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

Halo RCT Protocol

Short title: Halo Trial

Version number: 6.0 17-March-2026

Funder: NIHR Public Health Research Programme

Funder reference: NIHR157903

Sponsor: University of Hertfordshire (research-sponsorship@herts.ac.uk)

Sponsor reference: UHRS2425-19

ISCTRN registry number: ISRCTN51957984

IRAS reference number: 352986

REC reference: 25/L/0479

UH Protocol Number: LMS/SF/NHS/02315

Contents

Version history

Version number	Effective date	Description
1.0	28th May 2025	Reviewed by DMEC and TSC, and approved by all co-investigators Pending ethical approval
2.0	5th August 2025	Amended post-REC review. REC approved
3.0	4th September 2025	Amended post-HRA review Approved
4.0	25th November 2025	Amended post HRA approval Approved
5.0	3rd February 2026	Amended post HRA approval
6.0	17th March 2026	Amended post HRA approval Approved

This document provides details regarding the setting up, conduct, analysis and dissemination of the NIHR funded trial (REF: NIHR157903) Reducing sexually transmitted infections amongst those at highest risk: The Halo randomised controlled trial. It includes all the recommended items to address in a clinical trial protocol as set out in the SPIRIT 2013 checklist (1); see Appendix 1.

The University of Hertfordshire will sponsor this trial. The University of Sussex, Maastricht University, University of Birmingham, University College London (UCL) and Preventx Ltd will be collaborators on the trial. As such, a collaboration agreement will be signed by the parties, specifying responsibilities and financial arrangements.

The funder and sponsor had no role in the design of this trial and will not have any role during its execution, analyses, interpretation of the data, or decision to submit results. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

All members of the Halo Trial Management Group have contributed to and approved this trial protocol.

Chief Investigators	Katie Newby (CI) and Katherine Brown (joint-CI)
Trial Manager	Stefanie Williams
Sponsors	University of Hertfordshire
Study committees	Trial Steering Committee (TSC) Data Monitoring and Ethics Committee (DMEC) Trial Management Group (TMG) Trial Team (TT) Young People's Advisory Group (YPAG)

Competing interests: The joint-CIs (KN, KB) and the PI at Preventx Ltd (single trial site; MC) have no financial or other competing interests to declare.

Signature Page

The undersigned confirm that the following protocol has been agreed and accepted, and that they will conduct the trial in compliance with this. They further confirm that they will adhere to the principles outlined in the Good Clinical Practice (GCP) guidelines, the Sponsor's Standard Operating Procedures (SOPs), and any other relevant regulatory requirements.

They agree that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

They also confirm that they will make the findings of the trial publicly available through publication or other dissemination tools without any unnecessary delay and that an honest, accurate and transparent account of the trial will be given; and that any discrepancies and serious breaches of GCP from the trial as planned in this protocol will be explained.

Name: Katie Newby	Role: Chief Investigator	Signature: REDACTED
Name: Katherine Brown	Role: Joint Chief Investigator	Date: 07/04/25 Signature: REDACTED
Name: Dr Susan Grey (as Chair of the Governance of Clinical Studies Group)	Role: Sponsor	Date: 07/04/2025 Signature: REDACTED
Name: Karen Irvine	Role: UH CTU Manager	Date: 07/10/2025 Signature: REDACTED
Name: Stephen Bremner	Role: Lead Statistician	Date: 08/04/2025 Signature: REDACTED
Name: Louise Jackson	Role: Lead Health Economist	Date: 07/04/2025 Signature: REDACTED
Name: Rik Crutzen	Role: Intervention Uptake and Engagement Lead	Date: 08/04/2025 Signature: REDACTED
Name: Julia Bailey	Role: Qualitative study Lead	Date: 07/04/2025 Signature: REDACTED
Name: Louca-Mai Brady	Role: Public Involvement Lead	Date: 10/04/2025 Signature: REDACTED
Name: Kanika Leo	Role: PPI Co-investigator	Date: 07/04/2025 Signature:

		REDACTED Date: 09/04/2025
Name: Tia Broderick	Role: PPI Co-investigator	Signature: REDACTED Date: 10/04/2025
Name: John White	Role: Industry Partner	Signature: REDACTED Date: 24/09/2025

Organisations and personnel involved in the delivery of the trial

Name		Title	Representation	TT	TMG
University of Hertfordshire					
Professor Katie Newby*	KN	Professor of Behaviour Change and Public Health	Joint Chief Investigator	✓	✓
Professor Katherine Brown*	KB	Professor of Behaviour Change in Health	Joint Chief Investigator	✓	✓
Dr Stefanie Williams*	SW	Senior Research Fellow	Trial Manager	✓	✓
Mrs Kayleigh Kwah*	KK	Research Fellow	Research team member	✓	✓
Lauren Schumacher*	LS	Research Fellow	Research team member	✓	✓
Miss Isobel Simmons*	IS	Research Assistant	Research team member and DMEC administrator	✓	✓
Dr Karen Irvine	KI	Manager, UH CTU	UH CTU Manager	✓	✓
Dr Cathy Hamilton	CH	Head of Placement Learning	Safeguarding Lead		
Young People's Advisory Group					
Dr Louca-Mai Brady	LMB	Reader in Youth Involvement and Health, University of Hertfordshire	Co-investigator and Public Involvement Lead		✓
Miss Kanika Leo	KL	N/A	Co-investigator and public involvement member		✓
Miss Tia Broderick	TB	N/A	Co-investigator and public involvement member		✓
Maastricht University					
Prof Rik Crutzen	RC	Professor of Behaviour Change & Technology	Co-investigator		✓
University College London					
Dr Julia Bailey	JB	Associate Professor in Primary Care	Co-investigator		✓
University of Sussex (Brighton and Sussex Clinical Trials Unit)					
Prof Stephen Bremner	SB	Professor of Medical Statistics	Co-investigator and lead statistician	✓	✓
Dr Saskia Eddy	SE	Assistant Professor in Medical Statistics	Statistician	✓	✓
Debbie Lambert	DL	CTU Data Manager	Database Manager	✓	✓
University of Birmingham					
Professor Louise Jackson	LJ	Professor of Health Economics and Health Policy, University of Birmingham	Co-investigator and trial health economist		✓
TBC			Health economist		
Preventx Ltd					

Name		Title	Representation	TT	TMG
Dr John White	JW	Medical Director, Consultant Physician GUM/HIV	Co-investigator and industry partner		✓
Ms Jane Hosking	JH	Strategic Partnerships Manager	Industry Partner		✓

*UH core research team

Abbreviations and definitions

AE	Adverse Event
BSCTU	Brighton and Sussex Clinical Trials Unit
CI	Chief Investigator
CRF	Case Report Form
CTU	Clinical Trials Unit
DMEC	Data Monitoring and Ethics Committee
DMP	Data Management Plan
DPIA	Data Protection Impact Assessment
EU	European Union
GDPR	General Data Protection Regulations
HML	School of Health, Medicine and Life Sciences
HRA	Health Research Authority
ICF	Informed Consent Form
ISF	Investigator Site File
ISRCTN	International Standard Randomised Controlled Trial Number
Main REC	Main Research Ethics Committee
MRC PHIND	Medical Research Council (MRC) Public Health Intervention Development (PHIND) funding
NHS R&D	National Health Service Research & Development
NIHR	National Institute for Health and Care Research
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
QMMP	Quality Management and Monitoring Plan
Participant	An individual who takes part in a trial
PIS	Participant Information Sheet
PPI	Patient and Public Involvement
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan

SHS	Sexual Health Service
SOP	Standard Operating Procedure
SWAT	Study Within A Trial
TT	Trial Team
TMG	Trial Management Group
TSC	Trial Steering Committee
UH	University of Hertfordshire
YPAG	Young People's Advisory Group

Trial Summary

Full title	Reducing sexually transmitted infections amongst those at highest risk: The Halo randomised controlled trial
Short title/Acronym	Halo Trial
Protocol Version Number and Date	Version 5.0 3rd February 2026
Anticipated Recruitment Start Date	1st July 2025
Actual Recruitment Start Date	7th January 2026
Data Collection End Date	31st December 2027
Total Trial Duration	48 months (4 years)
Trial Design	Two-arm, parallel group RCT
Sponsor	University of Hertfordshire
Chief Investigators	Katie Newby and Katherine Brown
Funder	NIHR PHR
REC Number	25/L/0479
Trial Objective(s)	Primary objective: 1. To determine whether the addition of Halo to usual care reduces chlamydia positivity at 12 months Secondary objectives: 2. To determine whether the addition of Halo to usual care reduces gonorrhoea positivity at 12 months 3. To determine whether the addition of Halo to usual care reduces repeated infections or (cumulative) incidence of chlamydia or gonorrhoea

	4. To determine whether the addition of Halo to usual care increases the frequency of correct and consistent condom use during vaginal and/or anal sexual intercourse 5. To determine whether STI and behavioural outcomes differ by subgroup (ethnicity, sexual orientation, and deprivation) 6. To determine whether the effect of Halo on STI outcomes is mediated by changes in the targeted behaviour and behavioural determinants 7. To determine whether adding Halo to usual care is cost-effective and analyse impacts on equity 8. To describe the level and patterns of engagement with Halo, as delivered as part of the RCT, and to identify whether patterns of engagement differ by subgroup (ethnicity, sexual orientation, and deprivation) 9. To determine whether STI and behavioural outcomes differ by patterns of engagement with Halo
Planned Sample Size	N = 3576
Participants	<u>Inclusion criteria:</u> 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 personal mobile phone and the internet. 5) Able to read/understand English language <u>Exclusion criteria:</u> 1) Unlikely to have penetrative sex (penis in either vagina or anus) over the next 12 months 2) Do not feel able to commit to the trial over the next 12 months
Intervention	Halo is a web-based intervention. It includes two ordering features: • Sample pack: A free box of ten condoms, and sachets of lubricant, for users to try out. Box includes condom application instructions and is delivered in discreet packaging. • Condom ordering: A service delivering free condoms/lubricant to users (in discreet packaging), ordered online by the user. Each user is limited to one order per month, each order contains a bundle of 5 or 10 condoms and sachets of lubricant. The remaining sections provide written and video content (drawing on and featuring real-life testimony from young people), supported by graphics and custom illustrations that aim to increase knowledge and skills, and to build positive beliefs about condom use e.g. around putting condoms on, using condoms in ways that enhance pleasure and enjoyment,

	and effectively communicating about condom use and coping with resistance. Halo also contains the usual care information contained within the comparison website (see directly below). See section 5 for a detailed description of the intervention content.
Comparison	Usual care. All participants will be directed to a stand-alone website providing information on STIs and condom use akin to that of the NHS choices website.
Follow up duration	**Survey:** • Collected at baseline, 3 months, 6 months, and 12 months. **STI tests:** • Conducted at baseline, 3 months, and 12 months.
Outcomes	**Primary:** • Chlamydia positivity **Secondary:** • Gonorrhoea positivity • Incidence of repeat infections of chlamydia and gonorrhoea • Cumulative incidence of chlamydia and gonorrhoea • Correct and consistent condom use during vaginal and/or anal sexual intercourse • Condom use self-efficacy, social norms for condom use, attitude towards condom use, condom use skill, accessibility of condoms, condom use intentions • Resource use and Health-related quality of life (HRQL) • Engagement with Halo

1. Background and rationale

There were 401,800 diagnoses of Sexually Transmitted Infections (STIs) in England in 2023 (2). Whilst the number of STI diagnoses dropped between 2020-2021, due to disruption to STI testing caused by the Covid-19 pandemic, figures have now almost entirely returned to 2019 levels (2). Whilst chlamydia diagnoses dropped slightly in the last year, these remain high, and there have been large increases in gonorrhoea with diagnoses now the highest on record (2). Untreated STIs can have serious consequences such as pelvic inflammatory disease, ectopic pregnancy, infertility, cervical/anal cancer, stillbirth, and increased risk of contracting Human Immunodeficiency Virus (HIV) (3). STIs can have a profound impact on quality of life and are associated with stigma, which can impact on willingness to seek care and contribute to onward spread (3). Costs to the NHS of treatment are also significant (4).

People aged 15-24 years have the greatest prevalence of STIs. In 2023, 42% of all STI diagnoses were amongst this age group (2). Positivity is also high. This currently stands at 11% for chlamydia, the most common STI, with rates further elevated for young people who are Black (14%) and who live in the most deprived quintile (12%) (5). Gay, Bisexual or other men who have sex with men (GBMSM) are also disproportionately impacted by STIs (2). The

best way to avoid STIs from penetrative sex is to use a condom (2) but young people report inconsistent use (6). Targeted, inclusive interventions to increase condom use amongst young people are urgently required.

Dozens of behavioural interventions aimed at reducing sexual risk behaviour have been developed over recent decades. Accordingly, numerous systematic reviews and meta-analyses have been conducted to help make sense of the findings and enable conclusions to be drawn about their effectiveness. These include reviews focusing on specific populations, such as adolescents/young adults (7–10) and women (11–13), those which report on behavioural outcomes (11,14–16) and additionally objective STI outcomes (13,17,18), and those where interventions are delivered via face-to-face (9,15,16,19) or digital/computer-based (14,20–23) methods. In fact, such is the preponderance of these reviews, that there are now meta-reviews of meta-analyses in this area (24,25).

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. Whilst the majority of included studies use a randomised controlled trial (RCT) or quasi-experimental study, these are generally of low quality. This is demonstrated in a meta-analysis of RCTs by Free and colleagues (16) where of the 139 included trials, only four were judged as scoring adequately on all four quality criteria. 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 for sexual health promotion by Bailey et al. (20), 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. (20) for example, 5/15 studies had a follow-up of less than two weeks post-intervention, and the longest follow-up period was six 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 rare. These 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. The design of the current trial addresses all the limitations outlined above.

The intervention being tested in this trial aims to support young people to use condoms correctly every time they have penetrative sex. It has been co-created by researchers, professional stakeholders, and young people for users of web-based STI self-sampling services aged 16-24 years. Content addresses young people's salient barriers to condom use. The first iteration of the intervention, then named Wrapped (26), was developed in 2016-17 with support from Medical Research Council (MRC) Public Health Intervention Development (PHIND) funding. Its second iteration, to be tested in this RCT, has the same theoretical basis, and largely utilizes the same practical strategies, but with the presentation of content updated to reflect the modern-day expectations of young people. Wrapped has since been rebranded, with input from young people, and is now called Halo. The Halo intervention is well positioned to have population-level impact as there is potential for widescale implementation across the web-based STI testing sector. With support from the NIHR's Public Health Research programme, a feasibility randomised controlled trial (fRCT) of the intervention, then named Wrapped, was completed in May 2023. This showed that the intervention was acceptable to both users and service commissioners, and positively impacted condom use beliefs and behaviours. The trial methods were feasible and acceptable. The independent Data Monitoring and Ethics Committee (DMEC) and Trial Steering Committee (TSC) recommended progression to full trial.

The work undertaken as part of this project includes an RCT with implementation activities, a nested process evaluation, and a study within a trial (SWAT). This protocol covers the RCT and implementation activities only; the nested process evaluation and the SWAT are subject to separate protocols.

2. Research question and objectives

2.1 Research question

Is Halo plus usual care (usual STI prevention information provided by STI testing websites) effective and cost-effective in reducing STI positivity amongst 16–24-year-olds at 12 months in comparison to usual care only?

2.1. Objectives

Primary objective:

1. To determine whether adding Halo to usual care reduces chlamydia positivity at 12 months

Secondary objectives:

2. To determine whether adding Halo to usual care reduces gonorrhoea positivity at 12 months
3. To determine whether adding Halo to usual care reduces repeat infections or (cumulative) incidence of chlamydia or gonorrhoea at 12 months
4. To determine whether adding Halo to usual care increases the frequency of correct and consistent condom use during vaginal and/or anal sexual intercourse at 12 months
5. To examine whether STI and behavioural outcomes differ by subgroup (ethnicity, sexual orientation, and deprivation)
6. To determine whether the effect of Halo on STI outcomes is mediated by changes in the targeted behaviour and behavioural determinants
7. To determine whether adding Halo to usual care is cost-effective and analyse impacts on equity
8. 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)
9. To determine whether STI and behavioural outcomes differ by patterns of engagement with Halo

3. RCT timeline

Table 1 below presents the timeline for the RCT along with associated milestones.

Table 1. Halo trial planned timeline and milestones

Months	**Activities**	**Associated milestones** (to be achieved by end of time period specified unless otherwise stated)
-3 to 0	• TSC/DMEC set-up	• TSC/DMEC in place
-3 to 3	• Protocol development • Ethics application (RCT)	• NIHR approval of protocol (by end of month 5) • Ethics approval (RCT; by end of month 5)
-3 to 6	• Trial set-up • Legal agreements	• All legal agreements in place
1 to 6	• Intervention (formerly Wrapped) optimisation	• Optimisation of intervention (formerly Wrapped) complete

Months	Activities	Associated milestones (to be achieved by end of time period specified unless otherwise stated)
7 to 8	• REDCap (database) set-up • Set-up of Halo website on external server	• Database set-up complete • Halo hosted securely on external server; testing complete
9 to 26	• Recruitment to RCT	• RCT recruitment target met
9 to 39	• RCT data collection	• RCT follow-up complete
9 to 38	• Analytics data collection	• Analytics data collection complete
39-41	• Analytics data analysis	• Analytics data analysis complete
40 to 45	• RCT data analysis	• RCT data analysis complete
43 to 48	• (if cost-effective) Hold 'roadmap' stakeholder event • Report writing and dissemination activities	• All conference and stakeholder presentations delivered • Lay summary (written and video) distributed
43 to 48+2 weeks	• Journal article and synopsis production as part of threaded publication for NIHR journal library	• Submission of all articles (and post trial, publication)

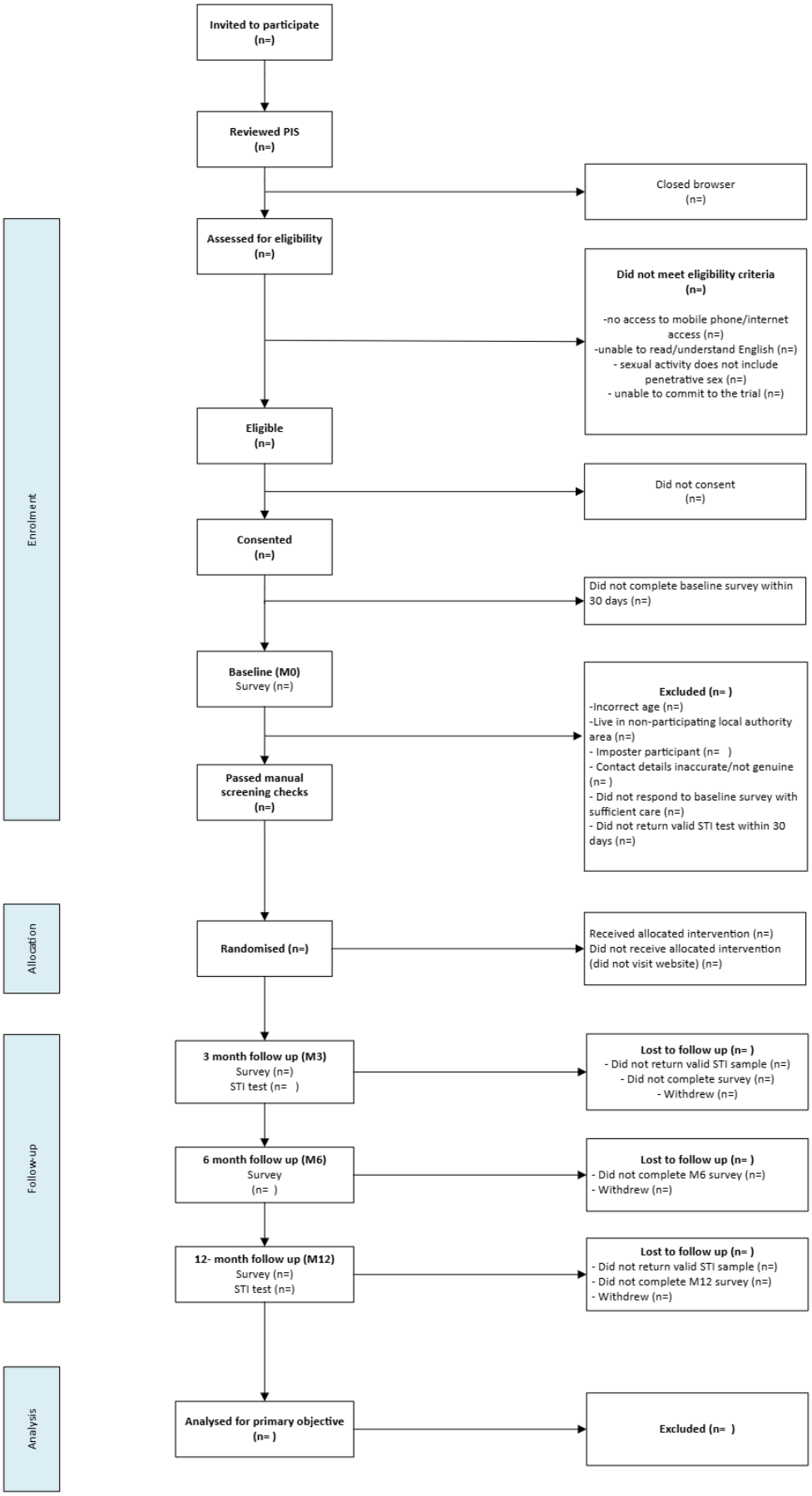
4. Methods

4.1. Trial design

A two-arm, parallel group RCT, in which Halo in addition to usual care (standard STI prevention information provided by STI testing websites) is tested against usual care alone. See figure 1 for an overview of participant involvement in the Halo RCT.

[space left intentionally blank]

Figure 1. CONSORT Diagram



4.2. Trial setting

Data will be collected in England. Participants will be recruited online from one of three STI self-sampling websites (SH.UK, Freetest.me or SHL.UK), operated by Preventx Ltd (a health technology company that provides remote STI self-sampling). Preventx provides web-based STI self-sampling services to over 70 local authority areas in England which for most young people, are free at the point of use. Users residing in local authority areas representing diverse demography, and a mix of urban, rural, and coastal locations, will be invited to participate. The study will not be available to users from local authorities that have commissioned Preventx's condom distribution service. Only a small number of local authorities use this add-on module and as such it does not represent usual care. Preventx will support recruitment of the required number of local authority areas needed to achieve our target sample size.

4.3. Trial participants and sample size

3576 users of three STI self-sampling websites (SH.UK, Freetest.me, or SHL.UK) operated by Preventx Ltd, will be randomised.

For the primary objective (objective one), 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 has 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 trial 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).

Secondary objectives include examining STI and behavioural outcomes by subgroup (ethnicity, sexual orientation, and deprivation). To detect these interaction effects (subgroup x treatment group), the sample size needs to be fourfold greater than for the primary outcome analysis if they are the same magnitude as the main effect (27). For smaller interaction effects, the sample size needs to be increased even further. Power to detect an interaction effect of the same magnitude as the main effect, between two binary variables (one of which is treatment group), will be approximately 33%. Given the low power for a test of interaction effects, these analyses will therefore be considered exploratory.

4.4. Eligibility

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 a self-sampling kit that includes a test for chlamydia and gonorrhoea from Freetest.me, SH.UK, SHL.UK websites
4) Access to personal mobile phone and internet access
5) Able to read/understand English language

Exclusion Criteria:

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

There are no plans to exclude individuals from the RCT based on knowing someone else who is already participating. As this presents a risk of contamination, this will however be monitored from the start by asking participants how they found out about the trial (with one option available for selection being 'I know someone else taking part in the trial'). If monitoring indicates that contamination may be an issue, we will begin to exclude these individuals. Before implementing this change, we would seek approval from the Trial Management Group and Data Monitoring and Ethics Committee/Trial Steering Committee.

5. Trial Procedures

5.1. Recruitment

All young people aged 16-24 years, who are users of either Freetest.me, SH.UK, or SHL.UK for STI self-sampling services, and residing in one of the participating local authority areas, will be invited to take part (thus meeting inclusion criteria 1-3). The trial advert, offering a £75 voucher incentive, will be positioned on the 'thank you' page of these websites, seen by users after ordering STI self-sampling kits. This will be followed up by a maximum of two SMS text message and/or email reminders.

Additionally, users of SH.UK and SHL.UK will be alerted to the trial by a notification positioned within their individual service user account area. trial advert may also be positioned at other appropriate points in the user journey (e.g. when users access their test results, confirm their details) during the trial. Further, any users who have placed an order for an STI self-sampling kit via these services since 1st July 2025 (planned recruitment start date) will be sent an SMS inviting participation.

The wording of the adverts will vary depending on location/mode of delivery, but all will contain the following elements:

Invitation: e.g. take part in a study to improve young people's sexual health
Incentive: e.g. earn up to £75 in vouchers
Call to action: e.g. click here to find out more and take part
Reminder (if relevant): e.g. You still have time to take part

The hyperlink in the advert will take users to the trial webpage (hosted on REDCap; a secure data capture and management platform hosted on a UH server) for participant information and to provide consent. No vulnerable groups are being specifically targeted for recruitment as we aim to have a representative sample of 16-24 year olds. Recruitment will end at 18 months or when the target sample size is achieved (whichever comes sooner).

5.2. Participant information

Clicking on a hyperlink embedded within the study advert will take individuals through to the study webpage hosted on REDCap. The trial webpage will provide potential participants with the participant information sheet (PIS) outlining, what the trial is about, who can take part, what is expected of them, trial procedures, confidentiality, data protection, risks/benefits, dissemination plans, how to contact the team, and how to make a complaint (see Appendix 3). Users will have time to review the information sheet and make an informed decision on whether to participate in the trial. They will have the opportunity to contact the research team to ask questions via email (halo@herts.ac.uk) and by phone.

5.3. Eligibility assessment

Ahead of providing consent, individuals will be asked to confirm that they meet the inclusion criteria (except criterion 2) and do not meet exclusion criteria 1-2 (see section 4.4; yes/no response to items). Once this confirmation provided, individuals will be able to proceed to the next webpage where informed consent is taken.

We will not ask participants to confirm whether they reside in a participating local authority area (criterion 2) as they will not be party to this information. Instead, at screening (see section 5.6) we will use participants' responses to the item on local authority area within the baseline survey to check for eligibility. At screening, we will additionally double check that responses given in the baseline survey are consistent with meeting criteria 1 (date of birth), and that baseline STI test results are available (demonstrating use of Preventx services for chlamydia and gonorrhoea testing; criterion 3).

5.4. Informed consent

Those who decide to take part will provide digital informed consent within REDCap by selecting 'I agree to the above statements and consent to taking part in the research project', and then by typing their name, selecting the date, and digitally signing the form (using touchpad if on tablet/phone, or using mouse if on a computer). See Appendix 4. In addition to providing overall consent to take part in the trial, specific consent will be obtained from all participants for the following:

- Accessing STI test results from Preventx at M(Month)0, M3, and M12
- Accessing personal details from Preventx to confirm their identity (if necessary, as part of screening checks; see section 5.6)
- Sharing data with their local sexual health service (NHS or local authority) to refer for treatment/aftercare following a positive STI test result (not applicable for M0 tests as clinical management will be the responsibility of local NHS trust as per existing agreements), and where applicable to refer for support with safeguarding concerns
- Tracking their use of the intervention using analytics software to provide individual level analytics data (relevant to objectives 8-9)
- To retain all data provided up to the point of withdrawal from the trial (if applicable)
- Sharing data outside of the UK for the purpose of data analysis
- To be contacted about other research opportunities related to the trial (optional consent item)

If during the RCT any safety information become known that results in a significant change to the protocol, and accordingly to the risk/benefit analysis, the participant information sheet and/or the consent form will be updated accordingly. Participants will be informed of the update via email and signposted to the revised information sheet on REDCap, and asked to indicate if they do not wish to continue in the trial.

5.5. Baseline

Baseline measures will be obtained through STI testing (Nucleic acid amplification (NAA) for chlamydia and gonorrhoea) and completion of a survey. Participants will be invited to complete the baseline survey in REDCap immediately after consent is obtained. The baseline measures of STI are those resulting from STI self-sampling kit requests made by participants at the start of the study . We will send one SMS reminder to individuals who haven't ordered a test kit (2 days after baseline completed) and haven't returned their test kit (5 days after baseline completed). The results of these baseline tests for chlamydia and gonorrhoea will be shared securely by Preventx with the UH core research team (see section 7.2.1 for more details).

On completion of the baseline survey and the STI test, the UH core research team will perform a series of screening checks (outlined in section 5.6); only individuals who pass these checks will be randomised.

We will ask those with positive results for chlamydia and/or gonorrhoea at baseline to self-report adherence to treatment. These individuals will receive a link via SMS text message, 14 days post-result, to a survey on REDCap to record whether the infection has been treated as prescribed (for most participants, this will allow them sufficient time to access and take their prescription). If the participant does not respond to this request, they will be sent two reminders (first by text message, second by both text message and email) to complete this survey, each spaced 3 days apart. If the participant confirms at either of these timepoints that they have taken the full course of treatment as prescribed they will not receive any further reminders. If however, they report that treatment is incomplete but that they intend to complete it, they will be sent a further SMS text message 7 days later asking them to confirm that treatment has been taken as prescribed. They will then be given a further 7 days to report whether treatment is complete[1]. Figure 2 displays this flow of communications visually.

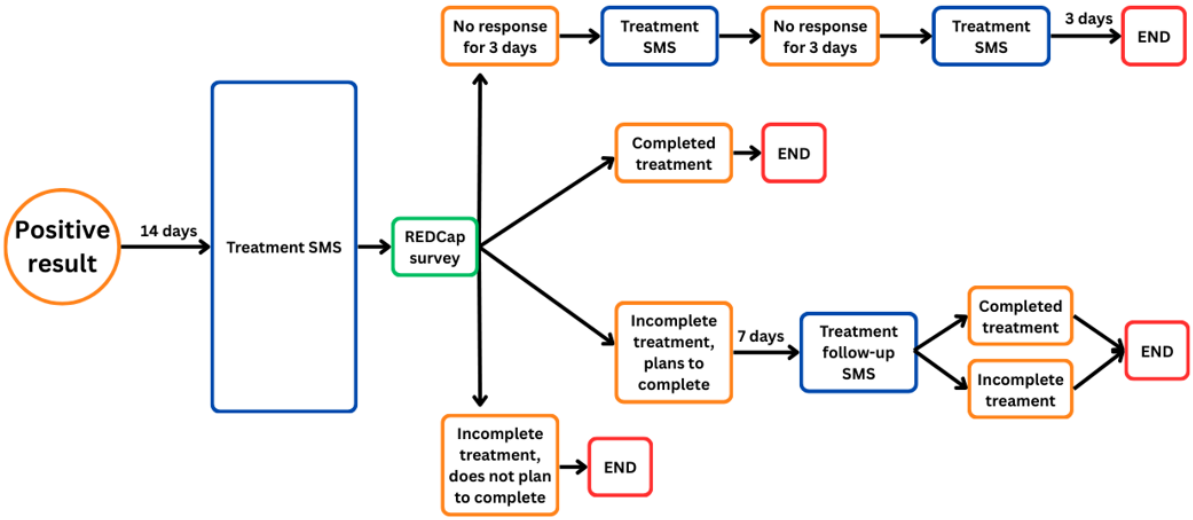


Figure 2 Flow of communications for treatment

5.6. Screening

On participant completion of the baseline survey, screening checks will be performed by unblinded members of the UH core research team to:

1) Detect and remove imposter participants who are 1) non- genuine users of SH.UK, Freetest.me, SHL.UK (including bots) or 2) people attempting to enter the trial more than once. This will be undertaken as follows:
   - Preventx will implement either or both of the following two methods to enable authentication of individuals as genuine users of SH.UK, Freetest.me, SHL.UK. These include:
     - Passing an ID/code through to REDCap from advert
       - When users of SH.UK, Freetest.me, and SHL.UK click on the RCT advert, their user ID/order number or a randomly generated code will be appended to the end of the URL used to access the trial webpage. This ID/order number will be captured by REDCap and associated with each individual participant. If this proves technically challenging,

[1] In line with BASHH guidelines, the maximum treatment window for uncomplicated chlamydia is 14 days. For uncomplicated gonorrhoea, this is one day. This schedule therefore allows for a 14-day treatment window but no longer (as this would indicate non-adherence which presents a risk of treatment failure).

individuals may instead be asked to self-report their Preventx ID/order number at the beginning of the baseline survey.
    - If screening identifies that there is no ID/order number, then access to the trial webpage will have been from a source other than Preventx (e.g bot) and the individual will not be randomised.
    - Where there is an ID/order number, this will be checked for uniqueness against the existing cohort of participants. If the details are already associated with an existing participant, this will either indicate that the same individual has attempted to enter the trial on more than one occasion, they have passed the URL onto someone else (who is ineligible to participate), or that a bot is attempting to gain access. Under these circumstances, this individual and any future individuals with the same details) will not be randomised.
    - On occasion, where we suspect there is a duplicate user, it may be necessary to validate who is the genuine user against personal details held by Preventx. Any sharing of such data will comply with UK Data Protection Act (2018) and the General Data Protection Regulations (EU GDPR) 2016/679 requirements.
    - If bots present a significant or recurring issue, we will embed a reCAPTCHA widget within the study webpage (at the point of assessing eligibility/taking consent) to help mitigate this.
  - Preventx will set the URL used to access the trial webpage as 'one-time use' or with a timed expiry.

2) Detect individuals who do not have accurate/genuine contact details (required to communicate with participants throughout the trial) so that these details can be corrected, or the individual excluded from the trial. Specifically, the following processes will be implemented:
    - To check that all mobile phone numbers are accurate, they will be verified by a text message. If an undelivered message is received, the individual will be contacted via one other available means to give them the opportunity to correct this. If the individual does not respond within 5 working days, they will not be randomised.
    - Where concerns exist that a postal address is not accurate or genuine, this will first be checked using the Royal Mail 'find an address' service. If concerns persist, the individual will be contacted via one other available means to give them the opportunity to correct this. If the individual does not respond within 5 working days, they will not be randomised.
    - Where concerns exist that an email address is not accurate or genuine (e.g. is made up of random letters and numbers) the individual will be contacted via this email address asked to send a reply; at the same time, they will also be contacted via one other available means in case an error was made in providing this information. If the individual does not respond within 5 working days, they will not be randomised.
3) Detect and remove participants whose date of birth makes them under 16 years or over 24 years at baseline
4) Detect and remove individuals who have not responded to the baseline survey with sufficient care.
   Specifically, the following processes will be implemented:
    - Anyone taking less than the minimum expected time taken to complete the survey will not be randomised (the minimum time will be determined following multiple rounds of test completion)
    - Anyone with evidence of random responding (against pre-identified questions) will not be randomised

A screening and enrolment log, including date and initials of UH core research team member conducting the screening, will be created within the REDCap database. Following the screening checks, randomisation will occur providing participants complete the following

activities within 30 days of consent 1) the baseline survey, and 2) return of the STI test kit they ordered at baseline (prior to seeing our trial advert) to the Preventx laboratory with a valid biological sample such that their STI status for chlamydia can be determined. The 30-day window is to ensure that the two sets of data are commensurate. Note, we will not require a valid biological sample for gonorrhoea as this is a secondary outcome measure. At this point we will also check the service ID provided alongside the result to ensure that the individual is aligned to a sexual health service supporting the study. This is necessary to confirm eligibility (only services linked to participating local authorities will advertise the study) and to ensure that we have agreements in place to make a referral to this service if needed (for STI treatment/support or safeguarding concerns).

The range of possible results for chlamydia and gonorrhoea are: detected (positive), not detected (negative), and other (this categorisation is used for unknown or unclear results due to, for example, insufficient specimen, contaminated specimen, or lab error). Randomisation decisions taken on the basis of test results for chlamydia are as follows:

- Those with a positive or negative result for chlamydia reported[2] within 30 days of consent will be randomised
- Those with 'other' results for chlamydia will be contacted by email to arrange further testing. If it is agreed that they can re-order another STI test (from SH.UK, Freetest.me, or SHL.UK) and return it within the 30-day window, we will ask them to go ahead and to inform us of the assigned kit code so that we can link the result of this test with their data. If there is insufficient time for this, we will ask them to repeat the process of providing consent and completing the baseline survey (to ensure that both sets of data are commensurate). Under these circumstances, a note of this will be made on the participants' case report form to avoid them being excluded as a duplicate participant.

We will randomise participants regardless of their result for gonorrhoea (positive, negative or other).

All the circumstances under which individuals may be excluded from randomisation to the trial will be outlined in the PIS. On occasions when randomisation does not occur, the individual concerned will be contacted by email setting out the reasons.

5.7. Randomisation and blinding

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

Randomisation of participants to treatment groups (1:1) will be managed within REDCap. The Clinical Trials Unit (Brighton and Sussex CTU, UKCRC ID 66) statistician (Saskia Eddy; SE); overseen by senior statistician Stephen Bremner (SB) will generate the randomisation list in .csv format for simple randomisation which will be uploaded to REDCap by the Database Manager (Debbie Lambert; DL). This list will determine the order in which participants are randomised into each of the two trial groups (stratified by group to maintain balance across key demographic criteria: ethnicity, sexual orientation, deprivation). A member of the UH core research team will perform the manual screening checks as detailed above (section 5.6) and then approve the participants for randomisation by the REDCap randomisation feature. Responsibility for this randomisation approval process will be undertaken by unblinded members of the UH core research team on a rotating basis. Participants randomised to the RCT will be documented on REDCap which will act as an enrolment log.

[2] 'reported' date will be taken as the date at which the sample was received by the Preventx laboratory; this allows for any delays which may occur in processing samples by the laboratory.

Participants will be blind to treatment group allocation since both groups will receive web-based STI prevention information. Laboratory staff who test STI samples will also be blind. Statistical Analysis Plans (SAPs) will be written and signed off prior to database lock and the final analysis commencing by the trial statistician (SE) and co-investigators responsible for secondary analyses. These individuals therefore need to be blinded up to this point but not beyond (the lead trial statistician SB will however be blinded throughout). No other UH core research team members need to be blinded as it will not be possible for them to influence randomisation or participant responses to surveys. Individuals responsible for telephoning participants to support collection of a minimum data set (see section 7.1.2), will be blinded to treatment allocation throughout.

Due to the nature of the intervention, it is very unlikely that there will be a need to break the randomisation code (see section 6 below). However, if this is necessary, for example due to a serious adverse event, then the joint-CIs (KN and KB) will be contacted in the first instance (including if out-of-hours). The Trial Manager will be able to identify/confirm the allocation of an individual participant using the REDCap system if the joint-CIs are still blinded at this point. Contact details of all members of the team are available within the Trial Team folder of the Trial Master File.

5.8. Intervention

5.8.1. Halo (intervention group)

Participants randomised into the intervention group will be sent an SMS text message with a hyperlink (containing a unique identifier to track website use) giving them access to the Halo website. The website uses an API to authenticate participant data held in REDCap (name, email address, participant ID number) prior to first access, to confirm that anyone trying to access the website is a genuine participant randomised to the intervention arm. On first access they will be asked to register (username and password set up by user; these credentials will be required by the participant to gain access on future visits). An SMS text message reminder to access the content will be sent to participants one week after first access is provided. This will be followed by an email and SMS text message reminder a further week later.

The Halo intervention was first developed nearly ten years ago. Its first iteration (26), then called Wrapped, was developed in 2016-17 with support from Medical Research Council (MRC) Public Health Intervention Development (PHIND) funding. Its second iteration (now rebranded as Halo), to be tested in this RCT, has the same theoretical basis, and largely utilizes the same practical strategies, but with the presentation of content updated to reflect the modern-day expectations of young people.

The Halo intervention aims to increase correct and consistent condom use through addressing condom accessibility and four sub-behaviours, namely storing condoms, carrying condoms, communication about condoms, and applying condoms (see logic model, Appendix 5). Targeted theoretical determinants of these sub-behaviours include self-efficacy, social norms, attitudes, skill. Key underlying knowledge and beliefs addressed include condom fit and feel, knowledge and skills required to store, carry and use condoms effectively, beliefs about the impact of condom use on pleasure, enjoyment, and condom use stigma. Content is delivered through a website. The website has recently been updated in collaboration with our Young People's Advisory Group (YPAG). The theoretical model remains the same, and largely the practical strategies through which the condom-use determinants are addressed are also retained. Where changes have been made, these are in response to a clear steer from young people. These important insights were gained through a process evaluation embedded within our feasibility trial (28), and a subsequent think-aloud qualitative study with young people (n=18 16-24 year olds) to gather further in-depth feedback on content that was less supported (29). The rebranding of the intervention to Halo was also supported by our YPAG and PPI co-investigators.

The current iteration of the intervention, now called Halo, to be tested in this RCT, is represented by the site map presented in Appendix 6. There are two ordering features:

Sample Pack**:** A free box containing ten different condoms (different brands, sizes, textures, thicknesses, internal/external) and sachets of lubricant for users to try out. The box includes step-by-step instructions on how to correctly apply condoms. It is delivered in discreet plain packaging. The aims of this component are to help young people identify their preferred type of condom/lubricant, to help them overcome any issues around the smell, fit & feel of condoms, and to make positive associations between condoms and pleasure by instructing users to interact with them on their own i.e. getting them out of packet, feeling them, unwrapping, smelling, tasting etc. Users will be encouraged to put the condoms on themselves or insert into their vagina. It will be suggested that users try out all the different types of condoms to identify their preferred type(s). Users will also be encouraged to practice applying condoms until they can do so confidently and with ease. The box itself is designed to be a permanent store for condoms at home. The inside bottom of the box has a reminder to keep it stocked up.

Condom ordering: A service delivering free condoms to users (in discreet packaging). Users will be able to select and change their preferred type(s) of condom and delivery address. Delivery will be triggered by an online order from the user. Each user will be limited to one order per month. Each order consists of one type of condom in bundles of five or ten. Users can also add lubricant to their order. A reminder email or SMS text (as selected by user) will be sent to users when they are able to order more condoms. As well as offering this service, users will be linked to information about other online and off-line places where they can access free or affordably priced condoms.

The remaining sections provide written and video content (drawing on and featuring real-life testimony from young people), supported by graphics and custom illustrations that aim to increase knowledge and skills, and to build positive beliefs about condom use. Those new to or less confident with condoms can access content on how to choose the ‘right’ condom, how to put them on (or insert them in the case of internal condoms), how to avoid common problems such as breaking/slipping, and how condoms can be used to enhance sexual pleasure and enjoyment. Content to build the knowledge and skills required by young people to ensure that they always have a ready-supply of usable condoms to hand is also included (i.e. condoms that are in-date, have been stored/carried correctly, replaced as needed). There is also content aiming to build strong beliefs in favour of condom use, including that which takes a rights-based approach through challenging stigma (particularly around young women having and carrying condoms). Further, how to initiate conversations about condom use and cope with resistance is modelled, with users encouraged to formulate plans for how they will act in different scenarios including where decision making is more challenging e.g. under the effects of alcohol. Finally, information on other forms of contraception and STIs, as well as how to access support for sexual health and wellbeing is also provided.

Participants will be able to choose what and how much of the intervention they engage with. Physical materials (i.e., sent as part of condom sample pack and condom ordering) will be delivered to the participant’s home address (or another address of their choosing). Digital materials (videos, illustrations and written information) will be available on the Halo website.

At the end of the trial, participants in the intervention group will be given access to the control intervention for two weeks.

5.8.2. Control group

Participants randomised into the control group will be sent an SMS text message with a hyperlink giving them access to the control website. An SMS text message reminder to access

content, followed by an SMS text message and email reminder, will be sent at one and two weeks respectively.

Existing STI self-sampling websites typically provide only basic information on STIs and condom use to their users (30). To replicate this level of health promotion content, and to provide an equivalent 'intervention' experience, participants randomised to the control group will be directed to a stand-alone WordPress website that presents comparable basic information. This will be akin to information provided by NHS Choices. The same basic information is also be duplicated within the Halo website.

At the end of the trial, participants in the control group will be given access to the Halo intervention website for two weeks.

5.9. Follow up procedures

Participants will complete follow up surveys via REDCap at 3 months (M3), 6 months (M6) and 12 months (M12). STI self-sampling test kits (Nucleic acid amplification (NAA) tests for chlamydia/gonorrhoea) will be sent to participants by Preventx at 3 months (M3) and 12 months (M12) follow up. As per baseline, at M3 and M12 participants will return their test kit to Preventx who will be responsible for processing the samples. In the case of a positive test result, treatment status data will be requested from participants as per the procedure set out in section 5.5.

5.10. End of Trial

The trial will end 48 months from the start (31st October 2028). Recruitment is anticipated to commence on 1st July 2025 and will end 18 months later on 31st December 2026 (or sooner if target sample size is reached). All participant involvement will end by 31st January 2028.

6. Safety

A full risk assessment has been conducted for the trial with relation to participant safety. Potential risks are considered in line with normal everyday risks.

6.1. Adverse events (AEs)

Adverse events (AEs) will be captured throughout the entirety of the trial, using both formal (survey) and informal (other direct communication) methods. Items to identify the AEs stated below will be included in the M3, M6 and M12 surveys. At M3, these will ask participants to self-report any AEs from the start of the trial (taken as the point at which they viewed the trial advert). At M6 and M12, these will ask participants to self-report any AEs that occurred in the intervening time periods. Participants will also be able to report AEs directly to both the Trial Team and Preventx at any time, using the contact details provided. AEs will be followed up by an email to participants, offering support and seeking further information on the event to establish severity, relationship to the intervention and outcome.

The Trial Manager and joint-CIs will be alerted of all AEs that occur during the RCT. A report will be created for each AE and stored in the TMF/Preventx Investigator Site File (ISF), and all safety events (regardless of origin and seriousness) will be recorded in an adverse events log on REDCap from trial commencement. All safety events will be reviewed by the UH core research team on a weekly basis and will be followed up until resolved (if applicable). AEs will be reported to the UH CTU and Sponsor.

All AEs will also be documented in each DMEC and TSC report, allowing members to confirm that adverse events have been appropriately managed and resolved. DMEC and TSC members will provide guidance and advice on how to address recurring and/or concerning AEs during the meetings.

Any events considered serious will follow the procedure outlined in 6.1.3.

6.1.1. Survey items used to identify Adverse Events (AEs)

We have identified four potential expected adverse events that could occur because of participation in the RCT:

1. Inadvertent disclosure to another person that the participant is sexually active/testing for an STI
2. Side effects of STI treatment (if relevant)
3. Experience embarrassment and/or distress because of referral for positive STI test result and/or safeguarding concern
4. Allergic reaction to condoms (e.g. due to latex)[3]

Participants will be asked to select whether any of the above events have occurred for them. There will also be an 'other' option to allow participants to record anything else that has happened.

Any safeguarding concern will be treated as an adverse event and reported as set out below.

6.1.2. Safeguarding

Oversight for safeguarding will be provided by UH's School of Health, Medicine and Life Sciences (HML) safeguarding lead. A Halo safeguarding procedure has been developed and will be applied to the RCT (see Appendix 7). This procedure is in line with HML departmental safeguarding policy. The Halo safeguarding procedure has been approved by a UH safeguarding lead (school level) and the DMEC.

UH will have responsibility for identifying safeguarding concerns. UH, together with NHS trusts, located within partner local authority areas from which participants are drawn, will have responsibility for acting on safeguarding concerns. The Halo safeguarding procedure is summarised here.

Questions will be included within all follow-up surveys (M3, M6, M12) to identify evidence of sexual exploitation, abuse, assault, or coercion. These questions have been reviewed by a UH safeguarding lead (school level) and UH Disability Services. Where indicated, participants aged 18+ will be sign-posted to sources of information and support via email, as well as being offered one-to-one support from the HML safeguarding lead. Those under 18 years will be referred to their local NHS Trust sexual health service for further investigation and support. This could involve further onwards referral to statutory services such as adult/child social services or reporting to the police where a crime has been committed; this would however be a decision made by the respective trust, in consultation with the participant where appropriate. They will be informed by email that this is happening and supported by the UH core research team through this process; the email will advise that contact will be by phone, that the person

[3]Allergic reactions to condoms will be managed as AEs, not Adverse Reactions (ARs), for the following reasons; i) this is a non-CTIMP trial, ii) the effect of the condoms on clinical outcomes is not being investigated; they are being provided as an optional product within the Halo intervention, and iii) condoms provided as part of this trial already have marketing authorisation within the UK.

making contact will be a sexual health nurse, and that they will confirm their identity and that it is safe to speak before proceeding. When making the referral, the UH core research team will send the trust the individual's contact details along with the responses they made to the relevant survey questions. This limit to confidentiality will be clearly outlined in the participant information sheet and reiterated within the survey just prior to completion of the relevant questions (which are optional).

During the research, it is possible that a participant may directly disclose that they are experiencing, or have experienced, sexual exploitation, coercion, assault or abuse to a member of the research team (e.g. when undertaking telephone calls to collect minimum data from surveys). Prior to the commencement of data collection, training will be delivered to the UH core research team and anyone else responsible for data collection by the HML safeguarding lead on how to identify and appropriately respond to safeguarding needs. 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, included within debriefing material, and embedded within the intervention and control group websites. In line with the Halo safeguarding procedure, if a participant is aged 18+, and there is no indication of specific vulnerability, they will be sign-posted to sources of information and support via email, as well as being offered one-to-one support from the HML safeguarding lead. If they are under 18 years of age (or they are considered vulnerable in other ways), the HML safeguarding lead would be contacted and the case discussed. If the individual is deemed to be at clear risk of harm, then confidentiality would be broken, and their contact details passed on to their local NHS trust as above. Where the level of risk is unclear, the HML safeguarding lead will ask that further information is gathered (without the need to break confidentiality) and then use this to decide on the appropriate course of action. Where the level of risk is considered low, the HML safeguarding lead may advise that the individual is signposted to sources of support (without the need to break confidentiality). As before, this is clearly explained within the participant information sheet. If any contact with the participant identifies that they are (or may have been) the victim of a crime, the HML safeguarding lead will support them to report this to the police, if that is their express wish.

For all participants, if a safeguarding disclosure constitutes an emergency, the UH core research team will call 999 immediately. If the disclosure indicates an urgent safeguarding concern that is not an emergency, the UH core research team will contact the relevant local authority safeguarding team by telephone for advice and act accordingly.

Note: just prior to entering the trial our participants will have been assessed for safeguarding by Preventx (using a set of questions which duplicate those used in our follow-up surveys). This occurs as part of the process of users ordering their STI self-sampling kit, with those requiring support being referred as required. To avoid confusion and parallel referrals for the same issue, we will therefore not include safeguarding items in our baseline survey. From the beginning of the trial, all our communication with participants will however provide details on how individuals can contact the team if they wish to discuss any concerns about their sexual health or wellbeing with us; this is also included in our participant information.

6.1.3. SAEs

An Adverse Event will be considered serious if the event:

- resulted in death
- is life-threatening
- required hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability or incapacity

- is considered medically significant by the joint-CIs/delegate[4]
- results in safeguarding due to experience of physical or sexual violence or abuse

Any research personnel who become aware of a possible SAE will notify the Trial Manager and joint-CIs within 24 hours of knowledge, who will then report this to the UH CTU and Sponsor immediately using the UH CTU SAE reporting form. All SAEs will be recorded in the AE log in REDCap and will be followed up until resolution, with any additional information reported to the UH CTU. Original SAE reporting forms and subsequent follow-up information will be stored within the TMF and Preventx ISF.

Reports of SAEs that are i) **related** to the trial (i.e. they resulted from administration of any of the research procedures, and ii) **unexpected** (i.e. not listed in this protocol as an expected occurrence) will be reported to the relevant NHS Research Ethics Committee (REC) using the HRA Non-CTIMP Safety Reporting Form within 15 days of the joint-CIs becoming aware of the event. A copy of the SAE notification and REC acknowledgement receipt will be copied to the UH CTU and Sponsor and stored in the TMF/Preventx ISF.

7. Data Collection, management and analysis

7.1. Data collection

Table 2 below provides an overview of measures and timepoints.

Table 2. Halo measures and timepoints

	Timepoint			
Measure	**M0**	**M3**	**M6**	**M12**
STI tests				
Nucleic acid amplification (NAA) tests for chlamydia/gonorrhoea	✓	✓		✓
Survey data				
Participant contact details (name, email address, postal address and mobile phone number for communication during the trial)	✓			
Demographic characteristics (date of birth, sex, gender identity, ethnicity, sexual orientation; postcode from postal address will be used to identify Indices of Multiple Deprivation quintile)	✓			
Current relationship status	✓	✓	✓	✓
Self-reported STI diagnoses		✓	✓	✓
Condom use behaviour (correct use and consistent use)	✓	✓	✓	✓
Behavioural determinants (Condom use self-efficacy, social norms for condom use, attitude towards condom use, condom use skill, accessibility of condoms, condom use intentions)	✓	✓	✓	✓
Health-related quality of life (EQ5D-5L)	✓	✓	✓	✓
Resource use and personal costs	✓	✓	✓	✓
Evidence of adverse events		✓	✓	✓
Evidence of contamination				✓
Safeguarding items (to identify evidence of sexual exploitation, abuse, assault or coercion).		✓	✓	✓

The total voucher incentive offered to participants is £75. Payment is staggered across the course of the RCT and paid in return for completing set activities as described in table 3 below.

[4] Participants reporting an active medical event will be referred to appropriate medical services for assessment (e.g. directed to 111, A&E, GP). The event will be followed up by the Trial Team in the same way as for other SAEs.

Table 3. Schedule of incentives

Timepoint	Trigger	Amount (£)
M0	Participant randomised (occurs when they have provided all baseline data within 30 days of consent and passed all eligibility and screening checks)	10
Between M0 and M3	Control website: participant clicks on link provided Halo website: participant registers	5
M3	Participant completes M3 survey within 30 days of M3 survey invite	5
	Participant returns STI self-sample within 30 days of M3 survey invite	15
M6	Participant completes M6 survey within 30 days of M6 survey invite	10
M12	Participant completes M12 survey within 30 days of M12 survey invite	10
	Participant returns STI self-sample within 30 days of M12 survey invite	20

7.1.1. Baseline (Month 0)

STI Tests

The results of self-sampling tests (for presence of chlamydia and/or gonorrhoea at genital sites) ordered by participants prior to seeing the advert for the trial, and which confer eligibility for participation in the RCT, will be considered the baseline measure (M0). The M0 self-sampling tests will be processed by Preventx. Reminders to return the M0 test kit (if required) will be managed by Preventx in line with their usual service pathway. Requests/reminders to confirm treatment status (in the case of positive test results) will be managed by the UH core research team and collected via a survey on REDCap (see section 5.5 for the schedule of requests/reminders).

At M0, the UH core team will on a weekly basis, complete an Excel file containing the user's first name, date of birth, telephone number and date of consent, for any new participants that have consented to participate in the RCT in the preceding week. The same information will also be included for any participants who consented prior to that week that we still do not have any baseline STI data for (until the 30-day window for providing a sample has passed; see section 5.6). This file will be stored in a folder on the Trial Master File/SharePoint. Access to this will be granted to a nominated member(s) of Preventx staff responsible for preparing and sharing baseline STI data with the UH core team. This nominated individual will be notified by the UH core team when the file is ready for their input. In response, they will record any known test results (detected, undetected, other) along with the date the sample was received at the laboratory, the date the result was reported and the ID number of the service that the user accessed.

Survey data

REDCap will be used to manage all survey data collected during the RCT. Completion of the M0 survey will occur immediately after consent is obtained.

The M0 survey will include:

- Participant contact details (name, email address, postal address, and mobile phone number for communication during the trial)

- Demographic characteristics (date of birth, sex, gender identity, ethnicity, sexual orientation; postcode from postal address will be used to identify Indices of Multiple Deprivation quintile)
- Current relationship status
- Condom use behaviour (correct use and consistent use)
- Behavioural determinants (Condom use self-efficacy, social norms for condom use, attitude towards condom use, condom use skill, accessibility of condoms, condom use intentions)
- Health-related quality of life (EQ5D-5L) (31)
- Resource use and personal costs

One email reminder will be sent to all participants who have not completed their M0 survey three and six days after consent has been provided. As set out in section 5.6, 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.

7.1.2. Follow up (Months 3, 6 and 12)

STI Tests

An account area, referred to as the Halo service area, will be set up by Preventx (on the secure external server they use for the sharing of STI data with NHS trusts) to enable Preventx and the UH core research team to co-ordinate the M3 and M12 processing of test kits and communication of test results. A user ID and password will be required to access the service area, which will be restricted to unblinded UH core research team members.

The UH core research team will trigger the distribution of STI self-sampling kits by Preventx via the Halo service area. As at baseline, these kits will be used to test for the presence of chlamydia and/or gonorrhoea at genital sites. Participants will receive an SMS text message six days before the test kit is sent, which provides a link to REDCap with the opportunity to check and amend their address details if required (address check'). Kits will contain the usual user instructions to collect a sample and return by Freepost to Preventx for processing.

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 yet 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), and the second after a further 8-day interval (again originating from the Halo service area). 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 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). Non-responders will continue to receive surveys and self-sampling kits at future time points, unless they request to withdraw from the trial. The communication of test results to the UH core research team differs for M3 and M12. For these timepoints, the results will instead be recorded by Preventx in the Halo service area.

Participants who return their test kit and yield a 'other' result for chlamydia will be contacted and offered an additional test kit if there is 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.

In line with the Preventx standard protocol, participants will be contacted by SMS text message (originating from Halo service area) when their result is known. In the case of negative results for both chlamydia and gonorrhoea, the results will be communicated within the body of the message. Where the result of either (or both) chlamydia and/or gonorrhoea is positive, the message will ask them to contact their local NHS trust sexual health service to discuss their result (contact details provided). This notification will be triggered in the Halo service area by the UH core research team (the team will be notified of the availability of new results via email). For those with a positive result, the UH core research team will make a direct referral to the same NHS Trust sexual health service (subject to data sharing agreements between UH and each NHS Trust; participant consent for this is required to enter the trial). This ensures that the service is aware of the positive case when the young person makes contact or can actively pursue contact if they are not forthcoming. Once contact is made, the sexual health service will inform the young person of their chlamydia and gonorrhoea results and arrange for appropriate treatment and support for positive cases. Referral forms will be sent by the UH core research team to a '.nhs' or '.gov' email using UH's encrypted File Exchange. The referral to the trust will be made following a standardised procedure, using the same form as used for the safeguarding referrals, and in accordance with the requirements of each NHS Trust.

Participants who receive a positive test result will receive the same SMS text message request and reminders for treatment status as sent at baseline (see section 5.5).

Survey data

Participants will be asked, via an SMS text message sent from REDCap, to complete survey measures at M3, M6 and M12. The message will include a link to the relevant survey. The follow-up surveys include all items included in the baseline survey (M0), except for contact details and demographic characteristics (items excluded from follow-up surveys). Participants will be asked to self-report STI diagnoses since the last measurement timepoint. Items to identify evidence of adverse events will be included at M3 (to identify events from the point of seeing the advert), M6, and M12. The M12 survey will also include items to identify intervention use and evidence of contamination between trial groups.

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

Figure 3 below displays the schedule of invites and reminders sent to participants requesting completion of surveys and STI test kits. At M6, only the survey invites and reminders are relevant (green bubbles).

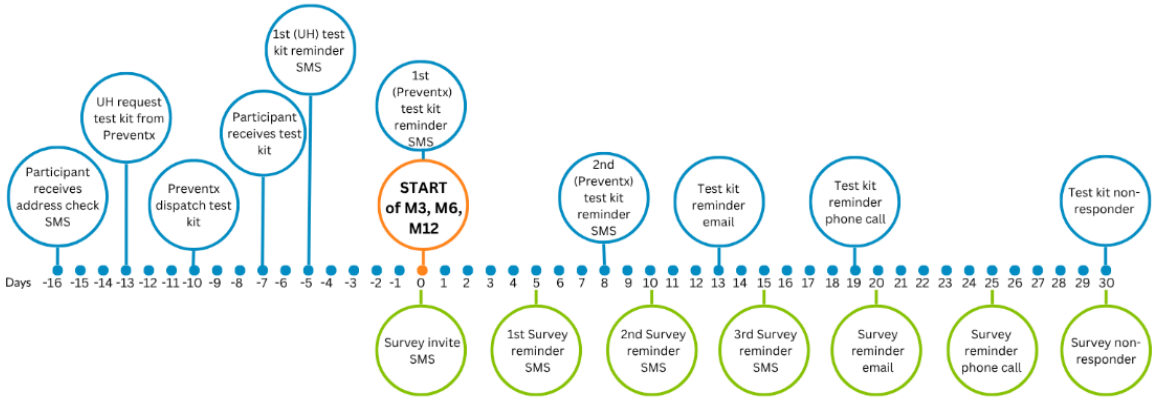


Figure 3. Schedule of survey and STI test kit invites and reminders at follow-up

7.1.3. Other data

Halo intervention website registration details

As part of the registration process for the Halo intervention website, participants will be asked to create log-in details (email and password) and enter the following data: name, postal address, mobile phone number, email address, date of birth (to determine age).

Characteristics of the sampling pool

Preventx will provide the UH core research team with weekly data on the demographic characteristics (age, biological sex, ethnicity, IMD quintile, sexual orientation) and levels of chlamydia positivity of users, by local authority area, who during the recruitment period: a) are shown the RCT recruitment advert, and b) click on the advert. This will enable analysis to determine whether those who choose to participate are representative of the sampling pool i.e. of Freetest.me/SH.UK/SHL.UK users.

Engagement with the intervention website

Data on individual-level engagement with the Halo website will be collected using within-website analytics. Participants' access to the Halo website will be via a unique URL (containing each participants trial ID) enabling individual-level use to be recorded.

For each participant randomised to receive the Halo intervention, we expect to collect the following data:

- Whether they register
- How many times they visit
- Whether the condom sample pack is ordered (one-off order)
- Whether they use the condom ordering service used (ever)
- For each visit:
    - Duration of visit
    - For each video, whether played, and if so, how long for
    - Pages visited and time spent on each page (not including time spent watching any videos)
    - Whether the condom ordering service used and if so:
        - Number of condoms orders (if applicable)
        - Number of sachets of lubrication ordered (if applicable)

We are still exploring what data will be available but it likely to include all the above as a minimum.

Engagement with the control website

Data on engagement with the control website will be collected using within-website analytics. Unlike for the intervention website, this will be aggregate-level data (rather than individual-level data). We are still exploring what data will be available but it likely to include, total number of visits to the site, mean duration per visit, and total number of visits to each page.

7.2. Data management

Data collected during the trial will be managed and processed in accordance with the Data Protection Act (2018) and the UK General Data Protection Regulations (UK GDPR). All data will be pseudo-anonymised prior to storage by removing name, mobile phone number, postal address, and email address. A participant identification number (PID) will be automatically allocated to every participant by REDCap upon their consent to take part in the trial. A pseudonymisation file will be maintained to ascertain a participant's identity where safeguarding concerns are raised or where there are data processing queries.

Data will be stored on REDCap during the trial. REDCap is a secure data capture and management platform hosted on a UH server and which has been assessed by UH's Data Protection Officer as meeting UK GDPR data standards. Unblinded members of the UH core research team, the trial database manager (DL), and the trial statistician (SE; once SAP signed off) will have access to data on REDCap. One individual from the website development team (SiW, RedBullet Data Protection Officer) will have restricted access to specific data items within REDCap to allow for authentication of Halo intervention users as trial participants. Co-investigators (Tia Broderick (TB) and Kanika Leo (KL)), and other delegated individuals, responsible for collecting survey data by telephone will enter this directly on to a separate REDCap instrument linked to the Halo REDCap database (thus they will remain blinded to treatment allocation).

A Data Protection Impact Assessment (DPIA) has been completed and approved by the UH Data Protection Officer. Procedures for data handling and archiving of specific types of trial data are detailed below and are specified in the Halo Data Management Plan.

7.2.1. During data collection

- **Consent, survey (M0 (including personal details), M3, M6 and M12) and STI treatment outcome data (M0, M3 and M12):** These will be stored on REDCap for the duration of the data collection.

- **STI test results (M0, M3 and M12):** M0 STI test result data from Preventx will be stored in a restricted MS Teams channel or SharePoint folder during the data collection period. M3 and M12 test result data will remain in the Halo Service area (with personal details and test kit codes) on the Preventx website, during data collection. Upon receipt of these data (all time points), results will be directly entered into REDCap by unblinded UH core research team members. Entered data will be monitored for accuracy by other unblinded members of the team. These STI test results will be stored in REDCap for the duration of the data collection.

- **Safeguarding and STI treatment referral data:** PID, referral type, and date of referral will be recorded within REDCap and referral forms will be stored on the Halo UH R Drive, encrypted with a password. The UH R Drive is a secure research data file storage system hosted on the University of Hertfordshire server that meets UK GDPR data standards.

- **Halo website registration data**: Halo registration data (name, email address, postal address, mobile phone number, date of birth) will be stored within the Halo website content management system for the duration of the data collection, accessible to the unblinded

members of the UH core research team and specified members of the website development team (Red Bullet). No registration is required to access the control website; no data is directly requested from participants using this site. For the Halo website, PIDs (appended to URL used to direct users to the site) will be automatically captured to enable individual-level analytics data to be associated with the trial data.

- **Intervention engagement data:** Engagement data will be stored within the Halo and control websites for the duration of data collection. This will be accessible to the unblinded members of the UH core research team. In addition, specified members of the website development team (Red Bullet) will have access to engagement data stored on the Halo website. These individuals will have administrative access during the trial to enable them to provide technical support as/when required.

- **Adverse Event data:** An AE log will be held within REDCap. Completed AE/SAE forms, and relevant supporting documentation, will be stored in the TMF and Preventx ISF (where appropriate). The TMF and Preventx ISF will be held on a Halo MS Teams site, with access restricted to individuals specified in the delegation log.

- **Sampling pool data:** For the purposes of data sharing with the Trial Team, the weekly sampling pool data will be stored in a restricted MS Teams channel or SharePoint folder.

- **SMS message data:** Participant telephone number and first name will be stored on Twilio (third-party service to send alerts/notifications/reminders via text message) during the data collection period.

7.2.2. During analysis

- **Consent data:** Consent forms will be downloaded and deleted from REDCap, then stored on the UH Halo R Drive for 6 years (as per Sponsor requirements).

- **Survey data (M0, M3, M6 and M12), and STI test result and treatment outcome data (M0, M3 and M12):** At the end of data collection, the trial database (containing survey data, and STI test result and treatment outcome data) will be locked and data downloaded from REDCap by the BSCTU Database Manager (DL). The downloaded data will be stored in a folder on a private channel within the Halo MS Teams site, or a restricted SharePoint folder, hosted on secure UH servers. Personal data (email address, postal address, phone number, date of birth) will be removed and then the data cleaned and coded in preparation for analysis; data will reside here until analysis is complete. Access to the data folder will be limited to the trial manager (SW), trial statisticians (SE, SB) and co-investigators undertaking analysis relating to some of the secondary outcomes (Katie Newby (KN), Katherine Brown (KB), Rik Crutzen (RC), Louise Jackson (LJ) and health economist TBC). In accordance with the respective data sharing agreements, and as specified in the DPIA, these co-investigators will be allowed to upload and process the data within relevant data analysis software providing this resides within a folder located on their secure university server**.**

  If data is transformed during processing, a new version will be created and named with a version history used to record these transformations. This will ensure that it is always possible to compare the original data with the processed data.

- **Safeguarding and STI referral data:** Referrals type and date recorded within REDCap will be managed as per the survey, STI and treatment status data.

- **Website registration data:** Registration data is not collected by the control website. Halo registration data will be retained on the website until the end of the trial.

- **Intervention engagement data:** Analytics data (along with PIDs; required for those randomised to Halo for linking purposes) will be downloaded from the Halo and control website content management systems. During data analysis an encrypted pseudonymised file containing the engagement data will be stored within a folder in a private channel within the secure Halo MS Teams site hosted on the secure UH server and access limited as described above.

7.2.3. End of trial

At the end of the trial, data will be archived in accordance with the procedures outlined in section 12.3 (record retention and archiving).

7.3. Data analysis

Sociodemographic, clinical, and quality of life data at baseline will be described by treatment group, and overall. Means, standard deviations and ranges will be calculated for normally distributed variables, and medians interquartile ranges and ranges for skewed continuous variables. Frequencies and percentages will be calculated for categorical variables. An overview of analyses per objective is provided as follows. This is subject to modification as our thinking evolves through the process of developing our Statistical Analysis Plans.

1. **To determine whether the addition of Halo to usual care reduces chlamydia positivity at 2 months (primary objective).**

Chlamydia positivity at 12 months (calculated using biological test data), will be compared, between treatment groups, using a log-binomial regression model, adjusting for baseline chlamydia positivity, including a fixed effect for treatment group and adjusted for the following covariates considered a priori, prognostic of outcome: sexual identity (MSM vs. all others), ethnicity (Black vs. all others), IMD quintile (each quintile vs. quintile 1 (most deprived)), gender (male vs. all others), and age (in years). We will report the relative risk, its 95% confidence interval and p-value. Should the model fail to converge, we will instead estimate the odds ratio by fitting a logistic regression model.

2. **To determine whether the addition of Halo to usual care reduces gonorrhoea positivity at 12 months.**

Analysis and reporting as per the primary outcome above, except adjusting for baseline gonorrhoea positivity.

3. **To determine whether the addition of Halo to usual care reduces repeat infections or (cumulative) incidence of chlamydia or gonorrhoea.**

Cumulative incidence of either infection will be compared between groups using a proportional hazards model for time-to-diagnosis based on the biological data. We will adjust for the same covariates listed in objective 1 as well as baseline positivity, reporting the estimated hazard ratio for Halo plus usual care versus usual care alone, the 95% CI and p-value. Repeat infections in the 12 months post-randomisation will be modelled using an ordinal logistic regression model with the outcomes being: no infection, one infection episode, or more than one infection episode (based on biological samples and self-report). We will adjust for baseline positivity and the same covariates listed in objective 1 and report the estimated odds ratio, 95% CI and p-value.

4. **To determine whether the addition of Halo to usual care increases the frequency of correct and consistent condom use during vaginal and/or anal sexual intercourse.**

Condom use at last sex will be analysed using mixed effects Poisson regression with cluster-robust standard errors adjusting for the same covariates listed in objective 1, plus a categorical variable for time point, treatment by time interaction term and a random effect to take account of the repeated quarterly survey sampling per participant. We will report the estimated prevalence ratio comparing the treatment groups, 95% CI and p-value. Condom use frequency in the last 3 months will be analysed using a mixed effects ordinal logistic regression model adjusting for baseline condom use frequency in the last 3 months and the same covariates listed in objective 1, plus a categorical variable for time point, treatment by time interaction term and including a random effect for the repeated quarterly survey sampling per participant. We will report the estimated odds ratios, 95% CI and p-value. For incidence of protected sex in the last 3 months, we will fit a mixed effects tobit model, adjusting for baseline incidence of protected sex in last 3 months and the same covariates listed in objective 1, plus a categorical variable for time point, treatment by time interaction term and a random effect for the repeated quarterly survey sampling per participant. We will report the estimated difference in mean proportions between trial groups, the 95% CI and p-value. Each of these models will be fitted separately for exclusive partner outcome data and non-exclusive partner outcome data.

5. **To examine whether STI and behavioural outcomes differ by subgroup (ethnicity, sexual orientation, and deprivation).**

Three separate models will be fitted including the interaction term between randomisation group and each of these subgroup variables in turn. The same covariates listed in objective 1 included.

6. **To determine whether the effect of Halo on STI outcomes is mediated by changes in the targeted behaviour and behavioural determinants.**

We will perform a causal mediation analysis by fitting parametric regression models. For each of the five potential mediators (condom use self-efficacy, social norms for condom use, attitude towards condom use, condom use skill, accessibility of condoms), two models will be estimated. The first model is for the mediator conditional on treatment group and the covariates listed above. The second model is for STI positivity conditional on treatment group, the mediator, and the covariates (as per objective 1), whereupon direct and indirect effects will be estimated. We will report the estimated effects, 95% CIs and p-values.

7. **To determine whether adding Halo to usual care is cost-effective and analyse impacts on equity.**

A within study analysis and a model based economic analysis will be undertaken.

Within study analysis: The within study analysis will primarily use the data collected within the RCT. Initially, the base case analysis will be framed in terms of a cost-consequences analysis, and data will be reported in a disaggregated manner on the incremental cost and important consequences assessed in RCT. The main economic analysis will involve a cost-utility analysis based on incremental cost per quality-adjusted life year (QALY) gained at 12 months (in line with NICE guidelines (58)), with a secondary cost-effectiveness analysis of cost per reduction in chlamydia positivity at the same time point (to reflect the primary clinical outcome of the trial).

Model-based analysis: If the trial shows that Halo is effective in reducing chlamydia positivity compared with usual care, the cost-effectiveness of the intervention over the longer term will be assessed. For this, a decision-analytic model will be used to evaluate the longer-term impacts of the intervention compared with usual care (59). The evidence used in the model will be drawn from the RCT, with data on longer term costs and outcomes derived from the literature. If data availability permits (based on an assessment of the results of the RCT and

a pragmatic literature review), a societal perspective will be adopted, alongside an NHS perspective. An appropriate time horizon for the model will be determined based on the results of the pragmatic literature review and if possible, based on assessment of the available data, a lifetime approach will be adopted (60). The uncertainty around key parameter estimates will be modelled using probability distributions to allow a probabilistic sensitivity analysis (PSA) to be undertaken (61).

As an additional analysis we will consider impacts on equity. These methods are still being refined, and a range of options will be considered (62). As such methods have not previously been used in a sexual health context, we will first conduct a pragmatic review of the literature to assess the most appropriate approach and be informed by emerging practice (63). For example, proposed approaches include equity impact analysis, equity trade-off analysis, and multi-criteria decision analysis (64). Drawing on this evidence base, we will undertake both a traditional economic evaluation and a fuller analysis taking into account equity considerations to inform decision-making.

The economic evaluation will be conducted and reported in accordance with relevant guidelines (e.g. (57)). For the longer-term analyses, discounting will be undertaken to reflect recommendations by NICE.

8. **To describe the level and patterns of engagement with Halo, and to identify whether patterns of engagement differ by subgroup (ethnicity, sexual identity and deprivation).**

We will describe engagement with Halo using analytics data This will include: frequency of registrations; percentage of conversions (proportion of those shown the advert who register); median and interquartile range for time spent on site, number of visits to site, number of videos played, and time spent watching videos; frequencies and percentages for order of condom/lube sample pack and condom carrier; the frequency/percentage of those making one or more monthly condom/lube orders, and the median and interquartile range for the number of orders.

To determine whether engagement differs by subgroup, we will first perform a hierarchical cluster analysis to identify meaningful groupings that reflect patterns of use e.g. ‘early dis-engagers’, ‘committers’. We will then perform logistic regression to identify whether sexual orientation, ethnicity, IMD, gender and age (groupings as per primary objective), predict cluster membership.

9. **To determine whether STI and behavioural outcomes differ by patterns of engagement with Halo.**

To address this objective, we will examine RCT outcomes across the engagement clusters (as identified previously - see objective 8 above). This will be performed using logistic regression for STI positivity, mixed effects Poisson regression with cluster-robust standard errors for condom use at last sex, mixed effects ordinal logistic regression for frequency of condom use, and mixed effects tobit regression for instances of protected sex. Covariates as per objective one will be entered into the models and for the mixed models, additionally time point as a categorical variable, treatment by time interaction and a random effect of the repeated quarterly survey sampling.

Trial data will be analysed following intention to treat principles. Patterns of missingness will be examined and multiple imputation may be performed as appropriate, with sensitivity analyses for data missing at random. Statistical analysis plans (SAPs), developed by the statisticians (SB & SE) and co-investigators, will be reviewed by the TSC statistician prior to

database lock and the final analysis commencing. The DMEC statistician and health economist, and the TSC health economist, will be invited to review the SAPs but this will not be a requirement.

Any deviations to analyses as specified in the SAPs will be made in agreement with the trial statisticians (SB & SE) from Brighton and Sussex CTU and the relevant co-investigators. A log of these deviations will be maintained in the TMF. They will also be fully described and justified in the final report.

A report for each participating local authority will be produced following the end of recruitment, based on the baseline characteristics of trial participants from each respective area. Baseline demographic, STI positivity and condom use data will be described using means, standard deviations and ranges for normally distributed variables, and medians interquartile ranges, and ranges for skewed continuous variables. Frequencies and percentages will be reported for categorical variables.

Recruitment, retention and safety data will be analysed on a 6-monthly basis and reported to the DMEC and TSC. These data will be described using frequencies and percentages, by treatment group (DMEC only, following unblinding of trial statistician) and overall. No other interim analyses are planned.

8. Ethical considerations

The Halo RCT will be undertaken according to the principles of ICH Good Clinical Practice (GCP), the Declaration of Helsinki (2024), and all relevant ethics and governance processes. Ethical approval will be sought from the UH research ethics committee and an NHS Research Ethics Committee (REC) prior to the start of recruitment. Protocol amendments will be approved by the Sponsor and relevant REC prior to their implementation; the ISRCTN registry record will also be updated.

Ethical considerations for the Halo Trial:

- **Fully informed consent**: participants will be required to provide informed consent prior to participation in the RCT. Participant information (including possible benefits and risks) will be provided, and participants will be given the opportunity to ask questions. Consent forms will be completed online.
- **Participants' rights**: participants will be able to contact the UH core research team at any time via email Halo@herts.ac.uk and telephone. Participants will be able to withdraw from the trial at any point, with no requirement to provide a reason.
- **Participants' safety:** the intervention and control material are unlikely to have any harmful effects on users. Nonetheless information on organisations that can offer help and support with regards to sex and relationships will be included on both the intervention and control websites and provided by default on completion of each survey and included within debriefing material following a qualitative interview. A Halo Trial-specific safeguarding procedure is also in place to identify and appropriately support individuals who disclose sexual abuse/coercion during the trial (see section 6.1 above). As research sponsor, the University of Hertfordshire will provide professional indemnity through its insurance cover.

An end of study declaration and final study report will be submitted to the REC at trial end. If the research is terminated early, or is temporarily suspended, the REC will be notified within 15 days.

9. Quality assurance and control

9.1. Risk assessment

A formal Risk Assessment has been completed for the trial. The risk assessment breaks down possible risks into four areas:

- Impact on the rights and safety of participants
- Risks associated with project concept (design) and reliability of results
- Risks associated with project management and governance
- Any other risk considerations

Participation in the Halo RCT is considered to pose limited risk. Participants will complete survey measures and provide STI self-samples. Participants will need to provide consent for sensitive personal data held about them by Preventx to be accessed (result of their M0, M3 and M12 chlamydia and gonorrhoea test result). This, along with all other data collected as part of the trial, will be handled in accordance with the latest data protection legislation and as stated in the Halo data management plan.

All participants will be provided with information about how to access support for anything related to their participation in the trial.

Those provided with a link to Halo will be able to access web-based resources designed to encourage and support condom use. These individuals will be free to choose whether they order products and/or view the material provided on the website. Risks associated with these actions are in line with normal everyday risk. As a result of engaging with the content, some people may attempt to use condoms and fail, and this may have some negative psychological impacts in the short-term.

Those provided with a link to the control website will have access to usual care information about STIs and condom use.

The Quality Assurance (QA) and Quality Control (QC) procedures for mitigating these risks, and those relating to project design, management and governance, are detailed in the formal Risk Assessment and described below.

9.2. Monitoring

The Trial Manager, with support from the unblinded members of the Trial Team and the CTSN, will be responsible for the monitoring of the trial. Monitoring oversight will be provided by the UH Clinical Trial's Unit (UH CTU). Monitoring will be conducted in accordance with the Halo Trial Quality Management and Monitoring Plan (QMMP), informed by the outcome of a formal Risk Assessment.

9.3. Trial oversight

The UH CTU and BSCTU will collaborate to provide trial oversight. The UH CTU will support the Trial Manager (SW) and oversee quality assurance (including monitoring). The BSCTU (SB, SE, DL) will oversee database management and provide statistical analysis.

The Halo Trial will be overseen by the following committees/groups:

1) Trial Steering Committee (TSC)
2) Data Monitoring and Ethics Committee (DMEC)
3) Trial Management Group (TMG)
4) Trial Team (TT)

9.3.1. Trial Steering Committee (TSC)

The TSC, led by an independent chair, will meet every six months. They will provide overall supervision for the trial on behalf of the project sponsor and the project funder. This will include stakeholders who will guide project planning, decision-making, project delivery, dissemination and impact planning and delivery, with reference to their experience of the contexts, people and infrastructures of relevance to web-based STI self-sampling. They will ensure that the trial is conducted to the standards set out in the Department of Health and Social Care's Research Governance Framework for Health and Social Care and the Guidelines for Good Clinical Practice.

The Committee will consist of at least 75% independent members and include a sexual health commissioner, a representative of sexual health service provision (e.g. a sexual health consultant), an independent health economist, an independent statistician, an independent senior sexual health researcher, third sector representation (e.g. Brook, Terrence Higgins Trust, Sex Education Forum), and representatives from the three main types of web-based STI self-sampling (commercial, third sector, and NHS). Members of the Young People's Advisory Group representing Patient and Public Involvement will also join the TSC, supported by the PPI lead (LMB).

9.3.2. Data Monitoring and Ethics Committee (DMEC)

The DMEC, led by an independent chair, will meet every six months, approximately four weeks before the TSC meetings and will provide overall supervision for the trial on behalf of the project sponsor and the project funder. All DMEC members will be independent, with no competing interests, and will include a statistician and health economist. The DMEC's role is to monitor trial data and make recommendations to the TSC on whether there are any ethical or safety reasons as to why the trial should not continue, ensuring the safety, rights, and wellbeing of the trial participants. However, the final decision to end the trial lies with the Sponsor.

9.3.3. Trial Management Group (TMG)

This will comprise of the Trial Team (see 9.3.4) and all the co-investigators. Should the Preventx co-investigator (MC) be unable to attend TMG meetings, another staff member (JH) will attend in his place. The TMG will be responsible for monitoring the progress of the trial, addressing key issues that may arise and reporting to the funder. Meetings will take place every three months, or more frequently if required. The TMG will meet a month before the DMEC so that the DMEC and TSC reports can be approved.

9.3.4. Trial Team (TT)

The Trial Team will consist of the UH core research team which includes the joint-CIs (KN and KB), Trial Manager Stef Williams (SW), Research Fellows Kayleigh Kwah (KK) and Lauren Schumacher (LS) and Research Assistant Isobel Simmons (IS). They will meet weekly, with additional ad hoc meetings and email discussion as required. In addition, BSCTU staff (DL, SE) and the UH CTU Manager (KI) will attend this meeting once a month at a minimum, but more frequently when required. The Trial Team will be responsible for managing day-to-delivery of the trial. This team will ensure all practical aspects of the trial are progressing well and identify potential issues as early as possible. Other co-investigators will attend these meetings and will have separate ad hoc meetings with members of the Trial Team as required.

9.3.5. Brighton and Sussex Clinical Trials Unit (BSCTU)

The Brighton and Sussex CTU will be providing trial oversight. Trial personnel from the BSCTU are the co-investigator and lead statistician (SB), statistician (SE) and database manager (DL). The BSCTU statisticians will:

- Develop the Statistical Analysis Plan (SAP) for the main primary and secondary outcomes, and support relevant co-investigators to develop SAPs for their planned analyses (other secondary outcomes), with input from the Trial Team
- Produce the DMEC reports, with support from the Trial Manager
- Conduct statistical analysis of data relating to the main primary and secondary outcomes, and support relevant co-investigators to perform their analyses (other secondary outcomes)

The database manager (DL) will support the design, delivery and management of the trial database, with support from Research Fellow (KK), and will support data cleaning.

10. Public and patient involvement

Public involvement will be embedded throughout the trial. The Halo Public Involvement Lead (LMB) has extensive expertise in supporting diverse young people's involvement in research using inclusive approaches. Young people's involvement will be planned in collaboration with the public co-investigators (KL and TB) and young people's advisory group (YPAG) members to be as flexible and inclusive as possible, with 'pockets of participation' depending on young people's interests, availability, and personal circumstances.

Young people's involvement will be led by LMB along with the other members of the 'public involvement team' (KN, IS, KL and TB), who will meet monthly to plan and review public involvement. Public involvement will also be a standing item on all TMG meetings, ensuring that it is seen as central to the project by the wider team, who will also be encouraged to attend YPAG meetings. Public involvement in the trial will include a combination of:

- A YPAG of up to 12 young people, who will be involved throughout the project. This number is anticipated to fluctuate throughout the project, in which case further recruitment can take place.
- We anticipate that the YPAG will meet mainly online four times per year and two in-person meetings have been costed for across the project. The timing, format and location of meetings will however be determined through discussions with YPAG members. The YPAG will also have opportunities to inform the project in other ways (e.g. contributing to documents in between meetings using digital platforms, sub-groups meeting to focus on specific elements where more intensive input is needed). The group will receive training and support as needed throughout the project.
- Two public co-investigators (KL and TB) will be involved throughout as part of the public involvement team and will co-facilitate YPAG meetings with LMB.
- Two YPAG members will be on the Trial Steering Committee and provide a link to/from the wider group.

All young people involved will be paid for their time. The public co-investigators will be employed on an 'Expert by Experience' contract and paid at the standard UH public involvement rate. Members of the YPAG will be paid for their time in either vouchers or BACS transfer (according to their preference) at £20 per hour.

<u>Young People's Advisory Group (YPAG) Recruitment</u>
Young people will be recruited through multiple routes to maximise reach and diversity across demographic characteristics including:

- Inviting those who participated in the former Wrapped feasibility trial
- Inviting those who participated in a user experience study of the former Wrapped intervention (who had been recruited by nationwide Preventx advert and via the UH psychology student cohort)
- Inviting those approaching the department for work experience enquiries
- Advertising via local schools, colleges and further/higher education

- Advertising via relevant charities e.g. Brook
- Word of mouth and snowballing

11. Protocol compliance

The joint-CIs will ensure that the trial is conducted in compliance with the principles of the Declaration of Helsinki (2024), and in accordance with all applicable regulatory requirements including but not limited to the Research Governance Framework, Trust and Research Office, and The University of Hertfordshire Clinical Trial's Unit (UH CTU) policies and procedures, and any subsequent amendments.

All potential breaches of GCP or deviations from the protocol, will be reported immediately to the joint-CIs or, in their absence, the Trial Manager. Any deviations will be documented in the Trial Master File (TMF). The joint-CIs (or Trial Manager) will carry out an assessment of whether the event should be treated as a serious breach i.e. it affects the safety, physical or mental integrity of trial participants, or the scientific value of the trial. If the event relates only to a protocol violation, this will be documented in the TMF.

Any possible serious breaches will be reported to the Sponsor and UH CTU immediately (within 24 hours). The UH CTU will discuss the issue with the joint-CIs and details of this discussion will be provided to the UH's Governance of Clinical Studies Group (GCSG) immediately. The GCSG/sub-group will assess the event and consider if it qualifies as a serious breach of GCP. If so, the Trial Team will be informed of further actions and recommendations. Serious breaches will also be reported to the relevant ethics committee within 7 days if the deviation is in breach of the ethical conditions of trial approval. The sponsor/UH CTU will work with the Trial Team to devise a formal plan of Corrective And Preventative Action (CAPA) to address the breach.

The sponsor will maintain a log of any non-compliance to ascertain if there are any trends developing which need to be escalated. The sponsor will assess the non-compliances and action a timeframe in which they need to be dealt with. Each action will be given a different timeframe dependant on the severity. If the actions are not dealt with accordingly, the Sponsor/UH CTU will agree an appropriate action, such as a full audit of the trial and general trial management systems and procedures.

12. Data protection and participant confidentiality

12.1. Confidentiality

The joint-CIs have a responsibility to ensure that participant anonymity is protected and maintained. They will ensure that participant identities are protected from any unauthorised parties. Information regarding trial participants will be kept confidential and managed in accordance with the UK Data Protection Act (2018) and the General Data Protection Regulations (EU GDPR) 2016/679, NHS Caldicott Guardian, The Research Governance Framework for Health and Social Care, and Research Ethics Committee (REC) Approvals.

In accordance with current Data Protection legislation, UH and Preventx will be joint data controllers for all data residing within the Halo service area, and UH will be data controller for all other data. The joint-CIs (KN and KB) are the 'custodian' of the data. All unblinded UH core research team members will have access to personal, identifiable data; this is required should a safeguarding concern arise. Pseudonymised data will be available to specified members of the TMG that are responsible for data analysis and reporting. Specified members of the website development team will have administrative access to the website database to provide technical support for the duration of the trial. One specified member of the website development team will have restricted access to specific data items within the REDCap

database via an API (Application Programming Interface). Data residing within the Halo service area will be accessible to nominated Preventx employees and unblinded UH core research team members. A Data Protection Impact Assessment (DPIA) has been completed.

Personal, identifiable data will be stored securely in the UK. The following personal identifiable information will be collected from RCT participants:

- Name
- Email address
- Mobile phone number
- Postal address
- Date of Birth

The following GDPR special category data will also be collected from RCT participants:

- Ethnic origin
- Physical or mental health information
- Sex life/sexual orientation
- Biometric data

Participants can withdraw from future participation in the trial at any point, resulting in them not receiving any future correspondence from the team. In the event a participant requests to withdraw from the trial we will keep any data that they have provided up to that point for analysis purposes. Any publications resulting from the trial will use anonymised data only.

12.2. Case Report Form

12.2.1. REDCap

REDCap will be used to set up the electronic Case Report Form (eCRF) for the Halo RCT. The eCRF (referred to within this protocol as the trial database) will be hosted on the UH secure server. Access to REDCap, and specific fields within the trial database, will be restricted using password protection according to pre-specified user requirements. A list identifying individuals permitted to add and make changes to the data will be stored in the TMF.

Database design

The REDCap database will be based on that used for the former Wrapped feasibility trial. The functional specification for the trial database will be developed by the Database Manager (DL), supported by a member of the UH core research team (KK), with guidance on data requirements provided by relevant co-investigators and Trial Team members.

Database build and Quality assurance

The database will be tested (as described above) to ensure it is fit for purpose and in accordance with the pre-specified functional specification. The trial statisticians will review the database, the database code book and the statistical analysis plans, and ensure that data collected is appropriate and in the correct format to enable analysis.

Prior to moving the REDCap project into production, the database will be thoroughly tested by the Database Manager (DL), statisticians (SB, SE), members of the YPAG, and the UH core research team. A database test plan will be developed by the Database Manager (DL) using the current BSCTU standard operating procedures. The test plan will include 1) System developer testing, ii) User Acceptance Testing, and iii) Export testing. Testing will take place on a test database, and the process will involve:

- The Database Manager, or delegated individual, will check the database against the design specifications, to include technical checks of mapping the data to the correct tables, format, lengths, variable types etc.
- One complete set of dummy data will be entered, containing both valid and invalid data e.g. some date fields with inconsistent dates such as a date of randomisation before date of birth. Deliberate errors such as boundary values or incorrect values should be included to ensure any form or rule-based input validation works as expected. Any inconsistencies or errors will be recorded on a REDCap Testing Issue Log and given to the Database Manager at the end of each testing cycle
- An export of the test data including at least two complete participants will be sent to the statisticians, and all co-investigators responsible for secondary analyses, for approval
- Relevant changes to the database will be made based on the Issue Log and a new version of the database released for further testing
- Each new version will be recorded on the REDCap Testing Report and Sign Off Form
- Testing will continue until no more errors are found in the design and the Trial Team are satisfied that the database has been thoroughly tested
- The joint-CIs will approve the final trial database using the REDCap Testing Report and Sign Off Form
- The Database Manager will then release a clean, live version of the database

All documentation including correspondence, dummy CRFs, REDCap Testing Issue Logs, and completed REDCap Testing Report and Sign Off Form, will be stored in the TMF.

Data entry

During the trial, data will be entered into the database by participants, UH core research team members and specific members of the TMG (TB, KL) as described below:

- **Trial participants**: Consent; M0, M3, M6, and M12 surveys; M0, M3 and M12 treatment status, M6 and M12 address check.

Participant-facing instructions on how to complete consent, surveys and treatment status within REDCap will be reviewed by the YPAG (see section 10 for details) to ensure that they are clear and easily understood. Text will be kept to a minimum. The survey items themselves will also be tested by the YPAG.

- **UH core research team:** Randomisation, participant eligibility checks, STI test results (taken from Excel file at M0 and Halo service area at M3 and M12), safeguarding and treatment referrals, adverse events reporting.
- **TMG members (TB, KL and other delegated individuals):** M3, M6, M12 survey data from telephone calls (short version of survey only)[5]. Answers to the survey questions will be entered into a separate REDCap instrument linked to the main database, to avoid unblinding.

During project set-up, all individuals responsible for data collection and entry will receive training in how to enter data into REDCap for this project, in accordance with a REDCap data entry guide developed by the core UH research team and the Database Manager (DL). Database checks will be completed to ensure the accuracy of the data entered (see 9.2 monitoring).

[5] Should the TMG members be unavailable to conduct telephone calls another HML staff member (LL, IF), both of whom are familiar with the project and have substantial experience of data collection, will do this. These individuals will be specified on the trial delegation log and will receive REDCap training as specified above.

12.2.2. Data analytics

Data on participant engagement with the Halo website and the control website will be collected using within-website analytics. The data capture fields will be determined prior to the websites going live and these will be thoroughly tested by the UH core research team prior to data collection. This will involve:

- Creating test data for both the intervention and control websites. Test data must allow testing of all scenarios of use
- Checking that unique PIDs are captured by the Halo website (through direct access from survey link, through link in access reminder email/ SMS text message)
- Reviewing test data to check that all planned data analysis to achieve research objectives can be performed

12.3. Record retention and archiving

During the Halo Trial, all records are the responsibility of the joint-CIs and will be stored securely (see section 7.2 on Data Management). Consent forms, referral forms, pseudonymisation files, pseudonymised research data from REDCap (surveys, STI tests and treatment status, registration data, engagement data) will be stored on the Halo UH R Drive for 6 years (folder encrypted with a password), then deleted. Consent data and data collected about any participants who did not go on to be randomised will be separated from the main data set and stored on the UH R drive for six years, it will then be deleted. Sampling pool data will not be retained within MS Teams or the UH R Drive past the trial end.

Preventx user IDs, Preventx kit IDs, personal data (postal address, email address, telephone phone number, date of birth), original safeguarding and treatment referral forms will not be stored on the UH R Drive and will be deleted at the end of the trial. All data will be deleted from REDCap, Twilio, and the intervention and control websites at the end of the trial. Co-investigator access to shared data (via Halo Teams channel and REDCap) will be revoked, and all data stored on external university servers will be deleted, at the end of the trial.

At the end of the trial, a copy of the pseudonymised research data will be anonymised (PID, and Preventx user ID or Preventx kit code ID numbers removed) and uploaded to the University of Hertfordshire Research Archive (UHRA). The documents contained within the TMF will be archived following trial conclusion in accordance with sponsor requirements and will be retained for 5 years after trial completion.

A summary of record storage and retention timeframes, according to data type, are specified in the Data Protection Impact Assessment (DPIA) and in the Halo data management plan.

13. Publication, dissemination and impact

Newsletters reporting on trial progress will be disseminated quarterly to trial participants and a range of stakeholders in sexual health. Upon completion of recruitment, each participating local authority will receive a report which provides area-specific demographic data and summary statistics on STI positivity and condom use (based on the baseline characteristics of trial participants from their area; see section 7.3).

The main trial findings publication will be reported in line with the CONSORT statement. Eligibility for authorship on any publications associated with this trial will satisfy the International Committee of Medical Journal Editors (ICMJE) criteria (32). Trial findings will be disseminated as widely as possible using a range of methods. As such, a publication,

dissemination and impact plan will be developed for the trial (32). These methods will include, but are not limited to, the following:

- Peer reviewed open-access articles
- NIHR Public Health Research threaded publication
- Conference presentations
- Stakeholder presentations
- Updates on a Halo trial webpage, hosted on UH website
- A lay summary and video co-produced with the YPAG; shared directly with participants, and to the wider public via the Halo trial webpage and social media channel(s).
- A presentation to the English HIV and Sexual Health Commissioners' Group at one of their meetings

In addition, if our trial demonstrates the cost-effectiveness of Halo, we will hold an in-person implementation stakeholder meeting. To this we will invite representatives from all three sectors of web-based STI testing infrastructure currently operational in the UK (commercial, third sector, and NHS), from front-line service provision, and from commissioning, to reflect on the current commissioning and service delivery context, discuss implementation issues, and to generate a road map for implementation. Following this, key possibilities for research impact include: improved condom distribution systems; wider access to condoms for young people; more efficient preventive sexual health services with better quality of data for commissioners; strong evidence (currently limited) on which to base future sexual health policy and local strategy; Improvements to public health via reduced STI positivity and improved sexual health and quality of life; reduced burden on sexual health care staff and reduced costs of STI treatment; reduced health inequality.

14. References

1. Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. BMJ 2013;346:e7586.

2. UKHSA. Sexually transmitted infections and screening for chlamydia in England: 2023 report. Internet; 2024. Available from: https://www.gov.uk/government/statistics

3. World Health Organization. Factsheet: Sexually Transmitted Infections (STIs) [Internet]. 2023 [cited 2023 Mar 2]. Available from: https://www.who.int/news-room/fact-sheets

4. Schnitzler L, Evers SMAA, Jackson LJ, Paulus ATG, Roberts TE. Are intersectoral costs considered in economic evaluations of interventions relating to sexually transmitted infections (STIs)? A systematic review. BMC Public Health. 2022 Nov 25; 22(1):2180.

5. National Chlamydia Screening Programme (NCSP). Chlamydia testing data in 15 to 24 year olds in England, 2019 to 2023. Internet; 2024. Available from: https://www.gov.uk/government/statistics

6. Mercer CH, Tanton C, Prah P, Erens B, Sonnenberg P, Clifton S, et al. Changes in sexual attitudes and lifestyles in Britain through the life course and over time: findings from the National Surveys of Sexual Attitudes and Lifestyles (Natsal). Lancet. 2013 Nov 30;382(9907):1781–94.

7. Pedlow CT, Carey MP. Developmentally appropriate sexual risk reduction interventions for adolescents: Rationale, review of interventions, and recommendations for research and practice. Ann Behav Med. 2004 Jun 1;27(3):172–84.

8. Picot J, Shepherd J, Kavanagh J, Cooper K, Harden A, Barnett-Page E, et al. Behavioural interventions for the prevention of sexually transmitted infections in young people aged 13–19 years: a systematic review. Health Educ Res. 2012 Jun 1;27(3):495–512.

9. Underhill K, Operario D, Montgomery P. Systematic review of abstinence-plus HIV prevention programs in high-income countries. PLoS Med. 2007 Sep;4(9):e275.

10. Goesling B, Colman S, Trenholm C, Terzian M, Moore K. Programs to reduce teen pregnancy, sexually transmitted infections, and associated sexual risk behaviors: a systematic review. J Adolesc Health. 2014 May;54(5):499–507.

11. Gonçalves TR, Faria ER, de Carvalho FT, Piccinini CA, Shoveller JA. Behavioral interventions to promote condom use among women living with HIV: a systematic review update. Cad Saude Publica. 2017 Jan 23;33(1):e00202515.

12. Lichtenstein B, Malow R. A critical review of HIV-related interventions for women prisoners in the United States. J Assoc Nurses AIDS Care. 2010 Sept;21(5):380–94.

13. Crepaz N, Horn AK, Rama SM, Griffin T, Deluca JB, Mullins MM, et al. The Efficacy of Behavioral Interventions in Reducing HIV Risk Sex Behaviors and Incident Sexually Transmitted Disease in Black and Hispanic Sexually Transmitted Disease Clinics Patients in the United States: A Meta-Analytic Review. Sex Transm Dis. 2007 Jun;34(6):319–32.

14. Noar SM, Black HG, Pierce LB. Efficacy of computer technology-based HIV prevention interventions: a meta-analysis. AIDS. 2009 Jan;23(1):107–15.

15. Shepherd J, Kavanagh J, Picot J, Cooper K, Harden A, Barnett-Page E, et al. The effectiveness and cost-effectiveness of behavioural interventions for the prevention of sexually transmitted infections in young people aged 13–19: a systematic review and economic evaluation. Health Technol Assess 2010;14(7):1-206

16. Scott-Sheldon LAJ, Johnson BT. Eroticizing Creates Safer Sex: A Research Synthesis. J Prim Prev. 2006 Nov ;27(6):619–40.

17. Free C, Roberts IG, Abramsky T, Fitzgerald M, Wensley F. A systematic review of randomised controlled trials of interventions promoting effective condom use. J Epidemiol Community Health. 2011 Feb;65(2):100–10.

18. Neumann MS, Johnson WD, Semaan S, Flores SA, Peersman G, Hedges LV, et al. Review and meta-analysis of HIV prevention intervention research for heterosexual adult populations in the United States. J Acquir Immune Defic Syndr. 2002 Jul;1(30): 106-17.

19. Johnson BT, Carey, MP, Marsh, KL, Levin, KD, Scott-Sheldon LAJ. Interventions to reduce sexual risk for the human immunodeficiency virus in adolescents, 1985-2000: a research synthesis. Arch Pediatr Adolesc Med. 2003;157(4):381-88.

20. Swanton R, Allom V, Mullan B. A meta-analysis of the effect of new-media interventions on sexual-health behaviours. Sex Transm Infect. 2015 Feb;91(1):14–20.

21. Bailey JV, Murray E, Rait G, Mercer CH, Morris RW, Peacock R, et al. Computer-based interventions for sexual health promotion: systematic review and meta-analyses. Int J STD AIDS. 2012 Jun;23(6):408–13.

22. Bailey J, Mann S, Wayal S, Hunter R, Free C, Abraham C, et al. Sexual health promotion for young people delivered via digital media: a scoping review. Public Health Research. 2015 Nov;3(13):1–120.

23. Portnoy DB, Scott-Sheldon LAJ, Johnson BT, Carey MP. Computer-delivered interventions for health promotion and behavioral risk reduction: a meta-analysis of 75 randomized controlled trials, 1988-2007. Prev Med. 2008 Jul;47(1):3–16.

24. Noar SM. Behavioral Interventions to Reduce HIV-related Sexual Risk Behavior: Review and Synthesis of Meta-Analytic Evidence. AIDS Behav. 2008 May;12(3):335–53.

25. von Sadovszky V, Draudt B, Boch S. A Systematic Review of Reviews of Behavioral Interventions to Promote Condom Use. Worldviews on Evid Based Nurs. 2014 Apr; 11(2):107–17.

26. Newby K, Crutzen R, Brown K, Bailey J, Saunders J, Szczepura A, et al. An Intervention to Increase Condom Use Among Users of Chlamydia Self-Sampling Websites (Wrapped): Intervention Mapping and Think-Aloud Study. JMIR Formative Research. 2019 May 1;3(2):e11242.

27. Brookes ST, Whitely E, Egger M, Smith GD, Mulheran PA, Peters TJ. Subgroup analyses in randomized trials: risks of subgroup-specific analyses; power and sample size for the interaction test. J Clin Epidemiol. 2004 Mar;57(3):229–36.

28. Schumacher L. Kwah K, Crutzen R, Brown, K; Bremner S, Jackson LJ, Newby, K. Mixed-methods assessment of engagement with a digital intervention: the Wrapped

feasibility Randomised Controlled Trial. Submitted to PLOS Digital Health.

29. Schumacher L, Gill B, Simmons S, Newby K. Personas and the optimisation of Wrapped, a digital health behaviour change intervention. In preparation.

30. Clarke E, Horner PJ, Muir P, Turner KME, Harding-Esch EM. Assessment of online self-testing and self-sampling service providers for sexually transmitted infections against national standards in the UK in 2020. Sex Transm Infect. 2023 Feb 1;99(1):14–20.

31. Devlin NJ, Shah KK, Feng Y, Mulhern B, Hout B. Valuing health-related quality of life: An EQ-5D-5L value set for England. Health economics. 2018;27(1):7–22.

32. International Committee of Medical Journal Editors: Defining the role of authors and contributors [Internet]. 2025 [cited 2025 Feb 25]; Available from: https://www.icmje.org/recommendations

Appendix 1- SPIRIT checklist

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	1
	2b	All items from the World Health Organization Trial Registration Data Set	Appendix 2
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	1
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	6-9
	5b	Name and contact information for the trial sponsor	1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	5

	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	39-41

Introduction

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	12-14
	6b	Explanation for choice of comparators	25
Objectives	7	Specific objectives or hypotheses	10-11/14
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	10, 15

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	17
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	11, 17-18
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	23-25, appendix 5/6
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	23-25, 29-32

	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	12/28-37
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	16, 32
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	17
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	17

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	22-23
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	22-23
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	22-23
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	22-23
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	22-23

Methods: Data collection, management, and analysis

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	28-33
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	28-33, 43
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	33-35, 39, 42-45
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	35-38
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	35-38
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	35-38

Methods: Monitoring

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	40
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	38, 40
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	25-31, 42
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	42

Ethics and dissemination

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	38
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	19, 38, 42
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	19
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	25-35, 39, 42-45
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	5
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	5, 33, 42-43
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	38, appendix 3
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	45-46
	31b	Authorship eligibility guidelines and any intended use of professional writers	45-46
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	45

Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Appendix 3/4
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

Appendix 2- World Health Organization Trial Registration Data Set

Section	Item No.	Information
Primary Registry and Trial Identifying Number	1	ISRCTN51957984
Date of Registration in Primary Registry	2	15/10/2025
Secondary Identifying Numbers	3	
Source(s) of Monetary or Material Support	4	NIHR Public Health Research Programme (NIHR157903)
Primary Sponsor	5	University of Hertfordshire
Secondary Sponsor	6	N/A
Contact for Public Queries	7	halo@herts.ac.uk
Contact for Scientific Queries	8	Professor Katie Newby; Professor of Behaviour Change and Public Health; College Lane Campus, University of Hertfordshire, Hatfield, AL10 9AB; +44(0)7842600795; k.newby@herts.ac.uk
Public Title	9	The Halo Trial
Scientific Title	10	Reducing sexually transmitted infections amongst those at highest risk: The Halo randomised controlled trial
Countries of Recruitment	11	England
Health Condition(s) or Problem(s) Studied	12	Sexually Transmitted Infections (STIs)
Intervention	13	Intervention: Halo. *Multi-component interactive digital intervention for users of web-based STI self-sampling services aged 16-24 years* Control: Usual care. *Website providing information on STIs and condom use, akin to that of the NHS choices website.*
Key Inclusion and Exclusion Criteria	14	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 Freetest.me, SH.UK, or SHL websites 4) Access to personal mobile phone and the internet. 5) Able to read/understand English language Exclusion criteria: 1) Unlikely to have penetrative sex (penis in either vagina or anus) over the next 12 months

		2) Unable to commit to the study over the next 12 months
Study Type	15	Interventional Allocation: randomised; two-arm, parallel assignment Primary purpose: prevention
Date of First Enrolment (anticipated)	16	1st July 2025
Sample Size	17	3576
Recruitment Status	18	Pending
Primary Outcome	19	Chlamydia positivity
Key Secondary Outcomes	20	Gonorrhoea positivity Incidence of repeat infections of chlamydia and gonorrhoea Cumulative incidence of chlamydia and gonorrhoea Correct and consistent condom use during vaginal and/or anal sexual intercourse Condom attitude, condom competence, condom availability, condom use self-efficacy, and condom communication self-efficacy Resource use and Health-related quality of life (HRQL) Engagement with Halo
Ethics Review	21	Approved
Completion date (anticipated)	22	31st December 2027
Summary results	23	
IPD sharing statement	24	Plan to share IPD: Yes, No Anonymised datasets will be shared via the University of Hertfordshire research archive (UHRA)

WHO Trial Registration Data Set (Version 1.3.1)

Appendix 3- Participant Information Sheet

Participant Information

Project title: Reducing sexually transmitted infections (STIs) amongst those at higher risk: The Halo randomised controlled trial.

IRAS Project ID: 352986

Thank you for your interest in our research project!

Key information

- This research project is being conducted by the University of Hertfordshire in partnership with Preventx, the STI self-testing service behind freetest.me, SH.UK, and SHL.UK
- The project aims to see if a new website can help reduce STIs among 16-24-year-olds who use online STI testing services
- To take part, you must meet certain criteria (see "Are there any restrictions that prevent me from participating?" below).
- Over 12 months, you would be asked to:

    1. Complete 4 short surveys (taking approx. 10-15 mins each)
    2. Take two home STI self-tests (for chlamydia and gonorrhoea)
    3. Use one of two websites

- If you take part, you will be randomly directed to one of two websites, both branded as 'Halo'. You won't know which one you receive. We ask that you don't share information about the website with others, as this could affect the research
- You'll receive an Amazon e-voucher each time you complete an activity (see "What are the possible benefits of taking part?" below)
- In this research project we will collect survey responses, STI test results (from Preventx), and website use data. We will only use information that we need for the research project. We will let very few people know your name or contact details, and only if they need it for this project
- Everyone involved will keep your data safe and secure. We will follow all privacy rules
- All data will be kept confidential but there are some limits to that confidentiality (see 'Are there any limits to confidentiality?' below)
- We will make sure no-one can work out who you are from any reports we write
- At the end of the project, we will save some of the data in case we need to check it
- The detailed information below tells you more about the project

Detailed information

Here is all the information you need to know about taking part. Please take time to read it carefully.

What is the full project title?

Reducing sexually transmitted infections (STIs) amongst those at higher risk: The Halo randomised controlled trial.

IRAS Project ID: 352986

Can you tell me more about why you are doing this research project?

The Halo Research Project is being run by researchers from the University of Hertfordshire in partnership with Preventx. Preventx runs the STI self-testing websites freetest.me, SH.UK, and SHL.UK. This study was advertised to you by one of these three websites. For the rest of this page, we will refer to this as 'your testing website'.

We have developed a website called 'Halo'. Halo aims to increase condom use and decrease diagnoses of sexually transmitted infections (STIs), amongst young people who use online STI self-testing services. What we want to know is whether Halo works. To find this out, we need to run a type of experiment called a Randomised Controlled Trial (RCT). It is this RCT that you are being invited to take part in.

Do I have to take part?

No, it is completely up to you whether or not you decide to take part in this research project. What we do ask is that you carefully consider what's involved first - this is described below (see 'What will happen to me if I take part and how long will it take?'). Each of the activities that you'll be asked to do will require some commitment on your part, such as finding time to complete the online surveys and STI self-test kits and to explore the website. These things are easy to do, they just take a little bit of time and dedication. We will reimburse you for this time (see 'Benefits of taking part' below). The success of this research project depends on those involved completing all activities.

Therefore, if you feel like this might be too much for you to commit to over the next 12 months, we ask that you please don't join the project.

Are there any restrictions that may prevent me from participating?

Yes, to take part in the project you must:

- Be aged 16-24 years at the start of the project (if you turn 25 during the project you can still participate)
- Be a user of either freetest.me, SH.UK or SHL.UK and have been invited to participate via this service
- Have your own mobile phone and access to the internet
- Be able to read and understand English

And you cannot take part if:

- You are unlikely to have penetrative sex (i.e. penis in vagina or anus) over the next 12 months (this is because STIs are mostly passed in this way, and this research project is focused on reducing STIs)
- You are unable to commit to the research project over the next 12 months

If you meet these criteria and wish to take part, you will be asked to provide your consent (next page) and then to complete the first of four surveys. To be accepted on to the research project we need

- You to complete this first survey, and do so with sufficient care and attention
- You to provide us with accurate and valid personal and contact details (your name, date of birth, postal address, mobile phone number, email address)
- A recent STI test result for you. As long as the timing of your STI result falls within 30 days of you providing consent, we can use this.
    - **Using a test result you already have**
      If you have received a chlamydia and gonorrhoea test result (from freetest.me, SH.UK or SHL.UK) in the last 30 days, it can be used for the study. If your result is older than 30 days, you can still take part – see 'using a new test result'.
    - **Using a new test result**

  If you ordered a self-test kit in the last 2–3 weeks, return it as soon as possible. If you have not ordered a kit recently, we will instruct you to return to your testing website and order one after completing the first survey. In both cases, the laboratory must receive your sample within 30 days of you giving consent. Samples must have a valid urine/vaginal sample that allows the lab to test for chlamydia and gonorrhoea.If the test does not show a clear positive or negative result (this sometimes happens if for example, the sample has been contaminated or damaged in the post), then we will contact you about your options. It will still be possible for you to participate but we would need to arrange for another test to be done.

We will be performing checks to make sure that everyone who signs up for the project meets the above criteria. If we think there may be an error in the contact details you have provided, we will contact you (by phone, email or post) to check these. You can only enter the project once; we will be running checks to make sure that each new person is unique (that is, they are not already participating). We will also check for bots (sign-ups by computer rather than real people). If we are concerned that a person is not a user of freetest.me, SH.UK, or SHL.UK, we may check their details against those held by Preventx, the operator of these services.

If you do not pass our checks, you **will not become a participant** in this project and you **will not receive any voucher payments** (see 'what are the possible benefits of taking part' section below). Under these circumstances, we will keep any data you have provided up to that point (responses to questions in first survey and/or result of first STI test) for analysis purposes, but any information that identifies you will be removed.

<u>What do I need to do to take part and how long will it take</u>?
The whole research project takes 12 months to complete but the activities are *well spaced out*, we will tell you everything you need to do and when, and we will *reimburse you for*

your time (see 'Benefits of taking part' section below), so don't be put off! Here's what we'll ask you to do:

1. *Complete an initial online survey* (takes approx. 10-15 minutes) – this asks questions about you (e.g. your age, gender, sexual orientation etc.), your thoughts on condom use, your sexual behaviour (condom use), and any recent STI testing and results. We also will also ask you to provide your contact details at this point – we need these so that we can send you future surveys and post out STI self-test kits.

2. *Get your initial STI test result on record* – at the end of the initial online survey, you'll receive next-step instructions. Depending on your situation, you may be asked to order a kit, return one, or wait (if you've recently tested). If you need to order or return a kit, we will send a reminder text a few days after completing the survey.

3. *Tell us about any treatment you've had if your initial STI test (ordered by you) is* ***positive*** (takes approx. 2 minutes). We will receive the results of this test from Preventx. If the test is positive for chlamydia and/or gonorrhoea, we'll send you a text message to ask you whether you completed the treatment prescribed.

4. *View one of the two websites* (time spent on this is up to you) – we'll send you a link to visit one of two websites (selected at random). The website will be available to you whilst you are participating in this research project (about 12 months). We will send you a link to this in a text message so that you can return there as often as you like. You must not share information about the website you have been allocated with anyone else - if people in the research do this then we might not get a clear result about whether Halo works.

5. *Take a second STI self-test for chlamydia and gonorrhoea at 3 months* (3 months from when you started the project; this takes approx. 5 minutes to complete) – this will be sent to you by Preventx, so as before, it will fit through your letterbox and arrive in the same plain packaging. You can choose what address we send this to (it doesn't have to be your home address); we will send you a text message before we post it out giving you the chance to check/amend the address we use. As before, if you test positive, we will send you a text message to ask about treatment.

6. *Complete a first follow-up online survey also at 3 months* (takes approx. 10-15 minutes to complete).

7. *Complete a second follow-up online survey at 6 months* (takes approx. 10-15 minutes to complete).

8. *Take a third STI self-test for chlamydia and gonorrhoea at 12 months* (takes approx. 5 minutes to complete) – as before, sent by Preventx and with the option to check/amend the address we use. Again, if you test positive, we will send you a text message to ask about treatment.

9. *Complete a final follow-up online survey at 12 months* (takes approx. 10-15 minutes to complete).

Info about the chlamydia and gonorrhoea tests at 3 and 12 months

- Chlamydia and gonorrhoea self-test kits will be sent to you in the post by Preventx. This will arrive in the usual plain packaging; the materials inside will be branded 'Freetest.me'.
- If you currently use the SHL.UK service, you will be familiar with kits that test for four STIs (HIV, syphilis, chlamydia and gonorrhoea). The kits we are using for this research project just test for chlamydia and gonorrhoea.
- Six days before the chlamydia/gonorrhoea self-test kit is posted, we will send you a text message to confirm your preferred delivery address.
- You will be asked to take a sample for chlamydia/gonorrhoea (urine or vaginal swab) and return it to Preventx by Freepost for processing (full instructions on how to do this will be provided in the box). Reminders to complete and return the self-tests will be sent.
- The sample you send back will be stored safely in the Preventx laboratory. Only trained staff who work at Preventx will be allowed to handle it; the research team will not have access to this, and samples will not be sent on to anyone else. Your sample will be kept for up to 30 days before it is destroyed. The form you send back with your sample, which includes your personal details, will be kept for at least 2 weeks. Sometimes, a digital copy of the form might be saved and linked to your sample in the laboratory's system. Preventx is responsible for keeping your sample in good condition and making sure that both your sample and any information linked to it stay private and secure.
- The result will be recorded by Preventx and shared securely with us. Participants will be contacted by text message when their result is known. In the case of negative results, the result will be communicated within the body of the message. Where the result is positive, the message will ask you to contact your local sexual health service to discuss the result (contact details will be provided). We will also notify this service so that they are aware of the result and can follow this up with you if needed. At enrolment, we will request your local sexual health service details from Preventx for this purpose. If you move during the study, your details will still be sent to that service, which will help arrange treatment elsewhere if needed.
- A little while later, we will contact you by text to find out if you have taken the prescribed treatment. We will send up to 3 texts to try and obtain this information and then stop. Based on your responses, it is possible we may send you a few extra text messages about treatment to help us understand your situation better.
- All our communication with you will be discreet (see the section: 'What are the possible disadvantages, risks or side effects of taking part?' for details on this). We may also make a friendly call to remind you to return the test or to provide us with information on the outcome of further follow-up testing or treatment. This phone call would only take a few minutes and before beginning, we would always make sure you were in a private space where you were able to talk.

Info about the follow-up surveys at 3, 6 and 12 months

- A link to each survey will be sent via text message at the appropriate timepoint.
- Four reminders (three text message and one email, each 5 days apart) will be sent to those who do not complete the survey after receiving the invite.

- Each follow-up survey will contain many of the same questions as the first survey. That's so that we can detect any changes that people experience in their condom use beliefs or behaviour – so please don't be put off by the repetitiveness, its deliberate!
- It is possible that we may make a friendly call to remind you to return a survey; we may use this opportunity to ask you a limited number of survey questions (just the most important stuff!). This phone call would take less than 5 minutes, and we would always first make sure you were in a private space where you were able to talk.

End of the research project

At the end of the 12-month research project we will send you a final email thanking you for taking part. Once we have collected data from everyone participating in the project (expected to be December 2027), we will let you know whether you received the website we developed or not and provide you with information about the other website that you didn't see.

What are my choices about how my information is used?

We understand that life can sometimes get in the way of plans. If you can't complete one of the activities, then it's no big deal; we will simply carry on sending you invites to future activities so you can continue to be involved.

You can stop being part of the research project at any time, without giving a reason, but we will keep information about you that we already have. Just email us at halo@herts.ac.uk to let us know – we won't ask you why you want to stop, we'll just respect your wishes and stop sending you invitations to complete activities.

You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the research project. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

Please know that a decision to withdraw at any time, or a decision not to take part at all, will not affect the service that you receive from Preventx via your testing website, or from the NHS (should this be relevant), either now or in the future. In the event of any significant change to the aims or design of the project you will be informed and asked to renew your consent to participate.

What are the possible disadvantages, risks or side effects of taking part?

Taking part in this project requires you to complete surveys and STI self-tests, respond to text messages, and to view a sexual health website. We therefore consider the risks of taking part to be low and in line with normal everyday activities.

All our communication with you will be discreet. For example, STI self-test kits will be sent in plain packaging and will fit through your letterbox, email subject lines will not reveal what the project is about, and our text messages won't refer to STI testing or treatment specifically (they will say for example, '*You should now have received your test results. Click the link below to let us know the outcome*' or '*You should now have been contacted about*

treatment following your test result. Can you tell us about any treatment received?'). If we make a phone call to you, or leave a voicemail message, it will be friendly and discreet in nature; we will mention the name of the project (Halo) and remind you to return your survey or self-test kit and ask if you need any help or have any questions; we won't refer to STI testing or to the nature of the project in any voicemail message.

Please note, whilst text messages sent by Preventx about your STI test results will be as discreet as possible, it may sometimes be necessary for these to refer to 'your sample', 'your test results', or to chlamydia or gonorrhoea specifically.

The website may lead you think about your own condom use and sexual health. Information will be provided on the website itself about how you can access condoms and support on issues relating to sexual health. An auto-generated email will also be sent to you on completion of each survey containing information on sources of further help and support should you need it.

If you are currently being supported by agencies or professionals (e.g. sexual health service, social worker or mental health team) because you have experienced any form of sexual abuse or harm, we advise that you carefully consider whether this research project is for you. Whilst you can still take part, it is best that you wait until you are in a good place (physically and mentally) before you do.
With regards to the STI self-test kits: Preventx will send these to you; they are therefore in the usual plain packaging and will fit though your letterbox. As with all testing of this kind, there is the chance that someone finds out you are testing for a STI when you didn't want them to know. *If you are anxious about this, we suggest that you do not participate.*

When you complete the STI self-test kit, there's a chance you might get a positive result. This could feel upsetting or stressful, and it's completely normal to worry about your health. If that happens, we'll send your result directly to your local sexual health service so that they can offer treatment and support.

Please note we will only be testing you for genital chlamydia and gonorrhoea as part of this project. We will not be testing for anal or oral infection, or for any other sexually transmitted infections (STI). If you want any additional testing, then you should return to your testing website to place another order or visit your local sexual health service.

<u>What are the possible benefits of taking part</u>?
You will be given access to one of the two websites which you may enjoy; you will be free to use this as much as you like whilst you are participating in the research project. Furthermore, anyone taking part should feel rightly proud of contributing to important science; only with the input of our participants will it be possible for us to learn if Halo has a positive impact on young people's sexual health. Because of this we really value everyone's input! Finally, in recognition of your time and effort, you will receive Amazon vouchers for each completed activity as follows:

ACTIVITY	**REWARD ***
• Joining the research project*	£10

- Visiting the website £5
- Completing the month 3 survey £5
- Returning the month 3 STI self-test kit £15
- Completing the month 6 survey £10
- Completing the month 12 survey £10
- Returning the month 12 STI self-test kit £20

To receive the vouchers, all activities need to be completed within **30 days** of you being invited to complete them – we will send you plenty of reminders and be on hand to help you throughout the process if you need it.

*We will send you your first voucher for joining the research project once:
1) You have completed the first survey
2) We have received your initial STI test result (
3) You have passed our screening checks (for those not passing these checks, we reserve the right to prevent further participation and to withhold voucher payments) - see 'Are there any age or other restrictions that may prevent me from participating?' section above for more information. As we will need to wait for all of this to be in place, there will be a delay in receiving your first voucher from us.

How will you use information about me in this research project?
We will need to use information from you and Preventx (the STI self-testing service that operates freetest.me, SH.UK and SHL.UK) for this research project.

This information will include your:

- Name
- Date of birth
- Preventx user ID, STI self-test kit code and order number
- Contact details (postal address, email address, phone number)
- Gender
- Ethnicity
- Sexual orientation, relationship status
- STI diagnosis and treatment outcomes
- Condom use
- Sexual wellbeing, quality of life
- Health appointment data
- Website use

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are, will not be able to see your name or contact details. Your data will have a code number (Participant ID) instead.

The University of Hertfordshire is the sponsor of this research. The University of Hertfordshire is responsible for looking after your information.

We will share your information related to this research project with the following organisations:

- Academic institutions (who are working with us to deliver this project)
- NHS and/or local authorities
- Preventx
- RedBullet Ltd (Website Development Company)
- WP Engine (Website Hosting Provider)
- Bird Email (Email delivery platform)
- Twilio (American cloud communications platform)

How will my taking part in this research project be kept confidential?

We will keep all information about you safe and secure by:

- Handling all data in accordance with the General Data Protection Regulations (GDPR) and the Data Protection Act 2018 (DPA).
- Using three secure pieces of software for data collection and storage: REDCap (used to collect and manage research data), the R Drive (secure data storage area) and the Halo Microsoft Teams Channel/SharePoint (also a secure data storage area). All these pieces of software are located behind the University's Firewall, are backed up daily, are password protected, and will only be accessible to the research team.

Your decision to take part and any data that you provide will be kept confidential. People who do not need to know who you are will not be able to see your name or contact details. Please note, there are circumstances under which we would break that confidentiality. Please see the 'Are there any limits to confidentiality?' section below for further detail on this.

If you decide to take part, you will be asked to complete an online consent form on the next page. These forms will be completed and stored in REDCap (you are viewing this information on REDCap now). Whilst your name will be on this consent form, it will not be associated with any of your survey responses or test results held by us. Rather than using names, we will identify participants using a unique number ID. This will be assigned at the time of consent. This ID will be used throughout the process of the project to link all your data together.

For the project, we need to collect information on your use of the website you are shown e.g. which pages you visit and how long you spend there. To reduce the burden on you, rather than ask you questions about this in our surveys, we will instead track your use within the website itself using website cookies. As this data is essential to our study, you will not have the option to opt-out of cookies when you access the website. The website will record this data along with your unique participant ID.

STI self-test result data: For the initial STI self-test (ordered by you), Preventx will share the result with us using a secure means of transfer. The research team will access this data and record your result within REDCap alongside your survey data. As described above, we will be asking you to take two additional STI self-tests; one 3 months into the project, and one at

the end (12 months). Preventx will process these additional tests for us. The self-test kits will be similar to the one you have just ordered. Preventx will record the results of these tests in a secure Preventx service area. We will access your result by logging in to the service area. We will use your name and the kit code to identify you on this system and then record this result on our REDCap database alongside your survey data. If the self-test you have just ordered comes back positive, you and your local sexual health service will be notified by Preventx directly. If your month 3 or month 12 STI self-test comes back positive, you will be notified by Preventx, and we will share this result with your local sexual health service ourselves. Either way, the outcome is the same for you - you will be notified and will receive support and treatment from a local service. To ensure that your data is treated with the upmost care and security, we (the University of Hertfordshire) have legal Data Sharing Agreements in place with both Preventx and a sexual health service in your local area.

Are there any limits to confidentiality?

Safeguarding means protecting a person's right to live in safety, free from abuse and neglect. Everyone who takes part in this research project will be provided with information on sources of help and support on issues relating to sexual wellbeing (within the websites themselves and via an automated email at the end of each survey).

We do however have a particular responsibility to protect individuals under the age of 18 years, or those who may be vulnerable in other ways. If you fall into either of these groups and reveal information to us during the project which indicates that you may be at risk of significant harm, our safeguarding procedure will be followed. By significant harm, we mean neglect, or physical, mental or emotional harm, or harm to your physical, mental or emotional well-being. There are questions in each survey which could alert us to this. We will highlight these to you so that you can choose whether or not to answer them. You may also reveal this to us if we ever have direct contact with you (e.g. through email, phone). Regardless of the source of the information, if there is a safeguarding concern, our confidentiality agreement would end, and we would pass on the information that you have provided to the relevant safeguarding organisation(s) so that they can support you. You cannot refuse this referral process, but we would tell you that it was happening and support you through it.

Factors that might put others at risk

If during the research you reveal evidence of any activity that has put others at risk, then we may be obliged to refer the matter to the appropriate authorities (e.g. police), and you may be removed from the research project.

Will my data be shared outside the UK?

Most data about you will be processed and analysed within the UK. We may share or provide access to data about you outside the UK for research related purposes to:

- conduct data analysis

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. If your data is shared outside the UK, it will be with the following sort of organisation:

- Academic institution where a research team member is based (University of Maastricht, The Netherlands)
- A cloud communications company (Twilio, United States)

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- we do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- we need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
- we have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when this is legally required. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website: https://ico.org.uk/for-organisations/report-a-breach

How will you store information about me during the research project?

Consent data- This data will be stored electronically on REDCap for the duration of data collection (expected end date December 2027).

Survey and STI self-test result data- This data will be stored electronically on REDCap for the duration of data collection (expected end date December 2027).

Website use data- This data will be stored within each website's content management system (CMS) for the duration of data collection (expected end date December 2027)

How will you use information about me after the project ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. We will keep your study data for the minimum period of time required by the University of Hertfordshire (further detail below)**.** The study data will then be fully anonymised and securely archived or destroyed.

Consent data- This data will be downloaded and stored within a folder on the R Drive at the end of data collection. At this point, the original data on REDCap will be deleted. This consent data will be kept on the R drive for 6 years and then deleted.

Survey and STI self-test result data- This data will be downloaded at the end of data collection and stored on the Halo Microsoft Teams channel/SharePoint for analysis purposes. Before storing the data, we will use your postcode to calculate an 'Indices of Multiple Deprivation' (IMD) score (you can find out more about what that score is

here if you're interested), and then delete it along with the rest of your address. We will also delete your email address, mobile phone number, and date of birth. At this point the survey data will contain no identifying information about you i.e. it will be 'pseudonymised'. Once analysis is complete, the survey data will be removed from the Teams channel/SharePoint and stored on the R drive for 6 years and then deleted.

Website use data- This data will be downloaded and stored on the R Drive alongside the survey data at the end of data collection. The original data will then be deleted. At this point the website use data will contain no identifying information about you i.e. it will be 'pseudonymised'. Once analysis is complete, this data will be stored on the R drive for 6 years and then deleted.

After we have finished our analysis, we will anonymise the survey, STI result data and the analytics data, so that can no longer be linked back to you. This will then be securely archived within the University of Hertfordshire's Research Archive (UHRA). Here it will be available to others on an 'open access' basis, meaning that it will be available indefinitely to others for the purposes of performing further analysis for the benefit of science. It will not be possible to identify any individual within this dataset.

Please click on **[this link]** to view/download our data privacy notice.

Will there be opportunities to take part in future research projects?
On the consent form, we will ask if you agree to be contacted about research opportunities related to this project (such as an interview). This is entirely optional. If you agree to this, we will store your name and contact information securely on the R drive so that we can contact you for this purpose. It will be kept until the end of the project (expected to be October 2028) and then deleted.

How have patients and the public been involved in this research project?
A group of 16-24 year olds, many of whom are users of online STI self-testing, are advising us on this project. This includes working with us to ensure that this project is acceptable and accessible to all young people who take part. They have approved this participant information, the consent form (on the next page), the surveys you will receive, and other types of participant-facing material.

Who has reviewed this research project?
This research project has been reviewed by:

- The University of Hertfordshire Health, Science, Engineering and Technology Ethics Committee with Delegated Authority (The UH protocol number is LMS/SF/NHS/02315)

- London Central NHS Research Ethics Committee (REC)- IRAS Project ID number (352986)

What will happen to the results of this research project, and will I find out about them?
We will write all our reports in a way that no-one can work out that you took part in the research project. We will publish the results of this research in scientific journals and present them at conferences. If our website is found to be effective at increasing condom use and decreasing STI diagnoses, we will work to make it available to as many young people as possible across the country.

Periodically through the project, we will text or email you with a brief update on our progress. Once we have completed our analysis (expected to be autumn 2028), we will also produce a short written and video summary of what we have found. We will ask you if you want a copy of this in the final survey and if you do, we'll send it to you via email.

Who can I contact if I have any questions?
You can contact the research team at any time by emailing halo@herts.ac.uk and we'll get back to you within 1-2 working days. You can also use the team phone number 07842600795. We're a friendly bunch and will try to answer any questions you have and/or help you with any problems you are experiencing. Please don't hesitate to get in touch.

Where can I find out more about how my information is used?
You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK:

- by accessing this leaflet http://www.hra.nhs.uk/patientdataandresearch
- by sending an email to the research team: halo@herts.ac.uk
- by ringing the research team on 07842600795
- by sending an email to our data protection officer: dataprotection@herts.ac.uk

Who should I contact if I have a complaint?
Although we hope it is not the case, if you are concerned about any aspect of this research project, please contact the chief investigators Professor Katie Newby (k.newby@herts.ac.uk; 07842600795) and Professor Katherine Brown (k.brown25@herts.ac.uk) in the first instance.

If you remain unhappy and wish to complain formally, you can do this by contacting the University's Secretary and Registrar using the details below.

Secretary and Registrar
University of Hertfordshire
College Lane
Hatfield
Herts
AL10 9AB

The University of Hertfordshire, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this research project.

Thank you very much for reading this information and considering participation in this research project.

Eligibility

If you would like to go ahead, please confirm that:

1. You are aged 16-24 years (Yes/No)
2. You have access to a personal mobile phone and internet access (Yes/No)
3. You are able to read and understand English (Yes/No)
4. You feel able to commit to the research project over the next 12 months (Yes/No)
5. You are likely to have penetrative sex (i.e. penis in vagina and/or anus) at some point over the next 12 months (Yes/No)
6. You have been directed to this page by freetest.me, SH.UK or SHL.UK and either:
    i) have received an STI result in the last 30 days; or
    ii) will receive an STI result in the next 30 days (by returning a recently ordered self-test kit, or by ordering one after completing the first survey).
    Only when we have the result of this test will you join the study and receive your first voucher. (Yes/No)

Appendix 4- Consent form

Project title: Reducing sexually transmitted infections (STIs) amongst those at higher risk: The Halo randomised controlled trial.

IRAS Project ID: 352986

Nearly there, please read the through the following statements…

1] I confirm that I have read the participant information and the [add hyperlink to privacy notice]

2] I have been assured that it is my choice about whether to take part and that I can choose to withdraw from the research project at any time without disadvantage or having to give a reason. If I withdraw from the research project, I understand that all data I have provided will be retained

3] I have been given information about the potential risks and benefits of taking part

4] I have been told how information relating to me (data obtained during the research project, and data provided by me about myself) will be handled: how it will be kept secure, who will have access to it, and how it will or may be used, including that anonymised data will be deposited in a repository with open access (i.e. freely available to others)

5] I understand that cookies will track how I use the website in this research project, and I won't be able to turn them off

6] I understand that the results of any STI tests that I complete whilst taking part in this research project (at months 0, 3 and 12) will be shared by the STI self-testing provider Preventx (who operate freetest.me, SH.UK, and SHL.UK) with the research team. I understand that some of my personal details may be shared with Preventx to verify my eligibility to take part

7] I understand that any positive chlamydia and/or gonorrhoea test results will be shared with my local sexual health service so that they can provide care and treatment

8] I understand the ways in which my taking part will be kept confidential but also that there are limits to that confidentiality

9] I understand that if I tell the research team about any activity that has put others at risk, they may refer the matter to the appropriate authorities

10] I confirm that I will not share information about the website that I am shown with anyone else

11] I understand that a portion of my data collected during this project will be transferred, with my name removed, outside the UK (with a team member at the University of Maastricht, The Netherlands) for the purposes of data analysis.

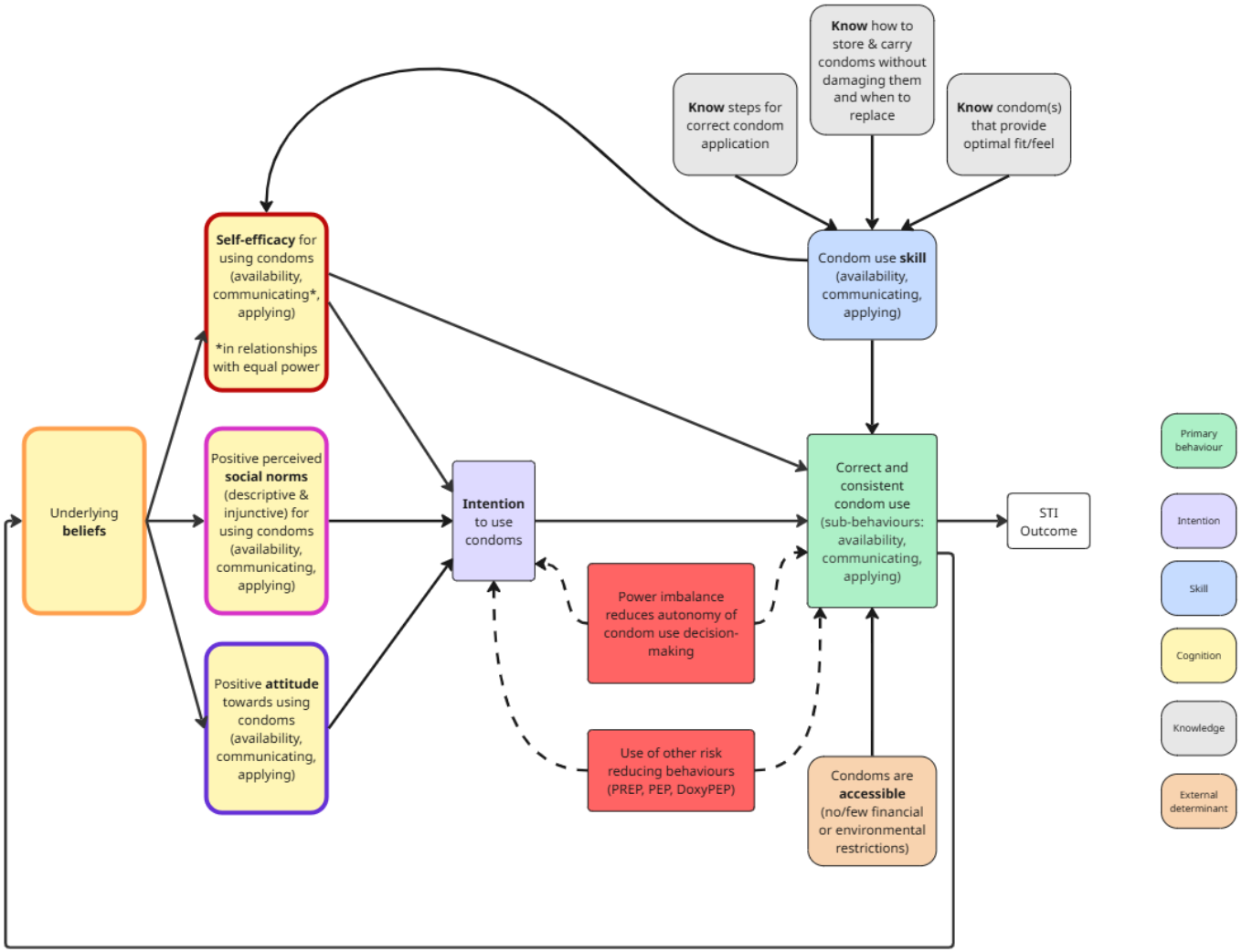
I agree to the above statements and consent to taking part in the research project **Yes/ No**

12] I consent to being contacted about other research opportunities related to this project (optional) **Yes/No**

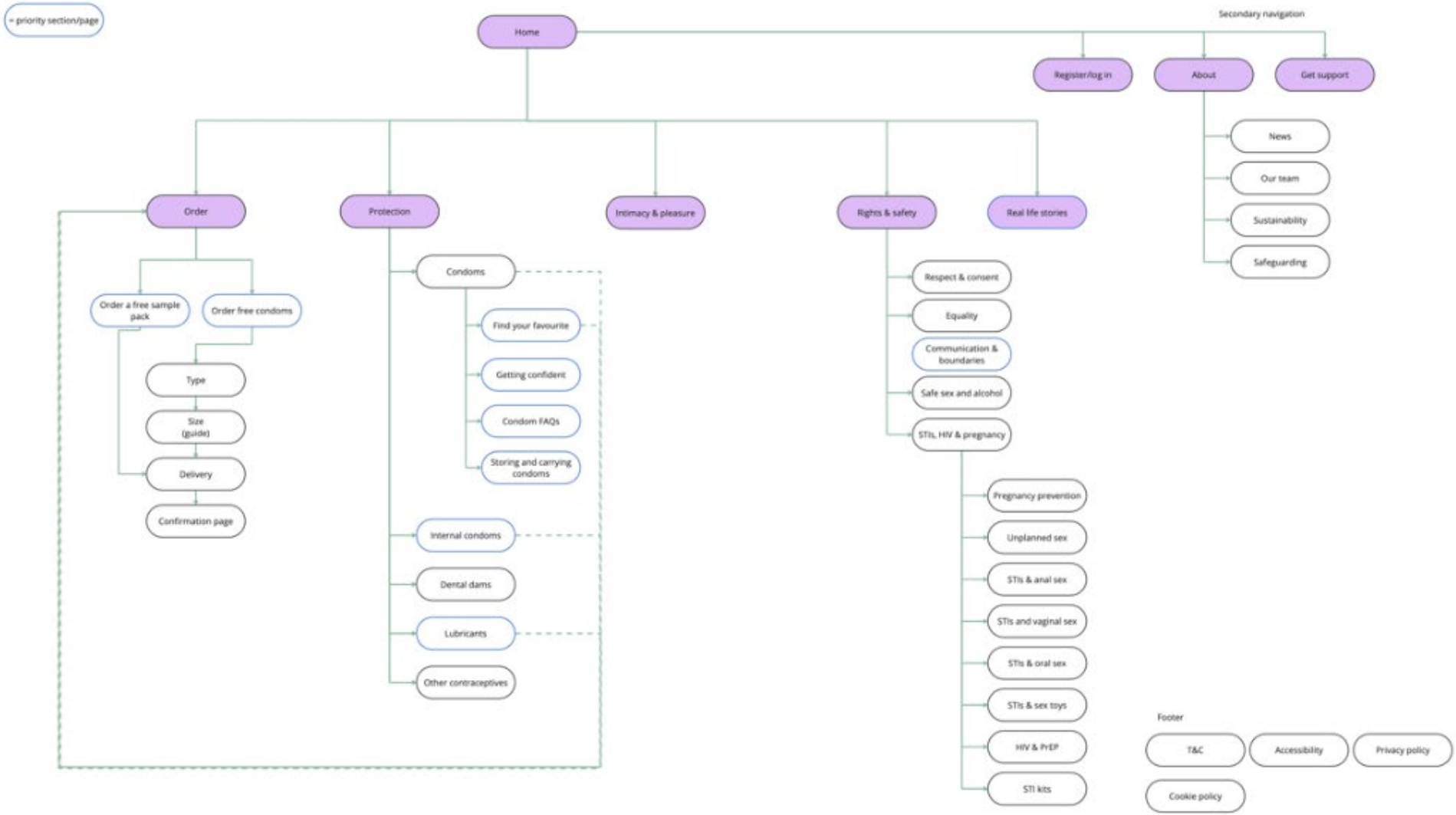
First name
Surname

Signature Date

Appendix 5- Halo logic model



Appendix 6- Site map



Appendix 7- Safeguarding procedure

Halo Randomised Controlled Trial: Safeguarding Procedure

This document details how we will identify and respond to safeguarding concerns that arise during the Halo trial. The procedure is summarised visually in the form of two flow diagrams below, after which further detail is provided.

Note: all safeguarding concerns will be recorded as adverse events within our 'adverse event log' held on REDCap. New/cumulative adverse events will be presented by the Trial manager at weekly Trial Team meetings and discussed. They will also be reported to the Data monitoring and Ethics Committee (DMEC) and Trial Steering Committee (TSC) via 6-monthly reports with the opportunity to discuss at the meetings which follow.

Flowcharts

The need to safeguard a participant could present itself either through their:

1. Completion of safeguarding items within a survey at any of our follow-up timepoints[6] (M3, M6 or M12)
2. Disclosure in a qualitative interview or through direct contact made with the research team via email or telephone.

There are different procedures to follow in each event, depending on the age of the participant (18+ years or <18) as set out in figures 1 and 2 respectively.

[6] Just prior to entering the study, all participants are screened for safeguarding concerns by the STI self-sampling provider Preventx and help/support arranged as required. We are therefore not duplicating this via our M0 survey to avoid parallel referrals. Participants from the start of the study (via our participant information and all communications) are informed that they can contact us at any point via email or phone.

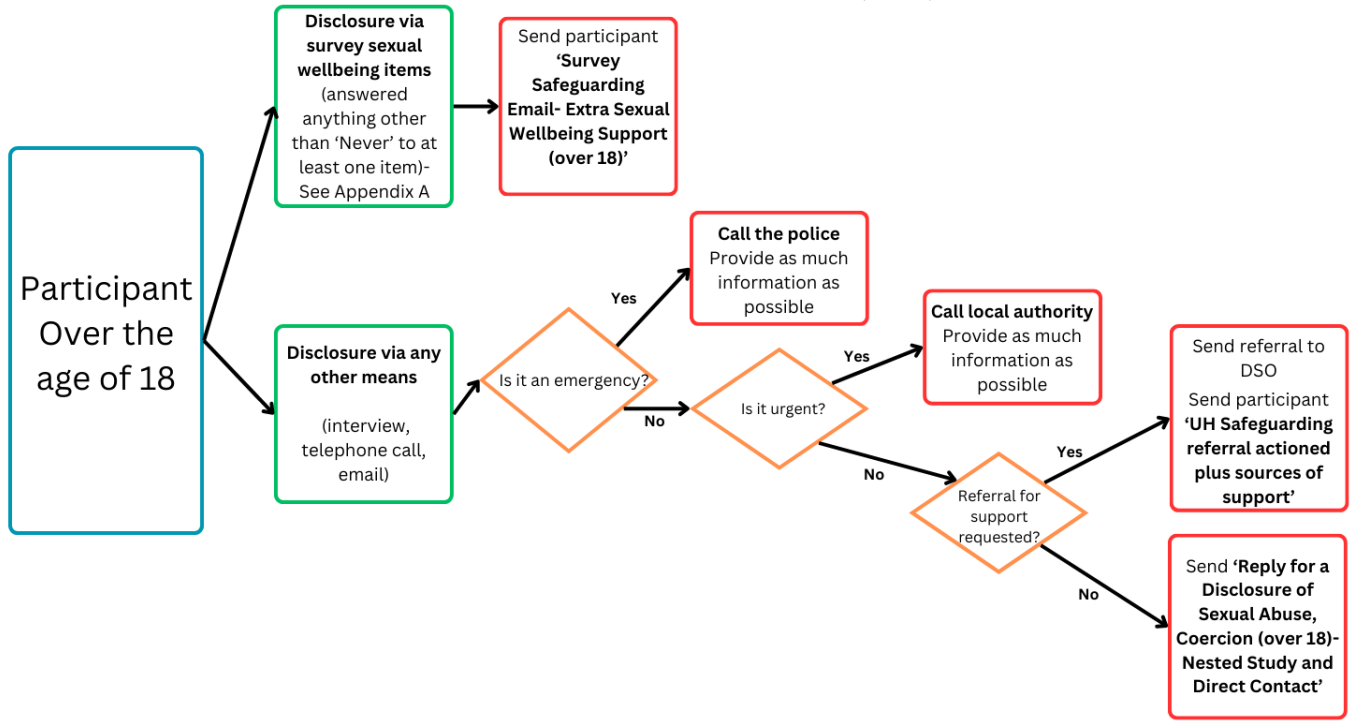


Figure 1. Flow diagram describing procedures to follow for participants aged 18 years or over

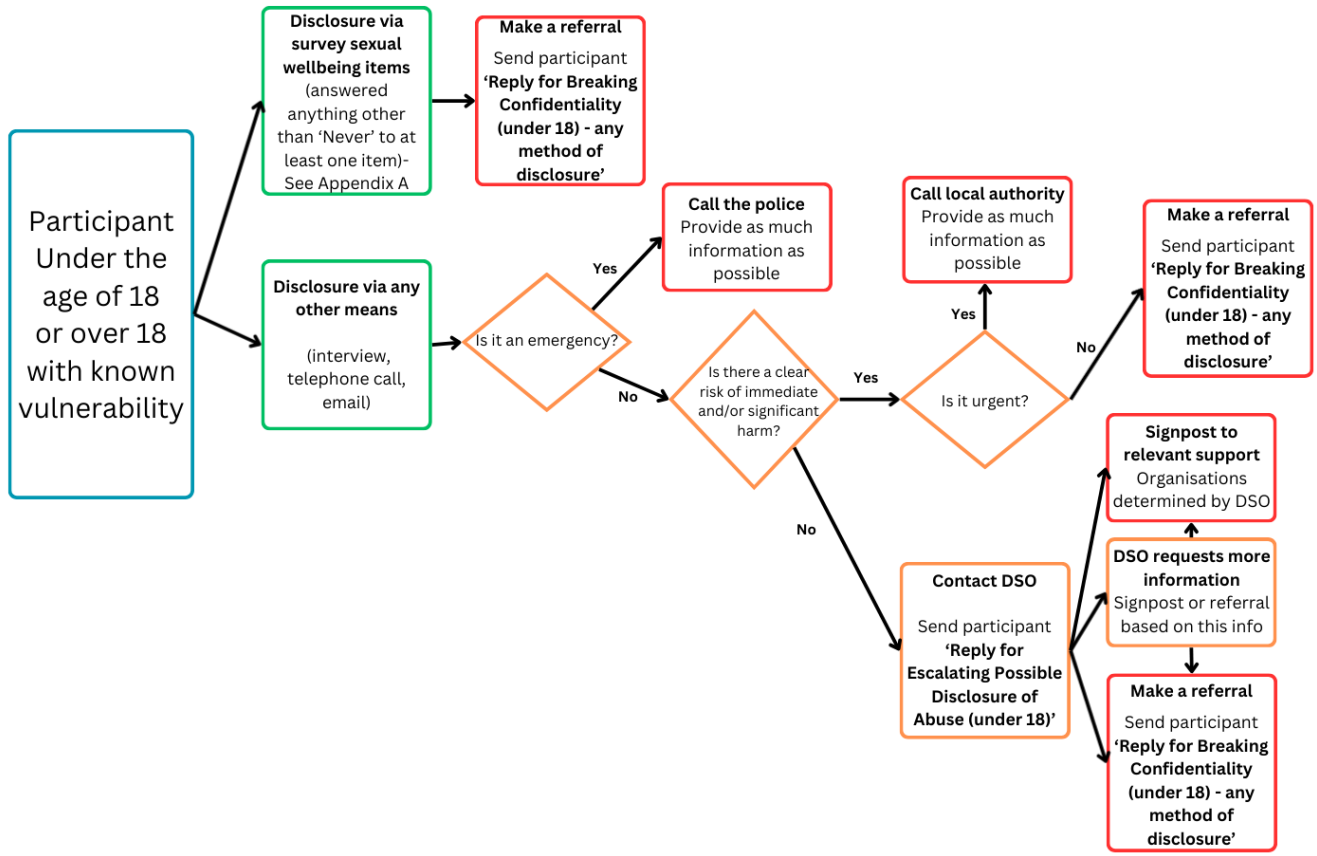


Figure 2. Flow diagram describing procedures to follow for participants aged under 18 years or over 18 with a known vulnerability

Sexual well-being support provided to all participants

All participants by default will receive our standard sexual well-being email after the completion of each survey (M0, M3, M6, M12) (See Email template - All - Standard Sexual Wellbeing Support provided at survey end). Information on help and support with sexual health and wellbeing is also provided to participants within both websites (intervention and control).

Participants 18 years or over

1. **Disclosure of safeguarding concern via Survey**

Within each follow-up survey (M3, M6 and M12) we ask safeguarding questions (see Appendix A). If a participant responds positively to one or more items, automated emails are triggered to both the participant and the UH core team as follows.

The UH core team will receive automated emails alerting them to any safeguarding concern arising as a result of responses to these items. In response they will record the event in the 'adverse event log' instrument on REDCap. The participant will simultaneously be sent an automated email (triggered within REDCap in response to survey responses) containing enhanced information on sources of support and the offer of talking to our UH Designated Safeguarding Officer (DSO) – see Email template - Over 18s - enhanced info and offer of UH support.

If the participant requests support from the DSO:

- The UH core team will:
  - Complete the UH Safeguarding Concern Form (see HS10-Apx-4-Safeguarding-Incident-Report-Form-adults-v02.0Safeguarding Incident Report Form - adults –) and email this to the DSO within 48 hours. Send this with a read and delivery receipt and mark as 'confidential' (under 'sensitivity' settings). Ask the DSO to reply to the email with a 'received and will now action' statement
  - Once DSO has confirmed that a response will be actioned, send an email to inform the participant that a request for support has been made (see Email template - Over 18 - UH support actioned plus enhanced info).
  - Record all actions, including that participant requested referral for UH support, and outcomes in the adverse events log.
- The DPO will contact the participant within **2 working days** and inform UH core team of the outcome (e.g. signposted to further support; referred to external organisation; etc.) within **5 working days** (set calendar reminder to follow-up)
- The UH core team will then record this in the adverse events log

Disclosure of safeguarding concern by any other means (interview, telephone call, email)

2. **Clear, immediate risk of significant harm in an emergency**

- Call the police on 999
- Provide as much information as possible (location, etc.)

NB. The police will continue with their own safeguarding procedure following our call to them, we will be guided by them as to whether we follow up with participants or need to take any other action

- Note all actions taken & outcome on the adverse events log
- Inform Joint CIs and Trial Manager
    - Support for the researcher will be arranged as required (in line with UH guidance)

3. Clear risk of significant harm- non-emergency, urgent situations

- Identify the relevant local authority safeguarding team, using the list of LA safeguarding contact details spreadsheet
- Call the telephone number stated and provide as much information as possible (location etc.)
- Follow advice given by the LA safeguarding team
- Note all actions taken & outcome on the adverse events log
- Inform Joint CIs and Trial Manager
    - Support for the researcher will be arranged as required (in line with UH guidance)

4. All other non-emergency situations

Actions required at time of disclosure:

- Listen/respond to the participant with empathy and remember that you are not an investigator: you don't need to ask questions
- Reassure the participant you believe what they are telling you
- Explain to the participant that whilst you are not trained to provide specialist support, you can put them in touch with others who are
- Tell them that we will send them an email listing sources of help and support
- And, that *if they wish*, we can additionally put them in touch with UH support services so that they can talk through their circumstances with someone who can help. Ask them if they would like us to do this.
- Ask if they have any questions and respond as best you can
- Make notes

Actions required afterwards - if UH referral has not been requested

- Send Email template – Over 18s – Enhanced info only to the participant
- Type up any handwritten notes and store in the designated folder on the R drive along with participant ID (shred any paper notes). If original notes digital, then move these to the R Drive (no digital copies to be kept elsewhere)
- Note all actions taken & outcome on the adverse events log
- Inform Joint CIs and Trial Manager
    - Support for the researcher will be arranged as required (in line with UH guidance)

Actions required afterwards - if UH referral has been requested

- The UH core team will:
    - Complete the UH Safeguarding Concern Form (see Safeguarding Incident Report Form - adults) and email this to the DSO within 48 hours. Send this with a read and delivery receipt and mark as 'confidential'

(under 'sensitivity' settings). Ask the DSO to reply to the email with a 'received and will now action' statement
    - Once DSO has confirmed that will be actioned, send an email to inform the participant that a request for support has been made (see Email template - Over 18 - UH support actioned plus enhanced info).
    - Record all actions, including that participant requested referral for UH support, and outcomes in the adverse events log.
    - Inform Joint CIs and Trial Manager
        - Support for the researcher will be arranged as required (in line with UH guidance)
- The DPO will contact the participant within **2 working days** and inform UH core team of the outcome (e.g. signposted to further support; referred to external organisation; etc.) within **5 working days** (set calendar reminder to follow-up)
- The UH core team will then record this in the adverse events log

Participants under the age of 18 and 18+ considered to be vulnerable [7]

5. **Disclosure of safeguarding concern via Survey**

Within each follow-up survey (M3, M6 and M12) we ask safeguarding questions (see Appendix A). If a participant under the age of 18 years responds positively to one or more items, automated messaging is triggered to both the participant and the UH core team. The participant will be sent both an automated text message and email (in parallel; triggered within REDCap in response to survey responses). The Text message – under 18 – referral alert has the dual purpose of flagging the email to the young person and providing instruction to open this email in a safe space. The Email template - Under 18 - Safeguarding referral to trust - any method of disclosure informs them that a safeguarding referral will be made. The UH core team will simultaneously receive an automated email alerting them to any safeguarding concern. In response they will:

- Record the event in the 'adverse event log' instrument on REDCap.
- Make a referral (see 'How to Make a Referral' below).

Disclosure of safeguarding concern by any other means (interview, telephone call, email)

6. **Clear, immediate risk of significant harm in an emergency**

- Call the police on 999
- Provide as much information as possible (location, etc.)

NB. The police will continue with their own safeguarding procedure following our call to them, we will be guided by them as to whether we follow up with participants or need to take any other action.

- Note all actions taken & outcome on the adverse events log
- Inform Joint CIs and Trial Manager
    - Support for the researcher will be arranged as required (in line with UH guidance)

[7] e.g. because they have care and support needs which make them unable to protect themselves from the risk or experience of abuse and neglect (e.g. learning disability).

7. Clear risk of significant harm- non-emergency, urgent situations

- Identify the relevant local authority safeguarding team, using the list of LA safeguarding contact details spreadsheet
- Call the telephone number stated and provide as much information as possible (location etc.)
- Follow advice given by the LA safeguarding team
- Note all actions taken & outcome on the adverse events log
- Inform Joint CIs and Trial Manager
    - Support for the researcher will be arranged as required (in line with UH guidance)

8. Clear risk of significant harm, non-emergency situation

Actions required at time of disclosure

- Listen/respond to the participant with empathy and remember that you are not an investigator: you don't need to ask questions
- Reassure the participant that you believe what they are telling you
- Thank them for telling you this. Explain to them that you are worried about their wellbeing and that because of their age, you are obliged to pass their details on to someone who could help.
- Explain that you will do this straight away, and that they will shortly be contacted by a specialist nurse from their local sexual health clinic who will work with them to understand what help they may need
- Reassure them that this person will confirm that it is them before proceeding and check that it is safe for them to talk first
- Make notes
- Tell them that you will send them an email which outlines what you have told them
- Ask if they have any questions and respond as best you can

Actioned required afterwards

- In parallel send Text message – referral alert and Email template - Under 18s - Safeguarding referral to trust - any method of disclosure
- Make a referral (see 'How to Make a Referral' below).
- Note all actions taken & outcome on the adverse events log
- Inform Joint CIs and Trial Manager
    - Support for the researcher will be arranged as required (in line with UH guidance)

9. Unclear risk of significant harm, non-emergency situation

Please note, as well as for <18s, this route is also for use by researchers for any young person aged 18+ years who they believe to be vulnerable in other ways e.g. because they have care and support needs which make them unable to protect themselves from the risk or experience of abuse and neglect (e.g. learning disability). The researcher does not need to know that this vulnerability exists, they just need to have reason to believe this may be the case.

Actions required at time of disclosure

- Attempt to gather information about the situation:
    - What is happening to them?

  - Who is doing this?
  - Do they feel safe?
- Tell them that you are worried about what they have said and that you would like to seek advice from someone at the university so that you know how best to respond. Explain that you won't tell this person their name, just speak to them about their situation.
- Tell them that you will send them an email outlining what you have said
- Ask if they have any questions and respond as best you can
- Make notes

Actions required:

- Send the participant Email template - seeking advice
- Telephone the DSO (see contact details below) for advice and agree/implement one of the following actions:

  1) signpost – send Email template - Offer of UH support and provision of personalised info as determined by DSO)

  2) seek further info/details from the individual – contact the individual to obtain this (for this, follow method of communication used up to that point)
    - Once response received, contact DSO with this information and consider options 1, 2, or 3 once again
    - if no response received within a fixed period (as agreed with DSO) then make a referral (see 'How to Make a Referral' below); inform individual

  3) In parallel send Text message – referral alert and Email template – Safeguarding referral to trust following advice and make a referral to safeguard them (see 'How to Make a Referral' below).
- Type up any handwritten notes and store in the designated folder on the R drive along with participant ID (shred any paper notes). If original notes digital, then move these to the R Drive (no digital copies to be kept elsewhere)
- Note all actions taken & outcome on the adverse events log
- Inform Joint CIs and Trial Manager
  - Support for the researcher will be arranged as required (in line with UH guidance)

How to make a referral

- Check which local authority area the participant resides in, and complete the Halo Referral Form
- If the local authority is not a participating in the trial, liaise with DSO to identify most appropriate trust and make contact with them for a referral.
- Save the referral form within the designated folder on the R drive.
- Send the referral form using UH File Exchange (secure, encrypted file exchange service) within *one working day*. Request that the safeguarding contact replies to this email with a 'received and will now action' statement - they are required to do this within 2 working days.
- Update adverse events log

UH Designated Safeguarding Officer (DSO) Contact Details

Cathy Hamilton is the DSO for this project and should be contacted in the first instance. In their absence, we will email the UH Dean of Students office (deanofstudents@herts.ac.uk) or alternative contact as advised by the DSO for this project.

	Designated Safeguarding Officer DSO
Name	Cathy Hamilton
Role	Head of Placement Learning
Email	c.j.hamilton@herts.ac.uk
Telephone number	5298
Working days	Monday-Friday

Local Authority and Trust Contact Details

Refer to 'positive cases and safeguarding referral contacts' spreadsheet.

Appendix A – Safeguarding questions used across all surveys

Title of section in survey

Sexual Wellbeing- abuse, assault & coercion

Information

Important, please read

- In this section we ask you about whether you have recently experienced unwanted sex or other types of illegal or unacceptable behaviour by a partner
- (message displayed to under 18's) If you are *under 18*, we have a responsibility to protect you. This means that if you tell us that you have been a victim, we will pass your contact details on to relevant organisation(s) in your local area who will try to get in touch so that they can work with you to find out what help (if any) is needed
- (message displayed to over 18's) In these circumstances, we would like to be able to offer you additional support. If you select one or more of these items, we will be in touch to see if you would like this.
- Everyone will receive an email on completion of this survey containing links to organisations that can help

Questions (16-17 year olds)

Please select any items that are true for you now or have been in the last [3 months/ 6 months]

If you have not experienced any of these things, please select none of the above.

1. Having a sexual partner who is more than 5 years older or younger than you, or in a position of trust (e.g. teacher, police officer)
2. Someone close to you (e.g. family member or partner) has physically hurt you, made you feel frightened or made you do something sexual that you didn't want to do/couldn't say no to
3. Someone has given you gifts, money, drugs, alcohol or protection for sex
4. You have sent or received messages of a sexual nature, or someone having sexual pictures of you
5. You have tried to hurt yourself or self-harm
6. None of the above

Questions (18 and over)

Please select any items that are true for you now or have been in the last [3 months/ 6 months]

If you have not experienced any of these things, please select none of the above.

1. A family member or partner has made you feel frightened or hurt you
2. A partner has made you feel like you are being controlled or manipulated (e.g. telling you who you can talk to or what you can wear)
3. Someone close to you has made you do something sexual that you didn't want to do or couldn't say no to
4. None of the above

Response options

- ❑ Select any that apply

Halo referral form

LOGO HERE

HALO REFERRAL FORM (sexual health and safeguarding support)

Reason for referral:

- Sexual health; chlamydia result (detected/not detected/other) (Date/time recorded_____)
- Sexual health; gonorrhoea result (detected/not detected/inconclusive or other) (Date/time recorded _____)
- Sexual health; gonorrhoea detected (unconfirmed) (Date/time recorded _____)
- Safeguarding; disclosure of abuse (Date/time recorded _____)

Safeguarding further information:

If no safeguarding disclosure, delete this whole section and replace with the statement ***'No safeguarding disclosure made to the research team'***]

Method of disclosure:

- Email contact
- Telephone contact
- Survey response
- Qualitative interview

Details of the disclosure: [complete below if survey response. If other form of disclosure, delete below survey items and add details about the disclosure]

Young person aged 16-17

- *Having a sexual partner who is more than 5 years older or younger than you, or in a position of trust (e.g. teacher, police officer)*
- *Someone close to you (e.g. family member or partner) has physically hurt you, made you feel frightened or made you do something sexual that you didn't want to do/couldn't say no to*
- *Someone has given you gifts, money, drugs, alcohol or protection for sex*
- *You have sent or received messages of a sexual nature, or someone having sexual pictures of you*
- *You have tried to hurt yourself or self-harm*

Vulnerable adult aged 18+

- *A family member or partner has made you feel frightened or hurt you*
- *A partner has made you feel like you are being controlled or manipulated (e.g. telling you who you can talk to or what you can wear)*
- *Someone close to you has made you do something sexual that you didn't want to do or couldn't say no to*
- *None of the above*

Personal details of the patient:

Name:

DOB:

Telephone number:

Address:

Preventx ID*:

(*provided only when participant originated from SHL or SH.UK and referral made to an NHS trust)

Details of the referrer:

Name:

Contact details:

Position:

Date/time of referral to trust: