ISRCTN17478654 https://doi.org/10.1186/ISRCTN17478654

Wrapped: A study to identify which strategies work best to recruit and retain participants in web-based sexual health research

Submission date
26/11/2020

Recruitment status
No longer recruiting

Registration date
03/12/2020

Overall study status
Completed

Last Edited
13/02/2026

Condition category
Urological and Genital Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Last year in England, 210,00015-24 yearolds were diagnosed with a Sexually Transmitted Infection (STI), half of all total diagnoses. The only way for sexually active people to avoid STIs is to use a condom, but young people report inconsistent use.It is important that we look for ways to reach young people at risk of future STIs and identify what will help them to increase their condom use.

Together with young people and stakeholders, we have developed a website called 'Wrapped'. Wrapped is a fully automated, multi-component and interactive digital intervention that aims to reduce future STIs through increasing correct and consistent condom use amongst users of STI self-sampling websites.

What we want to know is whether Wrapped works. To find this out, we need to run a type of experiment called a Randomised Controlled Trial (RCT). RCTs are time consuming and expensive, often involving thousands of participants. In line with good practice, to prepare for this we are going to run a feasibility trial. The primary aim is to identify whether we can recruit and retain the numbers of participants required for an RCT.

We will then test these strategies out by running a mini version of a full RCT (feasibility trial). Throughout, we will carefully monitor engagementand interview participants, including those who drop-out, to see what we can learn about what it is like to be a participant in our study. We will use this evidence to adaptour materials and procedures so that we are ready to carry out a full RCT.Conducting this future trial will enable us to determine whether Wrapped is cost-effective.

Who can participate?
People aged 16 - 24 years old, living in one of the Local Authority locations involved in the study .

What does the study involve?
Young people who participate in the focus groups will be asked to meet online (using video call

software) in groups of 5-7 people for a single discussion lasting approx. one hour. This discussion will be led by a researcher and a member of the PPI group. During the discussion they will be asked for feedback on our proposed materials and procedures. Young people who participate in the mini RCT will be asked to do the following over a period of 12 months: complete four surveys (each taking approximately 20 minutes), provide two STI self-samples using kits sent to their homes, and view a website. Those who take part in the interviews will be asked to join a researcher (using telephone or video call) for a one-off conversation lasting approximately 30 minutes. This will focus on their experience of being a participant in the mini RCT.

What are the possible benefits and risks of participating?
Benefits: participants will be given access to one of the two websites which they are free to use as much as they like during the study. In recognition of their time and effort, they will also receive Amazon vouchers for each completed survey and STI self-sample.
Risks: The risks of taking part are low and in line with those of normal everyday activities. All communication with participants will be discreet. Taking part may lead young people to think about their own condom use and sexual health. For those participating in the mini RCT, the websites will provide information on how to access condoms and support on issues relating to sexual health. An auto-generated email will also be sent to on completion of each survey containing information on sources of further help and support should they need it.

Where is the study run from?
The study is being run entirely online by a team based at the University of Hertfordshire (UK).

When is the study starting and how long is it expected to run for?
May 2020 to December 2022

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Katie Newby, k.newby@herts.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
285542

Central Portfolio Management System (CPMS)
47477

Study information

Scientific Title
An interactive digital behaviour change intervention (Wrapped) to decrease incidence of sexually transmitted infections (STIs) amongst users of STI self-sampling websites: Study protocol for a randomised controlled feasibility trial

Study objectives
Research question: Is it feasible to run an RCT to test the effectiveness and cost-effectiveness of Wrapped (a fully automated, multi-component and interactive digital behaviour change intervention that aims to reduce the incidence of STIs through increasing correct and consistent condom use amongst users of STI self-sampling websites aged 16-24 years old)?

Aim: to assess whether and how it is possible to carry out a future definitive RCT to evaluate the effectiveness and cost effectiveness of Wrapped in comparison to usual care (the provision of basic information on STIs and condom use).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/11/2020, Leicester Central REC (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 972 2568; leicestercentral.rec@hra.nhs.uk), ref: 20/EM /0275

Study design
Randomized controlled feasibility study with nested qualitative evaluation

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Reproductive health

Interventions

Feasibility study:

Baseline
Participants will be recruited from a STI self-sampling website, freetest.me. After requesting a self-sampling kit, users of the website will be shown one of six brief messages inviting them to take part in the trial. Upon clicking on the link, potential participants will be taken to REDCap (a secure data capture and management platform hosted on the University of Hertfordshire's server) where they will be presented with the participant information sheet with details about the trial. They will then be asked to complete eligibility questions before they are directed to the online consent form. Once the consent form has been completed, REDCap will create a unique ID for each participant and record their consent.

The completion of the consent form will trigger an email to the participant to thank them for deciding to take part in the trial. This email will list contact details for the research team and have a copy of the Participant Information Sheet attached for their records. On consent, they will be automatically directed to the baseline (M0) survey, where they will be asked to complete a set of questions covering; demographics information, STI diagnosis, sexual wellbeing, condom use, motivation, intentions and attitude, health economics and adverse effects. One reminder will be sent if the baseline survey is incomplete after 2 days. On completion of the baseline survey, we will complete a number of pre-defined manual data exclusion checks, put in to place to ensure participants are genuine and unique. Once the data exclusion checks have been satisfied, participants will be randomised to one of two websites (intervention website or control website) using REDCap's randomisation module. This randomisation will trigger an email to be sent to the participant containing a link to the website they have been randomised to, explaining they are free to use the website as much or as little as they like during the next 12 months (and reminding them that they have consented to us tracking their use of this site). Participants allocated to the control arm will view a website created by the research team, that replicates basic 'standard care' information. Please note, a waiting list control design was deemed inappropriate because it would mean control participants waiting an unacceptable length of time before being given access to the intervention (12 months) and because this length of wait would likely unblind them to condition.

Following completion of baseline, all participants will receive an autogenerated email thanking them for their time and emphasising the positive impact their input will have on the research. This email will also contain a link to a website listing sources of support for sexual assault, abuse, and/or coercion should this be required. Participants who complete the baseline will also receive a separate email with their voucher.

Ten days following the baseline survey, participants will be asked to self-report the result of the recent chlamydia self-sampling test they ordered via the freetest.me website (immediately prior to receiving the study invite). As this test will be requested and processed outside of the research study, we are unable to request these to be shared with us directly via freetest.me. This request will be made via SMS. Participants will receive a one-item within-SMS survey with the following response options: negative; positive; haven't received results yet; and kit not returned. If the participant does not respond, then we will send a repeat of this SMS 5 days later. If a participant reports that they have not returned their kit or received their results a follow up message will be sent 10 days later. Other follow up SMS messages will be sent if relevant.

Participants who have a positive test result will receive a one-item within SMS survey 14 days post-result to record whether their infection has been treated. Participants will be asked to indicate this with the following options: I was prescribed antibiotics and I took them all; I was prescribed antibiotics but I didn't take them all; I didn't get a prescription in the end. Reminders

and follow up SMS messages will be sent if relevant. As a last resort, we may make telephone contact with participants to remind them to complete activities and/or to obtain key outcome data (e.g. via a shortened survey).

Month 3
7 days prior to the first self-sampling test kit being sent out (month 3 test kit), participants will be sent an SMS asking them to confirm the address they would like their test kit to be sent to. Around the time of the first follow up survey at month 3, participants will receive a self-sampling kit in the post. They will be asked to complete the test and return to freetest.me in the usual way. A reminder SMS will be sent to all participants 3 days following the test being received by them, to remind them to return it if they haven't already done so. At 13 and 23 days following the test being received by participants, any participant who has not yet completed the test kit will be sent further reminders. Three months into the trial, participants will be sent an email with a link to the first follow up survey (M3). A total of three reminders will be sent at intervals of 5 days later if the participant has not completed the survey; the first two reminders will be sent by email with the final reminder sent by either email or SMS, to ensure the participant's email address is still valid and functional. After the three reminders have elapsed, participants will be contacted by email to check if they are having any difficulties completing the measures and ask if they need any support to complete. If this message is not responded to, a letter will be sent in the post to confirm the participant's contact details are correct; this letter will also include a postal version of the questionnaire with a freepost envelope to return it.

The chlamydia tests at M3 will be processed differently to that at M0, as these are managed within the study. For this purpose, freetest.me will provide the study team with a batch of self-sampling test kits, each marked with a unique freetest.me kit code. As and when kits are sent out to each participant through the post, the research team will record each individual participant's assigned kit code. A database will be set up specifically for this purpose within REDCap. The database will link the freetest.me kit codes with each participant's unique participant number. The kits that participants receive at M3 will contain the usual user instructions to collect the sample and return by Freepost to freetest.me for processing.A member of the research team (KK or KN) will be given secure access to a service area set up by freetest.me to retrieve participants' test results. These will then be inputted into the REDCap database. Participants who have a positive test result will receive a one-item within SMS survey 14 days post-result to record whether their infection has been treated, as per the procedure followed at baseline (outlined above). Participants who do not respond to this SMS will be sent an SMS reminder 5 days later. Reminders and follow up SMS messages will be sent if relevant. As before, as a last resort, we may make telephone contact with participants to remind them to complete activities and/or to obtain key
outcome data (e.g. via a shortened survey) if required.

Month 6
At month 6, participants will be sent a link for the second follow up survey (M6) via email. A total of three reminders will be sent at intervals of 5 days later if the participant has not completed the survey; the first two reminders will be sent by email with the final reminder sent by either email or SMS, to ensure the participant's email address is still valid and functional. After the three reminders have elapsed, participants will be contacted by email to check if they are having any difficulties completing the measures and ask if they need any support to complete. If this message is not responded to, a letter will be sent in the post to confirm the participant's contact details are correct; this letter will also include a postal version of the questionnaire with a freepost envelope to return it. As before, as a last resort, we may make telephone contact with participants to remind them to complete activities and/or to obtain key outcome data (e.g. via a shortened survey).

Month 12
7 days prior to the second self-sampling test kit being sent out (month 12 test kit), participants will be sent an SMS asking them to confirm the address they would like their test kit to be sent to. Around the time of the follow up survey at month 12, participants will be sent a self-sampling kit in the post. They will be asked to complete the test and return to freetest.me in the usual way. A reminder SMS will be sent to all participants 3 days following the test being received by them, to remind them to return it if they haven't already done so.
At 13 and 23 days following the test being received by participants, any participant who has not yet completed the test kit will be sent further reminders. The self-sampling test kit will be processed in the same way as the M3 test (outlined above).

If a positive result is entered into the database, an automated one-item within SMS survey will be sent to the participant 14 days later to ask if they have received treatment as per baseline procedure (outlined above). Participants who do not respond to this SMS will be sent an SMS reminder 5 days later. Reminders and follow up SMS messages will be sent if relevant.

At month 12 the participants will be sent a link via email for the final follow up survey (M12). A total of three reminders will be sent at intervals of 5 days later if the participant has not completed the survey; the first two reminders will be sent by email with the final reminder sent by either email or SMS, to ensure the participant's email address is still valid and functional. After the three reminders have elapsed, participants will be contacted by email to check if they are having any difficulties completing the measures and ask if they need any support to complete. If this message is not responded to, a letter will be sent in the post to confirm the participant's contact details are correct; this letter will also
include a postal version of the questionnaire with a freepost envelope to return it. As before, as a last resort, we may make telephone contact with participants to remind them to complete activities and/or to obtain key outcome data (e.g. via a shortened survey).

On completion of the 12 month survey, or after the final reminder, an email will be sent to each participant thanking them for being involved with the study and directing them to the NHS sexual health website should they have any sexual health concerns following on from their involvement in the trial.

Non-responders
Participants who do not complete the surveys (M0, M3, M6 and M12) four weeks after the last contact was made will be classed as non-responders. Similarly, those who have not returned their kit four weeks after the last contact was made will be classed as non-responders. Non-responders will be invited to complete all future activities (surveys and tests) unless they specifically make a request to be withdrawn from the study.

All timepoints
Participants who complete study measures will be reimbursed for their time (see Recruitment Section, amount and frequency of payment to participants).
Following completion of each survey, participants will receive an email thanking them for their input. This contains links to, sources of information on sexual health, and to help and support for issues concerning sexual abuse/coercion (see appendix 4 for a copy of the email template 'survey completion – Standard Sexual Wellbeing Support). All participants who disclose abuse /coercion will be further signposted and supported in line with our safeguarding procedure.

Participants will also receive 3-4 project updates by email throughout the 12 month study period. These updates will be brief, comprising around three sentences, and will emphasise how

each participant is making a difference to the study. Project updates will include a link to the study website where a longer, more detailed project update can be accessed should participants be interested in finding out more.

All timings and frequencies of notifications and reminders were determined by the proceeding qualitative study and in collaboration with the PPI group.

Nested qualitative study:
Throughout the current research, we will conduct a nested qualitative study. This qualitative data will provide further evidence to support or refute the hypotheses from the feasibility RCT about recruitment and attrition and will provide a better understanding of participant engagement with the intervention, in particular dose received (satisfaction), and aspects of the environment which may have affected dose received (context). The qualitative data will also explore participants' perceptions of any changes in condom-related beliefs and behaviour, this will include attempting to gain their insight into any components that may have been responsible for this.We will initially invite approximately 30 individuals (number to be determined by data saturation) participating in the feasibility RCT to take part in the study. We will also seek to gain an understanding of the influence of sexual partners on condom use decision making in light of the intervention. To further draw this out, we will attempt to interview the sexual partners of interviewees. Interviews will take place either over the phone or video call (MS Teams or Zoom), to be agreed upon between the participant and the researcher conducting the interview.
Participants who indicate that they were willing to be contacted about the nested qualitative study will be contacted via telephone to ask if they are still interested. If they confirm that they are, the researcher will send an email with the link to a page on REDCap where they will find the participant information sheet explaining the details of the nested qualitative interview study. Here they will also be presented with an online consent form. Once the participant has provided consent, a mutually convenient time to hold the interview will be agreed. The interview will be conducted via telephone or video call (MS Teams or Zoom), whichever the participant prefers. Each participant will be given a unique ID number (assigned automatically by REDCap at consent). At the end of each interview, we will discuss with participants our wish to also interview the sexual partners of those participating in the qualitative study. We will then follow up the interview with an email invitation which they can choose to forward on to their partner if they wish. It will then be up to the sexual partner to contact the research team if they wish to participate. They will be given the option to email the research team if they have any questions, or simply to follow a hyperlink straight to the relevant page on REDCap. Here they will be presented with a participant information sheet and then required to provide informed consent in order to take part in the study. They will also be asked to complete some demographic questions, and to enter some contact details so the research team can contact them to arrange a suitable time for the interview. All data will be collected, processed and analysed as described above for primary interviewees.
Each individual who participates will be given a £20 voucher in recognition of their time.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measures as of 23/06/2025:
1. The proportion of participants recruited to the feasibility RCT per day (assessed as the

number of participants randomised) out of those in the sampling pool
2. The percentage of randomised participants with valid primary outcome measure (chlamydia positivity measured using biological samples) at 12 months

Previous primary outcome measures:
1. The proportion of participants recruited to the feasibility RCT per day (assessed as the number of participants randomised) out of those using freetest.me in the four areas
2. The percentage of randomised participants with valid primary outcome measure (cumulative incidence of chlamydia measured using biological samples) at 12 months

Key secondary outcome(s))

Current secondary outcome measures as of 23/06/2025:
1. Percentage of participants with outcome data required to measure the cumulative incidence of chlamydia (measured using M3 and M12 chlamydia self-sample, and the relevant item within M3, M6 and M12 surveys)
2. Distribution of IMD quintile among those in the sampling pool compared to that of the final sample (deprivation assessed using IMD based on participants' postcodes)
3. Percentage of randomised participants with valid primary outcome measure at 12 months by group (gender, ethnicity, sexual identity, deprivation, randomised groups, chlamydia diagnosis at baseline)
4. Percentage of participants with a positive chlamydia test result at 12 months in the intervention and control groups
5. Attrition curves comparing the percentage of valid participants in the trial at randomisation, M3, M6 and M12 plotted for the intervention and control arms (drop-out attrition)
6. The percentage of valid participants in the two arms that don't achieve pre-determined intervention 'goals', and the bounce rate for home and content pages (assessed using web analytics data at 12M)
7. Completeness of data from outcome measures that would be needed in a definitive trial (including self-report of chlamydia result at baseline, results from biological samples [3M and 12M], demographic information [baseline survey], self-report of condom use [all surveys], and data needed for cost-effectiveness and cost utility analyses [all surveys])
8. The number of participants randomised as a direct result of each of the different recruitment messages employed (assessed using web analytics data at end of recruitment)
9. Completeness of data on costs and resource use that would be needed for the economic evaluation in a definitive trial (all surveys)
10. Proportion of participants in the control group who report (at 12M survey) any exposure to Wrapped
11. Proportion of participants who report (at M12 survey) having experienced an adverse event during the course of the study (inadvertent disclosure that sexually active/testing for STI if overseen using Wrapped, initiation or change in the consumption of pornography, or other)

Previous secondary outcome measures:
1. The mean deprivation score for users of freetest.me over the 3 month recruitment period, compared to the mean deprivation score of the final sample, within each of the four recruitment areas (deprivation assessed using IMD based on participants' postcodes)
2. The percentage of randomised participants with valid primary outcome measure at 12 months by group (gender, ethnicity, sexual identity, deprivation, randomised groups, chlamydia diagnosis at baseline)
3. Cumulative incidence of chlamydia in the intervention and control groups (at 3M and 12M, assessed using participant STI self-sampling kits)
4. Attrition curves comparing the percentage of valid participants in the trial at randomisation, M3, M6 and M12 plotted for the intervention and control arms (drop-out attrition)

5. The percentage of valid participants in the two arms that don't achieve pre-determined intervention 'goals', and the bounce rate for home and content pages (assessed using web analytics data at 12M)
6. Completeness of data from outcome measures that would be needed in a definitive trial (including self-report of chlamydia result at baseline, results from biological samples [3M and 12M], demographic information [baseline survey], self-report of condom use [all surveys], and data needed for cost-effectiveness and cost utility analyses [all surveys])
7. The number of participants randomised as a direct result of each of the different recruitment messages employed (assessed using web analytics data at end of recruitment)
8. Completeness of data on costs and resource use that would be needed for the economic evaluation in a definitive trial (all surveys)
9. Proportion of participants in the control group who report (at 12M survey) any exposure to Wrapped
10. Proportion of participants who report (at M12 survey) having experienced an adverse event during the course of the study (inadvertent disclosure that sexually active/testing for STI if overseen using Wrapped, initiation or change in the consumption of pornography, or other)

Completion date
31/12/2022

Eligibility

Key inclusion criteria
Feasibility trial:
1. Young people aged 16-24 years
2. Living in one of the Local Authority locations involved in the study

Nested qualitative study:
3. A participant of the trial
4. Sexual partner of someone participating in the trial

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Upper age limit
24 years

Sex
All

Total final enrolment

230

Key exclusion criteria
Feasibility trial:
1. No internet access
2. Having sexual preferences which mean that they are unlikely to have penetrative sex (penis in either vagina or anus) over the trial period

Date of first enrolment
11/01/2021

Date of final enrolment
31/10/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The University of Hertfordshire
College Way
Hatfield
England
AL10 9AB

Sponsor information

Organisation
University of Hertfordshire

ROR
https://ror.org/0267vjk41

Funder(s)

Funder type
Government

Funder Name

NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR128148

Funder Name
National Institute for Health Research (NIHR) (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository. Our data will be made available via the University of Hertfordshire Research Archive (UHRA): https://uhra.herts.ac.uk/. The data that will be shared is listed in the attached DMP. It will be available no later than 3 months after the of the end of the study and will remain there indefinitely. It will be available on request to anyone with a legitimate research interest. Detail on each set of preserved data and its format is on the attached DMP. All data will be fully anonymised. All participants will be required to explicitly consent to anonymised study data being deposited in the UHRA.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/08/2025	18/08/2025	Yes	No
Results article		31/10/2025	06/11/2025	Yes	No
Protocol article	protocol	11/05/2023	15/05/2023	Yes	No
HRA research summary			26/07/2023	No	No
Other files	DataManagementPlan version v3	12/11/2020	03/12/2020	No	No
Other		29/05	23/06		

publications		/2025	/2025	Yes	No
Other publications	Mixed-methods assessment of engagement with a digital intervention: The Wrapped feasibility randomised controlled trial	12/02/2026	13/02/2026	Yes	No
Participant information sheet	version v5	01/12/2020	03/12/2020	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes