.7)	1 (0.9)	3 (1.3)
18	4 (3.5)	7 (6.1)	11 (4.8)
19	5 (4.3)	8 (7.0)	13 (5.7)
20	15 (13.0)	26 (22.6)	41 (17.8)
21	27 (23.5)	10 (8.7)	37 (16.1)
22	16 (13.9)	21 (18.3)	37 (16.1)
23	21 (18.3)	23 (20.0)	44 (19.1)
24	24 (20.9)	17 (14.8)	41 (17.8)
Median age (IQR)	22 (2)	22 (3)	22 (3)
Age group			
16–19	12 (10.4)	18 (15.7)	30 (13.0)
20–24	103 (89.6)	97 (84.3)	200 (87.0)
Ethnicity (stratification factor)			
White	98 (85.2)	95 (82.6)	193 (83.9)
Mixed or multiple ethnic groups	6 (5.2)	10 (8.7)	16 (7.0)
Asian or Asian British	1 (0.9)	4 (3.5)	5 (2.2)
Black, African, Caribbean or Black British	8 (7.0)	5 (4.3)	13 (5.7)
Other ethnic group	2 (1.7)	1 (0.9)	3 (1.3)
Gender			
Female	79 (68.7)	86 (74.8)	165 (71.7)
Male	32 (27.8)	27 (23.5)	59 (25.7)

TABLE 5 Demographic characteristics overall and by trial arm at baseline for full sample (*continued*)

Characteristic	Intervention (*n* = 115) *n* (%)	Control (*n* = 115) *n* (%)	Total (*n* = 230) *n* (%)
Non-binary or gender fluid	3 (2.6)	2 (1.7)	5 (2.2)
Other	1 (0.9)	0	1 (0.4)
Gender not as assigned at birth			
	4 (3.5)	5 (4.3)	9 (3.9)
Sexual identity [a] ***(stratification factor)***			
Heterosexual	79 (68.7)	72 (62.6)	151 (65.7)
Gay	11 (9.6)	4 (3.5)	15 (6.5)
Bisexual	23 (20.0)	38 (33.0)	61 (26.5)
Other	2 (1.7)	1 (0.9)	3 (1.3)
Financial situation while growing up (stratification factor)			
Very comfortable – I had everything I needed and more	10 (8.7)	8 (7.0)	18 (7.8)
Comfortable – money was never an issue	24 (20.9)	26 (22.6)	50 (21.7)
Fairly comfortable but it was necessary to keep an eye on money	37 (32.2)	35 (30.4)	72 (31.3)
Things were OK but money was tight sometimes	27 (23.5)	29 (25.2)	56 (24.3)
Money seemed to be a problem a lot of the time	13 (11.3)	13 (11.3)	26 (11.3)
It was always a struggle to get the basics (food, clothes, heating)	4 (3.5)	4 (3.5)	8 (3.5)
IMD quintile			
1 (most deprived)	18 (15.7)	16 (13.9)	34 (14.8)
2	19 (16.5)	18 (15.7)	37 (16.1)
3	24 (20.9)	31 (27.0)	55 (23.9)
4	29 (25.2)	28 (24.3)	57 (24.8)
5 (least deprived)	25 (21.7)	22 (19.1)	47 (20.4)
Relationship status			
Single	44 (38.3)	45 (39.5)	89 (38.9)
In a casual relationship with one person	24 (20.9)	21 (18.4)	45 (19.7)
In casual sexual relationships with two or more people	14 (12.2)	13 (11.4)	27 (11.8)
In a serious relationship with one person	32 (27.8)	29 (25.4)	61 (26.6)
In a serious relationship with more than one person	0	1 (0.9)	1 (0.4)
Combining serious and casual relationships	1 (0.9)	4 (3.5)	5 (2.2)
Other	0	1 (0.9)	1 (0.4)
Missing			*1 (0.4)*

IQR, interquartile range.
a No participants self-reported their sexual identity as lesbian or asexual.

Table 41 for categorisation of these variables for stratification purposes. The distribution of participants across the intervention and control groups by demographic characteristics appeared broadly balanced with three exceptions. The observed proportions suggested imbalances across groups for bisexual participants (lower proportion in the intervention group) and across two age groups (20 years: lower proportion in the intervention group; 21 years: higher proportion in the intervention group) albeit comparisons across broader age groups (16–19 years and 20–24 years) and median age indicated balance.

See *Appendix 5*, *Table 42* for demographic characteristics at baseline for the restricted sample. Here, the distribution of participants across groups also appeared broadly balanced with, as before, the exception of bisexual participants and those aged 20 and 21 years (same trends as observed for the full sample). In addition, there also appeared to be less females and more males in the intervention group than in the control group.

Primary objectives

RO 1: estimate the rate of recruitment of eligible participants

Over the 31-week (217 days) recruitment period, 230 participants (full sample) were recruited to the study, at a recruitment rate of 1.06 participants per day (230/217), representing 2% of the total sampling pool (230/11,413). For the restricted sample (i.e. those recruited who met our additional criterion of self-reporting their M0 chlamydia test result, and treatment if relevant), the recruitment rate was 0.80 participants per day (173/217), representing 1.5% of the sampling pool (173/11,413).

RO 2: estimate the rate of participant follow-up for the definitive RCT primary outcome measure (chlamydia positivity at 12 months measured using biological samples)

Table 6 presents the number and proportion of participants who completed and returned a valid chlamydia self-sample at M12 within both the full and restricted samples. Confidence intervals have been provided for the total sample. As is evident, the response rate was higher within the restricted sample.

Secondary objectives

RO 3: estimate the rate of participant follow-up for the definitive RCT secondary outcome measure chlamydia cumulative incidence

Cumulative incidence is defined as the proportion of a closed population at risk that develops the first occurrence of an event of interest within a given period of time.[28] With respect to this study, the denominator for this calculation is the number randomised who are known to be infection free at baseline. The numerator is the number of this group

TABLE 6 The proportion of participants who provided a valid chlamydia self-sample at M12 by group (full and restricted samples)

	Intervention	Control	Total
Full sample			
Total number of participants in the sample	115	115	230
Number of participants who provided M12 self-sample	81	70	151
Percentage (95% CI)	70.4 –	60.9 –	65.7 (59.1 to 71.8)
Restricted sample			
Total number of participants in the sample	84	8	173
Number of participants who provided M12 self-sample	72	59	131
Percentage (95% CI)	85.7 –	66.3 –	75.7 (68.6 to 81.9)

who test positive at any point during the 12-month study period (as identified using M3 or M12 chlamydia self-sample, or the relevant item within M3, M6 or M12 surveys). Of those known to be infection free at baseline (*n* = 173), 114 participants completed all measures used to identify an instance of infection during the study period. The rate of follow-up for chlamydia cumulative incidence is therefore 65.9% (114/173). Note: Very few participants who completed M3, M6 and M12 surveys had missing data on the relevant items used to assess chlamydia infection (see *RO 8*). Absence of data is therefore largely due to non-completion of entire surveys or failure to return (valid) self-samples for testing (see *RO 7* for response rates).

RO 4: identify whether the level of deprivation of the final sample is representative of online STI self-sampling users

To identify whether the level of deprivation of participants in the final sample at 12 months (determined as those who returned a chlamydia self-sampling kit at M12) was representative of service users in the wider sampling pool, the proportion of individuals in IMD quintiles 1 (most deprived) to 5 (least deprived) in each population was compared for both the full and restricted samples. These data are presented in tabular (*Table 7*) and visual (*Figure 2*) formats below. For completeness, data on the proportion of participants across these groups at baseline are also included in *Table 7* and *Figure 2*.

These data indicated that the M12 full and restricted samples were broadly representative of the sampling pool across IMD quintiles with two exceptions. For IMD 3, it appeared that participants were less well represented at M12 than

TABLE 7 Distribution of IMD quintiles among service users in the sampling pool, the baseline sample, and participants in the study at M12 follow-up (full and restricted samples)

	Sampling pool (*n* = 11,413)	Baseline sample (*n* = 230)	M12 follow-up full sample (*n* = 151)	M12 follow-up restricted sample (*n* = 131)
IMD quintile	***N* (%)**	***N* (%)**	***N* (%)**	***N* (%)**
1 (most deprived)	1418 (12.4)	34 (14.8)	24 (15.9)	21 (16.0)
2	2136 (18.7)	37 (16.1)	22 (14.6)	19 (14.5)
3	3110 (27.2)	55 (23.9)	31 (20.5)	29 (22.1)
4	2770 (24.3)	57 (24.8)	36 (23.8)	32 (24.4)
5 (least deprived)	1979 (17.3)	47 (20.4)	38 (25.2)	30 (22.9)

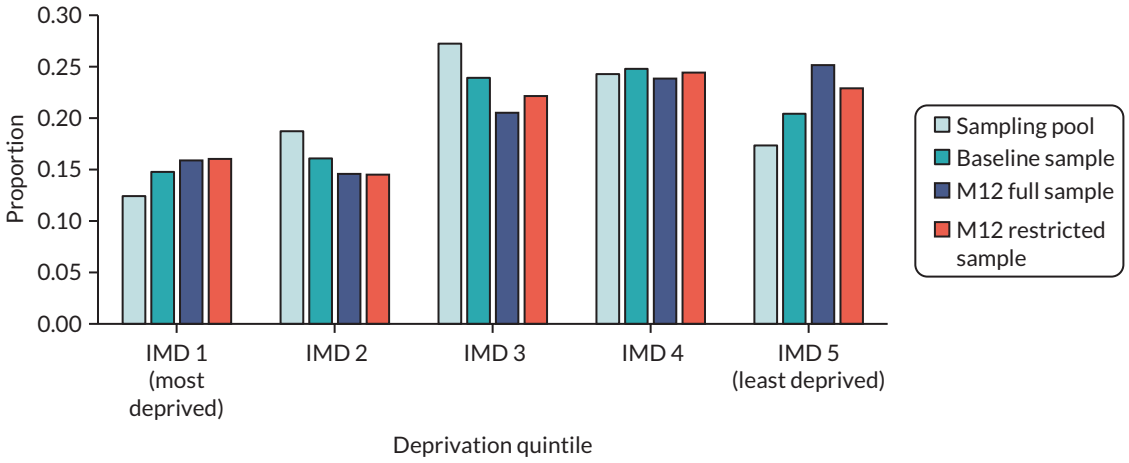

FIGURE 2 Bar chart displaying the proportion of individuals by IMD quintile within the sampling pool, the baseline sample, the full sample at M12 and the restricted sample at M12.

in the sampling pool. For IMD 5 (least deprived), there appeared to be a higher relative proportion of participants at M12 than in the sampling pool. In both cases, the difference between the proportion of participants at M12 and in the sampling pool was less pronounced for the restricted sample than for the full sample. These same patterns were reflected in comparisons of M12 data to baseline, that is, there appeared to be some evidence of a continued slight under-representation of IMD 3 and a slight over-representation of IMD 5. Again, these differences were less pronounced for the restricted sample than for the full sample.

Additional analysis was performed to compare the relative proportions of individuals in the sampling pool and at baseline with those in the full and restricted samples at M12 across age, gender, ethnicity and sexual identity (see *Appendix 5*, *Tables 43–46* and *Figures 6–9*). For age, participants were grouped as 16–19 years and 20–24 years as inspection across individual ages indicated differing trends across these broader categories and grouping aided making comparisons. Within both the full and restricted samples, some differences in the relative proportions were observed as follows. Compared to those in the sampling pool, there appeared to be a lower relative proportion of 16- to 19-year-olds and a higher relative proportion of 20- to 24-year-olds at M12. Participants in these age groups at M12 did however appear to represent those at baseline. For gender, participants at M12 broadly represented those in the sampling pool and at baseline. For ethnicity, there appeared to be a slight under-representation of white participants, and a slight over-representation of black participants, at M12 compared to the sampling pool. Participants at M12 did however appear to represent the baseline sample across all ethnic categorisations. Participants at M12 appeared to represent participants at baseline across all sexual identity categorisations (Note: Comparison to the sampling pool for this characteristic was not possible as data on sexual identity for the sampling pool was unavailable).

RO 5: identify whether differential retention occurs across groups (gender, ethnicity, deprivation, sexual identity, randomised groups, chlamydia diagnosis at baseline)

Note: Examination of differential retention across demographic groups (comparison of participants at M12 to baseline) has already been reported above alongside findings relating to RO 4. This section continues our examination of differential retention, presenting findings related to retention by randomised groups and by chlamydia diagnosis at baseline.

The proportion of participants in each of the randomised groups retained in the study at M12 (measured as the proportion of participants in the initial baseline sample who went on to provide a valid chlamydia self-sample at M12) was calculated. *Table 8* displays these data for both the full and restricted samples.

As can be observed in *Figure 3*, overall retention appeared to be higher for the restricted sample than for the full sample, and higher for the intervention group than for the control group in both samples.

To investigate differences between the intervention and control groups further, the relative proportions of participants at M12 across the randomised groups were compared for the different demographic characteristics. *Table 9* presents this for the full sample (see *Appendix 5*, *Table 47* for the restricted sample).

For both the full and restricted sample, the distribution of participants across demographic characteristics appeared broadly balanced with some limited exceptions. These exceptions mirrored those observed at baseline, namely a lower

TABLE 8 Proportion of participants retained in the study at M12 by randomised group (full and restricted samples)

Intervention	Control	Total		
			95% CI	
n/*n* (%)	*n*/*n* (%)	*n*/*n* (%)	Lower limit	Upper limit
Full sample				
81/115 (70.4)	70/115 (60.9)	151/230 (65.7)	59.1	71.8
Restricted sample				
72/84 (85.7)	59/89 (66.3)	131/173 (75.7)	68.6	81.9

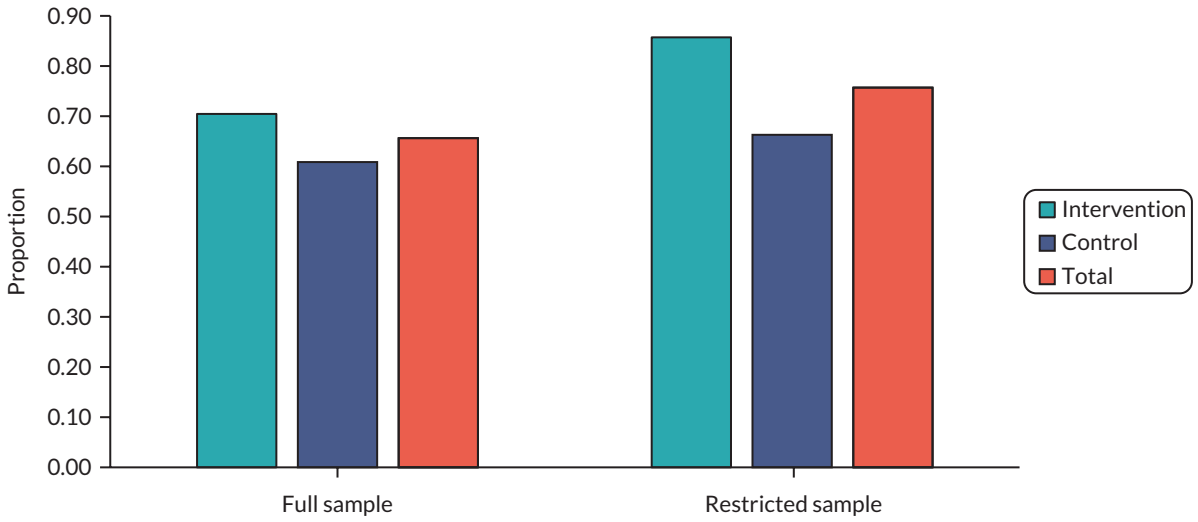

FIGURE 3 Overall retention by randomised group (full and restricted sample).

TABLE 9 Demographic characteristics of participants who completed baseline and who returned a valid M12 chlamydia self-sample by intervention and control group (full sample)

	N (%) with valid sample		Percentage difference	95% CI	
	Intervention (*n* = 81)	Control (*n* = 70)		Lower limit	Upper limit
Age					
16–19	6 (7.4)	9 (12.9)	−5.5	−15.2	4.2
20–24	75 (92.6)	61 (87.1)	5.5	−4.2	15.2
Gender					
Female	56 (69.1)	53 (75.7)	−6.6	−20.8	7.6
Male	22 (27.2)	16 (22.9)	4.3	−9.5	18.1
Other	3 (3.7)	1 (1.4)	2.3	−2.6	7.2
Ethnicity					
White	69 (85.2)	60 (85.7)	0.5	−11.8	10.8
Mixed or multiple ethnic groups	2 (2.5)	4 (5.7)	−3.2	−9.6	3.2
Asian or Asian British	1 (1.2)	2 (2.9)	−1.7	−6.3	2.9
Black, African, Caribbean or Black British	7 (8.6)	3 (4.3)	4.3	−3.4	12.0
Other ethnic group	2 (2.5)	1 (1.4)	1.1	−3.3	5.5
IMD quintile					
1 (most deprived)	12 (14.8)	12 (17.1)	−2.3	−14.0	9.4
2	11 (13.6)	11 (15.7)	−2.1	−13.4	9.2
3	15 (18.5)	16 (22.9)	−4.4	−17.4	8.6
4	22 (27.2)	14 (20.0)	7.2	−6.3	20.7
5 (least deprived)	21 (25.9)	17 (24.3)	1.6	−12.3	15.5

continued

TABLE 9 Demographic characteristics of participants who completed baseline and who returned a valid M12 chlamydia self-sample by intervention and control group (full sample) (*continued*)

	N (%) with valid sample		Percentage difference	95% CI	
	Intervention (*n* = 81)	Control (*n* = 70)		Lower limit	Upper limit
Sexual identity[a]					
Heterosexual	54 (66.7)	41 (58.6)	8.1	−7.3	23.5
Gay	8 (9.9)	4 (5.7)	4.2	−4.3	12.7
Bisexual	17 (21.0)	25 (35.7)	14.7	−29.0	0.0
Other	2 (2.4)	0 (0)	2.4	−1.0	5.7

a No participants self-reported their sexual identity as lesbian or asexual.

proportion of bisexual participants in the intervention group than in the control group (full and restricted samples), and a lower proportion of females and a higher proportion of males in the intervention group than in the control group (restricted sample only).

Also examined was the retention of participants by chlamydia self-report at baseline (see *Table 10*). This showed that retention among participants who reported positive and negative results at baseline was similar. Retention was observed as markedly lower among those who did not report a result at baseline; this further exemplifies the rationale for excluding this group at baseline.

RO 6: measure chlamydia positivity at 12 months in the intervention and control groups (to support sample size calculation for the definitive RCT)

Table 11 presents data on test positivity at M12, broken down by intervention and control group, for both the full and restricted samples.

Sample size calculation for definitive RCT

As indicated in the title of RO 6, our plan had been to use the derived estimates of chlamydia positivity in the intervention and control group to support a sample size calculation for a future full trial. In practice, with the agreement of our SSC and DMEC, other sources were prioritised. This was because we lacked confidence in the estimates obtained due to the small sample size (*n* = 173) and the COVID-19 context of the study, which may have had a downwards impact on population levels of chlamydia positivity (see the *Discussion* section for commentary on the possible impact of the COVID-19 pandemic on the observed levels of chlamydia positivity). Instead, extensive consultation and document review were used to estimate the parameters necessary for the sample size calculation as follows (see *Report Supplementary Material 10* for progression criteria report which includes further details on this process. Note: Changes

TABLE 10 Retention of participants by test result at baseline

	Participants at baseline with each test result	Participants with each result at baseline who went on to provide a valid chlamydia self-sample at M12		
Test result	*N*	*N* (%)	Lower 95% confidence limit	Upper 95% confidence limit
Positive	8	5 (62.5)	24.5	91.5
Negative	165	126 (76.4)	69.1	82.6
Not reported	57	20 (35.1)	22.9	48.9
Total	230	151 (65.7)	59.1	71.8

TABLE 11 Chlamydia positivity at M12

	Intervention	Control	Total
Full sample			
No. in sample	115	115	230
No. of positive cases reported	2	3	5
Test positivity	1.7	2.6	2.2
Restricted sample			
No. in sample	84	89	173
No. of positive cases reported	1	3	4
Test positivity	1.2	3.4	2.3

in national data on chlamydia positivity across test settings have been observed since the progression report was produced, and the sample size calculation presented below has been updated to reflect the most recent 2023 data). Chlamydia positivity in the control group is estimated at 10% based on data reported for the year 2023 in UK Health Security Agency STI data tables for 16- to 24-year-olds testing for chlamydia via the internet.[29] We consulted multiple sources to determine the target level of chlamydia positivity for the intervention group. These included (1) existing evidence concerning chlamydia positivity among young people in the general population (range estimates at 4–6%[30–32]), (2) level of chlamydia positivity among young people testing via community-based general practices (6%[29]) and (3) consultation with 13 sexual health commissioners and sexual health service managers across five English regions about what level would reflect a clinically meaningful reduction from that in the control group (consensus was between 4% and 6% in the intervention group, i.e. a difference of between 2% and 4% between the groups). Based on advice from an independent expert group, we decided that the study should be powered to detect a difference of 3.5% (i.e. 10% in control arm and 6.5% in the intervention arm). A power calculation using G*Power estimated that 2706 participants would be required to detect this difference, thus requiring a trial sample of 3574 participants [based on 75.7% retention (see *RO 2* above); 2706/0.757]. With a recruitment rate of 1.5% (see *RO 1* above), a sampling pool of 238,266 users is required to achieve this target (3574/0.015). The number of 16- to 24-year-olds using Preventx for chlamydia self-sampling varies annually, but the most recent data put this figure at 585,000 users (personal communication) indicating that this would provide a sufficiently large sampling pool at full trial to make recruitment over 12 months a feasible proposition.

RO 7: identify the rate of attrition at 3 months, 6 months and 12 months, and ways of minimising this

Unless a participant withdrew from the study, he or she continued to be invited to complete research measures regardless of his or her levels of prior completion. One hundred and thirteen participants (49.1%) completed all seven research measures. Attrition was explored by examining the proportion of participants who completed each of the study measurements. As can be seen in *Table 12* and *Figures 4* and *5*, completion was higher for the surveys than for the chlamydia self-sampling kits, and furthermore completion was higher overall for participants in the restricted sample than in the full sample.

Measure acceptability was also discussed during the nested qualitative study. Participants who also took part in qualitative interviews found the measures acceptable (see *Chapter 5*, *Subtheme 2.1: process of joining the study straightforward and as expected*).

TABLE 12 Proportion of participants completing each study measure

Measure	Proportion of participants[a] completing study measure	
	Full sample *n*/*N* (%)	Restricted sample *n*/*N* (%)
M0 survey	230/230 (100)	173/173 (100)
Self-report result of chlamydia test	173/230 (75.2)	173/173 (100)
M3 survey	192/230 (83.5)	158/173 (91.3)
M6 survey[b]	191/230 (83.0)	157/173 (90.8)
M12 survey	192/227 (84.6)	157/171 (91.8)
Valid chlamydia sample at M3	148/230 (64.3)	130/173 (75.1)
Valid chlamydia sample at M12	151/227 (66.5)	131/171 (76.6)

a Includes only participants invited to complete the measure; three participants in the full sample (two participants in the restricted sample) withdrew after M6 and were therefore not invited to complete the M12 self-sample or survey.
b Three participants in the full sample (two in the restricted sample) completed a brief version of the survey over the telephone; these participants are included in the total number of completers.

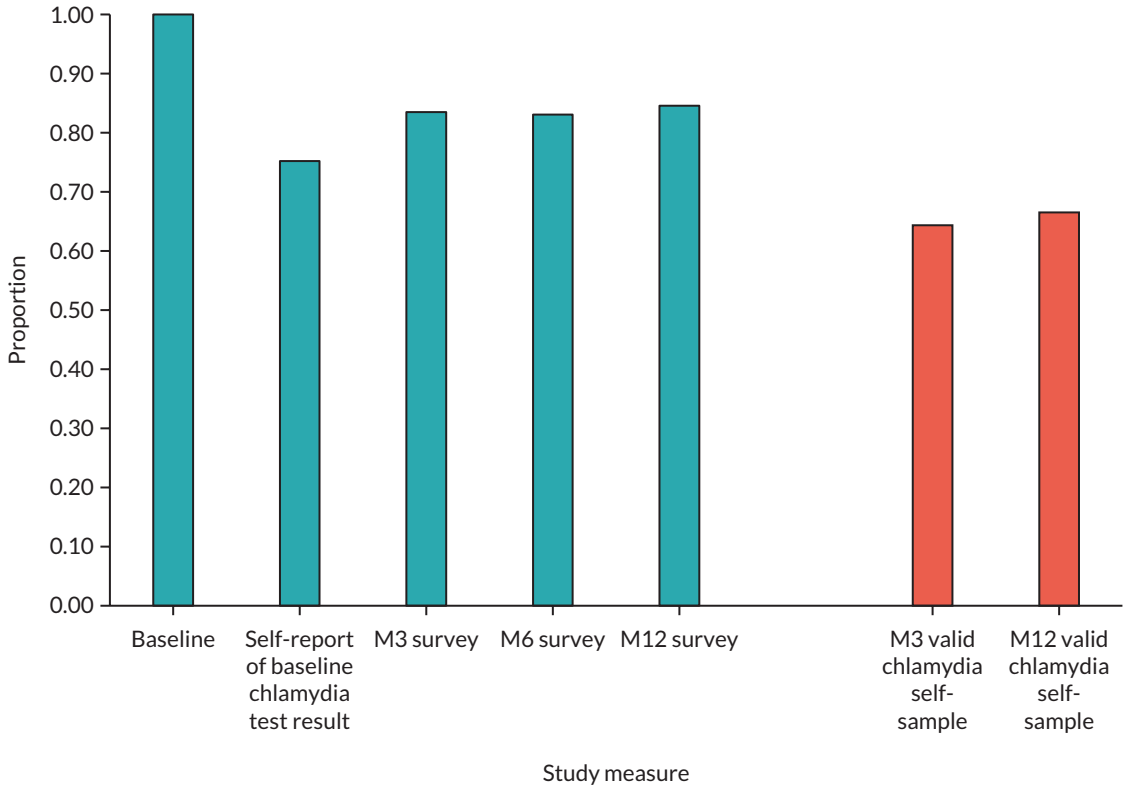

FIGURE 4 Bar chart displaying proportion of participants who completed each study measure (full sample).

RO 8: determine the feasibility and participant acceptability of all primary and secondary outcome measures (including health economic)

Data presented above on the overall completion of research measures (RO 7) provide an indication of participant acceptability. Missing data on survey items that would be used in a definitive trial to evaluate primary and secondary outcomes were also assessed as a further measure of acceptability. There were no missing data for any of the items collecting demographic information; participation in the study was dependent on completion of the baseline survey and

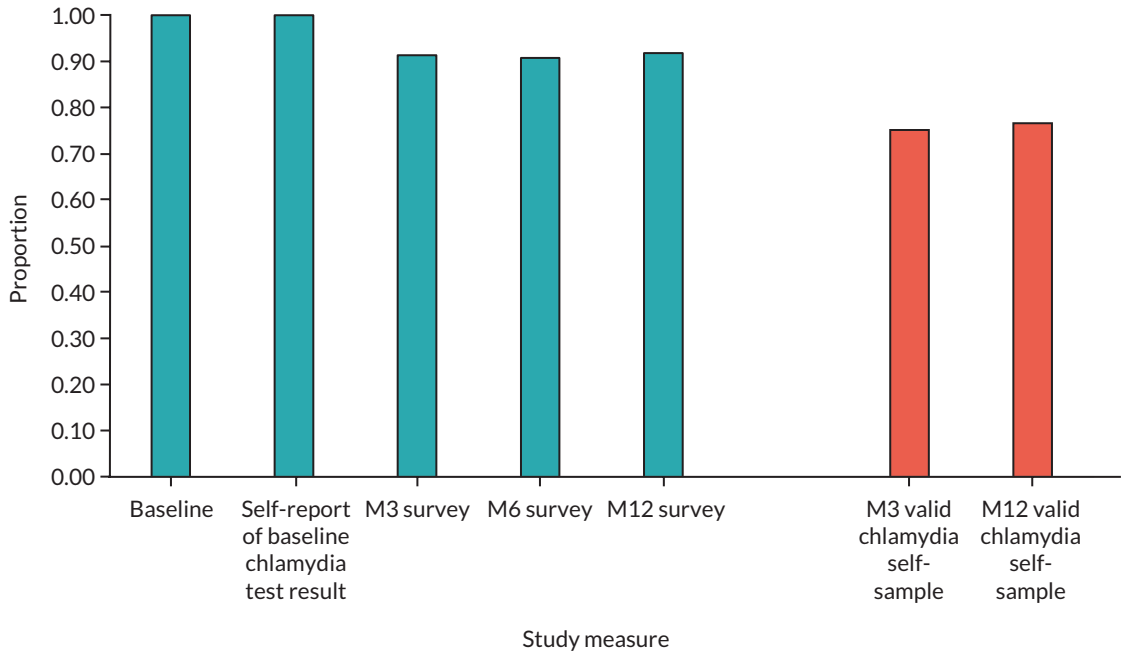

FIGURE 5 Bar chart displaying proportion of participants who completed each study measure (restricted sample). Note: Attrition is not presented using attrition curves as planned. As participants were invited to complete all measures (regardless of prior completion), this skewed the presentation of results.

these items were set as mandatory fields. *Table 13* displays the number and percentage of participants who completed each survey measure who had missing data on the remaining items. All survey items had fully complete or near-complete data, with the latter defined as < 5% missing data.

RO 9: identify which recruitment message(s) results in the highest rate of recruitment

As described in the *Methods* section, participants were recruited to the study via adverts displayed to Preventx service users, each of which contained a different set of value propositions. Over the course of the recruitment period, 13 different adverts were presented. *Table 14* presents the proportion of Preventx users that was randomised to the study following the presentation of the different messages. Given that the incentive amount offered to participants changed over the course of recruitment, this information is also provided.

Also see *Appendix 5*, *Table 48* for recruitment by age group for each combination of message/incentive offered. As can be seen from both tables, there was no clear pattern in terms of which voucher amount(s) or advert(s) displayed resulted in higher recruitment.

Also see findings from the nested qualitative study (Subtheme 2.1) views on the adverts used.

RO 10: identify and remove intervention 'friction points' to minimise attrition and maximise future intervention dose

Please note, in this section, data on the full sample are presented.

Engagement with the intervention and control material was measured using data from Matomo analytics, surveys, and the product ordering and dispatch logs held within the Wrapped website. For a small number of participants in the intervention condition (4/79; 5%), website engagement data reported by Matomo analytics were inconsistent with the logs held within Wrapped. Specifically, this related to occasions where a product was known to have been dispatched to the participant but Matomo had no record of the participant engaging with the Wrapped website. In the following section, the proportion of individuals who successfully accessed the Wrapped website and went on to use allocated components is reported. While not recorded by Matomo, these four individuals are reported as ordering products as

TABLE 13 Percentage of missing data on measures of primary and secondary outcomes

Item	*n/N* (%) of participants[a] with missing data	
	Full sample	Restricted sample
Chlamydia infection		
Self-report of any chlamydia infection (including whether treated, if applicable) within M0 survey	0/230 (0)	0/173 (0)
Self-report of any chlamydia infection (including whether treated, if applicable) within M3 survey	0/192 (0)	0/158 (0)
Self-report of any chlamydia infection (including whether treated, if applicable) within M6 survey[b,c]	0/191 (0)	0/157 (0)
Self-report of any chlamydia infection (including whether treated, if applicable) within M12 survey	0/192 (0)	0/157 (0)
Condom use		
Self-report of condom use at M0	1/230 (0.4)	1/173 (0.6)
Self-report of condom use at M3	1/192 (0.5)	1/158 (0.6)
Self-report of condom use at M6[b,d]	0/191 (0)	0/157 (0)
Self-report of condom use at M12	0/192 (0)	0/157 (0)
Cost-effectiveness and cost–utility data		
EQ-5D-5L at M0	0/230 (0)	0/173 (0)
EQ-5D-5L at M3	3/192 (1.6)	3/158 (1.9)
EQ-5D-5L at M6[e]	3/191 (1.6)	2/157 (1.3)
EQ-5D-5L at M12	2/192 (1.0)	2/157 (1.3)
SF-12 at M0	2/230 (0.9)	2/173 (1.2)
SF-12 at M3	3/192 (1.6)	3/158 (1.9)
SF-12 at M6[f]	8/191 (4.2)	6/157 (3.8)
SF-12 at M12	2/192 (1.0)	2/157 (1.3)

a Includes only participants invited to complete each measure; three participants in the full sample (two participants in the restricted sample) withdrew after M6 and were therefore not invited to complete the M12 self-sample or survey.
b Three participants in the full sample (two in the restricted sample) completed a brief version of the M6 survey over the telephone which included this item; these participants are included in the total number of completers.
c Three participants (all restricted sample) completed this item but not the full M6 survey and are not counted as missing.
d Two participants (both restricted sample) completed this item but not the full M6 survey and are not counted as missing.
e Two participants (both restricted sample) completed this item but not the full M6 survey and are not counted as missing.
f One participant (restricted sample) completed this item but not the full M6 survey and is not counted as missing.

recorded in the website logs and as successfully accessing the website (as this is a precursor to ordering). Whether these individuals engaged with their allocated video components is unknown.

Wrapped website

Of the 115 participants randomised to the intervention group, 34 (29.6%) did not click on the link provided to gain access to the Wrapped website. Two participants (1.7%) clicked on the link and created a user profile but did not complete the required tailoring questions to gain access to the site. Observation of user recordings suggests that while one of these individuals chose not to complete these questions, the other may have experienced an on-site technical error. The remaining 79 participants (68.7%) successfully completed this registration process and landed on the homepage. See figure 1 in *Report Supplementary Material 11* for acquisitions flow chart. *Table 15* presents the demographic characteristics of participants who did and did not gain access to the Wrapped website. Across most

TABLE 14 The proportion of Preventx users recruited to the study per recruitment message and total incentive offered

Advert number	Advert text	Length of time advert displayed (in weeks)	Incentive amount as communicated in advert and/or participant information (£)	Percentage (*n*/*N*) of service users recruited following presentation of advert
1	Help us make a positive change to young people's sexual health: make a difference by joining our study and get paid for your time!	2	65	1.9 (19/954)
2	Take part in a study to improve sexual health and earn up to £65 in Amazon vouchers, find out how you can make a difference today!	2	65	2.0 (19/941)
3	Your views are important: join our study to help improve sexual health for young people while being paid!	2	65	1.8 (17/941)
4	Make a difference to improve sexual health for young people – join our study and earn up to £65 in Amazon vouchers for your time!	1	65	3.5 (9/254)
5	Interested in sexual health research? Take part and get up to £85 in vouchers.	3	85	3.5 (20/577)
6	Help us make a positive change to young people's sexual health: make a difference by joining our study and get up to £100 in vouchers.	2	100	1.1 (5/460)
7	Take part in a study to improve sexual health and earn up to £100 in vouchers, find out how you can make a difference today.	2	100	1.6 (7/446)
8	Your views are important: join our study to help improve sexual health for young people and get paid up to £100 in vouchers!	2	100	2.6 (13/491)
9	Make a difference to improve sexual health for young people – join our study and earn up to £100 in vouchers for your time.	3	100	2.0 (25/1282)
10	Want to make a difference to young people's sexual health? Take part in our study and get up to £100 in vouchers for your time.	2	100	1.6 (15/922)
11	We need your help! Take part in a study to improve young people's sexual health and earn up to £100 in vouchers for your time.	2	100	0.9 (8/944)
12	Interested in sexual health research? Take part and get up to £100 in vouchers.	3	100	2.1 (28/1347)
13	*Shown to service users aged 20–24:* Interested in sexual health research? Take part and get up to £100 in vouchers.	3 (plus 1 day)	100	2.8 (39/1401)
	Shown to service users aged 16–19: Interested in sexual health research and aged 16–19 years? Want to earn up to £100 in Amazon vouchers?			1.3 (6/ 453)

demographic characteristics, access levels were broadly in line with the overall level. There was some limited evidence of higher access among participants in the younger age group (16–19 years) and among those in deprivation quintile 5 (least deprived), and of lower access among those in deprivation quintile 2. The small number of participants across these subgroups means that the findings should be treated with caution.

When participants landed on the homepage, they were presented with blocks representing each of their assigned components. All participants were assigned the sample pack by default, but all other assignments were in response to individuals' self-identified barriers. *Table 16* presents the proportion of participants who were assigned each Wrapped

TABLE 15 Demographic characteristics of participants in the intervention group (*n* = 115) who did and did not access the Wrapped website

	Accessed Wrapped *N* (%)	Did not access Wrapped *N* (%)	Percentage difference
Age			
16–19 (*n* = 12)	10 (83.3)	2 (16.7)	66.6
20–24 (*n* = 103)	69 (67.0)	34 (33.0)	34.0
Gender			
Female (*n* = 79)	53 (67.1)	26 (32.9)	34.2
Male (*n* = 32)	22 (68.8)	10 (31.3)	37.5
Other (*n* = 4)[a]	4 (100)	0 (0)	100
Ethnicity			
White (*n* = 89)	70 (71.4)	28 (28.6)	42.8
Mixed or multiple ethnic groups[a] (*n* = 6)	3 (50.0)	3 (50.0)	0.0
Asian or Asian British[a] (*n* = 1)	1 (100)	0 (0.0)	100
Black, African, Caribbean or Black British[a] (*n* = 8)	4 (50.0)	4 (50.0)	0.0
Other ethnic group[a] (*n* = 2)	1 (50.0)	1 (50.0)	0.0
IMD quintile			
1 (most deprived) (*n* = 18)	12 (67.7)	6 (33.3)	34.4
2 (*n* = 19)	11 (57.9)	8 (42.1)	15.8
3 (*n* = 24)	17 (70.8)	7 (29.2)	41.7
4 (*n* = 29)	20 (69.0)	9 (31.0)	37.9
5 (least deprived) (*n* = 25)	19 (76.0)	6 (24.0)	52.0
Sexual identity[a]			
Heterosexual (*n* = 79)	53 (67.1)	26 (32.9)	34.2
Gay (*n* = 11)	8 (72.7)	3 (27.3)	45.5
Bisexual (*n* = 23)	16 (69.7)	7 (30.4)	39.1
Other (*n* = 2)	2 (100)	0 (0)	100

a No participants self-reported their sexual identity as lesbian or asexual.

TABLE 16 Proportion of participants successfully accessing Wrapped who were assigned each component and then went on to complete the pre-determined goal

Component	Proportion of participants assigned *N* (%)	Proportion of participants assigned to each component who achieved the pre-determined goal *N* (%)
Sample pack	79 (100)	48 (60.8)
Condom ordering	70 (88.6)	37 (52.9)[a]
Condom carrying	63 (79.7)	31 (49.2)
Condom demo	70 (88.6)	7 (10.0)
Discussing condoms	59 (74.7)	4 (6.8)
Real life	66 (83.5)	9 (13.6)

a 25 of these 37 (67.6%) participants went on to make a repeat order.

component. Eight individuals (10.1%) 'bounced' off the homepage, that is, they left before visiting relevant pages for any of their assigned components. The remaining participants went on to visit at least one of their assigned components. Figures 2–7 in *Report Supplementary Material 11* display the user journeys through each of these components with achievement of a pre-determined goal as the endpoint. The pre-determined goals were as follows: ordered sample pack, placed at least one order for condoms, ordered condom carrier, watched condom demo video (any duration), watched one of discussing condom videos (any duration), watched one of the real-life videos (any duration). *Table 16* presents how many of the participants, assigned each component, achieved these goals.

The table and figures together show that the product-related components (sample pack, monthly condom/lube packs, condom carrier) were more likely to be visited than the video-related components (condom demo, discussing condoms, real-life). While some individuals visited their assigned product-related components and did not place an order, most did, and few were lost during the ordering process indicating little to no friction at this point. Of the small numbers of participants who visited-video related components, lower proportions of participants also went on to achieve the goal (i.e. watched one or more of the videos) than for the product pages. This suggests that the descriptor on the homepage for these components, and the video stills and associated captions on each of the component pages, were not attracting individuals to access and play the videos. Furthermore, few of the videos played were watched in full, suggesting that either these were not sufficiently engaging and/or perceived as irrelevant or too long.

Three information and support pages are available to all Wrapped website users. The content of these pages is a duplication of that provided within the control website. Of those who accessed Wrapped, 10.1% (8/79) visited the sexual health information and support page, 5.1% (4/79) visited condom information page and 13.9% (11/79) visited STI information.

Participants were asked about their experience and use of the intervention within the fRCT surveys. At M3, participants were asked how useful they found the website and how they would rate the design. Of all those who had accessed Wrapped and responded to these questions (n = 68), 70.6% (n = 48) reported finding the site very or extremely useful, and 80.9% (n = 55) rated the design as good or very good.

At M12 survey, participants assigned to the intervention group were asked about their use of the sample pack and condom carrier. *Table 17* summarises this feedback.

Control website

Of the 115 participants randomised to the control group, 76 (66.1%) clicked on the link and visited the site. Of these, 14 (18.4%) bounced off the home page, that is, they did not visit any of the content pages. The proportion of those visiting the site who accessed each content page is as follows: 57.9% (44/76) visited information and support, 63.2% (48/76) visited condom information and 63.2% (48/76) visited STI information. Of those who visited and responded to the relevant M3 survey items, 31.1% (19/61) reported the website as very or extremely useful, and 72.1% (44/61) rated the design as good or very good.

TABLE 17 Use of Wrapped products by those who accessed the site and placed an order

Use of Wrapped products	Proportion of participants who used each product (as described in the table) out of all those who placed an order n/N (%)
Tried condoms in sample pack	35/39 (89.7)
Tried lube in sample pack	32/39 (82.1)
Looked at leaflet inside the sample pack	36/38 (94.7)
Used box (that sample condoms delivered in) to store condoms	26/39 (66.7)
Used carrier for condoms	10/24 (41.7)
Attached the carrier (used for condoms) to keys or bag	7/10 (70.0)

RO 11: identify costs and resource use associated with the intervention for healthcare services and users (to inform the design of the definitive RCT and the future economic evaluation)

See *Chapter 4* for findings of health economic analysis.

RO 12: measure contamination of intervention effect in the control group

Of the total number of participants in the control group who completed the M12 follow-up survey (*n* = 96), 42 (43.3%) reported exposure to Wrapped, that is, they indicated that they recognised one or more images from the intervention website (presented to them as screenshots within the M12 survey). This level of contamination was unexpected and therefore investigated further.

One potential route to contamination that was explored was a participant telling another person(s) about the study, them going on to enrol and be randomised into a different group, and then these individuals sharing experiences of differing intervention content. There is some limited evidence that this occurred. The research team was contacted twice during the study by participants asking how to refer a friend to the study. These participants were told that the study was only for people who were self-testing for STIs. Whether these participants went on to instruct their friends on gaining access via Preventx is unknown. There was also a group of three house-sharing participants (one in the intervention group and two in the control group) who may have signposted each other to the study, albeit this could not be verified as this would have led to a breach of participant confidentiality. There were also two occasions where participants in the control group e-mailed the research team to ask where to 'register' on the control website, one adding that this was for the purpose of 'ordering condoms'. As the control website does not require registration, and condom ordering is not a feature, this indicated that details of the intervention website had been shared with them.

While there was the above evidence of friendship pairs/group participation, there was nonetheless no evidence that the intervention website had been directly accessed by anyone outside of the intervention group. Access to the intervention website was strictly controlled during the study. Each intervention group participant was provided with a unique URL (appended with their participant number) and was required to enter valid log-in credentials at each access. Examination of the intervention website log and data analytics records showed that the intervention website had only been accessed by individuals with one of the assigned participant numbers (i.e. no rogue/fake numbers). The sharing of log-in details was also considered unlikely due to the limited number of repeat visits by participants (other than by those who were using the condom-ordering component). A further possibility considered was that participants in the intervention group had shown the website to others in the control group (i.e. allowing them to physically view their screen). There is no means of verifying the occurrence of this but given that product ordering is restricted by design (either one per user or limited in quantity/frequency), and that there were few repeat views of videos, this scenario seems unlikely to have occurred.

Given that there is limited evidence that contamination of the control group did occur, the most likely explanation for the level of contamination reported in the M12 survey is that the question designed to detect this was not reliable. This question asked participants if they recognised 'some or all of the images' within three screenshots of the intervention website. Given that consistent branding (website name, logo, colour palette, icons) was used across both the intervention and control websites, it is possible that participants interpreted the question literally (i.e. they recognised the branding and therefore 'some of the images'), or that the branding gave the screenshots a feeling of familiarity.

RO 13: identify possible adverse effects of the intervention

Within all follow-up surveys, participants were asked to self-report any adverse events related to their participation in the study. There were four fixed response items, three for anticipated adverse events, and one for 'other problem' which if endorsed routed participants to an open-ended question asking for further information. Two of the anticipated events (inadvertent disclosure that sexually active or testing for a STI) were considered a potential risk for all participants, predominantly as a result of receiving chlamydia self-sampling kits by post; a risk that was further enhanced for intervention participants if they chose to order products from the Wrapped website. The third anticipated event, increase in use of pornography, was only considered as a risk to those in the intervention group as a result of exposure to content aiming to eroticise condoms.

In line with the study protocol, all adverse events were reported to the NHS ethics, the sponsor, the SSC and the DMEC. On each occasion, all groups were satisfied that appropriate measures were being taken to manage these risks. Any participant who reported an adverse event was contacted by e-mail to offer support. On one occasion, a participant replied to the research team, reflecting on the event. Six months before the end of data collection, on the advice of the SSC and with ethical approval, an additional open-ended question was asked from all participants who indicated that they had experienced any adverse event. This invited them to provide details on why they thought that taking part in the study had led to this outcome; one participant provided an open-ended response to this at M12.

Table 18 presents each of the event types, the number of reported instances across all time points, and any qualitative comments received via e-mail or survey. Most adverse events that were reported concerned disclosure of STI testing. Although one individual reported that participation in the study had led to an increase in their use of pornography, this participant was allocated to the control group. Participants were contacted and asked if they would be willing to provide further information, but none was received.

Review of progression criteria

On completion of data analysis, separate meetings were convened with the DMEC and with the SSC to review the progression criteria. A report was sent to members in advance setting out evidence against each criterion (see *Report Supplementary Material 10*). At each meeting, this evidence was presented followed by questions and discussion. A section of the meeting was closed (research team not present) to enable members to discuss their views in confidence. DMEC members cast their votes during this closed section of the meeting. The SSC cast their votes after the meeting via a Microsoft form. Both groups were quorate and agreed unanimously that the progression criteria had been met.

TABLE 18 Frequency of adverse events reported along with any qualitative comments received about the event

Adverse event	Number of instances reported	Qualitative comments
Led to someone finding out I was having sex when I did not want them to know	1	None
Led to someone finding out I was testing for a STI when I did not want them to know	9	E-mail response on offer of support: 'It's OK this hasn't caused me too much trouble, there is no need for any discussion, it wasn't a serious matter and there is no reason to change anything that you currently do' Open-ended response in M12 survey: 'It has made some uncomfortable conversations, but they have also been positive in showing that I am trying to be safe'
Led to an increase in my use of pornography	1	None
Other problem	0	None

Chapter 4 Health economic assessment: method and findings

Introduction

The aim of the economic component of the Wrapped study was to assess the feasibility of the methods to collect cost and outcome data to inform the design of a future definitive RCT. Wrapped is a tailored behaviour change intervention to increase condom use among young people using web-based STI-testing services, and hence the additional resources required to deliver the intervention need to be compared with usual care. This is important because any additional benefits associated with the Wrapped intervention (e.g. in terms of reducing STI rates) must be assessed in terms of any additional costs that can be attributed to it.[33]

The economic costs associated with STIs are considerable, and these impact on young people, the healthcare sector, the wider public sector and society.[34] STIs remain a serious public health challenge, with 401,800 new diagnoses in 2023 in England[1] at a cost of around £620 million annually.[35] Those most at risk are young people, GBMSM, those who identify as black and those who live in areas of higher deprivation.[36] There are also important equity concerns connected with poor sexual health. The stigma which surround STIs and contraception results in specific and significant barriers to accessing services and, in contrast to other services, direct patient self-referral accounts for the overwhelming majority of attendees.[37] Furthermore, in England, compared to other healthcare services, there has been a substantial reduction in sexual and reproductive healthcare budgets which means that there is a heightened pressure on costs.[38]

Methods

The objective of the economic analysis was to establish and assess methods for collecting the cost and outcome data for the intervention and control groups. In line with guidance from the NICE for public health interventions,[39,40] we explored methods to measure costs from the perspective of the NHS, and wider public sector. The study also attempted to assess private sexual and reproductive health costs incurred by participants, for example, for the purchase of condoms or contraception.

Recruitment costs

Participants were recruited via websites offering free STI self-sampling kits to young people living in England, based in five local areas. We assumed that the costs associated with recruitment would not be required if the intervention was rolled out, as such costs would be included within local sexual health commissioning arrangements; thus the costs associated with recruitment were not included in the analysis. There is further consideration of funding and commissioning arrangements in *Chapter 6*.

Intervention costs

For both the intervention and the control groups, resource use data were collected prospectively by the research team. Ongoing costs associated with interventions can be considered in terms of fixed costs and variable costs, with fixed costs being those which are not affected in the short term by the number of people who use them.[41] In contrast, variable costs change according to the number of people accessing the intervention; cost items such as consumables are typically variable costs.

The Wrapped intervention is complex and involves several different elements, including a website, video content and provision of condom/lube samples. The website and video content were developed in a previous study,[26] and hence the costs associated with developing the website and content were not included in our analysis, as these were assumed to be 'sunk' costs which would not need to be reincurred if the intervention were rolled out at scale. The costs associated with the maintenance of the website element of the Wrapped intervention, and updating of video content, to ensure content continued to be appropriate and appealing to young people, were explored as part of the evaluation. For

interventions which involve websites and digital content, a high proportion of the total costs are often fixed costs, for example in relation to maintaining systems and storing data.[42] Such costs do not tend to vary (overall) in terms of the number of people who use them. This means that the cost of delivering the digital component of the intervention (per participant) will be determined primarily by the number of participants assumed to be accessing the intervention (the denominator), with the cost per participant assumed to be lower as the digital component is delivered at larger scale.[43] Thus, reporting costs based on the number of participants included in a feasibility trial will not provide an accurate reflection of the true cost per participant if the intervention was rolled out at scale.[44] It is therefore recommended that the likely take-up rate is taken into account to more accurately estimate the average costs per participant associated with an online intervention.[44] We therefore analysed the costs associated with the website and video content to give a more accurate estimate of these if the intervention were rolled out.

Taking into account possible take-up rates, we assumed that the cost would be £2.00 per participant to cover the costs of maintaining the Wrapped website and associated video material, including updating content, following methods adopted previously in similar studies.[45] In calculating this cost, we assumed that the Wrapped intervention could be widely used across local authorities, as it could be used alongside different models of commissioning and delivering web-based STI-testing services (see *Chapter 6*).

For the intervention arm, variable costs were associated with the provision of condom sample packs, condom carriers and the condom distribution service. Methods to capture the resource use and costs linked to the provision of these components were developed during this feasibility trial. This included costs relating to the assembling, packaging and postage of the sample packs, sourcing and tailoring the condom carrier, and the costs associated with the ongoing condom/lube distribution service, and any other materials used.

The Wrapped intervention is tailored to address the particular barriers reported by each user. Costs and resource use in the intervention group therefore varied according to the particular barriers to condom use reported by each participant. All participants in the intervention group were eligible to order a condom sample pack. This pack contained different makes and types of condoms and lubricant. Those participants who reported that there were issues around being able to order the type of condoms that they wanted, or with the cost of condoms, or that they felt embarrassed buying condoms, could order a maximum of 12 condoms and up to three sachets of lube each month. Those participants who stated that they did not always have a condom with them when needed were given the option to order a condom carrier.

Those randomised to the control group received usual care. This was a web page with standard information on STIs and details about how to access condoms. In line with the assumptions above, we assumed £1.00 per participant to cover the costs associated with maintaining and delivering the control website, given the scale at which this could be available across local areas.

Healthcare resource use and costs

During the fRCT, healthcare resource use by participants was collected via survey for participants in both intervention and control groups at all time points. Data were collected on whether participants had visited a sexual health clinic, their GP/nurse at a GP surgery, or a GP out of hours service, on the number of A&E visits, and any other use of health services. Unit cost estimates were applied to resource use data to estimate overall costs. The sources of unit costs were from the published literature and published reference costs.[46]

Public sector and private costs

Costs may fall on other sectors, apart from health, and hence we included questions to capture broader public sector resource use. In particular, we explored whether participants who reported being in education had accessed services connected with their sexual and reproductive health at school, college or university.

Other costs incurred by participants associated with their sexual and reproductive health, for example ordering and paying for condoms, STI testing, and contraception, were also captured. This included access to counselling and other services which might be provided outside of the NHS. Questions were included in the surveys at all time points to measure these costs.

Outcome data

As shown in *Chapter 3*, a wide range of outcome data were collected. For the health economics component, the main aim was to test the feasibility and acceptability of using a range of different outcome measures required for a future definitive economic evaluation. This included data on health-related quality of life (HRQL) collected across all time points using the EQ-5D-5L instrument, to allow a cost–utility analysis to be performed.[24] Following NICE guidance, we calculated utility values by mapping the 5L descriptive system data onto the 3L value set.[47] Utility values were calculated for feasibility processes only, as the trial was not powered to detect any changes in outcome measures. We also assessed the feasibility and acceptability of using the SF-12 questionnaire to measure HRQL at baseline, M3, M6 and M12.[25] This is because there are limitations with using the EQ-5D in a sexual health context, particularly because many of those who are infected with a STI such as chlamydia do not experience symptoms.[48] It has been suggested that the SF-12 instrument might have strengths in such contexts due to the larger descriptive system and broader coverage of HRQL.[49,50]

Analysis

The analysis focused on evaluating the feasibility of collecting cost and outcome data to inform the design of a definitive trial involving an economic evaluation. This involved the establishment and assessment of trial processes for obtaining cost data and the acceptability/completion of questions within the questionnaires. As this was a feasibility study, the purpose was not to produce a definitive result with respect to the cost-effectiveness of the intervention, but to conduct an exploratory analysis to design and refine the methods for an economic evaluation alongside a future definitive trial. Data on the full sample were used.

Results

Cost and outcome data were successfully collected and analysed over the full period of the fRCT. Costs were captured in relation to the delivery of the intervention and wider resource use. A range of outcome data were successfully collected and are presented below.

Intervention costs

For the intervention group, resource use linked to the provision of the Wrapped intervention was successfully collected. As detailed above, the intervention was tailored to meet the reported barriers for participants, and this meant that the resources received in the intervention group varied according to the needs of participants.

Condom sample packs

The sample pack was available to all those randomised to the intervention group. In total, 48 people ordered a sample pack. Costs associated with the products included in the sample packs and assembling costs are detailed in *Table 19*.

TABLE 19 Cost details for sample packs

Item	Unit cost (£[a])
Condom sample pack – packaging	
Condom sample pack – box	1.41
Condom sample pack – leaflet printing	0.94
Condom sample pack – inlay printing	0.34
Condom sample pack – condom menu sheet printing	0.07
Total cost of packaging	2.76
Condom sample pack – contents	
Durex Pleasure Me	0.53
Durex Thin Feel	0.43

TABLE 19 Cost details for sample packs (*continued*)

Item	Unit cost (£[a])
EXS Air Thin	0.10
EXS Extra Large	0.08
EXS Snug Fit	0.08
MyONE Perfect Fit	1.17
Pasante Cooling	0.09
Pasante Sensitive	0.08
Pasante Warming	0.09
Skyn Extra Lubricated	0.46
Skyn Intense Feel	0.50
Skyn Original	0.29
Lube – silky TLC	0.08
Lube – light/gentle	0.08
Total condom and lube costs	4.06
Other costs	
Postage bag	0.13
Address sticky label	0.03
Postage costs	1.53
Thank you card	0.07
Assembly costs[b]	0.36
Total other costs	2.12
Grand totals	
Total cost of one sample pack[c]	8.94
Total orders of sample pack	48
Total cost	429.12
Cost per participant in the intervention arm	3.73

a Costs are presented in GBP (2021–22) and include VAT where applicable.
b Assumes packs are assembled by administrative assistant and this takes 2 minutes (based on trial data and assuming £10.90 hourly rate).
c Based on costs recorded in the trial. Assumes that unused sample packs can be utilised in other ways.

Condom carrier

All those who were allocated to the intervention group, who reported that having easy access to condoms when needed was a barrier for them, could order a condom carrier. In total, 31 people ordered a carrier. The costs associated with the case are detailed in *Table 20* for the full sample.

Condom-ordering service

For those participants in the intervention group who reported affording condoms as a barrier to use, a condom distribution service was available. This allowed young people to select and order free condoms which were delivered

TABLE 20 Cost details for condom carrier

Item: condom carrier	Unit cost (including VAT and shipping costs) (£[a])
Condom carrier	3.17
Condom	0.08
Postage bag	0.10
Thank you card	0.07
Address sticky label	0.03
Postage costs	0.88
Assembly costs[b]	0.36
Grand totals	
Total cost of one carrier[c]	4.69
Total orders of condom carriers	31
Total cost	145.39
Cost per participant in the intervention arm	1.26

a Costs are presented in GBP (2021–22) and include VAT where applicable.
b Assumes packs are assembled by administrative assistant and this takes 2 minutes (based on trial data and assuming £10.90 hourly rate).
c Based on costs recorded in the trial. Assumes that unused carriers can be utilised in other ways.

by post. Over the study period, 37 participants ordered condoms, with 115 separate orders being placed. The costs associated with this condom-ordering service are shown in *Table 21*.

Healthcare resource use

Costs and resource use were collected and analysed for all time points (baseline, M3, M6 and M12). In the sections below the costs collected at M12 are presented as an illustration of how the data would be used as part of an economic evaluation in a future definitive trial. As part of the study, data were collected from participants on healthcare resource use associated with sexual health. As can be seen from *Table 22*, the main healthcare resource use reported relates to Sexual Health clinics and GP visits.

TABLE 21 Condom-ordering service costs (over the trial period)

Item	Unit cost (£[a])	*N*	Total cost (£[a])
Condoms			
Durex Pleasure Me	0.53	222	117.66
Durex Thin Feel	0.43	234	100.62
EXS Air Thin	0.1	60	6.00
EXS Extra Large	0.08	48	3.84
EXS Snug Fit	0.08	12	0.96
MyONE Perfect Fit	1.17	78	91.26
Pasante Cooling	0.09	30	2.70
Pasante Sensitive	0.08	60	4.80
Pasante Warming	0.09	42	3.78

TABLE 21 Condom-ordering service costs (over the trial period) (*continued*)

Item	Unit cost (£[a])	*N*	Total cost (£[a])
Skyn Extra Lubricated	0.46	123	56.58
Skyn Intense Feel	0.50	243	121.50
Skyn Original	0.29	129	37.41
Total cost of condoms			547.11
Other costs			
Text messages/e-mail reminders	0.01	37	0.37
Instruction sheet	0.60	115	69.00
Thank you card	0.07	115	8.05
Postage bag	0.10	115	11.50
Address sticky label	0.03	115	3.45
Postage costs	0.96	115	110.40
Assembly costs[b]	0.36	115	41.40
Total other costs			244.17
Grand totals			
Total costs for condom-ordering service (condoms and other costs)[c,d]			791.28
Number of people in the intervention arm		115	
Cost per participant in the intervention arm			6.88

a Costs are presented in GBP (2021–22) and include VAT where applicable.
b Assumes orders are assembled by administrative assistant and this takes 2 minutes (based on trial data and assuming £10.90 hourly rate).
c Based on costs recorded in the trial. Assumes that unused condoms/other materials can be utilised in other ways.
d This is the total cost for 115 orders placed by 37 participants.
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TABLE 22 Number of patients reporting use of healthcare services (reported at M12)

Resource use	*N* intervention group	*N* control group	Total
Sexual health clinic	7	11	18
GP consultation	2	5	7
GP nurse consultation	2	2	4
NHS walk-in centre	1	0	1
NHS 111 calls	1	0	1
GP out of hours	0	0	0
Pharmacy	1	1	2
A&E	0	0	0
Gynaecology	0	2	2
Other	0	0	0
Total number of participants reporting use of healthcare resources	10	16	26
Total number of participants completing this item at follow-up	96	95	191

Table 23 shows the healthcare resource use reported by participants and the associated costs. It is evident that the most frequently reported resource use related to sexual health clinics and primary care.

The study included information about STI self-sampling kit ordering and access to contraception. As is shown in *Table 24*, a proportion of participants reported that they had ordered STI self-sampling kits. Participants reported that most kits ordered were returned (and hence processed).

We collected data on other NHS prescriptions and services accessed by participants in relation to their sexual and reproductive health. For example, participants were asked whether they had ordered STI self-sampling kits via NHS services, or contraception. There were issues with obtaining sufficient detail on how long some products had been prescribed or accessed, and the particular nature of products. Thus, some assumptions needed to be adopted to estimate costs for services and products accessed (shown in *Table 25*).

As part of the fRCT, we explored the collection and analysis of costs relating to other aspects of the public sector, such as costs incurred by schools, colleges and universities. Overall, around a quarter of participants reported that they were currently studying in school, college or university (26%, 60 participants). As is shown in *Table 26*, a small number of participants reported accessing services at school, college or university in connection with their sexual health.

Costs borne by participants

We attempted to capture the costs incurred by participants in relation to sexual and reproductive health, for example in terms of purchasing condoms, STI self-sampling kits, contraception etc. The costs shown in *Table 27* are based on reported costs. Those in the control group reported slightly higher costs associated with sexual health.

Summary of costs

Table 28 summarises key data collected during the trial. The summary is illustrative only due to the small sample size. However, the data collected demonstrate the importance of a comprehensive approach to cost collection, particularly

TABLE 23 Healthcare resource use (reported at M12)

Resource use	Cost item	Unit cost (£[a])	*N* wrapped intervention group	*N* control group	Cost–intervention (£[a])	Cost–control (£[a])
Sexual Health Clinic (face to face and telephone)	Per consultation	136.00	22	22	2992.00	2992.00
GP consultation (face to face)	Per consultation	42.00	2	6	84.00	252.00
GP consultation (telephone)	Per call	15.80	4	7	63.20	110.60
GP nurse consultation (face to face)	Per consultation	13.00	3	1	39.00	13.00
GP nurse consultation (telephone)	Per call	8.69	2	5	17.38	43.45
NHS walk in centre[b]	Per visit	42.00	1	0	42.00	0
NHS 111 calls[c]	Per call	8.69	1	0	8.69	0
Pharmacy[d]	Per visit	8.83	2	2	17.66	17.66
Gynaecology	Per visit	131.00	0	4	0	524.00
Total cost					3263.93	3952.71
Number of participants completing this item			96	95		
Total cost per participant					34.00	41.61

a Costs are presented in UK£ (2021–22).
b Assumes equivalent to GP consultation.
c Assumes equivalent to nurse-led telephone consultation PSSRU 2021–22.
d Assumes band 6 pharmacist and 10-minute appointment.

TABLE 24 Sexually transmitted infections kit ordering costs (reported at M12)

Resource use	Unit cost (£[a])	*N* intervention group	*N* control group	Total cost–intervention group (£[a])	Total cost–control group (£[a])
Chlamydia kit ordered	7.27	29	10	210.83	72.7
Gonorrhoea kit ordered	7.27	0	1	0	7.27
Chlamydia and gonorrhoea kit ordered	7.27	20	5	145.4	36.35
Chlamydia, gonorrhoea, HIV and syphilis kit ordered	9.60	29	22	278.4	211.2
Chlamydia kit processed	3.00	28	10	84.00	30.00
Gonorrhoea kit processed	3.00	0	1	0	3.00
Chlamydia and gonorrhoea kit processed	3.00	15	5	45.00	15.00
Chlamydia, gonorrhoea, HIV and syphilis kit processed	6.00	23	22	138.00	132.00
Total cost				901.63	507.52

a Costs are presented in UK£ (2021–22).

TABLE 25 Other NHS costs associated with sexual and reproductive health (reported at M12)

Resource use	Cost item	Unit cost (£[a])	*N* intervention group	*N* control group	Total cost–intervention group (£[a])	Total cost–control group (£[a])
Contraceptive pill[b]	Per 3-month prescription	4.93	18	17	88.74	83.81
PEP (post-exposure prophylaxis for HIV)[c]	Course of treatment	525.95	2	1	1051.90	525.95
Counselling	Per course (6 weeks)	360.00	6	4	2160.00	1440.00
Medical abortion[d]	Per medical termination	353.40	1	2	353.40	706.80
Coil insert/removal		42.00	2	1	84.00	42.00
Contraceptive implant/injection/patch		42.00	5	2	210.00	84.00
Total cost					3948.04	2882.56

a Costs are presented in UK£ (2021–22).
b Assumes Desogestrel 150 microgram, Ethinylestradiol 30 microgram, 63 tablets.
c Assumes Emtricitabine 200 mg, Rilpivirine (as Rilpivirine hydrochloride) 25 mg, Tenofovir disoproxil (as Tenofovir disoproxil fumarate) 245 mg, in line with British Association for Sexual Health and HIV guidelines.[51]
d Assumes medical abortion < 9 weeks of gestation.[52]

in relation to the need to collect costs incurred by participants. As shown, participants reported that they had incurred a range of costs themselves, particularly in relation to condom ordering, contraception etc. It is worth noting that although the short-term costs below are important to understand, in the longer term these costs could be heavily outweighed by savings associated with preventing STIs and onward transmission.

TABLE 26 Resource use via schools, colleges, universities (reported at 12 months)

Resource use	Cost item	Unit cost (£[a])	*N* intervention group	*N* control group	Total cost–intervention group (£[a])	Total cost–control group (£[a]) (UK £)
Nurse consultation[b]	Per consultation	23.00	1	0	23.00	0
Welfare or support worker consultation	Per consultation	7.67	4	0	30.68	0
Total					53.68	0
Cost per participant					0.56	0

a Costs are presented in UK£ (2021–22).
b Assumes equivalent to GP nurse – 30 minutes.

TABLE 27 Private costs incurred in connection with sexual and reproductive health (reported at 12 months)

Resource use	*N* intervention group	*N* control group	Total cost–intervention group (£[a])[b]	Total cost–control group (£[a])[b]
Condoms	12	25	229.00	415.00
Lube	29	31	326.00	350.50
STI kits	0	2	0	80.00
Contraceptive pill	4	4	105.00	70.00
PEP	0	1	0	10.00
Emergency contraception	6	2	137.50	26.00
Counselling	1	2	620.00	1040.00
Total cost			1417.50	1991.50
Total number of participants who completed M12 follow-up survey	96	97		
Cost per participant			14.77	20.53

a Costs are presented in UK£ (2021–22).
b Costs are based on respondent reported data leading to costs being different across groups even when the level of ordering is the same.

Outcome data collection

As part of the fRCT, a range of outcome measures were successfully collected. This included data on health-related quality of life via the EQ-5D-5L instrument, and the SF-12 instrument. The EQ-5D-5L and SF-12 instruments were administered to inform the economic analysis, as they are preference-based measures and can be used to calculate Quality-Adjusted Life-Years (QALYs). The results are presented in *Table 29*. Completion rates were similar as for the other outcome measures included in the trial (see *Chapter 3*, *Results*, *RO 8*). As the trial was not powered to detect any changes in outcome measures over time or differences between intervention groups, the aim of this component was to explore the feasibility of collecting the health-related quality-of-life outcome measures.

Summary

This element of the study focused on the development and evaluation of processes to capture data on the costs and outcomes that would be necessary to inform the design of a future definitive trial involving an economic evaluation. Processes were successfully established to measure the costs associated with delivering both the intervention and

TABLE 28 Illustrative summary of costs collected

Type of resource use	Total cost – intervention (£[a])	Total cost – Wrapped control (£[a])
Intervention costs		
Website	230.00	115.00
Sample packs	429.12	
Condom carrier	145.39	
Condom-ordering service	791.28	
Total cost	1595.79	115.00
Average cost per participant	13.88	1.00
Resource use costs		
Healthcare service resource use (at 12 months)	28.63	34.67
Other NHS resource use – average costs per participant (reported at 12 months)	34.63	25.29
Resource use via schools, colleges, universities (at 12 months)	0.47	0
Private costs (at 12 months)	12.43	17.47
Average cost per participant	76.16	77.43

a Costs are presented in UK£ (2021–22).

TABLE 29 Health economics outcome measures

Outcome measure	Wrapped intervention *N*[a]	Wrapped intervention – Mean value (SD)	Control *N*[a]	Control mean value (SD)
EQ-5D-5L – Baseline[b]	115	0.784 (0.2)	115	0.768 (0.209)
EQ-5D-5L – Follow-up at 12 months[b]	95	0.779 (0.227)	95	0.758 (0.237)
SF-12 – Baseline (SF-6D)[c]	113	0.681 (0.117)	115	0.678 (0.114)
SF-12 – Follow-up (SF-6D)[c]	95	0.691 (0.128)	95	0.678 (0.109)

a *N* relates to the number of participants who completed this item.
b For the EQ-5D-5L, a value of 1 would indicate full health. EQ-5D-5L data were mapped on to the EQ-5D-3L value set.
c For SF-6D, a value of 1 would indicate full health.

the control. Generally, a range of comprehensive cost data were collected, including the private costs borne by the participants and resource use in other sectors such as education. The findings have implications for the design of a future definitive trial as a broad range of resource use and costs were reported, including private costs (such as for condoms, contraception and testing), which would need to be fully considered. Some difficulties were found with capturing detail on some types of resource use, such as in relation to contraception and other products. Any future definitive trial should include a cost-consequences analysis and ensure that sufficient detail is captured on resource use.

Within the trial, relevant outcome data were collected successfully, including for EQ-5D-5L and SF-12. For a future definitive trial, it would therefore be possible to consider a range of types of economic evaluation. This would include a cost–utility analysis as recommended by NICE,[39,40] and in addition it would be possible to consider the inclusion of a cost-effectiveness analysis involving the main clinical outcomes included in the study. There might also need to be consideration of further outcomes that might be relevant in this context, for example around general well-being.

Chapter 5 Nested qualitative study

Methods

Aim

The aim of the nested qualitative study was to explore participants':

- Experience of trial procedures and materials.
- Views and experiences of the Wrapped intervention.
- Perceptions of whether the intervention changed their condom use beliefs or behaviours.

Design

Qualitative interviews.

Public and patient involvement

The Wrapped PPI group (as described in *Chapter 2*) worked with the research team to draft participant information and consent statements for this qualitative study to ensure they were clear and easy to understand. Two PPI members also piloted the interview schedule and changes were made accordingly.

Study population, setting and recruitment

In response to an item in fRCT M0 survey, 89 participants indicated interest in being interviewed about their views and experiences of the trial. Maximum variation sampling of this group was used to obtain a sample that represented: experience of intervention and control conditions, different levels of engagement with the trial, and varying demographic characteristics (age, gender, ethnicity, sexual identity, level of deprivation). To that end, recruitment proceeded iteratively, with individuals invited in turn to maximise inclusion across these categories. Those who wished to take part were sent a link via e-mail to an online participant information sheet, consent form and booking system. Interviews were conducted in three waves during the fRCT (M3, M6 and M12) to enable experiences across the timeline of the study to be captured.

To gain additional insight into perceptions of how intervention content may have changed condom use beliefs or behaviours, interviewees (referred to hereon in within this chapter as 'primary participants') were asked if a sexual partner(s) could also be invited for interview. Those providing verbal assent (n = 12) were sent an e-mail to forward on to a partner(s) if they wished. E-mail invitations contained a link to an online participant information sheet, consent form, and booking system. No pressure was put on any primary participant to forward this e-mail, and no direct contact made with partners until this step had been completed. Sexual partners who participated are referred to hereon in within this chapter as 'secondary participants'.

Procedure

Thirty interviews with primary participants, and three interviews with secondary participants were conducted between August 2021 and September 2022 using a semistructured interview schedule designed to address the three main aims stated above. Interviews were conducted by telephone and were recorded and transcribed. Primary participant interviews lasted 7–50 minutes (mean 21 minutes), and secondary participant interviews between 2 and 13 minutes (mean 6 minutes).

Analysis

Two researchers (KK and LS) analysed transcripts using Framework analysis.[54] Four interview transcripts were first independently coded by the two researchers and a preliminary analytical framework agreed. Further independent coding of four transcripts by the two researchers, using the initial analytical framework, and subsequent discussions about any codes that did not fit, resulted in an agreed final framework. The final agreed framework was then applied to all transcripts by KK using Nvivo software (indexing, QSR International; 2018). Microsoft Excel (Microsoft; 2023) was used to record illustrative quotes and a summary of the data related to each code of the framework (charting to framework matrix). The final framework consisted of five themes containing 21 sub-themes. Quotations have been selected to illustrate themes. In the presentation of the results, codes follow each quotation to indicate the participant's number and whether each individual was a primary (PP) or secondary (SP) participant.

Results

Participant characteristics

The sample of primary participants consisted of 30 young people aged between 19 and 24 years. Most participants identified as female and of white ethnicity. Half (n = 15) of the participants were in the intervention group. Secondary participants (n = 3) all identified as white males and were between 18 and 28 years old. See *Appendix 6*, *Table 49* for full demographic information.

Presentation of themes

Themes are aligned to each of the three research aims.

Aim 1: participant experience of trial procedures and materials

Theme 1: motivation for involvement in the research

Participants talked about motivational factors that impacted their decision to join the study and continue engaging throughout the 12-month trial period. Most participants were motivated by a combination of factors, but some solely by the monetary reward.

Subtheme 1.1: the role of financial incentive The voucher incentive offered played a role in motivating most participants to take part in the study. This reward however was held with varying degrees of importance. For some participants, it was front and centre of their decision-making. Others viewed this as a bonus, or one of several motivating factors.

> *Probably just the Amazon vouchers, if I'm being completely honest. I probably wouldn't have done it without. So, yeah, that was definitely an incentive.*
>
> *PP24*

> *It sweetens the deal, but I wouldn't say it's the sole reason I'm doing it.*
>
> *PP4*

Another role the vouchers played for some participants was keeping them engaged throughout the whole of the 12-month study period. Some participants felt that without this ongoing recognition, they may have stopped engaging. For others the vouchers were encouragement for timely completion of activities.

> *A lot, to be honest. I could have seen myself only doing one [survey]. But I don't think I would have continued doing it for a year, if it wasn't for those.*
>
> *PP34*

> *To be honest, I would have done that anyway, but I think it kind of – I'd say if it wasn't for them [vouchers], I might have not do them as quick, but that's about it, really.*
>
> *PP39*

Subtheme 1.2: the role of non-financial incentives In most cases, even when financial reward was cited as a driving factor in taking part, participants went on to talk about other motivating factors that played a role. A number of participants cited altruistic reasons for participation, including contributing to research or having a positive impact on sexual health services and support.

> *I just – I thought … I remember my initial thought was that I was really pleased that there was research going on in this area, and that there was a study that I could be a part of that could potentially help in any way, like sexual health for anyone else.*
>
> *PP7*

Other participants recognised that the study could directly benefit their own sexual health, through an increased focus on this over the period of the study.

> *I think a part of it, was getting repeat tests being sent, without having me to almost remember.*
>
> *PP36*

Other participants just thought the research looked interesting and appealed to them. These participants sometimes went on to say that they had a general interest in research.

> *I'm quite interested in sexual health, really, actually, and I just think it's really interesting.*
>
> *PP6*

BOX 1 Summary of Theme 1

Summary of Theme 1: motivation for involvement in the research

- The vouchers played an important role in recruiting and retaining participants for the duration of the 12-month trial.
- Other factors, such as altruism, were also important motivators for many.

Theme 2: participant experience of research materials and procedures

Subtheme 2.1: process of joining the study straightforward and as expected Participants recalled the process of joining the study as easy, quick and straightforward. They talked about how the process felt 'normal' and as expected for a research study. Some participants expressed that the level of detail provided at sign-up resulted in a reduced effort for them (e.g. not having to search for additional information), which had a positive impact on their experience. Other participants did not specifically remember the details of joining the study and then attributed this to the process presumably having been straightforward.

> *It was really easy. It was literally just filling out my information, and I think it had the terms and conditions, and reading through there, saying what they're going to do with my information. And then I think it went pretty much straight to a survey. It was really easy.*
>
> *PP35*

> *And there was everything there that I needed, so I didn't have to, like, think about it much.*
>
> *PP13*

> *It must've been pretty quick, or at least not too long, because I wouldn't have bothered if it took up too much time.*
>
> *PP52*

Most of the participants talked broadly about the process of study sign-up, but of those that talked more specifically about the materials, such as the information sheet and consent form, positive feedback was given about the content being clear and easy to understand. Some felt the level of detail added an element of trust in the research.

> *I remember it being really straightforward and everything was clear and made sense.*
>
> *PP7*

> *The consent form, and I think that it detailed how my information would be used, and stuff like that. It was very detailed, which I was kind of like, if it was a scam, it's not going to be that detailed.*
>
> *PP16*

When reflecting on their thoughts about the advertising of the study, some participants were unable to recall much detail. Of those who could, the advert was deemed appealing and detailed enough to pique their interest, with some participants particularly recalling the mention of an incentive and a call for people of their age. One participant felt that the advert could have been more prominent and included more detail what the study was about.

> *I just remember – yeah, I just remember it was about sexual health and learning more about sexual health within our age group.*
>
> *PP35*

> *I just think I just remembered seeing, oh, your test has been sent to you and, by the way, do you want to become part of this? And I just kind of like – it was quite … It wasn't obvious. I think maybe mention a bit more about what it was, because I didn't realise what it was about, really, until I clicked through.*
>
> *PP6*

Subtheme 2.2: experience of completing the online surveys Most of the comments about the online surveys were positive, specifically in relation to the ease of completion. Most commented that the language used, and the instructional information provided, made everything clear and that this resulted in reduced participant burden. Some attributed the ease of completing the questions to a significant proportion being multiple choice, with a good variety of responses that represented all possible answers. One participant however indicated that the wording of some of the questions may have been too complex.

> *The language used was quite basic, which is useful. So you always know what the question was asking.*
>
> *PP16*

> *I remember there was quite a lot of questions, and there was a lot of options to answer. So you could literally answer how you feel, because there would have been a sentence that would have matched someone.*
>
> *PP20*

> *Not really. I think sometimes if you overthought the questions, like I did at first, and trying to figure out what they meant, was quite difficult.*
>
> *PP48*

The participants mostly described the surveys as the right length, reasonably quick to complete, laid out clearly, and easy to navigate. In some cases, participants described the experience of completing the surveys as interesting and enjoyable. It was mentioned a few times that the questions and surveys at different time points felt a little repetitive, but in most cases, these participants expressed an understanding and appreciation for the reason behind this.

> *It was fairly quick. It wasn't too time-consuming, so I think it was a good amount, a good length of time.*
>
> *PP23*

> *No, not at all. Yeah, it was really easy to use, and I remember the interface being really good.*
>
> *PP7*

> *In some ways, it felt a little bit repetitive. But then I also noticed a change in my answers, as I participated in the study, which was quite interesting to see.*
>
> *PP48*

When commenting more specifically on the content of the surveys, there was a general feeling that the questions were quite personal, but no concern was expressed about answering them. In fact, in some cases, participants described understanding the importance of these questions.

> *Some of the questions, obviously they are a little bit personal, but I think that's good, and it helps make you think about everything.*
>
> *PP16*

> *I feel like it started making me think a little bit, going, oh, it makes you think about yourself and what you could do yourself as well. It puts a light onto it, because I don't think it's talked about enough.*
>
> *PP23*

Also see the 're-evaluating sexual health' subtheme within *Report Supplementary Material 12* for related findings.

Subtheme 2.3: experience of chlamydia self-sampling kits The arrival of the M3 and M12 chlamydia self-sampling kit in the post was mostly expected but in a few cases was not. This was usually due to participants not recalling receiving the automated SMS notification (note: our logs show that all SMS notifications were successfully sent). Regardless, when the package did arrive, it was considered discreet enough that no one else would know the contents of the package, which was important for participants' privacy.

> *I remember, it just came through the door, and I'm bit like, what's this? And I was like, oh, I remember!*
>
> *PP16*

> *When they come, they're small and they're discreet, so that's fine.*
>
> *PP45*

The self-sampling kits felt familiar to participants, with the exception that they were testing for a single STI, which for some was at odds with the kits they had received previously from the same provider. The kits used were gender-neutral, thus containing materials required to take a urine sample or vaginal swab. Some participants liked this element of choice but others felt this was wasteful.

> *I feel like it was interesting to me, because obviously I normally order four-in-one kit. So having a test which just focuses on one thing alone, was a little bit strange, because it's not usually what I get. But considering I have used the four-in-one kits before, it was nothing unusual, nothing out of place.*
>
> *PP15*

> *And then I remember that there were both the options to give a urine sample, or to do a vaginal swab. I think that you had the option – although there was also a side of me that was like, oh, I just … It was like, oh, it's a bit wasteful.*
>
> *PP7*

Participants appreciated the handwritten note signed by one of the research team put within the test kit that indicated that the test kit was part of the research study.

> *I remember receiving – I really liked the personal touch of that little card that comes with it, and then you guys writing your name as well, that, for me, it was like a nice personal touch to it all. So it feels quite human, and it's not just computer-generated kind of thing.*
>
> *PP23*

Also see 'feeling valued' within *Report Supplementary Material 12* for related findings.

The process of completing the test was described as easy. This was attributed both to existing familiarity with self-sampling kits and to the instructional information provided. Returning the kits was also perceived as straight forward, and participants appreciated not having to self-report the results to the research team.

It's all very smooth. The test kit coming out to me, it was in a black bag, a handwritten address label, so you couldn't tell at all what was in it. Doing the test kits, very self-explanatory, very clear, and then simply returning it was really easy, and just putting it in a post box.

PP48

I think it was easy, in the sense that I didn't have to submit my results to you guys, because you guys already had the results submitted, when I did the test.

PP23

BOX 2 Summary of Theme 2

Summary of Theme 2: participant experience of research materials and procedures

- Joining the study was a smooth and straightforward process for participants.
- The study advert, although sufficient, could be more prominent and pithier.
- Participants found the surveys easy to use and understand, and quick to complete. Moreover, participants appreciated the way they were set up to reduce participant burden.
- In general, the test kits felt familiar and were easy to complete and return.

Theme 3: research communications engaging and of appropriate frequency

Subtheme 3.1: frequency of communications All participants were positive about the communications (e-mails, SMS text messages and phone calls) they received during the study. Most commented on the frequency being appropriate which allowed them to feel in the loop without being overwhelmed. Often communication was perceived as well-timed, acting as a valuable reminder to complete research activities.

I'd say that it was the right amount, and it was perfect. Anymore, I probably would have got a bit worried about, but any less I wouldn't have been included, if that makes sense?

PP16

Yeah, it was great. I mean, there's been a lot of times where I forgot to do something, or something slips my mind. I had an email, I had a text message reminding me, or even a phone call to see if I'm okay, if I'm still happy to go on with the research. Yeah, so there was a lot of communication between yourselves and I, so, yeah, I was really happy with it.

PP20

Subtheme 3.2: mode of delivery of communications There were mixed views about preferred mode of delivery used to communicate with participants. Some participants' personal preference was text message, with the reasoning being that this was more prominent (less likely to be missed). Others however preferred e-mails because they felt that these were more private or hidden, which was perceived as important given the topic of the study.

Probably the text message was the one that I seen first, because you're always on your phone, aren't you? And then emails, obviously, I check my emails as well because I'm a student now, so I study, but text messages were probably the things that I would catch straightaway.

PP20

I don't mind on the email, because I feel like emails are quite hidden, like, nobody gets onto your emails, so I don't mind it on the email. When we get test results by text, I don't particularly like it.

PP45

Subtheme 3.3: content and style communications Participants felt the content of the communications was concise and clear. Furthermore, it was perceived as sufficiently detailed to be informative while also discreet. This allowed for participants to easily engage with the communications. A few participants described the communications as professional and liked the inclusion of personalisation.

Short and concise. They gave you the information that you needed, yeah.

PP36

So you can feel the professionalism in it.

PP7

Yeah. Yeah, it's just been like, all been really nice and personalised as well, which was quite nice.

PP4

Participants understood and enjoyed the digital nature of the study but also appreciated the personal touches applied to communications. This made participants feel connected to the research team. Participants also spoke about how the research team felt approachable and how they liked that the same three researcher names were included in the communications. There were however some participants who were unsure about how they could contact the research team.

I know it sounds really silly as well, but I like how, at the end, like the emails or whatever communication it is, it's signed off your names. It adds that little bit of a personal touch, it just adds that little bit more that you are being listened to, so you just don't end up thinking, oh, I'm just part of the … I'm just a number in a study.

PP16

Really good. It's easy to contact them.

PP21

I really liked the personal touch of that little card that comes with it, and then you guys writing your name as well, that, for me, it was like a nice personal touch to it all. So it feels quite human, and it's not just computer-generated kind of thing. So I really like the personal touches that was through it, and it was like, oh, you kind of remember who we are.

PP23

Also see 'feeling valued' within *Report Supplementary Material 12* for related findings.

BOX 3 Summary of Theme 3

Summary of Theme 3: research communications engaging and of appropriate frequency

- Communications felt balanced in quantity and well thought out.
- Participants had varying views on the preferred mode of delivery, some liking the privacy that e-mails afforded, and others liking the prominence and immediacy of text messages.
- Participants were happy with the style and content of communications. The human touches stood out and made participants feel connected to the research team despite the study being predominantly digital.

Aim 2: participant views and experiences of the intervention

Theme 4: wrapped intervention website

Subtheme 4.1: reflections on accessing and using the Wrapped website Eleven of the 15 participants in this qualitative study that were assigned to the intervention condition accessed the Wrapped website. These individuals reported finding the process of registration straightforward. Those who did not access the website reported time as a barrier to access. Some also didn't remember receiving an invite (which was sent via e-mail) with the suggestion of sending the link via text message instead in the future.

So I honestly must have just not completely read through it. Yeah, if I had, I probably would have gone on to the website.

PP20

All the participants described the website as easy to navigate and found the process of ordering products smooth. Most participants liked the appearance of the website, stating that it was simple, smart and not medicalised in feel. Two participants, however, felt the design could have been more exciting.

> *I really liked it, and it was really simple to use. I liked how it wasn't overloaded with information, and the information you wanted to find was quite simple. I liked the little icons and the style of it all, and that was really nice as well.*
>
> *PP23*

> *It's quite neutral colours and quite friendly. It's not like boring, this is medical. If you go on the NHS website kind of thing, it's all like blue and medical and that kind of thing. Whereas it was a bit more friendly, and stuff.*
>
> *PP6*

> *Honestly it's nothing special but it works. It's simple and easy to navigate.*
>
> *PP52*

Subtheme 4.2: views of the intervention components ***Condom sample pack*** The sample pack was ordered by most of the participants who accessed the website (8 out of 11). Participants were pleased with the content, some expressing that the amount and variety of condoms included was more than they expected. The choice of condoms was also viewed as better than the usual free condoms offered elsewhere and thoughtful in the fact that they were all affordable and easily accessible for future purchase.

> *It was quite good, actually, and I was actually quite surprised. I was expecting a few, and not … About one or two or three maybe, but not the variety that actually comes with it.*
>
> *PP13*

> *I like how it was that was the range that was given, and it's easily accessible, and it's not super exclusive.*
>
> *PP23*

The tailoring element of the product (choosing colour of condom box and pattern of insert) was liked and appreciated by many, but ultimately wasn't viewed as a deciding factor in ordering the pack. The information leaflet provided in the pack was viewed mostly as a refresher, one participant stated that they found it informative, but often participants felt this could benefit others more.

> *I think not necessarily learning things new, but it's more refreshing old stuff.*
>
> *PP15*

Monthly condom-ordering service The condom-ordering service was used by 9 of the 11 participants who accessed the website (all of whom were assigned this component), and in most cases more than once. The component was well liked, and one participant described it as feeling private and secure. The information provided about each condom was appreciated, and the variety of condoms and lubes available was again acknowledged and valued.

> *It was pretty good, I can't fault it for a free service.*
>
> *PP52*

> *So it's absolutely amazing the fact that there's such a selection as well. And, yeah, tried both the lubes as well and it's just great products there, so why would we not use them?*
>
> *PP16*

> *Well, it's more private and secure [than in-person settings].*
>
> *PP13*

> *I guess some people are a bit, I don't know, iffy about buying them themselves, I don't know. So I just thought, oh, actually, it's kind of like a private way of getting this stuff, I thought from that side of it, it was quite cool.*
>
> *SP10*

Condom carrier The condom carrier had mixed reviews. Of those who were offered and ordered the carrier (8 out of 10), half were pleased with the product. They reported that the quality and style were good, and they appreciated its discreet nature, and multi-purpose function. Other participants, while thinking the idea was good, felt less positive about the quality and the usefulness of the product, and as a result didn't use it.

> *So it was like discreet, and I could just have it around with me. And it's also really useful, and I use it to store my cards in and everything like that, so it's useful just to have it in there.*
>
> *PP23*

> *I wasn't a massive fan, to be honest. I just put it straight in the drawer and haven't used it. I know it's supposed to be inconspicuous, but it's a bit boring. I thought it would draw more attention to itself, and it was just not the most attractive thing to look at.*
>
> *PP6*

Video components Of the 10 participants who accessed the intervention and had been assigned the video components, half told us that they didn't engage with them. Some stated they were unaware of the videos and others chose not to watch them because of preconceptions that they would be 'cheesy' or irrelevant, mainly due to the name or description of the content.

> *Other than potentially bad acting and second-hand embarrassment not really – but I imagine they would be useful for someone less informed about sex.*
>
> *PP52*

Of the participants interviewed who did watch the 'condom demonstration' and 'discussing condoms' videos, one felt they were too long, but two participants felt the length was fine. They all liked the idea of video content and preferred this to purely written content. They also found the content to be well written, enjoyable and relatable.

> *It was very well thought out and scripted, and you could tell that everyone was trying to be as honest as they could … about everything. And it was almost similar to a conversation I would have with my friends.*
>
> *PP4*

Two of the participants did however comment that they felt the content was aimed at a younger, less experienced audience.

> *Potentially, I think it's slightly aimed at younger people, but, yeah, I thought it was really interesting. And, yeah, I would quite like my sister, for example, who is a few years younger than me, to have seen that, growing up.*
>
> *PP6 – aged 24*

Only one participant remembered watching the 'real-life' videos. They recalled finding these interesting, educational and relatable.

> *But it was definitely something I looked through, because I was like, oh, this is really interesting. And it's not – it was real people, and it's not porn and it's more for actual educational purposes, and I quite liked that. It wasn't awkward, like watching the videos you watched in school, where you cringe a bit, because your teacher is there, and it just … Yeah, I felt comfortable to watch them.*
>
> *PP23*

> *Yeah, I definitely think I could, because it was like, well, they're just normal people. They're not people you think that are in porn, and they're like naked, unrealistic and stuff. And the fact that it's just kind of this could be an actual real-life situation, instead of the weird fantasies that I don't really understand.*
>
> *PP23*

The remaining participants either reported that they had not watched the 'real-life' videos or could not remember if they had.

BOX 4 Summary of Theme 4

Summary of Theme 4: wrapped intervention website

- The Wrapped website was viewed as simple, smart, and easy to access and use.
- The free condom products were viewed positively, with comments focused on the amount, and variety of condoms provided.
- The condom carrier received mixed reviews but was generally viewed as discreet.
- The videos were perceived to be more relevant and useful to younger age groups; as a result, access was low.

Aim 3: participant perceptions of whether the intervention changed their condom use, beliefs or behaviours

Theme 5: addressing condom beliefs, removing barriers and facilitating condom use

Participants who had received the Wrapped intervention largely said that it had positively altered their condom related beliefs and/or behaviour.

Subtheme 5.1: condom beliefs Some participants already had positive views about condoms, and as such their views remained the same. One common theme was the increase of knowledge and awareness of condom variety attributed to the sample pack provided, and a move away from the belief that all condoms are the same. Furthermore, some participants said that their preconceived notion that condoms provided for free are poor quality had been shifted.

> *Yes, it was one of those, I just thought it's a condom. How can there be like 25 more different varieties of them? But there is!*
>
> *PP15*

> *So, no, I've never been a fan [of condoms], but, obviously, you know the thin feel and stuff like that, it's, I don't know, made me more aware that it's not just one glove-like fit. There's so many different ones.*
>
> *PP13*

> *I don't know why, but I've just, in the past, always just assumed that condoms that you get for free aren't good quality, that unless you pay for the quality of condoms.*
>
> *PP7*

For many, the sample pack provided a unique opportunity to explore the variety of condoms without the associated barrier of cost. This allowed them to find a condom that suited them. These positive views were also reported to have had an impact on condom use.

> *I think it has, and it's opened my eyes to go, there's lots of different condoms out there, and maybe they might have helped me feel different, or them feel different. And it just – it kind of made me feel like it's okay to explore. It's a good, safe practicing thing that shouldn't make the experience any worse, or make it in a bad way. So it's just finding the right one that will be useful.*
>
> *PP23*

> *It was very good, and it had a nice variety, and it allowed you to figure out which ones would be more beneficial to you.*
>
> *PP13*

> *Yeah, definitely, knowing that there's more different sizes and shapes. I think men are liars now. Yeah, definitely! It definitely has changed my outlook on using condoms, so it's something that I'm always going to want to use now. It makes me want to use them, if anything, because I've never really been the type of person to use condoms, but now I'm definitely going to give them a try.*
>
> *PP8*

But for a couple of participants, the intervention wasn't enough for them to change their views about condoms.

> *I: And did they change your views on condoms?*
> *R: No, not really.*
>
> *PP41*

Subtheme 5.2: condom availability The sample pack, and the subsequent opportunity to order condoms via the monthly ordering service, facilitated condom use by providing an online service that was viewed as private and removed the barrier of embarrassment associated with getting condoms in-person. This meant they had condoms readily available.

> *Well, before when I've – I used to have a c:card, and you would have to go into the pharmacy, and I used to find that quite awkward. Yeah, so having them delivered to your door is a lot easier.*
>
> *PP8*

> *Just because it's that kind of embarrassment and going, oh, no, which one do I get?*
>
> *PP23*

Subtheme 5.3: carrying condoms The condom carrier was not ordered by everyone who was allocated it (eight out of ten). Of those that did order, a few (all female) made comments about the intervention having empowered them to carry condoms and providing them with a way of doing this discreetly.

> *I just thought it was a really good idea to have them on you easily. Most of the time, it's not really subtle to have condoms on you, is it? Everyone knows what the package looks like, so if you have it in a little purse-looking thing, I was like that's a really good idea to be able to carry around normally, and not be worried that someone's going to see it.*
>
> *PP35*

> *And it's also very silly, but it's just like, as a woman, just carrying around and I was like, oh, yeah, nice. I've got a little thingamy bag now, so I can carry it around.*
>
> *PP16*

Subtheme 5.4: discussing condoms with sexual partners All participants who accessed the intervention and were assigned the discussing condoms content reported a positive impact on their confidence around this behaviour. Some expressed that they were already confident but that the intervention reinforced their position in condom discussions and further supported them to continue saying no to condomless sex. In one case, this was identified as specifically relevant when experiencing resistance from a partner to use condoms.

> *They [partners] always try to, like not use it, but then I just threaten them with like, well, I'm not going to do it then. [I feel] more confident to like to persuade the person to [use condoms now].*
>
> *PP4*

Other participants explicitly reported that they felt more confident initiating or holding discussion about condom use than they did before. One participant specifically stated that they felt the videos had provided phrases to use that would facilitate future condom use and another commented that the intervention had led them to reframe condom use as something that they would be less 'discussing', more 'insisting' on in the future.

I'm more comfortable talking about it, probably.

PP41

Yeah, I'm more confident in discussing it now. Well, it's like not really discussing it, and I'm like, right, but it's allowed me to think, right, I'm going to, because that's what I want to do. But also I'm not afraid to actually bring it up, and discuss what I want to.

PP13

Maybe a little bit, and I think there were some good lines in there that were, like, oh, actually, they'd be good lines to steal, to use in the future.

PP6

I definitely feel like it made me feel more okay to go, this is what I want.

PP23

Subtheme 5.5: condom-use behaviour When participants assigned the Wrapped intervention were explicitly asked whether it had had an impact on their condom use, while some said that they already use condoms, others said they now use them (when they did not previously) or used them more often. A minority reported that they continued to not use them.

I definitely use them a lot more frequently than I ever had in the past, and they've made me a lot more aware to have them on hand.

PP48

Yeah, I've definitely tried to use them more often.

PP35

I would say I'm 95 per cent sure those [condoms] that have been used have been part of the study.

SP10

BOX 5 Summary of Theme 5

Summary of Theme 5: addressing condom beliefs, removing barriers and facilitating condom use

- Participants reported that Wrapped increased their awareness of the variety of condoms. This appeared to facilitate a change in condom belief and/or behaviours.
- Wrapped increased the availability and access to condoms for participants, directly addressing barriers around embarrassment and cost.
- Most participants reported an increase in confidence related to discussing condoms and for some this directly impacted their condom-use behaviour.
- The condom carrier reduced barriers related to carrying condoms, such as embarrassment and taboo associated with females carrying condoms.
- Some participants reported an increase in their use of condoms as a result of engaging with Wrapped.

Additional findings

Findings that did not directly answer any one of the three aims outlined above but were thought to provide valuable insight into other related issues concerning participation and sexual health, are included in *Report Supplementary Material 12*. Themes include feelings about the research and the research team; the control website being informative but not persuasive; and wider impact of the research study.

Qualitative comments from month 12 survey

At the end of the M12 survey, participants were invited to provide written comments ('good or bad') about participating in the study or about the surveys. These qualitative data add further process evaluation data to the qualitative interviews. A total of 45 participants (23.4%) responded to this item. Almost half of responses included reference to participation as enjoyable. Typical comments included 'It's a really interesting study and I'm happy to be part of it!' and 'I've enjoyed taking part in this project'. Participants also expressed keenness to hear the results and to learn of any future opportunities to take part in research. Responses conveyed finding the research team supportive and friendly and the ease of taking part, for example 'Really great help and support if needed. Easily understood all parts of it' and 'The study was run by a super supportive team who were always quick to help with any issues. Thanks guys!'. Several participants detailed that they had experienced a change in their condom-use beliefs and behaviours because of participation, including an increase in knowledge, confidence and use, such as 'Made me much more comfortable wearing condoms' and 'Positive impact. Made me more aware of condom usage & found a condom both my partner and I enjoy'. Comments also reinforced recruitment and retention strategy decisions, such as 'Great communication in regards to sending emails, calls, and voicemails. Enough time was given to complete particular tasks and reminders were sent after a reasonable period of time. The reminders were not overbearing or continually sent'. None of the comments received were negative but a few participants offered constructive suggestions for improvements to the study, such as the addition of a back button on the surveys, adding additional survey items (to measure contraceptive use) or clarifying existing items, and wanting to be able to allow friends to take part in the research so they could benefit from it as well. One participant reported, 'Taking part in the research while in a relationship made me feel uncomfortable but my partner was understanding'.

Chapter 6 Potential pathways for the implementation of Wrapped

Introduction

This section aims to consider the potential pathways for the implementation of Wrapped if it were found to be effective and cost-effective in a definitive future trial. The development of this analysis involved 11 discussions with 19 organisations and local decision-makers involved in the delivery and commissioning of web-based STI-testing services. The aim of these discussions was to explore the views of decision-makers about how Wrapped might complement existing services and their perspectives on the likely barriers and opportunities for implementation.

This chapter draws on these discussions, and analysis of a range of documentation and evidence, to consider the potential constraints and opportunities that would need to be considered as part of planning for the future potential implementation of Wrapped. We also consider how the implementation of Wrapped could support existing policy priorities and help local areas achieve their commitments and aims around improving sexual health.

Assessment of sexual health landscape

Commissioning arrangements

The commissioning and provision of sexual health services in England is complex. Commissioners with responsibility for sexual health within local authorities have responsibility for procuring services for the management of HIV and reproductive services as well as other STIs.[55] Specifically, they are responsible for:

- Comprehensive sexual health services including most contraceptive services and all prescribing costs (but excluding GP provided contraception).
- STI testing and treatment, chlamydia screening and HIV testing.
- Specialist services, including young people's sexual health, teenage pregnancy services, outreach, HIV prevention, sexual health promotion, and services in schools, colleges and pharmacies.

Other aspects of sexual health care, including but not limited to abortion services, sterilisation, cervical screening and sexual assault referral centres (SARCs), are commissioned by either NHS England or Integrated Care Systems (ICSs).[55]

The exact nature of service procurement for which local authorities are responsible varies considerably in different local authority regions and may be affected by historical collaborative relationships, the set-up of local NHS trusts, the type of authority in place (e.g. unitary vs. two-tier), the make-up of the geographical area, and its population and their needs. Many local authorities operate 'block contracts' where they procure a single provider, often an NHS trust, to deliver all the required activities and they in-turn, may sub-contract other organisations to provide the full range of services. Alternatively, the authority may operate several contracts with different providers but expect collaboration as necessary to provide effective care.

Two specific indicators for sexual health are a focus of any local authority sexual health commissioning specification. These are reductions in under 18 conceptions and chlamydia diagnoses in the 15- to 24-year-old age group.[56] In order to address these outcomes, services are mandated to provide open access care to everyone within their local population, and they may also provide targeted or specialist support for at-risk subgroups to best meet local need. They must also provide free STI testing and treatment and partner notification.[57] While they are not mandated to provide outreach, youth services, condom distribution, or health promotion, it is highly recommended that there is provision of this type of activity as part of a preventive approach.[57] Effective prevention can help reduce the incidence of STIs and unintended pregnancy and reduce burden on and costs of services. Commissioners therefore typically include a requirement for outreach, health promotion and prevention work, including condom distribution and specialist services

for young people, within their service specifications and include a requirement to report against key performance indicators (KPIs) related to these activities.

More recently, ICSs have been established in England to bring together healthcare providers and commissioners, alongside local authorities and other local partners. ICSs will plan, coordinate and commission health and care services for defined geographical areas.[58] The Health and Care Bill in 2022 represented a move away from a focus on competition, with an emphasis on collaboration between commissioners, providers and other partners to meet the needs of people in the local area. It is still too early to assess what the implications of the creation of ICSs will be for the immediate challenges facing sexual and reproductive health services.[59]

The Faculty of Sexual and Reproductive Healthcare and the British Association for Sexual Health and HIV are the leading professional organisations dealing with all aspects of reproductive and sexual health care. Both organisations have produced relevant and informative guidance documents and standards of care related to web-based STI testing, condom distribution, outreach and health promotion. Any future implementation of Wrapped would need to work in partnership with these and other organisations to ensure alignment with guidance and standards.

Funding challenges and technological change

There have been overall reductions in funding for sexual health in recent years, with estimates suggesting that local authority spending on sexual health decreased by 14% between 2013–4 and 2017–8 (from £668 to £572 million).[60] At the same time, rates of STI screening have increased.[1] These decreases in funding and increasing demand have led to growing pressures on sexual and reproductive health services,[61] and there is a need for local partners to work together to develop joined up, coordinated and collaborative approaches for sexual and reproductive health systems.[62] This would allow a focus on achieving better outcomes, reducing inequalities, and ensuring more efficient use of resources across the sexual and reproductive health system as a whole. ICSs, with their responsibilities to plan and deliver joined up approaches to service delivery, would seem well-placed to play a role in such developments.

Alongside such funding pressures, sexual and reproductive health services have experienced rapid technological changes.[63] These include the introduction of web-based STI testing and remote consultations. Digital sexual health interventions have also been implemented for a range of other purposes including partner notification and care pathways.[64] In addition, there has been expanded provision of sexual and reproductive health services in a greater range of settings such as pharmacies and community settings.[62] There are calls for a greater focus on how services can be provided in ways that are more sustainable and equitable, embracing the potential of digital health to improve and increase access to screening, testing and care.

Assessment of health systems into which Wrapped could be implemented

As sexual and reproductive health systems vary considerably in England, there are a range of possible options for how Wrapped could be implemented in the future, if a definitive trial demonstrated effectiveness and cost-effectiveness. As part of this feasibility study, it was therefore important to assess and evaluate different strategies and opportunities for embedding the Wrapped intervention within these systems.

The provision of web-based STI testing is recommended within English national commissioning guidance.[65] A range of models are currently established, with a rapid expansion in web-based STI testing particularly evident since the COVID-19 pandemic.[66] The involvement of commercial partners in web-based STI-testing delivery is varied. In some areas, commercial partners are contracted to provide all aspects of these services and follow-up, whereas in others they provide only certain aspects of delivery. For example, commercial partners may provide the website, ordering and distribution of STI self-sampling kits, laboratory services and triage, while local sexual health clinics provide clinical care and follow-up.[67] Such services may be commissioned by an individual local authority, or by a group of local authorities who form a consortium (e.g. London's SHL service).[68] In contrast, in some areas a local NHS Trust may provide all aspects of web-based STI testing and follow-up 'in-house'.[69] There are also a number of other approaches, determined by local population needs, historical patterns of provision and contracting arrangements.

Condom distribution schemes are also varied, with some schemes delivered directly by local authorities, and some commissioned out to sexual and reproductive health service providers, who may themselves partner with other organisations.[70] All of the local commissioners we spoke to had a 'C-card' scheme in place whereby young people could register for free condoms and lube which could be collected from range of in-person services such as pharmacies and youth centres. We are however aware of some existing and planned services offering condoms and lube through online registration/ordering and postal delivery. These include for example established schemes operated by Solent NHS trust and the Royal Borough of Greenwich, and a scheme currently undergoing tender which was jointly put forward by Devon county council and Torbay council. Planning for the future implementation of Wrapped would need to consider alignment with different models of web-based STI-testing provision and existing online and walk-in condom distribution schemes.

There are two main routes for the future implementation of Wrapped. Firstly, the service could be hosted and delivered by one or more of the commercial web-based STI-testing providers operating across England. Secondly, for local authority areas managing their own STI self-sampling services 'in-house', the intervention could additionally be devolved to the provider in that local area. It is anticipated that both sets of providers would have responsibility for website maintenance, resolving technical issues, and fulfilling orders, and would need to have the expertise/resources available to manage and maintain the intervention. It would be recommended that the academic team be retained (via sub-contract) to review and update the content on a regular basis. There could be scope for local variation and branding to match other services in the local area via either route (commercial providers are able to tailor the services they offer according to commissioner requirements). Each route has its own strengths and limitations. The first approach would allow dedicated technical expertise and development, and efficiencies associated with purchasing supplies at greater scale. In contrast, a devolved approach might allow greater flexibility and tailoring to needs and preferences of local areas. Partnering with one of the main commercial web-based STI-testing providers would allow Wrapped to be implemented in many areas simultaneously, as part of existing commissioned services. However, this would need to be balanced around commercial interests and considerations which might prevent the intervention being available in areas where web-based STI-testing services are maintained 'in-house' within the NHS.

Our conversations with the two largest providers of web-based STI self-sampling have demonstrated that there is interest in delivering greater support to users around condom use and recognition that what is currently offered could be improved. Both have begun providing condom distribution (online order and postal delivery), bundled up with the ordering of self-sampling kits, to users in a small number of areas (two and one local authority areas respectively for each provider). Both noted that while demand for this service was high among young people, commissioners despite recognising its value and benefits, often reported being unable to procure this within their current funding envelopes. There was a strong sense from one of the providers however that this picture was changing as local areas continually strived to achieve cost efficiencies (see *Assessment of sexual health landscape*). This could include for example, local areas looking to move all or some of their existing in-person condom distribution services online.

One of the two providers we spoke to felt that Wrapped was inconsistent with the 'tone of voice' conveyed through their own service and would want to see some changes made prior to any future implementation. This underlines the importance of ongoing stakeholder involvement as interventions move to implementation, and the routes to market and thereby key influencers, become more defined. Prior to any future trial, further stakeholder engagement would therefore be required to create a version of Wrapped which balances the needs and wishes of end users and potential commissioners, without compromising its theoretical basis.

We conducted a range of discussions with commissioners and providers in local areas. All those consulted felt that there should be some flexibility in the overall approach to implementation, as the commissioning landscape has evolved and is likely to undergo further change. For those who provided web-based STI-testing services 'in-house' in the local NHS, there was a suggestion that services would need be tailored for the local context and aligned to existing services. For those who partnered with commercial organisations, there was a perception that an enhanced offering to include sexual health promotion and outreach alongside condom distribution would be of interest, however, pressures on budgets would need to be borne in mind (see below), and there would need to be clarity about the added benefit of the enhanced offering compared to standard web-based STI-testing services.

Barriers and facilitators of scale-up

Discussions with providers and commissioners revealed that there are a range of barriers and facilitators to be considered for future implementation of Wrapped. A key factor was funding pressures and the reductions in spending on sexual health in recent years. There was a general perception that the costs and benefits of Wrapped would need to be carefully analysed and articulated, given the challenges associated with finding or reallocating resources for new services and interventions, and the intense pressures on local sexual and reproductive health budgets. There were also perceived challenges associated with the complexity of local commissioning arrangements, which would require a range of partners to be involved in any decision-making, and varied priorities would need to be considered and addressed.

There were some facilitators that were evident in these discussions. In particular, since the COVID-19 pandemic, there was an increasing recognition of the need and potential offered by digital services. In addition, there was an appreciation that STI rates were continuing to increase in many areas, and hence new approaches to information provision and sexual health promotion were needed. There was also a recognition that since the pandemic the importance of tackling health inequalities had been highlighted, and this was seen as important as STIs disproportionately affect marginalised groups. Hence, in terms of a future trial, commissioners and providers not only wanted outcome data concerning the effectiveness of Wrapped in reducing STI rates overall, but also clear data about its effects on underserved groups, and those who experienced reinfection.

Summary

Funding pressures on sexual health budgets mean that commissioners are increasingly looking to ways to reduce their costs while still meeting service requirements. These requirements include STI testing and treatment, and many areas are now commissioning third parties to provide web-based STI testing. Other areas have their own 'in-house' operations. While local authorities are not mandated to have STI prevention programmes in place (e.g. health promotion, condom distribution), this is recommended and there is recognition from commissioners that this could help to reduce burden on and costs of services. Many areas have in-person C-card schemes in place for condom distribution and there are a small number of areas that supplement this with online condom ordering and postal delivery. Web-based STI-testing providers are also beginning to offer this to commissioners as an add-on service, allowing service users to request a bundle of condoms at the same time as ordering a STI self-sampling kit.

Wrapped could be implemented as an add-on module offered by one or both of the two major web-based STI-testing providers. This could be offered in addition to their current condom distribution module or alongside it. As condom distribution is new for both organisations, the service is not yet established and there is scope and flexibility to adapt. Both organisations have shown an interest in Wrapped, albeit for one of these, some changes to the intervention would be required before they would consider offering it as an add-on service. For local authorities who have commissioned their own 'in-house' provision of STI web-based testing, Wrapped could be implemented directly within their existing web-based service. Commissioners (of third-party providers and those with in-house operations) have shown interest in Wrapped and have provided us with valuable information about what data they would need from a future trial to help them decide whether Wrapped is effective (including for underserved groups) and should be made available for users in their local area. The major barrier to implementation of Wrapped for all commissioners is cost. However, the increasing movement towards digitisation of services to help reduce costs, which could include moving condom distribution online, may free up some budgets to support the implementation of Wrapped. We would argue that while improving access to condoms through online distribution is important, the effective targeting of other determinants of condom use (such as increasing behavioural capability and self-efficacy for putting on condoms correctly) is necessary for behaviour change.

Chapter 7 Discussion

We developed a recruitment and retention strategy with young people and then tested this in a fRCT to see if it would be possible to conduct a future definitive trial of Wrapped (a digital intervention to increase condom use among users of web-based STI testing aged 16–24 years). This study demonstrates the feasibility of delivering the Wrapped intervention and of conducting the full trial. Furthermore, our nested qualitative study and implementation assessment showed that the intervention was acceptable and positively impacted condom-use beliefs and behaviours. Our independent DMEC and SSC recommended progression to full trial.

Recruitment and retention strategy

Strategies behind successful trial recruitment and retention are not well evidenced.[71] Planning for recruitment and retention which involves consultation with key stakeholders maximises the potential for success.[72] In preparation for a fRCT of Wrapped, we co-developed a comprehensive recruitment and retention strategy with a PPI group representing our target sample.[18] Using evidence from a rapid review of strategies utilised in trials of digital interventions, and from focus groups with young people, a detailed plan was developed through iterative rounds of strategy refinement and voting by the PPI group. The resulting plan included six study adverts highlighting different value propositions; an agreed schedule for voucher payments which increased in value with study duration; agreement on the modes and frequency of messaging for invites and reminders; and selected strategies to maintain participant engagement over the 12-month duration of the study (e.g. study newsletters, personalised communications). Largely the strategy was delivered as planned, with a small number of in-study changes made predominantly in response to unexpected challenges. The success of the strategy was evaluated on completion of data collection with the PPI group. The 'recommendations for future research' outlined below reflect the consensus opinion of the PPI group and the research team.

Feasibility randomised controlled trial

In a two-armed parallel-group fRCT, in which our recruitment and retention strategy was applied, we assessed whether and how it would be possible to carry out a future definitive RCT of Wrapped.[21] Over a 31-week period, 230 participants were recruited, representing 2% of the sampling pool, or 1.5% if the additional criterion of requiring self-report of baseline chlamydia test result was applied. This latter group, referred to as the 'restricted sample' is discussed hereon in, as it better reflects the true nature of the sample that would be recruited at full trial.

Recruitment

Recruitment duration was prolonged due to permanent and temporary losses of some local authority sites. One permanent loss was due to the contractor changing supplier at the end of their agreement term. Two temporary losses were due to service migration between different Preventx services in response to COVID-19. In any future RCT, it is imperative that partner areas have contracts with Preventx for at least the duration of the recruitment period and that agile arrangements are in place to allow recruitment to be transferred between Preventx services if required.

The overall proportion of the sampling pool recruited was lower than expected. While this does not threaten the feasibility of recruiting a sufficiently large sample at full trial given the size of the sampling pool available (see *Chapter 3*, *Results*, *RO 6*), if this can be increased then the rate of recruitment will also increase thus reducing trial length and costs. All adverts appeared to work equally well, and the change in voucher amount had no discernible effect on recruitment; changes to these variables at full trial are therefore unlikely to have any substantial impact. Visibility of the advert may however have been a critical factor. With support of a user experience (UX) expert, we have reviewed the recruitment user journey experienced by individuals invited to the study. This identified that anyone ordering a chlamydia self-sampling kit from Preventx via their mobile phone (applicable to 92% of Preventx service users; data provided by Preventx in personal communication) will not have seen the advert unless they actively scrolled down. Given that the advert was located on the 'thank you' page of Preventx, with messaging indicating the end of the ordering journey,

it is likely that a substantial proportion of users closed their browser without scrolling down and seeing the advert. Furthermore, the advert could have been more visually distinct, as suggested by participants who took part in our qualitative study. Finally, as advised by the UX expert, the advert should aim to utilise the power of the Preventx brand, given that Preventx is trusted by our target population to perform their STI testing. The advert could include, for example, wording such as 'Preventx are partnering with Wrapped to run a study to…'. This endorsement could also be carried through to the study project page to reassure participants that the study is genuine and credible. In any future trial, we will address these issues as a strategy to increase uptake.

There was evidence of some imbalances across demographic subgroups at baseline between the randomised groups. For the full sample, there appeared to be a lower proportion of bisexual participants in the intervention than the control group. Further, in comparison to the control group, there appeared to be lower proportion of 20-year-olds and a higher proportion of 21-year-olds in the intervention group. This is likely a product of our stratification strategy. To keep the total number of stratification categories to within reasonable limits, we did not stratify by all demographic characteristics and where stratification did occur, sub-categories of variables were collapsed. Age was one of the unstratified characteristics. Sexual identity was stratified but a binary categorisation of 'heterosexual' versus 'other' was used. These imbalances do not present concern in terms of a future full trial. This is because at full trial a stratification strategy would not be used as balance would be expected to occur naturally given the large number of participants required. The same imbalances across groups for bisexual participants and the above age groups carried through to the restricted sample, but also there appeared to be less females and more males in the intervention than the control group here. This difference across gender categorisations was introduced as a result of selecting the 'restricted' sub-sample of participants after randomisation. Again this does not present any concerns for a future full trial as we would not be selecting a sub-category of the sample for analysis; randomisation would occur once a participants' STI status as baseline was known and all randomised participants would be included in the analysis. Chlamydia positivity at baseline in our sample (4.6%) was lower than the national figure for users of internet test settings (8.8%) at the time of data collection.[29] This difference may in part have been as a result of the COVID-19 pandemic that coincided with data collection. The pandemic resulted in reductions in the frequency of sexual behaviour among young people, particularly for those not in a steady relationship.[73,74] Given that this group are most likely to have new and casual sexual partners,[75,76] both of which are key risk factors for STI transmission, it follows that instances of STI may have reduced during this time. It is possible therefore that the reduced levels of positivity evident in our study reflect this. Why there is a discrepancy with national level data on positivity is unclear. It may reflect local differences in behaviour or changes to service delivery in response to COVID-19 for areas participating in our study that are not evident in the national picture. A future trial conducted outside of this context may observe levels chlamydia positivity more typical of the national figure. Lower overall positivity in the sample may also reflect a tendency for participation among service users with lower sexual risk behaviour. This is potentially problematic for two reasons. Firstly, the sample size calculation for full trial is based on chlamydia positivity in the control group being 10% (see *Report Supplementary Material 10*) and lower than expected positivity may increase the sample size required to detect an intervention effect. Secondly, if participants have lower levels of chlamydia positivity (and sexual risk behaviour) than typical users of STI self-sampling services, this could result in biased study outcomes that threaten external validity. Other sexual health-related research is equivocal on whether recruited samples tend to exhibit higher or lower sexual risk behaviour.[77–79] Less is known about the relationship between participation and STI status, but a recent longitudinal Dutch study reported that baseline STI positivity was a predictor of non-participation.[77] While caution should be adopted given the small-scale nature of the present study and that chlamydia positivity at baseline was self-reported; it is prudent to consider how we could address disproportionate uptake of individuals by STI test outcome at full trial. Discussions with Preventx have indicated that they could identify service users with higher sexual risk behaviours prior to the point of study invite (service users are required to provide relevant information when ordering STI self-sampling kits) allowing us to customise the advert displayed to this subgroup. There is potential to work with a future PPI group (including those with a recent STI diagnosis) to develop and test alternative types of messaging that could be used at full trial to encourage their participation. Furthermore, we could introduce a stopping point within a full trial when half the sample has been recruited at which chlamydia positivity is assessed and a continuation decision made by the trial's independent DMEC and SSC only if this is at the expected level.

Retention and data completeness

Follow-up for our primary outcome measure at main trial (i.e. chlamydia positivity, measured in the present study as the proportion who returned a valid chlamydia self-sample at M12) was 75.7%. It is worth noting that the response rate for the full sample, which includes those who did not self-report their chlamydia test result at baseline, was lower at 65.7%. As discussed, the restricted sample is most representative of the sample that would be used at full trial, but it is acknowledged that it is not the same. That is because at full trial, we would seek to obtain objective STI test result data from Preventx rather than relying on participant self-report. This increases uncertainty about whether recruitment estimates obtained in the present study can be confidently applied to decision-making at full trial. It is possible, for example, that the self-selecting nature of the restricted sample may have artificially inflated the M12 response rate, with the self-report of the baseline chlamydia test result (a requirement of membership of this subgroup) acting as a proxy for ongoing engagement. To test this hypothesis, post analysis, we sought objective baseline chlamydia test result data from Preventx for all participants in our sample and then examined the M12 response rate for all those with a valid result. Based on this, the response rate was higher at 78.8% (134 provided a valid self-sample at M12/170 with objective test data provided by Preventx at M0) indicating that we can be confident in obtaining a response rate of at least 75% at full trial. This is further supported by other studies which have achieved similar response rates, such as the recent sexual health trial by Free and colleagues which reported 74.8% return of STI self-sample at 12 months by 16- to 24-year-olds,[80] and the recent longitudinal study by van Wees and colleagues where STI self-sample kit return at 6 months by 18- to 24-year-olds was 75.7%.[77]

Also measured in the present study was return of a valid chlamydia self-sample at M3, and survey completion and completeness at M0, M3, M6 and M12. Return of a valid sample at M3 was similar to that obtained to M12 at 75.1%, and survey response at all time points exceeded 90%. This level of survey response is equivalent to that of similar recent trials of digital sexual health interventions, for example 88% at M1 follow-up[80] and 72% at M3 follow-up.[81] Maintaining this level of completion across all surveys up to M12 follow-up is particularly encouraging given that trials of internet-delivered interventions can be particularly prone to attrition.[82,83] Further, on items required to assess key primary and secondary outcomes at main trial there was over 95% completion indicating high levels of measure acceptability. These positive outcomes are likely the result of the investment in the recruitment and retention strategy and the repeated testing and refinement of the measure delivery and completion with our PPI group. This is further supported by the positive feedback received from participants in the nested qualitative study and by those who provided feedback on participant experience at the end of the M12 survey. These participants attributed their ongoing engagement to, for example, the ease of completing measures, personal touches such as hand-written notes included in self-sampling kits, and responsive communication from the research team.

Differential attrition by participant characteristics

Attrition by participant characteristics was examined to identify potential threats to internal and external validity. The demographic characteristics of participants who returned a valid chlamydia self-sample at M12 (primary outcome any future RCT) were compared to those of individuals in the sampling pool and at baseline to examine patterns of attrition and assess whether the sample available for analysis at full trial was likely to represent typical web-based STI-testing users. Participants at M12 were broadly equivalent to web-based STI testers in the sampling pool and to participants at baseline across all gender categorisations. Participants at M12 was also broadly equivalent to those at baseline across all sexual identity categorisations (note the same comparisons to the sampling pool could not be made as the required data were unavailable). There was however evidence of the sampling pool and the baseline sample being less well represented at M12 across other demographic characteristics. In terms of deprivation, there was some evidence that M12 participants were under-represented in deprivation quintile 3 and over-represented in deprivation quintile 5 (the least deprived) in comparison to the sampling pool. There was also some evidence of a continued slight under-representation of quintile 3 and slight over-representation of quintile 5 when comparing participants at M12 to those at baseline. These observed discrepancies partly reflect the under and over-recruitment of participants in quintile 3 and 5 respectively, but also a degree of attrition for quintile 3 and strong retention for quintile 5. Evidence of the over-recruitment of participants in the least deprived group, combined with high levels of retention, presents some concern for the future trial as this could threaten both internal and external validity. This picture warrants particular effort being made in any future trial to balance this out through improved recruitment and retention of participants across other deprivation quintiles. Encouragingly, representation of service users at both baseline and M12 (full and restricted samples) in deprivation quintile 1 (most deprived) was good. However, given that it is not unusual for trials to

struggle to engage participants from the higher end of the deprivation spectrum,[84] and that caution should be adopted in drawing too much inference from our findings given the small overall number of participants, a future trial strategy ought to be to focus most attention on the recruitment and retention of participants in quintiles 1 to 3. In a future trial, we would work with members of our PPI group to understand what incentivises young people from more deprived backgrounds to participate in research and what barriers exist to their ongoing participation. Any appropriate strategies recommended by the group will be implemented, and uptake and retention across deprivation groups carefully monitored throughout.

Participants at M12 appeared to represent all ethnic group identities at baseline thus there was no evidence of attrition by ethnicity. When comparing M12 participants to the sampling pool there was however evidence of a higher proportion of black participants and a lower proportion of white participants, reflecting differing levels of study uptake by these groups. While this pattern of recruitment is encouraging given that people of black ethnicity carry a disproportionately high burden of STI infection, and higher representation increases the potential for important subgroup analyses examining the equity of intervention effects, this does again threaten external validity. Furthermore, there was a tendency at M12 for lower representation of those aged 16–19 years, and higher representation of those aged 20–24 years, compared to the sampling pool. These differences by age group are the result of differential study uptake rather than dropout during the study itself as the M12 sample was representative of the baseline sample for this characteristic. While it is unlikely that measures would be taken at full trial to limit participation of participants according to their ethnic identity, efforts would likely be made to increase participation by those at the lower end of the age range. Lower participation by the under 20 seconds may be due to this age group being more likely to live at home and having concerns over parents/carers finding a STI self-sampling kit or intercepting notifications of results.[85] This is partly supported by our examination of adverse events, whereby over half of cases of the reported event, 'someone finding out I was testing for a STI when I didn't want them to know', were reported by participants under 20 years despite this age group representing only 13% of the total sample. The under-recruitment of younger participants may also have been because we were unsuccessful in developing adverts to attract them to the study. In a future full trial, we would work with younger members of our PPI group to review the study sign-up journey and identify changes that could help to increase uptake by this age group, for example developing bespoke adverts, and highlighting the discrete nature of STI kit delivery and result notification in the participant information. Regarding the latter strategy, it would however be important to strike a balance between providing reassurance while advising those who are particularly concerned about disclosure of STI testing not to participate in order to minimise adverse events.

As discussed above, at full trial we would carefully monitor the representativeness of the sample during recruitment taking corrective action if necessary. If we were concerned that the final sample did not reflect the sampling pool, then there would also be the further option of estimating a weighted intervention effect to match that of the sampling population. This strategy would be implemented if there was evidence that our primary outcome differed by demographic characteristics, suggesting that intervention effects were not equivalent across groups.

Dropout attrition

Dropout attrition, whereby the degree of attrition differs between the intervention and control group, is a threat to a trial's internal validity. This can be a particular problem for trials of behavioural interventions where the blinding of participants to group allocation is more difficult to achieve.[86] In the present study, retention (return of a valid chlamydia self-sample) was higher at M12 in the intervention group than the control group. This is at odds with evidence from meta-analyses which have examined attrition across trials of health behaviour change interventions, including for HIV-prevention, and have found slightly higher retention within control groups.[87,88] This may be the product of participants experiencing the costs of participation in the intervention study (e.g. time and effort required to engage with intervention material) as greater than the benefits received, particularly if the targeted health risk behaviour is not perceived as problematic.[88] In this sense our pattern of attrition reflects well on Wrapped, suggesting that at least within a research context, those in the intervention group did not perceive the costs of participation as greater than the benefits receiving Wrapped.

Despite our attempts to create an equivalent intervention experience for participants in the control group, the observed differential attrition may suggest that blinding was not entirely successful, and that participants' perceptions of group allocation influenced their ongoing engagement. Why perception of being in the intervention group or control group

might have led to higher and lower levels of retention respectively, is unknown. It may be that participants given access to the intervention materials (such as free condoms) felt more of an obligation to complete follow-up assessments than those in the control condition[89] or that those in the control group felt disappointed, a sentiment which influenced ongoing engagement. Encouragingly, our examination of the demographic characteristics of participants at M12 showed that, with the exception of some observed differences that were a present at baseline, there were no systematic differences between the intervention and control groups indicating that attrition was not patterned. Any future trial should nonetheless introduce strategies aimed at increasing participant retention within the control group. This could include for example, ensuring that the research team effectively communicate to participants that all participation is of equal importance and value regardless of group assignment. Further at full trial, information that may be informative in terms of predicting missingness should be considered and measures taken to collect this so that multiple imputation can be performed as required.

Engagement with intervention materials

In this study, we successfully collected a breadth of data on participant engagement using Matomo analytics, information stored within the Wrapped website on product ordering and dispatch, and the fRCT surveys. Overall, Wrapped access levels were encouraging (68.7%) albeit with room for improvement. At a full trial, we would aim to increase this by sending access details through SMS in addition to e-mail, by sending more than one access reminder, and by potentially increasing the incentive amount up from £5. There was some evidence of higher access among younger participants (16–19 years) and those in the least deprived quintile (IMD 5), and lower access among those in deprivation quintile 2, relative to overall access levels. Given the small number of participants across these subgroups, these findings should be interpreted with caution. Nonetheless, it would be important to explore ahead of any future trial whether there may be any barriers to access among those in lower deprivation groups, for example, relating to perceptions of what a sexual health website may have to offer.

While information on access is informative from a trial perspective, this does not provide a valid assessment of use outside the confines of a RCT where there is no incentive for use or associated research measures to complete. To assess this, a future study should examine levels of Wrapped uptake and engagement, including by group, when it is made available outside of a research context. If implemented, this type of study could be run in parallel to a full trial in one discrete local authority area (not participating in the trial), with intervention uptake and use recorded unobtrusively using analytics data. To enable uptake and use to be compared across subgroups, analytics data could be linked to demographic and behavioural data shared by Preventx (subject to user consent and a data sharing agreement). These data are likely to be of importance to service commissioners should Wrapped be identified as effective and cost-effective and local implementation therefore being under consideration.

Users evaluated the website as useful and liked the design. Furthermore, we identified little evidence of friction points within the site, that is, aspects of the site that make it difficult or inconvenient for a user to complete an action such as registering, completing tailoring questions, or placing an order. This is backed up by data from the nested qualitative study (see *Nested qualitative study*). Higher levels of engagement were observed for product-related components than video-related components. High proportions of users ordered the products and reported using them as intended. The accounts of individuals participating in the nested qualitative study also attest to this. The large majority of those assigned to video components however did not access the relevant page, and those that did were unlikely to play the videos. Those that did play the videos were also unlikely to watch them in full. A user experience (UX) review of the video components is therefore necessary to explore and address any potential issues concerning usability and appeal.

Contamination

A large proportion of participants in the control group of the present study reported that they recognised the Wrapped website. Owing to technological measures put in place to prevent access to Wrapped by anyone other than participants assigned to the intervention group, and an analysis of analytics data which showed that only these individuals went on to gain access, we can be reasonably confident that no one in the control group gained direct access. An alternative possibility is that some participants in our study were known to each other, assigned to alternate conditions, and then showed each other the respective websites. While there was some limited evidence of participants being known to each other, there is no way of knowing whether content was shared. Either way, this would not account for the extent of contamination reported and instead the most likely explanation is that the question used to assess contamination

was not reliable. Any future trial should only allow one participant per household to participate; checks performed at randomisation can be used to verify this. In addition, participants should be requested not to signpost others to the study and stress the importance of not sharing intervention materials with anyone else. Furthermore, the contamination question should be improved such that it can reliably assesses receipt of the active intervention.

Health economic assessment

The economic component of the study aimed to design processes, and capture data on the costs and outcomes associated with the intervention and control arms, to inform the methods for a future economic evaluation alongside a definitive trial. Overall, processes were successfully put in place to measure costs associated with delivering the intervention and the control (usual care). A range of outcome data were collected successfully, including for the EQ-5D-5L and SF-12. The cost data collected were comprehensive, and the private costs borne by the participants were well captured. The findings of this feasibility trial suggest that in a future definitive trial, it would be important to capture a broad range of costs, as participants reported that they had incurred a range of private costs which would need to be considered (e.g. condoms, self-sampling kits etc.). A difficulty encountered was capturing full data on NHS healthcare resource use (including information on contraceptive use and other products). We would recommend therefore that in any future trial, attention is paid to capturing further detail for both arms in relation to NHS resource use and private costs.

The relevant outcome data were collected successfully. This would permit different types of economic evaluation to be conducted in a future definitive trial. Firstly, a cost-effectiveness analysis could be conducted, using the primary clinical outcomes included in the trial, including on cost per STI averted. In addition, collection of EQ-5D-5L/SF-12 data would allow a cost–utility analysis to be undertaken as recommended by NICE.[39,40] Finally, collection of data on more general well-being (via general well-being instruments such as ICECAP-A) would enable a broader analysis to be undertaken, which would focus on outcomes beyond health.

In a definitive trial the costs associated with attempting to improve condom use and sexual health would need to be offset against the longer-term savings associated with reductions in STIs. As is the case with many public health preventative programmes, longer term costs and outcomes would need to be considered.[90] Hence, it is recommended that a decision-analytic model is used to extrapolate costs and benefits beyond the follow-up period. There is a range of evidence that could guide the development of the model, including the model used to inform NICE guidance on condom use and other more recent work in this area[91,92] and adaptation of an existing model would need to be explored. The development of a model would require data on transmission rates and the longer-term sequalae associated with STIs.[48] The aim of the decision-analytic model would be to provide information on the potential longer-term costs/savings and health benefits associated with the Wrapped intervention.

Nested qualitative study

Interviewees in the nested qualitative study were asked to reflect on the trial materials and procedures that they had experienced. Relevant feedback was also received within the M12 survey. Materials and procedures were viewed positively, with only a few minor amendments suggested. This experience is likely testament to the detailed work undertaken to develop the recruitment and retention strategy and the iterative testing of materials. In line with insights from our analytics data, feedback from interviewees also indicated few friction points within the Wrapped website. The condom sample pack was enjoyed and reportedly shifted views on the variety of condoms available. The ability to choose the colour of the box and the image displayed on the insert, while liked, was not considered necessary; this could be removed in any future delivery to reduce costs. Participants who had used the condom-ordering service also felt positively about this, enjoying the discrete nature of this service which for some removed the embarrassment of obtaining condoms in-person. The condom carrier however was valued less, in terms of its quality and potential usefulness. As a result, there is a need to reassess this product; given that some of the more positive feedback was from women who found the idea of the product empowering, it may be that different products/solutions need to be considered for different gender groups. Feedback on the videos fits with insights from the analytics data; there was a

tendency for participants to lack awareness of their existence and to have preconceptions about their tone and content. As indicated above, a UX review of their position and framing within the site is required.

Implementation of Wrapped

Our discussions with local decision-makers indicated that there was receptivity in a range of different sexual health systems for the Wrapped intervention. In particular, there was recognition of the need and potential offered by digital health approaches, and it was felt that sexual health promotion and condom distribution were important areas where more digital provision was needed. Given the complexity of local commissioning arrangements and the changing nature of local landscapes, it was suggested that flexibility would be important in developing a strategy for the implementation of Wrapped. It thus seems that further exploration and analysis will be needed, taking into account evolving commissioning structures and partnerships to determine optimal routes for implementation, as part of a full RCT.

Strengths and limitations of the work

This study assessed the feasibility of conducting a future full trial of Wrapped. The methods that were tested addressed the limitations of previous trials of sexual health interventions.[16,17] The generation and concealment of allocation sequences was successful; the allocation sequence was computer-generated within REDCap and researchers were not able to influence this process. Furthermore, all REDCap reports and datafiles identified allocation group by number only, thus group assignment was successfully concealed from the individuals performing data analysis. Finally, high follow-up was achieved over a good follow-up period (12 months) for a biological outcome measure (chlamydia positivity). Given this, it is likely that any future trial would have a low risk of bias and contribute robust evidence concerning the effect of Wrapped, and more broadly of behavioural interventions, on condom use and STI incidence.

The comprehensive work undertaken to develop a recruitment and retention strategy likely contributed to low attrition, high measure acceptability, and the positive feedback received from participants. Future studies may wish to draw on the strategies used to maximise retention. Uptake rate, while low, resulted in a baseline sample where participants appeared balanced across most demographic characteristics and largely representative of web-based STI testers. There was evidence of imbalance at month 12 between the intervention group and the control group, although encouragingly there was no evidence that this difference was patterned. Chlamydia positivity at baseline was lower than the national levels of chlamydia positivity for internet test settings. Strategies to address these imbalances in any future full trial have been discussed. Nonetheless, a stopping point should be implemented once half the sample has been recruited to assess levels of uptake and chlamydia positivity to determine ongoing trial feasibility.

The nested qualitative study was able to demonstrate the acceptability of trial procedures and measures and provided tentative evidence of impact on condom-use beliefs and behaviour. While we achieved our target of 30 interviews with trial participants, the sample lacked diversity constituting mostly of white female participants thus limiting the generalisability of findings. Obtaining a more diverse sample was challenging due to the dual importance of having a sample which also represented experiences of those in the intervention and control groups, and with different levels of intervention engagement. In a future trial, the increased number of participants available would widen these categories and facilitate achievement of a more representative qualitative sample. Interviews with the sexual partners of trial participants were limited in number and value. Twelve participants were willing to refer their partners for interview and while four viewed the participant information sheet, only three took part. Furthermore, their responses lacked depth and contributed little to our understanding of intervention impact. Accordingly, continuing this approach at full trial is not recommended.

Interviewees participating in the nested qualitative study also provided valuable feedback on the Wrapped intervention. This was combined with data from several other sources, including data analytics, ordering/dispatch logs, and the surveys, to provide detailed information on engagement. While this triangulation of data made for a robust approach, it also identified some evidence that Matomo did not pick up all cases of interaction with the Wrapped website. Following consultation with a Matomo expert, we believe that the most likely explanation for this inconsistency is that some of

our participants had software in place on their device that blocked Matomo. This could be resolved in a future trial by changing the nature of the tracking code used.

Equality, diversity and inclusion

The burden of STIs is known to be unequal among young people, with those who identify as black, GBMSM, or who live in areas of higher deprivation, experiencing disproportionately high levels of diagnosis.[1] Any trials testing interventions which aim to reduce STIs must therefore include representation of these groups within the sample and perform subgroup analyses to identify the impact on health inequalities. Given that the purpose of this study was to assess the feasibility of conducting a full trial, planned analyses included examination of whether the sample available for analysis represented the sampling pool across demographic characteristics, namely, age, gender, IMD quintile and ethnicity. As discussed above, the sample was identified as largely representative, with actions to address the exceptions proposed. Unfortunately, data on sexual identity were not made available by Preventx. This meant that we were unable to examine whether the study sample represented the sampling pool on this measure. We did however collect these data ourselves at baseline which were used to assess whether differential attrition was patterned by sexual identity along with the above participant characteristics. At full trial, it would be imperative to obtain data on sexual identity for the sampling pool to enable comparison with our sample to be made.

Our PPI group reviewed all participant materials thoroughly, assessing their accessibility and inclusiveness. Several iterations in line with this were made before sign-off by the group. It is however acknowledged that our PPI group, in addition to the wider research team, lacked ethnic diversity and therefore opportunities to improve the cultural competence of the materials and procedures may have been missed. Furthermore, the PPI group lacked representation of 16- to 19-year-olds, as did the sample of participants consulted in development of the recruitment and retention strategy. The latter was also predominantly female. While the research team would remain the same for any future full trial, a new PPI group would be formed such that it is more balanced and that all groups disproportionately affected by STIs have good levels of representation (see *Public and patient involvement*).

Public and patient involvement

PPI work was strongly embedded within this research. This included an assessment of all participant materials for the fRCT and nested qualitative study (participant information, consent statements, surveys, focus group and interview schedules), representation on the SSC, co-development of the recruitment and retention strategy, and development of recommendations for future research (see below). Their involvement undoubtedly improved the participant research experience and likely contributed to the observed level of retention and the positive feedback received from participants. As noted above (see *Equality, diversity and inclusion*) the PPI group, while representative of the target population (all were current or former users of Preventx), had some gaps in diversity. Although there was a good mix of males and females (four males, two females), no other gender groups were represented. All members identified as white ethnicity and were in the upper end of the age bracket (all 20–24 years). Information on sexual identity was not collected. If a full trial of Wrapped is undertaken, a new PPI group should be formed which represents underserved groups, particularly those who experience disproportionately high levels of STIs. Given that the fRCT under-recruited 16–19 years olds, having representation of this age group on the new PPI group would be important to enable focused work on how to maximise their uptake. It would also be important to include individuals with a recent STI diagnosis given the importance of maximising uptake and retention in this group.

Recommendations for future research

The findings of the fRCT and nested qualitative study were discussed with the PPI group at study end. Reflections were made on the success of the recruitment and retention strategy and changes that should be considered. Guidance was also received from the DMEC and SSC throughout. The following project-specific recommendations for full trial are the product of these discussions:

- Ensure partner sites have contracts with Preventx for at least the duration of the recruitment period.
- Work with Preventx to ensure that should an area migrate between their services, that there can be a seamless transfer such that recruitment is unaffected.
- Ensure that study adverts placed on the STI self-sampling website are visually distinct, utilise user trust in the Preventx brand, and are visible via a mobile phone interface without scrolling.
- Ensure that data on sexual identity of individuals in the sampling pool is made available by Preventx to allow comparisons to the sample to be made.
- Form a new PPI group which better represents the target population and includes good levels of representation by groups disproportionately affected by STIs.
- Work with the PPI group to develop and test alternative types of messaging that could be used to encourage participation of higher-risk service users.
- Review study process and procedures with the PPI group to identify changes and opportunities that could help to increase uptake by those under 20 years, and to increase the recruitment and retention of those from more deprived backgrounds.
- Explore and implement strategies aimed at increasing participant retention within the control group.
- To inform what input variables to include in multiple imputation at full trial, consider those which may predict missing data, or correlate with the value of the missing data, and ensure that relevant information is collected.
- Introduce a stopping point when half the sample has been recruited at which recruitment rate and chlamydia positivity of the baseline sample are assessed and a continuation decision made by the SSC/DMEC.
- If the final sample available for analysis does not match the sampling pool on one or more demographic characteristics found to interact with STI and/or behvioural outcomes, estimate a weighted intervention effect from the trial data to match that of the broader sampling population.
- Conduct a user experience (UX) review of the Wrapped video components to explore and address any potential issues concerning usability or appeal.
- Remove tailoring aspects of the condom sample pack (choice of box and insert) to reduce costs.
- Reassess the condom carrier with service users; consider whether different products/solutions are needed for different gender groups.
- Estimate the level of uptake and engagement with Wrapped, including by demographic group, should Wrapped be made available outside of a research context.
- Improve the reliability of the measure used to assess control group contamination.
- Exclude participation of individuals from the same household.
- Explore using a different form of Matomo tracking code that will not be blocked by device software.
- Capture detailed information via the surveys on NHS resource use and private costs.
- Use a decision-analytic model to extrapolate costs and benefits of Wrapped beyond the follow-up period.
- Ensure that individuals participating in any qualitative aspects of a future trial represent the target population.
- Conduct further stakeholder engagement (involving end users, sexual health commissioners, and decision makers working within commercial web-based STI-testing services) to assess the appropriateness and appeal of Wrapped thus maximising future opportunities for implementation.
- Continue to explore optimal routes for implementation, taking into account evolving commissioning structures and partnerships.

The following recommendations are made for others embarking on feasibility studies or full trials of behavioural interventions:

- As part of standard study risk assessments, carefully consider all assumptions regarding recruitment (e.g. continued ability of sites to recruit) and develop contingency plans that can be swiftly enacted if necessary.
- Work closely with PPI groups and UX professionals to review the entire participant journey from study advert, through engagement with intervention, and to completion of all study materials. Removing identified friction points could help to increase participant recruitment and retention.
- Develop a study recruitment and retention strategy with support from PPI members. As far as possible, base decisions on existing evidence of what works for the specific participant group and study context; review plans with representatives of the target population and adjust as necessary. If possible, test the strategies in a feasibility study prior to implementation in a full trial.

- Aim to develop a PPI group that reflects the participant sample as closely as possible. If there is evidence to suggest that any particular group(s) may be more challenging to recruit or retain, ensure that they are well represented by the PPI membership.
- During recruitment, work closely with the SSC and DMEC to review the number and representativeness of the participant sample and discuss/agree steps to address this where appropriate.
- Consider assessing the 'real-world' uptake of the intervention being tested by offering it outside of the study context. This information could be invaluable to future commissioners.
- Identify potential future commissioners and work with them to identify (and then collect) data that would be important to them in commissioning decisions, and also to identify/explore potential routes to market.

Conclusion

Using multiple methods and a multidisciplinary team, we have shown that the Wrapped intervention is acceptable and that a full definitive trial is feasible. We have recently been awarded funding from the NIHR to conduct that trial (NIHR award NIHR157903). The above research recommendations will be implemented to further enhance the robustness and value of this research.

Additional information

Contributions of authors

Katie Newby (https://orcid.org/0000-0002-9348-0116) (Associate Professor, Health Psychology) conceived the idea for the Wrapped intervention, led the application for fRCT funding, led study delivery and co-wrote this monograph.

Kayleigh Kwah (https://orcid.org/0000-0003-2307-1285) (Senior Research Assistant, Health Psychology) undertook day-to-day management of the study, ran the qualitative data collection and analysis, led on PPI input, led on data management and co-wrote this monograph.

Lauren Schumacher (https://orcid.org/0000-0003-3430-1816) (Senior Research Assistant, Health Psychology) undertook day-to-day management of the study, ran the qualitative data collection and analysis, led on PPI input, led on data management and co-wrote this monograph.

Rik Crutzen (https://orcid.org/0000-0002-3731-6610) (Professor of Behaviour Change and Technology, Health Psychology) supported development of the recruitment and retention strategy and supported study delivery.

Julia V Bailey (https://orcid.org/0000-0002-5001-0122) (Associate Professor, Primary Care) supported measure development and study delivery.

Louise J Jackson (https://orcid.org/0000-0001-8492-0020) (Senior Lecturer, Health Economics) led on the health economic assessment, led on the Wrapped implementation assessment, supported study delivery and co-wrote this monograph.

Stephen Bremner (https://orcid.org/0000-0003-0790-7070) (Professor of Medical Statistics, Statistics) advised on all statistical analysis and reporting of statistics and supported study delivery.

Katherine E Brown (https://orcid.org/0000-0003-2472-5754) (Professor of Behaviour Change in Health, Health Psychology) led on measures development, contributed to the Wrapped implementation assessment, supported study decision-making throughout, provided mentoring to KN and co-wrote this monograph.

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Patient data statement

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety, and plan NHS services. Patient data should be kept safe and secure, to protect everyone's privacy, and it's important that there are safeguards to make sure that they are stored and used responsibly. Everyone should be able to find out about how patient data are used. #datasaveslives You can find out more about the background to this citation here: https://understandingpatientdata.org.uk/data-citation.

Data-sharing statement

All data requests should be submitted to the corresponding author for consideration. Access to anonymised data may be granted following review.

Ethics statement

All participants provided informed consent prior to data collection. Ethics approval for the fRCT and nested qualitative study granted on 16 November 2020 by NHS East Midlands – Leicester Central Research Ethics Committee (reference 20/EM/0275). Ethics approval for the qualitative study embedded within work to develop the recruitment and retention strategy, granted on 4 February 2020 by Health, Science, Engineering and Technology Ethics Committee with Delegated Authority (ECDA) at the University of Hertfordshire (reference LMS/SF/UH/04061). This study was conducted according to the principles expressed in the Declaration of Helsinki.

Information governance statement

The University of Hertfordshire is committed to handling all personal information in line with the UK Data Protection Act (2018) and the General Data Protection Regulation (EU GDPR) 2016/679. Under the Data Protection legislation, the University of Hertfordshire is the Data Controller, and you can find out more about how we handle personal data, including how to exercise your individual rights, and the contact details for our Data Protection Officer here www.herts.ac.uk/about-us/legal/freedom-of-information-data-protection/data-protection.

Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/LKOT7404.

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At the time of conducting this study, Wrapped (the intervention under examination) was the Intellectual Property of Coventry University. A license was granted by Coventry University to the University of Hertfordshire to use Wrapped for research purposes for a period of 10 years (26 March 2020–26 March 2030).

Katie Newby was an unpaid committee member of the European Health Psychology Society Specialist Interest Group (SIG) in Digital Health and Computer Tailoring between 2019 and 2023. She is a review panel member for the World Health Organization (WHO) Sexual and Reproductive Health Research Project (unpaid) and a member of the Health and Care Research Wales Integrated Funding Scheme (unpaid).

Kayleigh Kwah has been a committee member of the European Health Psychology Society Specialist Interest Group (SIG) in Digital Health and Computer Tailoring since 2023 (unpaid) and has been a hub coordinator (paid) for the Behavioural Science and Public Health Network (BSPHN) since 2022.

Lauren Schumacher was a hub coordinator (paid) for the Behavioural Science and Public Health Network (BSPHN) between 2021 and 2023.

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Publications

Newby K, Kwah K, Schumacher L, Crutzen R, Jackson L, Bremner S, *et al*. Intervention to increase condom use among users of sexually transmitted infection (STI) self-sampling websites (Wrapped): feasibility randomized controlled trial. *J Med Internet Res* 2025;**27**:e71611. https://doi.org/10.2196/71611

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Appendix 1 Development of recruitment and retention strategy – additional material

TABLE 30 Focus group schedule (Stage 3)

Category	Questions
Value propositions/ adverts	We want people to see a short message on the freetest.me website that grabs their attention and makes them want to join the study there and then. On the flip side, we want to attract people who want to commit to the study for the full 12 months, not just 5 minutes. We are going to discuss some potential messages. Would you change any of them? If you could create a better message, what would it be?
Now you are in our study, please stay!	What can we as a research team do to support and engage participants to keep completing the surveys and chlamydia test kits?
Prompts: how delivered?	Prompts have been used by other studies as a way to message people before they receive the survey or test kit to let them know it is coming and to encourage them to complete it. How should prompts be delivered: e-mail, text message or post?
Prompts: how far in advance?	How many days ahead of a survey or test kit should we send a prompt – 3, 5 or 7 days?
How should we send out surveys?	The surveys will be online. What is the best, most reliable, better guarantee someone will actually see that we have sent them the survey and then go on to complete it?
Reminders: how delivered?	Reminders have been used by other studies to help encourage people who may have forgotten to complete the survey or test kit. How should we send them out to participants that will guarantee people will see them and take action to complete it? Text or e-mail? Or a combination of the two? Or something else?
Reminders: how long after survey or test kit?	How long after we have sent a survey or test kit should we send a reminder to someone who has not completed – 5, 7, 10 or 14 days? What are your thoughts on using different or the same time periods for survey reminders versus test kit reminders?
Reminders: how many total?	How many total reminders should we send to someone who has not completed – 2, 3 or 4? What are your thoughts on using different or the same amounts of reminders for surveys versus test kits?
Prompts and timing	The hope is that participants will receive the survey and immediately act on it and fill it out. Or in the case of the reminders, they will remember to take action on either the survey or the test kit. Thinking about the prompts, surveys and reminders, what is the best time of day to catch someone? Should test kit reminders come at the same time of day as the survey reminders? Or should they come at a different time of day? We want to stick to our timelines for the study as best as possible, but is there a day or days of the week that would be best to catch someone on?
Voucher strategies	Taking part in the research is time consuming, and we want to recognise that participants are freely giving up their time for us. Sending out vouchers to participants is a frequently used method to thank participants for their efforts. Other past studies have used different strategies to distribute vouchers. We would like your honest thoughts on how successful they might be in encouraging people to complete the surveys and test kits and potentially how they might backfire. What are your thoughts on offering increasing amounts? What are your thoughts on offering something for nothing?
Vouchers	The next big question is how to divide the vouchers up according to each research activity completed. What are your thoughts on the different voucher schedules shown?
Long-term engagement in the study	A lot can happen in 12 months! Despite this, we still want people to remember the study and continue to complete surveys and test kits when they arrive. For the first 6 months something happens in the study every 3 months, but then we go quiet for a whole 6 months. Is there anything we could do as a research team to let participants know we are still whirring away in the background so that when the 12-month survey and test kit come around people are not wondering who the heck we are. What are your ideas about keeping people in the loop about the study in a useful, not annoying way?

TABLE 31 Types of value propositions identified in the rapid review (Stage 1)

Strategy	Definition	Example message
Altruism: help with research	Messages focused on how potential participants could contribute to science by joining the study.	'Interested in sexual health? Willing to help us with our research?' (Bailey *et al.* 2013).
Altruism: potential to help others	Messages emphasised how potential participants would be helping improve people similar to themselves by joining the research.	
Financial incentive mentioned	Messages directly mentioned that participants would earn money and/or vouchers through their involvement in the research.	'Looking for people who smoke. Join and you can get up to $180. Click here to learn more' (Ramo *et al.* 2014).
Improve health and/or well-being	Messages aimed to reach specific populations with targeting messages highlighting how the research might improve their health and/or well-being.	'Feeling tired? Essential nutrients in vegetables can enhance your well-being. Learn how to eat a little more veg every day through the 4-week smartphone program designed by researchers at The University of Sydney' (Nour *et al.* 2019).
Messages indicated scarcity of spaces in trial	Messages highlighted how only a few spaces were available for the research.	'Only a few spaces left in Tobacco Status Project. Click to see if you are eligible' (Ramo *et al.* 2014).
It is easy to take part	Messages indicated that being a participant in the study would be easy to complete.	
Messages were created in collaboration with experts/ members of the target population	Messages were specifically created with user groups and subject experts, such as organisations that work directly with the target population.	
Professional design/use of logos, so as to indicate message coming from an expert source	Recruitment messaging maintained a continuous look and tone, so as to convey that it was coming from a trusted source.	

TABLE 32 Value proposition development (Stage 2)

Value proposition category	Adverts drafted at workshop 1	Adverts presented at workshop 2	Votes at workshop 2	Proceed to Stage 3?
Altruism	If you are getting tested four times a year already, how would you like to turn that into making a positive change for everyone's sexual health? Click here to find out more.	No change	1 yes, 0 no	Yes
Altruism	Looks like you are doing your bit to keep yourself and others safe, would you like to help us improve access to information about sexual health?	No change	4 yes, 0 no	Yes
Altruism	Interested in being a part of a movement towards better sexual health for young people?	No change	0 yes, 0 no	No
Altruism; financial incentive mentioned	Are you interested in being paid to help develop safer health services?	No change	0 yes, 0 no	No
Improve health and/or well-being; financial incentive mentioned	Want to subscribe to frequent testing kits? If so, get rewarded for your participation and feedback!	No change	4 yes, 0 no	Yes

continued

TABLE 32 Value proposition development (Stage 2) (*continued*)

Value proposition category	Adverts drafted at workshop 1	Adverts presented at workshop 2	Votes at workshop 2	Proceed to Stage 3?
Altruism; financial incentive mentioned	Join our research team and get paid to improve sexual health services!	No change	1 yes, 0 no	Yes
Altruism; financial incentive mentioned	Take part in a research study to improve sexual health services and receive high street vouchers for your time!	No change	0 yes, 0 no	No
Altruism; financial incentive mentioned	Join a study to help improve sexual health services and get paid for your time	No change	1 yes, 0 no	Yes
Improve health and/or well-being		Sexual health is important for your well-being. Find out how you might improve your sexual health by joining our research.	0 yes, 0 no	No
Messages indicated scarcity of spaces in the trial		[Add 'last few spaces' remaining to any of the value propositions]	0 yes, 0 no	No
Altruism; it is easy to take part		Sexual health research is surprisingly easy to take part in, find out how you can make a difference today.	0 yes, 0 no	No
Altruism		You can make a difference to improve sexual health services, find out more about joining our research.	4 yes, 0 no	Yes

TABLE 33 Public and patient involvement feedback on provisional strategies (Stage 2)

Retention strategy	Summary of feedback	Quotes
Engaging participants with the research		
Personalised communications with each participant	Addressing participants by name in all communications makes participants feel valued and appreciated by the research team and will lead to higher retention rates.	*I feel that engaging with someone personally will make them feel more involved and important to the project. This involvement will want them to engage more as they feel like an asset to the research.*
Continuity of materials (logos, colours, fonts, templates, formatting)	Clear, uniform and simple designs, colours and formatting will ensure that key information will be noticed and acted on by participants; this will also build a reputable relationship between the research team and the participants.	*Would feel more trustworthy if everything is coherent, in my opinion. Bold, simple text works really well – especially on mobile devices. Too many colours can be too much on a mobile screen. Simplicity works really well when used correctly.*

TABLE 33 Public and patient involvement feedback on provisional strategies (Stage 2) (*continued*)

Retention strategy	Summary of feedback	Quotes
Clear, simple, brief instructions/ communications		*Keep things simple.*
Newsletters (updates on how the research is going)	The group was divided on the utility of newsletters and how effective they might be in increasing the retention rates. Feedback differed between it being effective in keeping the participants involved and reminded about the study, while others thought it would be a waste of time for the researchers and potentially annoying to the participants. After further discussion, it was agreed that newsletters would remind participants of their ongoing participation; must be brief, relevant and interesting; and feel personal in tone.	*I think one monthly newsletter sent out with key information on would be good to help keep people in the loop and aware of the project. Once a month seems just right as I think of newsletters were more frequent people are more likely to just delete it or be deterred from coming back.* *Although I think most people get a lot of unwanted e-mails/newsletters so for the energy it takes to produce something like this is may not be read that widely.* *I think a quarterly e-mail would be good to keep the study in people's minds but I would include more info and updates to keep it relevant and not seem like spam.*
Direct contact by the research team	Maintaining direct, personal contact with participants is key to increasing engagement; a WhatsApp group was suggested as a good communication method.	*WhatsApp is a good feature – the business tools are fantastic, there's some really decent features for this. It would good for maintaining contact with participants.*
All communications containing a social desirability statement (such as 'you're contributing to research, go you'; 'most people in the study are completing the surveys/test kits')	Social desirability statements were deemed important as they would encourage retention by making participants feel like a valued member of a team of people contributing to the study.	*Feeling like you're adding value to the study is important to people, and making them feel like they're doing a good thing by staying on the study makes people feel good about themselves and then are probably more likely to carry on engaging*
Birthday greetings	Birthday greetings would make participants feel valued, leading to improved retention rates.	*I like this idea, it gives it a personal touch! And keeps people feeling like they're personally important to the study!*
Christmas greetings	Although it would make participants feel valued, there was a concern that this would be perceived as spam.	*I get so many emails around Christmas about shopping and offers that I think this could get ignored.*
Timing and nature of survey invitations		
Sending survey invites via different modes of delivery	Send by e-mail and SMS text message (with preference for the latter if can only choose one) and stagger delivery so that does not feel too overwhelming for participants.	*I think in the test kit that is delivered there should be a reminder about the survey online. Then a text, with the email link, then an email as well. All staggered so that it doesn't feel too overwhelming on one day!*
Use of prompts (ahead of invite)	Prompts considered acceptable and useful. Should be brief and sent by SMS a few days before.	*Prompts are good, just little non-invasive ways of giving someone information.* *Short and sweet and maybe incorporate some humor. Having something funny will make it feel more memorable and more friendly.*

continued

TABLE 33 Public and patient involvement feedback on provisional strategies (Stage 2) (*continued*)

Retention strategy	Summary of feedback	Quotes
Value and implementation of financial incentives		
Increasing amounts	Increasing the value of financial incentives as the trial progresses will maximise engagement.	*Keeps people interested as they will view it as getting more rewards the longer they participate.*
Something for nothing	Giving small upfront vouchers to participant prior to completing an activity was considered unacceptable.	*Payment after completion.*
Reminders to complete activities		
Repeated (limited) reminders, with increasing levels of direct contact with ongoing non-response	Workshop 1: Reminders considered acceptable and useful. Should be brief, relaxed in tone, and mention the financial incentive and how completion has an impact on the research. Delivery by SMS text message most popular option. Increasing level of direct contact considered acceptable with continued non-response. No consensus on total number of acceptable reminders: split decision on whether this should be three or four. Also no consensus on reminder intervals: split decision on 3 days or 5 days. Group suggested that more reminders might be needed for test kits as these required more effort to complete.	*Short and sweet and emphasise that their participation is important. 'We still need to hear from YOU!'* *Keep it friendly, but quite to the point. You can be direct without being rude 'Have you forgotten something? There's a survey waiting for you – it's worth: £5!'* *The test kit might need reminders to actually post it etc., so maybe more regularly, whereas there are less steps to the survey*
Actions to minimise non-response		
If someone does not complete the surveys, calling them and asking them to complete three to four questions over the phone	Although this was considered to be a suitable way of catching any stragglers who might still be able to complete a few questions, if not the entire survey, it was also thought to be a way for participants to initiate a withdrawal from the study.	*This would be a good way to follow up, I would suggest using text messages that incorporate a link to the shortened survey questions. Maybe along with a message that says something like 'We know you may not have to time to complete all of the survey- -mind answering just a few important questions?' I think this is good idea, and could frame it as an easy exit strategy maybe, i.e. we hope everything is okay, if you don't want to be a part of the study anymore we understand, we'd be really grateful is you could answer these few questions before leaving though!*
If a participant does not complete a survey, calling them and asking them to complete over the phone	This tactic was considered too confrontational; a more personal approach, such as checking in with a participant to see how they are doing, was considered more acceptable.	*I think this may come across as annoying, maybe a better way to frame it would be phoning to check if everything is okay, and if they need any support completing the study, then giving an option to do the study over the phone.*
Offering telephone support to a non-completer to ask if they need help completing the survey online	This was considered an acceptable idea – so long as it was prearranged with the participant in advance.	*Yeah telephone support could be good, just schedule a time with them prior so they are expecting a the call.*

TABLE 34 Elements of value propositions considered most important by focus group participants (Stage 3)

Element	Description	Quotes
Brief, clear and snappy	Messages need to be brief and to the point; each message should be able to be read and understood quickly.	*Participant 8: I also think this one's a bit wordier as well, and I think keeping it shorter will increase the chances of someone properly reading it as well.* *Participant 5: You see, that one is quite good and snappy, to be fair. It's very snappy and down to the point.*
Mention financial incentive	Financial incentives were considered the most important element of a message as it would pique potential participants' interest, encourage them to join the study, and take away some of the embarrassment of taking part in sexual health research.	*Participant 13: If there's an incentive at the end of it, I feel like people are more likely to be connected because they know that they're going to get something at the end of it, actually physical and they can use that little money.*
Altruism	Although not as strong a motivator as financial incentives, messages that draw attention to helping others and making a difference will encourage people to find out more about the study.	*Participant 14: Because it says you can make a difference, and I think that will resonate with people that want to help others.*
Convey that participation is valued	Messages should communicate that participants will be appreciated as an individual making a valued contribution and will not be treated as a research specimen.	*Participant 3: That sounds more interesting, I think, for a lot of people. Because it makes them sound like they're someone important, you know what I mean? People like to have the importance like on them, and it makes them sound like they're part of like a research team, which they kind of are, but they're obviously the participant.*
Indicate commitment required	To avoid significant dropout following baseline, messages should convey that an element of commitment will be required.	*Participant 7: say you can earn money by giving your ideas and your knowledge, and into what this is going to be. I'm not quite sure how you would want to word it, but, certainly, maybe have it earn money and you can earn this if you just put some effort in, put some work in. And not even that much, really, but you can still earn what we're going to give out and all we need is information from you.*
Feel easy to take part in	Participation needs to be described in a way that does not feel difficult or time consuming.	*Participant: 18: With that, 'it looks like you're doing your bit message', and the thing that I like about that is that it kind of creates like a low-pressure environment. Because, obviously, you want them to commit to the study, but it's kind of like you don't need to stress, we're not going to ask you to write a paper on it sort of thing. So I feel like that will entice people if you just kind of start off a bit casual, and then give a few details, and then once they click on it, you can explain more, if that makes sense?*

TABLE 35 Potential adverts created by focus group participants

1. 'Join our study to help improve sexual health services whilst being paid!'
2. 'Less positive tests, more positive change'

TABLE 36 Focus group participant (Stage 3) feedback on provisional strategies

Retention strategy	Description	Quotes
Engaging participants with the research		
Personalised communications with each participant	In all messaging, participants should be addressed by name and the sender should be a person's name, not the name of the study.	*Participant 3: It's fair to speak to them by person, you know what I mean? It just shows more effort, doesn't it? So, yeah, it incites more effort on their behalf too, because someone's making an effort towards you, and you feel more inclined to make effort towards them.* *Participant 18: Also – it's also if it's possible for the sender of the email [unclear 50:00] the thing that appears is this person has sent … That's the sender. Could you make the sender a person's name, instead of the name of like a company?*
Continuity of materials (logos, colours, fonts, templates, formatting)	Messages should have a continuous look, that is, logos, colours, fonts, etc.	*Participant 9: Well, I think it's very important [having a continuous look], because I feel like you know it's all coming from the same place. I really know it's all – I don't know, you just tie it altogether in your head. I don't really know why else it's important, but I just think it's important to know that it's the same people that care about you as a human being; it's coming from them, and it's not coming from another place.*
Clear, simple, brief and impactful instructions/ communications	Message should not feel overly scripted, should feel fun and relevant. Subject lines for e-mails should be attention grabbing and playful in nature. Genuine and encouraging social desirability statements would be effective, but statements that sounded false or made participants feel bad about themselves would backfire. Instructions should be clear, easy to read, free of jargon and with a series of steps with accompanying pictures if applicable.	*Participant 7: So I have joined this thing and it's called Uniboob, where they send messages every month just to check your bodies for cancerous lumps, or anything. But they don't go, hey, oh my God, you're going to die! They go, yo, it's like Halloween check your boobs, check your muscles, check your pecs and it's really fun.* *Participant 13: Yeah, on the point of email marketing, yeah, like you were saying with the headings, because even add like a bit of humour into it to captivate people, and get them to click on the email, something like, oh hey, we're not just a one-night stand, we're in like a relationship.* *Participant 7: Just making sure it [social desirability statement] doesn't sound sarcastic – you're doing really well! Literally, yeah, because I think it's nice to have a little message like, you know what? Thank you for completing this, this is really helping people. And then having that most people are doing this, so you're almost good enough. I don't know, like trying to convey the right meaning, like thank you for what they're doing.* *Participant 8: I'd say probably brief, but really sort of clear, which is a hard balance to find, but you don't want a massive message with lots of tiny writing or something, because then it'll just seem really tiresome to read. But if there was something that was fairly simple with like numbers one, two, three, and maybe like images, then you've already got so much information just from a quick look, without having to read every single line to know what you're doing.*
Tell participants the impact they are having	Tell participants the difference they are making to the trial – this will make them feel valued, thereby increasing completion of data collection measures.	*inform them that they will have a direct/important impact on sexual health services — ANONYMOUS [Psych Undergrads Padlet] make it clear the exact impact they will make, i.e. make an impact on the number of other young people who put themselves at risk from catching chlamydia — ANONYMOUS [Psych Undergrads Padlet] Maybe explain some key stats about sexual health* (e.g. *chlamydia is present in 1 in X amount of people) so they feel that it is an important thing to help improve — ANONYMOUS [Psych Undergrads Padlet]*
Send project updates or newsletters	Newsletters would be a good method of showing participants the impact they were having and were considered effective for maintaining engagement throughout the trial.	*Participant 3: if you could give them like some results or something, or like say that you give them some results of the research, then, obviously, that would keep them more interested, because then they can see the direct impact they've had.*
Send birthday greetings	Mixed opinions of the role of birthday greetings: some felt it would be a kind gesture that would in turn encourage continued participation, others thought it was weird and awkward.	*Participant 19: That sounds good. That sounds really good. Yeah, it does, it make the person feel special, so then the whole thing around teamwork and how you're part of this, and you're part of this doesn't just sound like what is being said. But, oh my God, they actually remember my birthday, yeah.* *Participant 3: I think that's weird! I don't even send half of my friends one, so why would I get one off of them? I don't know, I think that's really weird, getting a card off someone you don't know … it would be kind of weird I'd imagine, and it's like happy birthday from your sexual health clinic, or whatever it is.*

TABLE 36 Focus group participant (Stage 3) feedback on provisional strategies (*continued*)

Retention strategy	Description	Quotes
Timing and nature of survey invitations		
Survey invites by e-mail	Surveys should be sent by e-mail and should mention the financial incentive and how long it will take to complete.	*Participant 20: Emails should have the link [to the survey]. I think a good thing to like include in it, is how long this survey is going to take you, because if … I don't know, if I open it and I'm just about to go out the door, and I'm like it's going to take me five minutes, I might as well do it while I'm waiting for someone to get ready, or if I'm at work and I'm trying to pass some time, you might as well … I don't know, if it's only like five or ten minutes, but if it's going to take you an hour, I need to set time apart for it, because I don't have an hour of time right now.* *Participant 13: Saying like payday is pending just to remind them that they are getting paid to do these surveys.*
Use of prompts	Prompts by text message for test kits were perceived as valuable as it was a call to action to expect its arrival in the post in plain packaging and remind participants of the financial incentive. Mixed opinions of the utility and effectiveness of prompts preceding the arrival of surveys. The first two focus groups thought it would be useful to job their memory, but the final focus group perceived prompts as bombardment and would encourage non-responsiveness as it was not a call to action.	*Participant 12: But with the test kits, I think a prompt might be helpful for that, just that they are expecting it to come. Because I don't know what shape they come in or whatever, but whether it can fit through the letterbox…* *Participant 18: So then, yeah, on the day itself, as well as a few days before, I think that will be nice, or a few days before so you get your mind ready, oh, this is going to happen. And on day, just so that in case you missed it and to remind you that, well, you're getting money for this, so you may as well do it.* *Participant 14: But, personally, I would be more inclined to get a text or an email saying, oh, our survey is here and I just do it there and then. Whereas if I got a text or an email saying it's in a few days, I'm probably … It'll be on my mind, which is obviously a good thing, but then when I get the next email I might not be inclined to do the survey straightaway if I'm used to reading emails, and not acting upon them at the time.*
Value and implementation of incentives		
Award increasing amount overtime-period of the trial; do not offer 'something for nothing'	While increasing amounts was considered acceptable and likely to provide motivation for participants to continue participating for the duration of the trial, something for nothing was mostly considered a terrible idea that would lead to low commitment and poor-quality data. No consensus was reached on how to distribute the vouchers, although there was a preference for increasing amounts with the largest payment at the end of the trial.	*Participant 18: Yeah, that is definitely a nice incentive knowing that. Not only am I getting paid for it, but I'm going to be getting more, so then I'll be looking forward to it. It's like, oh yeah, I get to get more money the next time, or the next time, I may as well just do everything.* *Participant 3: Not with something for nothing. You're going to get people with no commitments* *Participant 7: Or certainly they continue on with the tests and stuff, they do it to a lower level of completeness, and you just click all the 'yes' answers, all the no answers and then they've gone. And that'll swerve any information that the study gets.* *like that the last month has the most incentive so people actually finish it — ANONYMOUS [Psych Undergrads Padlet]*
Reminders to complete activities		
Repeated (limited) reminders by SMS text message	Reminders were viewed positively for increasing response rates. Reminders should be sent by text message, feel casual in tone and mention the financial incentive. Some focus group participants advocated for a completion deadline to encourage prompt participation.	*Participant 18: In the reminder about doing it, could there be something about how, well, that amount of whatever you're being paid is slipping out of your hands in just five minutes, it could be yours, just do this. You know you want to do it! Or just something like that, so that you are reminded that, well, you could potentially be getting money for it and that you'd be losing. I mean, I know myself, and I know that if I had the chance to make money and it only takes us five minutes to make that money, I wouldn't leave it on.* *Participant 12: Sorry. I think with what someone said earlier, the idea of deadlines is quite good, because they are getting paid for it, so they should be providing you with what they committed to. But maybe like make them 24 hours or 48 hours, just so that they don't feel under pressure like, oh, if you don't do it in the next two hours you're not getting anything out of this. So maybe just like set loose deadlines, just to know that it needs to get done soon.*

continued

TABLE 36 Focus group participant (Stage 3) feedback on provisional strategies (*continued*)

Retention strategy	Description	Quotes
Actions to minimise non-response		
Tone of communication should be supportive	Non-responders should be e-mailed, letting them know that the researchers noticed they had not completed a few measures, and ask if everything was alright. Messages should feel personal in tone, encouraging the participants to continue with a reminder of the financial incentives; messages should not make them feel guilty for having not completed something.	*Participant 18: If someone has not really done what they had to do. So the missing you, or it looks like you haven't done this, is there anything we should know about, or are you okay? Yeah, are you … Yeah, so like are you okay with something that is personal.* *Participant 3: You could carrot and stick them with that. You could be like, oh, you can still get this money for doing this, and … Or you could be like, oh, your research is almost done, or you've already done this and you're almost done and you can get your money if you finish it.*
Do not use phone calls but letters OK	Non-responders should never be called by telephone nor asked to complete a shortened version of the survey (key measures only). It would be acceptable to post a letter asking to confirm if their e-mail address and phone number had changed, as this was a likely occurrence among young people.	*Participant 20: I think the only issue with like calling people now, is I think – at least, personally, a lot of people I know in the age range you're going to – they don't like being called; they're like very rarely on the phone. So I think you might then make them feel like they're being quite bombarded with this, and it might make them want to just disconnect from the study completely. So I think maybe trying to stay over email and text might be more useful, because of your age range.* *Participant 3: I would worry a bit, because 16 to 24-year-olds, in that six months, the amount of people who would change their phone number is quite a bit. Like it won't be anywhere near all of them, but I'd say at least like 8 to 10 per cent of people will change their phone number in that time.* *Participant 5: Yeah, that's what I was about to say, send a letter and just … Do you know like that one [unclear 43:52] them little things with the free post envelopes, so they can send it back. Do one of them, and they can just, it can be their choice if they want to tick it or not, and send it back to you.*

TABLE 37 Adverts and PPI voting outcomes (Stage 4)

Advert	Voting	Quotes
Get paid to join a study that supports young people's condom use (included from Stage 3)	No votes	N/A
Join our research team and get paid to improve young people's sexual health (included from Stage 3)	3 yes, 0 no	N/A
You can make a difference to improve the sexual health of young people, find out more about joining our research (included from Stage 3)	No votes	N/A
Want to subscribe to frequent testing kits? If so, get rewarded for your participation and feedback! (included from Stage 3)	1 yes, 0 no	N/A
Looks like you are doing your bit to keep yourself and others safe, would you like to help us improve young people's condom use by taking part in a study? (included from Stage 3)	No votes	N/A
Earn up to £65 in vouchers by taking part in a study to improve sexual health, find out how you can make a difference today (created based on analysis of Stage 3)	3 yes, 0 no	*This is my favourite choice*
Make a difference to improve sexual health for young people – join our study and get paid for your time (created based on analysis of Stage 3)	2 yes, 0 no	N/A

TABLE 37 Adverts and PPI voting outcomes (Stage 4) (*continued*)

Advert	Voting	Quotes
Ready to help change young people's sexual health for the better? Your input can make a difference: join our study and get paid for your time (created based on analysis of Stage 3)	2 yes, 0 no	N/A
Be a part of more positive change and less positive tests: make a difference by joining our study and get paid for your time (created by focus group participants at Stage 3)	3 yes, 0 no	*I really like the first part of this message; it's good fun and attention-grabbing. I can't stop my inner pedant from pointing out that it should be 'fewer positive tests' though:D*
Your views are important: join our study to help improve sexual health for young people while being paid! (created by focus group participants at Stage 3)	2 yes, 0 no	N/A

TABLE 38 Public and patient involvement voting on advert component parts (Stage 4)

Advert component	Voting	Quotes
Call to action		
Want to make a positive change?	No votes	N/A
We need your help!	3 yes, 0 no	N/A
Views of young people needed!	No votes	N/A
Want to make a difference?	3 yes, 0 no	N/A
Join our research team!	No votes	*Someone pointed out in the focus group that this may sound too much like a full-time job*
Description of the research		
Take part in a study to improve young people's sexual health.	3 yes, 0 no	N/A
Take part in a study on young people's sexual health.	No votes	N/A
Take part in a study on supporting young people's condom use.	No votes	N/A
Support other young people to improve their sexual health by taking part in our study.	3 yes, 0 no	N/A
Incentive		
Get paid for your time.	3 yes, 0 no	N/A
Get rewarded for your time.	No votes	*This is a bit more vague compared to the others*
Earn up to £65 in vouchers for your time.	2 yes, 0 no	N/A
Last few spaces remaining!	No votes	N/A

TABLE 39 Final PPI voting on strategies for use in fRCT (Stage 4)

All messages should:	Feedback	Votes	Quotes
Engaging participants with the research			
Messages should be fun and relevant, especially subject lines for e-mails	There was agreement that messages should be fun but there was concern that the type of messages as suggested by the focus groups might make people feel uncomfortable. Important that messages should have a professional feel.	2 yes, 1 no	*I like the idea of being fun, but I don't like the vibe of the messages in the examples could just be me though! Maybe something along the lines of 'Spent that voucher yet? We have another one waiting for you!'. Not really that fun I guess, but think it's a catchy way to entice someone.*
Feel current – like mentioning seasonal holidays or events	Voting unanimously indicated that this was acceptable.	3 yes, 0 no	N/A
The sender should be a researcher's name	Voting unanimously indicated that this was acceptable.	3 yes, 0 no	*I think this a really nice idea, or 'The Wrapped Team' rather than 'Project' maybe?*
Messages should contain photos of the research team	Including pictures of the research team was not considered a good idea as it may make participants feel uncomfortable.	0 yes, 2 no	*Don't think that's too relevant, I guess it's always nice to put a face to a name but not a necessity in this case. I think by keeping things a little more anonymous participants would and it easier to be more open when answering questions.*
All messages should be sent midweek: Tuesday, Wednesday or Thursday	Voting unanimously indicated that messages should be sent any day of the week as this would make no difference to response rates.	0 yes, 3 no	N/A
Sent at a particular time of day (such as 12:00 or 5:00)	Voting unanimously indicated that 5:00 was an ideal time for all messages to be sent out as this would catch the majority of participants at an opportune time to respond immediately.	3 yes, 0 no	*This way it will be fresh in participants minds when they get home and have time to complete activities*
If messages could only be e-mail or SMS, but not both, what is the preference?	E-mails were seen as preferable if only one communication method could be used, as it would be more accessible by multiple devices, would likely be easier for the research team to format the messages, and would be easier to personalise for participants, which would be better for retention.	3 yes, 0 no	*Emails are available on both phones and computers, which might increase likelihood of participants seeing the messages. Formatting is also a bit easier/more customise-able*
Should we collect data over the Christmas/New Year period?	Feedback was unanimous that attempting to collect data over the holiday period would result in lower response rates.	0 yes, 3 no	*Even if people aren't actively annoyed by being contacted over this period, there is a very good chance they will forget to participate*
Newsletters	Newsletters should: • be sent by e-mail • not be combined with other messaging (such as reminders, etc.) • include an opt-out function, if possible	3 yes, 0 no	N/A
Birthday greetings	Not considered acceptable; likely perceived as annoying spam at best, at worst participant would feel uncomfortable receiving birthday greetings from sexual health researchers.	0 yes, 3 no	*It might help people be more open if there is a degree of separation between their personal info (birthday) and the messages they receive*
Timing and nature of survey invitations			
Invites by e-mail	See above – preference for all communications by e-mail		
Prompts	Mixed opinions on the utility of prompts. Research team decided to use test kit prompts as an opportunity to check participants' postal address and include brief mention that survey would arrive by e-mail in a few days.	2 yes, 1 no	N/A

TABLE 39 Final PPI voting on strategies for use in fRCT (Stage 4) (*continued*)

All messages should:	Feedback	Votes	Quotes
Value and implementation of financial incentives			
Voucher schedule 1	Month 0 (joining the study) £5 Month 3 kit £10 Month 3 survey £5 Month 6 survey £10 Month 12 kit £25 Month 12 survey £10	0 yes, 2 no	–
Voucher schedule 2	Month 0 (joining the study) £5 Month 3 kit £10 Month 3 survey £5 Month 6 survey £10 Month 12 kit £20 Month 12 survey £15	3 yes, 0 no	–
Reminders to complete activities			
Reminders	A total of 3 reminders were decided upon for the test kits and surveys. Members were in favour of test kit reminders 10 days apart. The research team decided to have the first reminder 3 days after test kit receipt, with the remainder 10 days apart, due to concerns that leaving 10 days might miss vital opportunity to nudge participants to complete their sample and post it back in a timely manner. Members in favour of a deadline being mentioned in reminders, but research team concerned that this would discourage completion and instead opted to emphasise the incentives of completion.	2 yes, 1 no	N/A
Actions to minimise non-response			
No voting; all strategies had mutual agreement from Stages 2 and 3			

Appendix 2 Consolidated Standards of Reporting Trials 2010 checklist

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial			
Section/topic	**Item no.**	**Checklist item**	**Reported on page no.**
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	i
	1b	Structured summary of pilot trial design, methods, results and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	iii
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	1–2
	2b	Specific objectives or research questions for pilot trial	13
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	13
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	Deviations from protocol: 14 15 17
Participants	4a	Eligibility criteria for participants	14
	4b	Settings and locations where the data were collected	14
	4c	How participants were identified and consented	14
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	16
Outcomes	6a	Completely defined pre-specified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	15–16 17–18
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	Deviations from protocol: 18
	6c	If applicable, pre-specified criteria used to judge whether, or how, to proceed with future definitive trial	17
Sample size	7a	Rationale for numbers in the pilot trial	17
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial			
Section/topic	**Item no.**	**Checklist item**	**Reported on page no.**
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	14–15
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	14–15
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	14–15
Implementation	10	Who generated the random allocation sequence, who enrolled participants and who assigned participants to interventions	14–15
Blinding	11a	If done, who was blinded after assignment to interventions (e.g. participants, care providers, those assessing outcomes) and how	15
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	17–18
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	18
	13b	For each group, losses and exclusions after randomisation, together with reasons	21–22
Recruitment	14a	Dates defining the periods of recruitment and follow-up	20 20
	14b	Why the pilot trial ended or was stopped?	20
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	19–20
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	Provided throughout results section 21–35
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	21–35
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	34–35
	19a	If relevant, other important unintended consequences	N/A
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	69–70
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	63–69

continued

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial			
Section/topic	**Item no.**	**Checklist item**	**Reported on page no.**
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	63–69
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	63 71–72
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	14
Protocol	24	Where the pilot trial protocol can be accessed, if available	14
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	xvii
	26	Ethical approval or approval by research review committee, confirmed with reference number	14

Appendix 3 Feasibility randomised controlled trial methods – additional material

TABLE 40 Schedule of voucher payments

Activity	First wave (£)	Second wave (£)	Third wave (£)
Month 0 (joining the study)	5	10	15
Self-report of baseline test result	0	5	5
Visiting the website	0	5	5
Month 3 test kit	10	10	15
Month 3 survey	5	10	10
Month 6 survey	10	10	10
Month 12 test kit	20	20	25
Month 12 survey	15	15	15
Total	65	85	100

TABLE 41 Stratification groupings

Item in baseline survey	Stratification groupings
Ethnicity *How would you describe your ethnic background?*	
White	White
Mixed or multiple ethnic groups	Mixed or multiple ethnic groups
Asian or Asian British	Asian or Asian British
Black, African, Caribbean or Black British	Black, African, Caribbean or Black British
Other ethnic group	Other ethnic group
Sexual identity *How would you describe your sexual identity?*	
Heterosexual	Heterosexual
Lesbian	Other
Gay	
Bisexual	
Asexual	
Other	

continued

TABLE 41 Stratification groupings (*continued*)

Item in baseline survey	Stratification groupings
Deprivation[a] *How would you describe your financial situation while you were growing up?*	
Very comfortable – I had everything I needed and more	Low deprivation
Comfortable – money was never an issue	
Fairly comfortable but it was necessary to keep an eye on money	Medium deprivation
Things were OK but money was tight sometimes	
Money seemed to be a problem a lot of the time	High deprivation
It was always a struggle to get the basics (food, clothes, heating)	

a This measure of deprivation was used for stratification purposes as IMD quintile (manually obtained using each participant's postcode) was unavailable at the point of randomisation.

Appendix 4 Feasibility randomised controlled trial rationale for protocol changes

Original per protocol progression criteria and detailed rationale for changes

1. An average of 1.8% of freetest.me users (out of those who place an order for self-sampling kit in our four areas) per day recruited over 3 months (estimated rate required to recruit sufficient numbers to the definitive RCT over 12 months)

   To estimate the recruitment rate for the main trial, and therefore the target recruitment rate for the fRCT, two key pieces of information were determined as necessary: (a) size of sampling pool required for the main trial and (b) size of sample required for the main trial. Fluctuations in levels of business (number of 16- to 24-year-olds visiting online services for STI testing), and market share held by Preventx, meant that the available sampling pool most accurately determined as close to start of the main trial as possible (using the number of orders placed via Preventx in the 12-month period up to the date that the data request is made). Similarly, sample size most accurately estimated as close to start of the main trial as possible to enable sample size calculation to include the most up-to-date data available on population levels of chlamydia positivity, and level of chlamydia positivity observed in the control group of the fRCT. For this reason, it was agreed that the target sample size should be set at the endpoint of the fRCT.

2. 80% of participants (those randomised) followed up for the definitive RCT primary outcome measure at 12 months

   DMEC/SSC advised that 80% retention was too ambitious (based on evidence in the literature on typical retention in similar studies) – the advice was to reduce to 60%.

3. Mean deprivation score of the final sample is ±10% that of users of freetest.me in each of the four areas (as measured over the 3-month recruitment period)

   Amended as Preventx was only able to provide data on IMD quintile (as opposed IMD score) for the sampling pool. With categorical data (as opposed to continuous level data), it was not possible to test whether the mean deprivation score of final sample was within ±10% of users of freetest.me/SH.UK. It was agreed instead that the proportion of participants in each quintile across the two samples would be compared.

4. Absence of serious/frequent adverse events

   This change was made at the request of the DMEC/SSC, with committee members preferring wording that better reflected the subjective nature of this assessment.

Appendix 5 Feasibility randomised controlled trial results – additional material

TABLE 42 Demographic characteristics overall and by trial arm at baseline for restricted sample

Characteristic	Intervention (*n* = 84) *n* (%)	Control (*n* = 89) *n* (%)	Total (*n* = 173) *n* (%)
Age (years)			
16	1 (1.2)	2 (2.2)	3 (1.7)
17	1 (1.2)	1 (1.1)	2 (1.2)
18	3 (3.6)	6 (6.7)	9 (5.2)
19	3 (3.6)	4 (4.5)	7 (4.0)
20	11 (13.1)	19 (21.3)	30 (17.3)
21	21 (25.0)	9 (10.1)	30 (17.3)
22	9 (10.7)	18 (20.2)	27 (15.6)
23	15 (17.9)	17 (19.1)	32 (18.5)
24	20 (23.8)	13 (14.6)	33 (19.1)
Median age (IQR)	22 (2)	22 (3)	22 (3)
Age group			
16–19	8 (9.5)	13 (14.6)	21 (12.1)
20–24	76 (90.5)	76 (85.4)	152 (87.9)
Ethnicity (stratification factor)			
White	73 (86.9)	76 (85.4)	149 (86.1)
Mixed or multiple ethnic groups	2 (2.4)	6 (6.7)	8 (4.6)
Asian or Asian British	1 (1.2)	4 (4.5)	5 (2.9)
Black, African, Caribbean or Black British	7 (8.3)	3 (3.4)	10 (5.8)
Other ethnic group	1 (1.2)	0	1 (0.6)
Gender			
Female	56 (66.7)	72 (80.9)	128 (74.0)
Male	24 (28.6)	16 (18.0)	40 (23.1)
Non-binary or gender fluid	3 (3.6)	1 (1.1)	4 (2.3)
Other	1 (1.2)	0	1 (0.6)
Gender not as assigned at birth			
	3 (3.6)	3 (3.4)	6 (3.5)
Sexual identity[a] (stratification factor)			
Heterosexual	58 (69.0)	56 (62.9)	114 (65.9)
Gay	8 (9.5)	3 (3.4)	11 (6.4)

TABLE 42 Demographic characteristics overall and by trial arm at baseline for restricted sample (*continued*)

Characteristic	Intervention (*n* = 84) *n* (%)	Control (*n* = 89) *n* (%)	Total (*n* = 173) *n* (%)
Bisexual	16 (19.0)	29 (32.6)	45 (26.0)
Other	2 (2.4)	1 (1.1)	3 (1.7)
Financial situation while growing up (stratification factor)			
Very comfortable – I had everything I needed and more	7 (8.3)	7 (7.9)	14 (18.1)
Comfortable – money was never an issue	18 (21.4)	20 (22.5)	38 (22.0)
Fairly comfortable but it was necessary to keep an eye on money	27 (32.1)	27 (30.3)	54 (31.2)
Things were OK but money was tight sometimes	19 (22.6)	21 (23.6)	40 (23.1)
Money seemed to be a problem a lot of the time	9 (10.7)	10 (11.2)	19 (11.0)
It was always a struggle to get the basics (food, clothes, heating)	4 (4.8)	4 (4.5)	8 (4.6)
IMD quintile			
Quintile 1 (most deprived)	11 (13.1)	14 (15.7)	25 (14.5)
Quintile 2	14 (16.7)	13 (14.6)	27 (15.6)
Quintile 3	18 (21.4)	26 (29.2)	44 (25.4)
Quintile 4	21 (25.0)	23 (25.8)	44 (25.4)
Quintile 5 (least deprived)	20 (23.8)	13 (14.6)	33 (19.1)
Relationship status			
Single	34 (40.5)	35 (39.8)	69 (40.1)
In a casual relationship with one person	18 (21.4)	15 (17.0)	33 (19.2)
In casual sexual relationships with two or more people	9 (10.7)	9 (10.2)	18 (10.5)
In a serious relationship with one person	22 (26.2)	24 (27.3)	46 (26.7)
In a serious relationship with more than one person	0	0	0
Combining serious and casual relationships	1 (1.2)	4 (4.5)	5 (2.9)
Other	0	1 (1.1)	1 (0.6)
Missing	0	1 (1.1)	1 (0.6)

a No participants self-reported their sexual identity as lesbian or asexual.

TABLE 43 Distribution of age among service users in the sampling pool, the baseline sample and participants in the study at 12 months follow-up (full and restricted samples)

	Sampling pool (*n* = 11,413)	Baseline (*n* = 230)	M12 follow-up – full sample (*n* = 151)	M12 follow-up – restricted sample (*n* = 131)
Age	***N* (%)**	***N* (%)**	***N* (%)**	***N* (%)**
16–19	2855 (25.0)	30 (13.0)	15 (9.9)	11 (8.4)
20–24	8558 (75.0)	200 (87.0)	136 (90.1)	120 (91.6)
Median age	22	22	22	22

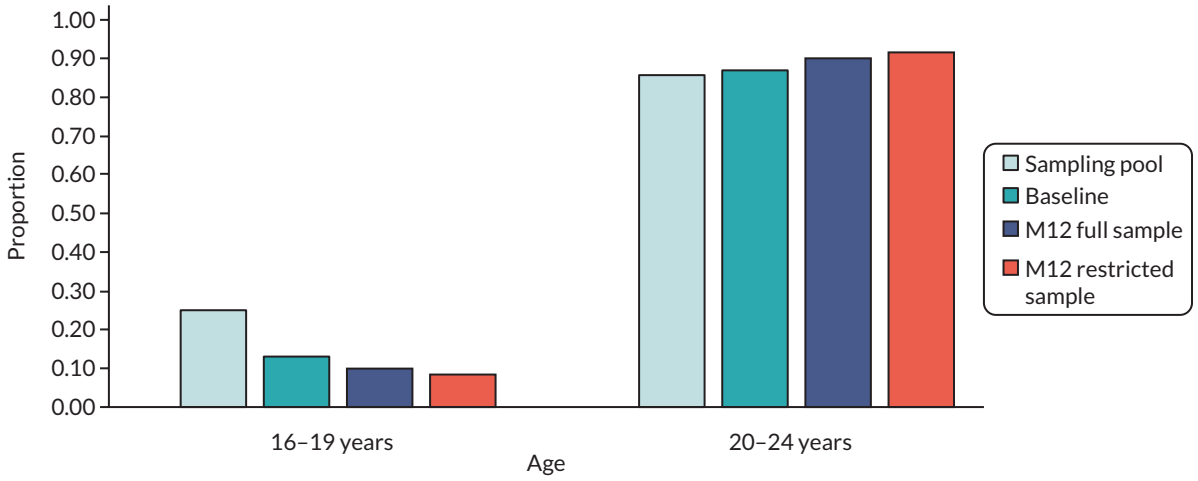

FIGURE 6 Bar chart displaying the proportion of individuals by age (in years) within the sampling pool, the baseline sample, the full sample at M12 and the restricted sample at M12.

TABLE 44 Distribution of gender among service users in the sampling pool, the baseline sample and participants in the study at 12 months follow-up (full and restricted samples)

	Sampling pool (*n* = 11,413)	Baseline (*n* = 151)	M12 follow-up – full sample (*n* = 151)	M12 follow-up – restricted sample (*n* = 131)
Gender	***N* (%)**	***N* (%)**	***N* (%)**	***N* (%)**
Female	8057 (70.6)	165 (71.7)	109 (72.2)	96 (73.3)
Male	3305 (29.0)	59 (25.7)	38 (25.2)	32 (24.4)
Other[a]	51 (0.4)	6 (2.6)	4 (2.6)	3 (2.3)

a Other includes transgender and non-binary/fluid gender (data on these gender categories not reported by Preventx and therefore unavailable for comparison purposes).

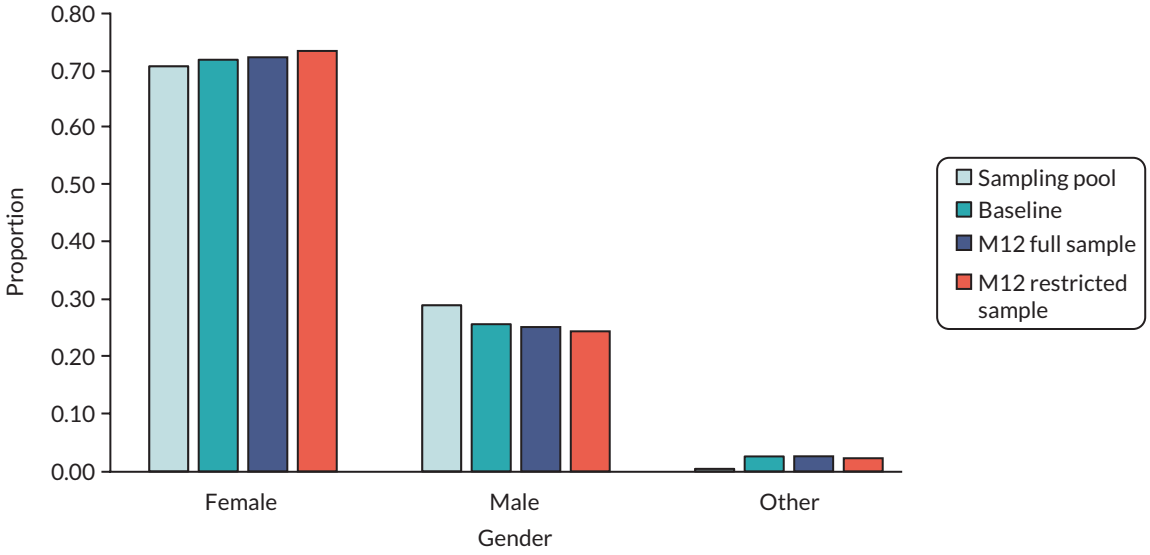

FIGURE 7 Bar chart displaying the proportion of individuals by gender within the sampling pool, the baseline sample, the full sample at M12 and the restricted sample at M12.

TABLE 45 Distribution of ethnicity among service users in the sampling pool, the baseline sample and participants in the study at 12 months follow-up (full and restricted samples)

Ethnicity	Sampling pool (*n* = 11,413) *N* (%)	Baseline (*n* = 230) *N* (%)	M12 follow-up full sample (*n* = 151) *N* (%)	M12 follow-up restricted sample (*n* = 131) *N* (%)
White	11,413 (89.0)	193 (83.9)	129 (85.4)	113 (86.3)
Mixed or multiple ethnic groups	578 (5.1)	16 (7.0)	6 (4.0)	4 (3.1)
Asian or Asian British	254 (2.2)	5 (2.2)	3 (2.0)	3 (2.3)
Black, African, Caribbean or Black British	276 (2.4)	13 (5.7)	10 (6.6)	10 (7.6)
Other ethnic group	142 (1.2)	3 (1.3)	3 (2.0)	1 (0.8)

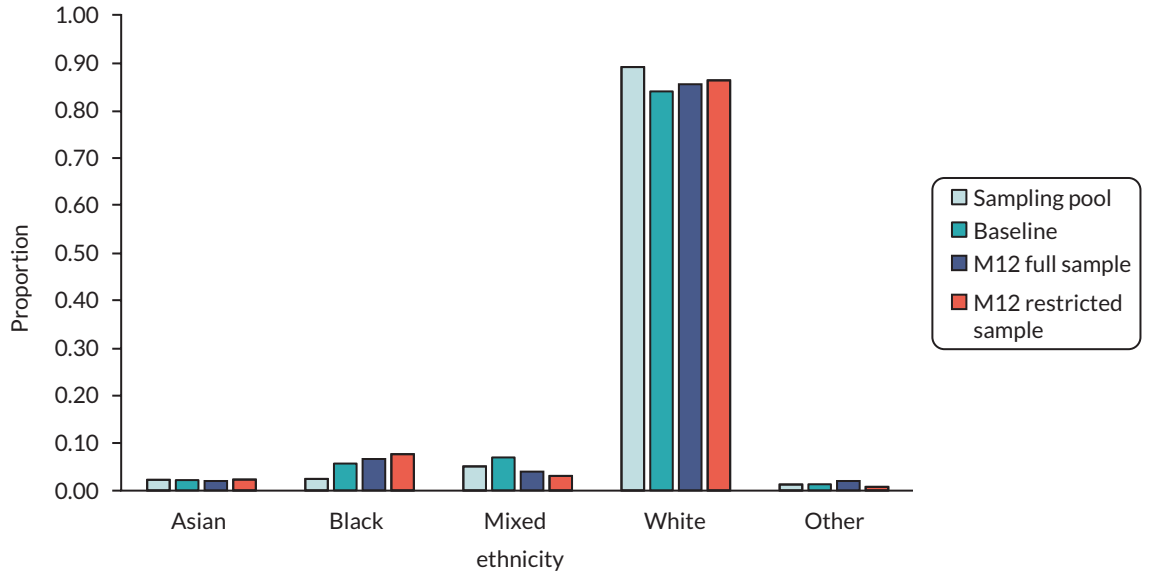

FIGURE 8 Bar chart displaying the proportion of individuals by ethnicity within the sampling pool, the baseline sample, the full sample at M12 and the restricted sample at M12.

TABLE 46 Distribution of sexual identity among service users in the baseline sample and participants in the study at 12 months follow-up (full and restricted samples)

	Baseline (*n* = 230)	M12 follow-up full sample (*n* = 151)	M12 follow-up restricted sample (*n* = 131)
Heterosexual	151 (65.5)	95 (62.9)	83 (62.9)
Gay	15 (6.5)	12 (7.8)	10 (7.6)
Bisexual	61 (26.5)	42 (27.8)	36 (27.5)
Other	3 (1.3)	2 (1.3)	2 (1.5)

Note
No participants self-reported their sexual identity as lesbian or asexual.

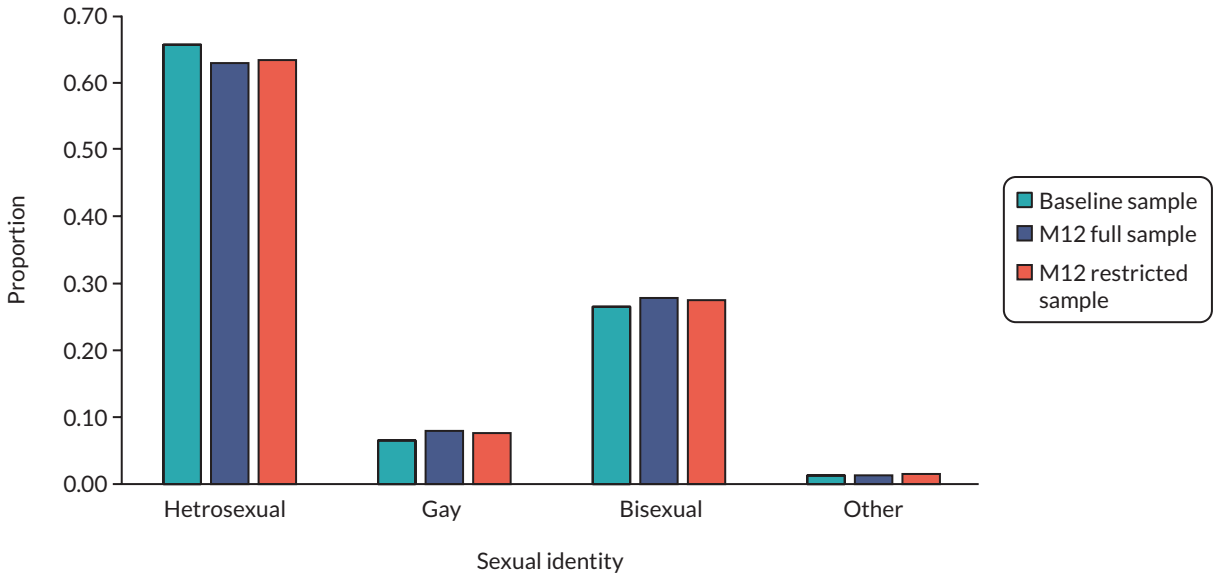

FIGURE 9 Bar chart displaying the proportion of individuals by sexual identity within the baseline sample, the full sample at M12 and the restricted sample at M12.

TABLE 47 Demographic characteristics of participants who completed baseline and who returned a valid M12 chlamydia self-sample by intervention and control group (restricted sample)

	N (%) with valid sample			95% CI	
	Intervention (*n* = 72)	Control (*n* = 59)	Percentage difference	Lower limit	Upper limit
Age (years)					
16–19	4 (5.6)	7 (11.9)	−6.3	−16.1	3.5
20–24	68 (94.4)	52 (88.1)	6.3	−3.5	16.1
Gender					
Female	48 (66.7)	48 (81.4)	−14.7	−29.4	0.0
Male	21 (29.2)	11 (18.6)	10.6	−3.9	25.1
Other[a]	3 (4.1)	0 (0)	41	0.0	8.7

TABLE 47 Demographic characteristics of participants who completed baseline and who returned a valid M12 chlamydia self-sample by intervention and control group (restricted sample) (*continued*)

	N (%) with valid sample			95% CI	
	Intervention (*n* = 72)	Control (*n* = 59)	Percentage difference	Lower limit	Upper limit
Ethnicity					
White	61 (84.7)	52 (88.1)	−3.4	−15.1	8.3
Mixed or multiple ethnic groups	2 (2.8)	2 (3.4)	−0.6	−6.6	5.4
Asian or Asian British	1 (1.4)	2 (3.4)	−2.0	−7.4	3.4
Black, African, Caribbean or Black British	7 (9.7)	3 (5.1)	4.6	−4.2	13.4
Other ethnic group	1 (1.4)	0 (0)	1.4	−1.3	4.1
IMD quintile					
1 (most deprived)	11 (15.3)	10 (16.9)	−1.6	−14.3	11.1
2	9 (12.5)	10 (16.9)	−4.4	−16.6	7.8
3	14 (19.4)	15 (25.4)	6.0	−20.4	8.4
4	20 (27.8)	12 (20.3)	7.5	−7.1	22.1
5 (least deprived)	18 (25.0)	12 (20.3)	4.7	−9.6	19.0
Sexual identity[a]					
Heterosexual	48 (66.7)	35 (59.3)	7.4	−9.2	24.0
Gay	7 (9.7)	3 (5.1)	4.6	−4.2	13.4
Bisexual	15 (20.8)	21 (35.6)	14.8	−30.2	0.6
Other	2 (2.8)	0 (0)	2.8	−1.0	6.6

a No participants self-reported their sexual identity as lesbian or asexual.

TABLE 48 The proportion of Preventx users by age group, recruited to the study per recruitment message and total incentive offered

Advert number	Advert text	Length of time advert displayed (in weeks)	Incentive amount as communicated in advert and/or participant information (£)	Age group	Percentage (*n*/*n*) of service users recruited following presentation of advert per age group
1	Help us make a positive change to young people's sexual health: make a difference by joining our study *and* get paid for your time!	2	65	16–19	0.3 (1/310)
				20–24	2.8 (18/644)
2	Take part in a study to improve sexual health and earn up to £65 in Amazon vouchers, find out how you can make a difference today!	2	65	16–19	0.8 (2/248)
				20–24	2.5 (17/693)

continued

TABLE 48 The proportion of Preventx users by age group, recruited to the study per recruitment message and total incentive offered (*continued*)

Advert number	Advert text	Length of time advert displayed (in weeks)	Incentive amount as communicated in advert and/or participant information (£)	Age group	Percentage (*n*/*n*) of service users recruited following presentation of advert per age group
3	Your views are important: join our study to help improve sexual health for young people while being paid!	2	65	16–19	0.4 (1/241)
				20–24	2.3 (16/700)
4	Make a difference to improve sexual health for young people – join our study and earn up to £65 in Amazon vouchers for your time!	1	65	16–19	7.2 (5/69)
				20–24	2.2 (4/185)
5	Interested in sexual health research? Take part and get up to £85 in vouchers.	3	85	16–19	0.7 (1/147)
				20–24	4.4 (19/430)
6	Help us make a positive change to young people's sexual health: make a difference by joining our study and get up to £100 in vouchers.	2	100	16–19	0 (0/118)
				20–24	1.5 (5/342)
7	Take part in a study to improve sexual health and earn up to £100 in vouchers, find out how you can make a difference today.	2	100	16–19	0.9 (1/109)
				20–24	1.8 (6/337)
8	Your views are important: join our study to help improve sexual health for young people and get paid up to £100 in vouchers!	2	100	16–19	3.6 (4/110)
				20–24	2.4 (9/381)
9	*Earn £100 Amazon vouchers* Make a difference to improve sexual health for young people – join our study and earn up to £100 in vouchers for your time.	3	100	16–19	0.7 (2/281)
				20–24	2.3 (3/1001)
10	*Earn £100 Amazon vouchers* Want to make a difference to young people's sexual health? Take part in our study and get up to £100 in vouchers for your time.	2	100	16–19	0 (0/240)
				20–24	2.2 (15/682)
11	*Earn £100 Amazon vouchers* We need your help! Take part in a study to improve young people's sexual health and earn up to £100 in vouchers for your time.	2	100	16–19	0.4 (1/225)
				20–24	1.0 (7/719)
12	*Earn £100 Amazon vouchers* Interested in sexual health research? Take part and get up to £100 in vouchers.	3	100	16–19	2.3 (7/304)
				20–24	2.0 (21/1043)
13	*Shown to service users aged 20–24: Earn £100 Amazon vouchers* Interested in sexual health research? Take part and get up to £100 in vouchers.	3 (plus 1 day)	100	16–19	2.8 (39/1401)
	Shown to service users aged 16–19: Want to earn up to £100 in Amazon Vouchers? Interested in sexual health research and aged 16–19 years?			20–24	1.3 (6/453)

Appendix 6 Nested qualitative study – additional material

TABLE 49 Demographic characteristics of nested qualitative study sample

	Primary participants	Secondary participants
Age range (mean)	19–24 (22)	18–28 (21)
Ethnicity	24 White 2 Asian, or Asian British 2 Black, African, Caribbean or Black British 1 Other ethnic group 1 Mixed or multiple ethnic groups	3 White
Gender	23 Female 6 Male[a] 1 Non-binary or gender fluid	3 Male
Sexual identity	20 Heterosexual 8 Bisexual 1 Gay 1 Other	Not reported
Level of deprivation[b]	5 High 17 Medium 8 Low	Not reported
Group assignment	15 Intervention 15 Control	1 Intervention 2 Control

a Includes 1 trans-male.
b See *Appendix 3, Table 41* for categorisation.

EME
HSDR
HTA
PGfAR
PHR

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