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Reducing sexually transmitted infections amongst those at highest risk

Submission date
12/09/2025

Recruitment status
Recruiting

Registration date
15/10/2025

Overall study status
Ongoing

Last Edited
07/01/2026

Condition category
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
There were 401,800 diagnoses of Sexually Transmitted Infections (STIs) in 2023, and 45% of those were from people aged 15-24 years. The only way for sexually active people to avoid STIs is to use a condom, but young people often report not doing this. More young people are now using STI testing websites, but these websites do not offer much advice on how to prevent future infections. Together with young people and health professionals, the team developed a digital intervention called Halo, which aims to support young people to use condoms properly every time they have sex and reduce future STIs. The aim is to find out whether Halo works. To do this, a study called a randomised controlled trial (RCT) will be run. The study will recruit 3,576 users of STI testing websites, aged 16-24 years. Participants will either get the usual STI prevention information offered by STI testing websites (usual care) or this usual information plus Halo. The primary aim of the study is to determine whether adding Halo to usual care is effective and cost-effective at reducing chlamydia positivity, compared to usual care only, in young people.

Who can participate?
Young people aged 16-24 years old, living in one of the local authority locations, participating in the study.

What does the study involve?
Participants will take an STI test for chlamydia and gonorrhoea using a self-sampling kit at the start of the trial, then 3 and 12 months later. They will also complete surveys asking about STI diagnoses, condom use and quality of life at the start and 3, 6 and 12 months later. The information from both groups will be compared to see if Halo increases condom use and reduces STIs, including amongst those in higher-risk groups. The costs and benefits of each approach will be compared. A young people's advisory group, co-facilitated by two young co-applicants, will advise us throughout.

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, all participants will receive gift vouchers for the completion of research activities.

Risks: The risks of taking part are low and in line with those of normal activities. All communication with participants will be discreet, minimising the risk of inadvertent disclosure to another person that the participant is sexually active/testing for an STI. Survey questions about sexual wellbeing (safeguarding items) may be distressing or triggering to some participants, as such participants do not need to complete the questions if they do not wish to, and an auto-generated email will also be sent to them on completion of each survey containing information on sources of further help and support should they need it. Participants may also experience feelings of embarrassment and/or distress if they are referred to their local sexual health service for a positive STI test result/safeguarding concern identified during the study, or experience side effects due to STI treatment.

Where is the study run from?
The University of Hertfordshire, UK

When is the study starting and how long is it expected to run for?
November 2024 to October 2028

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

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

Contact information

Type(s)
Public

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Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
352986

ClinicalTrials.gov (NCT)
Nil known

Central Portfolio Management System (CPMS)
69123

National Institute for Health and Care Research (NIHR)
157903

Study information

Scientific Title
Reducing sexually transmitted infections amongst those at highest risk: The Halo randomised controlled trial

Acronym
Halo Trial

Study objectives
Primary objective:
To determine whether adding Halo to usual care reduces chlamydia positivity at 12 months

Secondary objectives:
1. To determine whether adding Halo to usual care reduces gonorrhoea positivity at 12 months
2. To determine whether adding Halo to usual care reduces repeat infections or (cumulative) incidence of chlamydia or gonorrhoea
3. To determine whether adding Halo to usual care increases the frequency of correct and consistent condom use during vaginal and/or anal sexual intercourse
4. To examine whether STI and behavioural outcomes differ by subgroup (ethnicity, sexual orientation, and deprivation)
5. To determine whether the effect of Halo on STI outcomes is mediated by changes in the targeted behaviour and behavioural determinants
6. To determine whether adding Halo to usual care is cost-effective and analyse impacts on equity
7. To describe the level and patterns of engagement with Halo, and to identify whether patterns

of engagement differ by subgroup (ethnicity, sexual orientation, and deprivation)
8. To determine whether STI and behavioural outcomes differ by patterns of engagement with Halo

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 12/08/2025, London Central Research Ethics Committee (3rd Floor 3 Piccadilly Place, London Road, Manchester, M1 3BN, United Kingdom; +44 (0) 207 104 8282, 207 104 8077, 207 104 8061; londoncentral.rec@hra.nhs.uk), ref: 25/LO/0479

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Infections with a predominantly sexual mode of transmission

Interventions
Intervention (Halo plus usual care):
Multi-component digital intervention to increase correct and consistent condom use.

Control arm (usual care):
Usual care in this instance is 1) the usual testing (and if relevant, follow-up treatment) of chlamydia and gonorrhoea, and 2)provision of basic information on STIs and condoms. The latter is typically present on internet STI self-sampling websites, including those provided by Preventx Ltd, where participants will have been recruited. To provide an ‘intervention experience’ to participants in the control arm, and to ensure that participants in both arms receive identical ‘usual care’, this basic information is presented within both the intervention and control websites. Halo also contains the additional content that is being testing via the RCT.

Sample:
Preventx Ltd provides web-based STI testing services via three STI self-sampling websites (SH.UK, Freetest.me, SHL.UK) to over 75 local authority areas in England. 3576 users of these STI self-sampling websites aged 16-24, residing within participating local authority areas, will be invited to participate in the RCT.

Sample size calculation: The trial has been designed to detect a reduction of chlamydia positivity from 10% to 6.5% i.e. 3.5 percentage points. To have 90% power (α=0.05) to obtain the projected difference in the comparative analysis, 1353 (2,706 total) participants per treatment group are required. The recruitment target and the size of the sampling pool required to achieve this have been calculated based on the levels of recruitment and retention observed in the fRCT. Attrition (for primary outcome) was 24.3% at 12 months. To allow for this, the baseline sample needs to be 1788 per treatment group (1353/0.757; 3576 participants in total). During the feasibility RCT (fRCT), 1.5% of all Preventx users shown the study advert were recruited. A

sampling pool of 238,400 users of SH.UK/Freetest.me/SHL.UK aged 16-24 years is therefore required to achieve this target (3576/0.015). It is estimated that the size of the available sampling pool will be at least 585,000 users (877,500 over 18 months; based on recent Preventx data).

Recruitment:
After requesting an STI self-sampling kit, eligible website users will be shown a brief message inviting them to take part in the trial:
"Your voice matters. Help shape the future of sexual health. Take part in groundbreaking sexual health research. Earn up to £75 in vouchers for your time and insights"

Additionally, users of SH.UK and SHL.UK will be alerted to the study by a notification positioned within their individual service user account area. This will inform users that to take part, they need to order a test kit (access to which is also via their user account area).

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. No vulnerable groups are being specifically targeted for recruitment as the aim is to have a representative sample of 16-24 year olds.

Informed consent:
Those who decide to take part will then provide digital informed consent within REDCap.

Baseline (M0) - STI test and online survey:
Participants will complete the baseline survey in REDCap immediately upon providing consent. The baseline survey will include a set of questions covering; demographics information, self-reported STI diagnosis, condom use behaviour, behavioural determinants, health-related quality of life, health economics and safeguarding. One text message reminder will be sent to all participants who have not completed their M0 survey three and six days after consent has been provided. Those who have not completed their M0 survey 30 days after they completed consent will be classed as a non-responder and will not be randomised.

The baseline STI objective measures are those resulting from the STI self-sampling kit request made by participants just before seeing the study advert (Nucleic acid amplification (NAA) for chlamydia and gonorrhoea). STI test results will be shared securely by Preventx Ltd with the trial team, who will then enter this into the trial database in REDCap.

Participants with a positive result for chlamydia and/or gonorrhoea will be asked to self-report adherence to treatment via a link to REDCap within an SMS message, 14 days post-result.

On completion of the baseline survey and the STI test, a series of screening checks will be performed; only individuals who pass these checks will be randomised. Screening checks aim to detect and remove: 1) imposter participants, 2) individuals who do not have accurate/genuine contact details, 3) participants who have provided baseline responses that are inconsistent with the eligibility criteria, and 4) individuals who have not responded to the baseline survey with sufficient care. Details of the screening checks can be found in the trial protocol.

Further, only individuals with a positive (detected) or negative (undetected) result for chlamydia, received within 30 days of consent, will be randomised. We will randomise participants regardless of their result for gonorrhoea.

Randomisation:
Participants will then be individually randomised to one of two treatment groups: Halo plus usual care (intervention) or usual care alone (control).

Month 3 (M3)
Participants will complete a follow-up survey via REDCap and STI test (Nucleic acid amplification (NAA) tests for chlamydia/gonorrhoea). Participants will be sent an SMS message with a link to the M3 follow-up survey, which will include all items included in the baseline (M0) survey, except contact details and demographic characteristics (items excluded from all follow-up surveys). Participants will also be asked to self-report STI diagnoses since the last measurement time point, and items to identify evidence of adverse events will be included (to identify events from the point of seeing the advert). STI self-sampling test kits will be sent to participants by Preventx. The order of this test kit will be triggered by the trial team in the Halo service area of the freetest.me website. 6days before this, participants will be sent an SMS allowing them to confirm/change the address they would like the test kit sent to. Participants will return completed test kits to Preventx for processing, using the same process as for the baseline (M0) self-ordered test kit. STI test results will be shared securely by Preventx Ltd with the trial team via a restricted Halo service area on the freetest.me website (regardless of which website participants were recruited from), and the trial team will then enter this into the trial database on REDCap. Participants with a positive result for chlamydia and/or gonorrhoea will be asked to self-report adherence to treatment via a link to REDCap within an SMS message,14 days post-result.

Month 6 (M6)
Participants will complete a follow-up survey via REDCap. Participants will be sent an SMS text message with a link to the M6 follow-up survey, which will include all the same items as the M3 survey.

Month 12 (M12)
Participants will complete a follow-up survey via REDCap and STI test (Nucleic acid amplification (NAA) tests for chlamydia/gonorrhoea). Participants will be sent an SMS message with a link to the M12 follow-up survey, which includes the same items as the M3 and M6 surveys, with the addition of items to identify intervention use and evidence of contamination between trial arms. STI self-sampling test kits will be sent to participants by Preventx. The order of this test kit will be triggered by the trial team in the Halo service area of the freetest.me website. 6days before this, participants will be sent an SMS allowing them to confirm/change the address they would like the test kit sent to. Participants will return completed test kits to Preventx for processing, using the same process as for the baseline (M0) self-ordered test kit. STI test results will be shared securely by Preventx Ltd with the trial team via a restricted Halo service area on the Freetest.me website (regardless of which website participants were recruited from), and the trial team will then enter this into the trial database on REDCap. Participants with a positive result for chlamydia and/or gonorrhoea will be asked to self-report adherence to treatment via a link to REDCap within an SMS message, 14 days post-result.

Non-responders:
If an M3, M6 or M12 survey has not been started, or is incomplete, five days after the invitation was sent, participants will receive up to three SMS text message reminders, then one email reminder, each spaced five days apart. If after five days there is still no response, participants will be telephoned and invited to provide verbal responses to a reduced set of survey questions (self-reported STI diagnoses, STI treatment if relevant, condom use intentions, and condom use). Participants will be classed as non-responders if they have not completed the survey within 30 days of the initial invitation.

Participants will receive an SMS text message reminder (originating from REDCap) to complete and return their self-samples five days after the test kit is dispatched (if no result has yet been reported in the Halo service area). If the sample remains unreturned, up to two additional SMS text message reminders will be sent, the first after a further 5-day interval (this time originating from the Halo service area on freetest.me), and the second after a further 8-day interval (again originating from the Halo service area on freetest.me). If the self-sample remains unreturned after these reminders, one email reminder 5 days later, followed by a phone call 6 days later, will be made if needed. Where no sample is received by the Preventx laboratory within 30 days of the M3 or M12 timepoint, or where this is received but the sample is classed as 'other', the participant will be classed as a non-responder (although see below for our offer of secondary kits for those with 'other' results).

Participants who return their test kit and yield an 'other' result will be contacted and offered an additional test kit if there are at least 14 days left before the end of the 30-day window (thus allowing us sufficient time to send them another test kit and for them to return it). If they agree to this, a second self-sampling kit will be sent out. This will also be offered on occasions where a participant tells us that their kit is lost or undelivered. Participants receiving these secondary kits will receive one SMS text message reminder to complete and return their self-samples 5 days after their test kit is dispatched.

Non-responders will continue to receive surveys and self-sampling kits at future time points unless they request to withdraw from the trial.

All participants will be given sources of information, advice, and support in relation to sexual exploitation, abuse, assault and coercion. This will be provided by default on completion of each survey.

Participants will receive a voucher incentive in return for completing each of the above activities (£5-£20 per activity).

Payment is staggered across the course of the RCT, and the total voucher incentive offered to participants is £75.

Analysis
Statistical Analysis Plans will be developed by the trial statisticians (SE, SB), joint-CIs (KN, KB) and co-investigators (LJ, RC) prior to database lock and the final analysis commencing. These will also be reviewed by TSC and DMEC statisticians and health economists.

Reports for each participating local authority, or groups of local authorities as required, will be produced following the end of recruitment, based on the baseline characteristics of trial participants from each respective area.

Recruitment, retention and safety data will be analysed on a 6-monthly basis for reporting to the DMEC and TSC. No other interim analyses are planned.

The broad timetable for the stages of the research:
Recruitment: October 2025-December 2026
RCT data collection: July 2025-January 2028
Analytics data collection: July 2025- December 2027
RCT data analysis: Feb-July 2028
Analytics data analysis: 1) April-June 2027, 2) January-March 2028

End of trial:31st October 2028
Journal article and synopsis production as part of threaded publication for NIHR journal library: 14th November 2028

What procedures will be in place to detect and compensate for any possible "researcher effects" and "researcher bias":
The trial statisticians (Brighton and Sussex CTU, UKCRC ID 66) will generate the randomisation list, which will be uploaded to REDCap by the Database Manager. Randomisation will be at the individual level as control group contamination is not anticipated. Stratification across groups will be performed to balance participants across the trial arms. Blinding will also be in place, both for participants and the individuals performing the analysis. Participants in the control group will be directed to a usual care website, therefore creating an equivalent intervention experience. Decisions about the research methodology and design have been developed in collaboration with a PPI group (YPAG) to minimise any possible researcher effects.

Public involvement in design and methodology:
For the funding application for this trial, a co-applicant involved as a young advisor in our previous feasibility randomised controlled trial (fRCT) reviewed the plain English summary and initial plans for public involvement, along with members of the University of Hertfordshire's young people's research advisory group (Herts YPAG) which is led by our public involvement lead and co-applicant (LMB).

To inform the Stage 2 application, the team successfully applied for NIHR Research Design Service public involvement funding to involve a diverse group of young people in the development of the proposal. This funded both a workshop with young people and payment for young co-applicants' time. Former fRCT participants were invited to attend, as well as young people working with Brook (a sexual health charity). The workshop, in November 2023, was facilitated by LMB and KN and attended by six young people (4 from the fRCT and 2 from Brook). Attendees represented a mix of different ethnicities, sexual identities, and social backgrounds. There was, however, a lack of diversity in terms of gender (all cis-female) and age (all 22-24 years). The young people identified this as something that should be addressed in the current trial.

In the two-hour workshop, the team discussed the proposed research methods and public involvement plans with the young people generally and in relation to reviewer feedback from Stage 1. Key points from the discussion which informed the current trial:
Support for our safeguarding protocol - considered appropriate and acceptable; one attendee had some excellent ideas for encouraging disclosure and supporting young people through this process. This is embedded in the current procedure.

Suggestions for our trial advert and participant information - ways of indicating research credibility, providing a participant roadmap.

Ideas for recruiting (diverse) members to the Halo YPAG for this trial and how this should operate - being flexible, making payment clear, targeted recruitment, meeting online, but allowing budget for the group to occasionally get together face-to-face.

Two young people agreed to be PPI co-applicants (KL, TB), one of whom was previously involved in the fRCT and one is involved in participation work with Brook. Both PPI applicants were involved in the development of public involvement plans and contributed to the funding application. KL and TB are now leading the Halo YPAG for this trial, with support from LMB and IS, and as such are members of the Halo Trial Management Group (TMG).

Young people's involvement considerably strengthened the design of the trial, and the team remain committed to involving young people inclusively from the outset and throughout the research process.

Intervention Type
Other

Primary outcome(s)
Chlamydia positivity at 12 months, measured using biological STI tests (Nucleic acid amplification; NAA) for chlamydia (baseline, M3, M12)

Key secondary outcome(s))
1. Gonorrhoea positivity at 12 months, measured using biological STI tests (Nucleic acid amplification; NAA) for gonorrhoea (baseline, M3, M12)
2. Incidence of repeat infections of chlamydia and gonorrhoea in 12 months post-randomisation, measured using biological STI tests (Nucleic acid amplification; NAA) for chlamydia and gonorrhoea (baseline, M3, M12) and self-report (baseline, M3, M6, M12)
3. Cumulative incidence of chlamydia and gonorrhoea, measured using biological STI tests (Nucleic acid amplification; NAA) for chlamydia and gonorrhoea (baseline, M3, M12) and online survey (baseline, M3, M6, M12)
4. Condom use behaviour (condom use during vaginal and/or anal sexual intercourse: last sex, frequency, and number of protected sex acts; and correct use: using the adapted Condom Use Errors Scale), measured using an online survey (baseline, M3, M6, M12)
5. Behavioural determinants (condom intention, condom use social norms, condom attitude, condom competence, condom accessibility, condom use self-efficacy), measured using an online survey (baseline, M3, M6, M12)
6. Difference in STI and behavioural outcomes by subgroup (ethnicity, sexual orientation and deprivation; demographic characteristics measured using online survey at baseline)
7. Effect of changes in target behaviour and behavioural determinants on STI outcomes
8. Resource use and personal costs, measured using an online survey (baseline, M3, M6, M12)
9. Health-related quality of life (HRQL), measured using the EQ5D-5L via online survey (baseline, M3, M6, M12)
10. Engagement with Halo, measured using within-website analytics during the entire data collection period
11. Difference in engagement with Halo by subgroup (ethnicity, sexual orientation and deprivation), measured using within-website analytics during the entire data collection period

Completion date
31/10/2028

Eligibility

Key inclusion criteria
1. Young people aged 16-24 years old at baseline
2. Living in one of the local authority areas participating in the trial
3. Ordered an STI self-sampling kit that includes tests for chlamydia and gonorrhoea from SH.UK, FreeTest.me or SHL.UK websites
4. Access to a personal mobile phone and the internet
5. Able to read/understand the English language

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
0

Key exclusion criteria
1. Unlikely to have penetrative sex (penis in either vagina or anus) over the trial period
2. Do not feel able to commit to the trial over the next 12 months

Date of first enrolment
07/01/2026

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Preventx Ltd
Meadowhall Business Park, Carbrook Hall Road
Sheffield
England
S9 2EQ

Sponsor information

Organisation
University of Hertfordshire

ROR
https://ror.org/0267vjk41

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

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 publicly available repository. These data will be made available via the University of Hertfordshire Research Archive (UHRA): https://uhra.herts.ac.uk/. It will be available no later than 3 months after the end of the study and will remain there indefinitely. It will be available on request to anyone with a legitimate research interest. 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?
	version 3.0				

Protocol file	version 4.0	04/09/2025	24/09/2025	No	No
Protocol file		25/11/2025	31/12/2025	No	No