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Synopsis

Home-based intervention strategy to reduce new chlamydia infection among young men: the HIS-UK RCT

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Abstract

Background: Sexually transmitted infections pose a significant public health challenge in the United Kingdom, prompting the Department of Health and Social Care to prioritise sexually transmitted infection rate reduction as a means of addressing sexual health inequalities. Correct and consistent condom use is the most effective method of reducing sexually transmitted infection transmission.

Methods: A randomised controlled trial with three arms (two intervention arms and one control arm) was conducted to evaluate the effectiveness and cost-effectiveness of the home-based intervention strategy United Kingdom intervention in reducing chlamydia test positivity among 16- to 25-year-old men, and individuals with a penis, at risk of sexually transmitted infections. The home-based intervention strategy United Kingdom intervention, delivered either face to face by health promotion professionals or digitally through an interactive website, aimed to enhance condom use experiences and improve correct and consistent condom use. The control group received usual condom distribution care. Chlamydia screening was conducted at baseline and 6 months post randomisation, with follow-up through online questionnaires.

Of the 2387 individuals assessed for eligibility, 1233 were eligible, and 725 participants completed all baseline assessments and were randomised (health promotion professionals: 241, interactive website: 243, control: 241). Five hundred and eighty men received the intervention arm as randomised (health promotion professionals: 51.9%, interactive website: 93.8%, control: 94.2%); 51.7% of participants engaged during follow-up, with 21.4% providing baseline and follow-up chlamydia screening results.

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Results: Findings showed the home-based intervention strategy United Kingdom to be well received, with participants valuing the condom kit and materials promoting pleasurable condom use. At the primary end point, home-based intervention strategy United Kingdom participants showed a 4.9 percentage point reduction in chlamydia test positivity compared to the control (7.9% vs. 12.8%). The odds of a positive test were 55% lower for home-based intervention strategy United Kingdom participants compared to the control. However, this reduction was not statistically significant due to the lower-than-planned participant recruitment (a consequence of COVID-19) affecting the trial's power. Home-based intervention strategy United Kingdom positively impacted recent condom use along with significant reductions in condom use errors and problems compared to the control. While no marked effect on consistent condom use emerged, attitudinal shifts were highly significant, with sustained positive condom attitudes, reduced perceived barriers and increased confidence in condom use among home-based intervention strategy United Kingdom participants.

Conclusion: The home-based intervention strategy United Kingdom education and training programme, in conjunction with the provision of a broad selection of products, demonstrated a positive impact on attitudes towards condoms and lubricants, increased confidence in correct condom use and reduced errors and problems. Recent condom and lubricant use increased, but consistent condom usage showed no significant improvement. The odds of a positive chlamydia test were lower for home-based intervention strategy United Kingdom participants, though not statistically significant. This study provides valuable insights into the potential of home-based intervention strategy United Kingdom to enhance sexual health practices among at-risk populations. While it is recognised that home-based intervention strategy United Kingdom is more costly than usual condom distribution care, incorporating key elements of the intervention and messaging into existing practice could offer benefits without making implementation unfeasible.

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Introduction

Background and rationale

Correct and consistent condom use is the most effective method to reduce sexually transmitted infection (STI) transmission.[1] Public Health England (now the UK Health Security Agency) and others have run various campaigns to help protect young people from STIs through the promotion of condom use.[2] Despite this, there is substantial evidence to show that condoms are frequently used incorrectly and inconsistently.[3]

Behaviour change intervention programmes typically try to improve knowledge and skills to increase condom use but seldom focus on addressing the reasons for condom non-use as important determinants. Issues with the fit and feel of condoms are commonly cited by men who report inconsistent or incorrect condom use along with application problems, reduced sensation and erection difficulties.[4–6] These negative experiences are highly likely to be responsible for most variations in condom use self-efficacy and outcome expectancies known to be related to consistent use.[7–9] In a review of the evidence, we found that only 5 of 123 interventions promoting the use of male condoms focused on improving condom fit and feel.[10]

The Department of Health and Social Care recommends the usage of evidence-based preventative interventions to reduce STI rates.[11] Yet, current national guidelines regarding behavioural interventions to prevent STIs are limited. A review of the evidence on safer sex advice recommended that brief behaviour change interventions targeting individuals and focusing upon skills acquisition, communication competences and motivation to adopt safer sexual behaviours should be provided as part of routine care of those at elevated risk of STIs.[12] In practice, there is scant information about whether such discussions occur and, if so, whether they are effective in reducing risk behaviour. Moreover, many communication and motivational interventions are very resource- and cost-intensive. Funding for sexual health services (SHSs) has reduced dramatically, so novel ways of delivering strategies to prevent STIs, that reduce staff time and clinic attendance, are being sought.

Digital interventions (DIs) are one solution. They remove accessibility barriers that contribute to health inequalities and enable participation at a time and location convenient to users, provide anonymity and can reduce fear of stigmatisation. DIs also have the advantage of providing consistency and standardisation in delivery along with implementation costs that are typically low compared to other delivery methods. Indeed, given the increasing use of

the internet by young people to obtain health information, NHS England has identified the need to make fuller use of digital technologies.[13]

Furthermore, guidelines from the National Institute for Health and Care Excellence (NICE) include the need to teach young people to use condoms effectively and safely (using education, information and demonstrations) before providing them and to provide a range of condoms and lubricants.[14] NICE goes on to recommend that information, motivation and behavioural skills model approaches and motivational interviewing techniques are used to guide conversations about risk reduction or safer sex practices and address informational-, motivational- and skills-based barriers to change. Furthermore, future research should explore what behaviour change techniques are most effective for supporting the consistent and correct condom use following their distribution.[14–16]

Systematic reviews of the efficacy of behaviour change interventions for the promotion of consistent condom use have produced mixed results.[17–19] Poor-quality trials and a failure to identify the active components (or behaviour change techniques) of interventions have reduced the ability of studies to inform future intervention development. Yet, there is emerging evidence, mainly from US studies, that brief behavioural interventions designed with identifiable and evidence-based components can reduce STI acquisition.[8,12,20]

The home-based intervention strategy (HIS-UK) was adapted from an intervention previously piloted in the USA and Canada [The Kinsey Institute Homework Intervention Strategy (KI-HIS)]. Pilot studies of KI-HIS showed improvements in condom use experiences, self-efficacy for condom use and condom fit and feel as well as a reduction in breakage and erection problems among heterosexual young men and men who have sex with men.[21,22]

The HIS-UK aims to improve men's condom use skills, self-efficacy and enjoyment by providing information and guidance on condom experimentation, practice and usage (using a range of different condoms and lubricants). During its development, the behaviour change techniques and potentially active components of existing promising condom promotion interventions were coded to enable the development of a brief behavioural intervention that is evidence-based and theoretically driven.[23,24]

The HIS-UK was designed with two delivery models: delivery by a trained professional [health promotion professionals (proHIS)] or as a DI using an interactive website (eHIS). proHIS was devised as an extension of the usual condom demonstration and distribution care model currently practised by proHIS and was offered to young people in condom distribution settings. eHIS, the digital version of the intervention, aimed to facilitate improved access to a preventative STI intervention without the need for a specialist provider contact.[25]

Objectives

Box 1 presents the objectives.

BOX 1 Objectives

1. To assess the effectiveness of HIS-UK among young men aged 16–25 years by comparing face-to-face delivery (proHIS), digital delivery (eHIS) and usual condom distribution care using:
   - chlamydia test positivity at 6 and 12 months
   - episodes of condomless anal and/or vaginal sexual intercourse at months 1–12
   - reported condom use errors and problems at months 1–12
   - enhanced condom use experiences ('fit & feel', sensitivity, pleasure and self-efficacy) at months 1–12
   - positive condom use attitudes at months 1–12.
2. To conduct a mixed-method process evaluation to explore the ways in which HIS-UK delivered by proHIS and eHIS may work, possible mediators and mechanisms of change, and participants' experiences of engaging with the intervention and trial.
3. To estimate the costs associated with HIS-UK delivered by proHIS and eHIS and their cost-effectiveness as compared to usual condom distribution care.

The HIS-UK evaluation proposed to identify whether HIS-UK delivered by two models [face-to-face (proHIS) and digital (eHIS)] was effective in promoting behaviour change and reducing STIs among young men and to assess the cost-effectiveness of the two delivery models as compared to usual condom information and distribution care offered to men by the NHS and more widely.

The primary objective was to evaluate the impact on chlamydia positivity of HIS-UK compared to usual care through the enhancement of condom use experiences and improvement of correct and consistent condom use. The secondary objectives included evaluating performance characteristics of the two delivery models, engagement and satisfaction with HIS-UK, and thirdly, the cost-effectiveness of HIS-UK in the context of the NHS.

Impact of COVID-19

The HIS-UK trial was initially opened to recruitment in March 2020 just prior to the COVID-19 pandemic (protocol v5).[26] Site set-up and participant recruitment to the trial were detrimentally impacted by the pandemic as services closed, NHS staff were redeployed, non-essential research activities were halted and the UK population went into lockdown. On 30 March 2020, 2 weeks after

opening, the HIS-UK trial was halted in line with National Institute for Health Research (NIHR) guidance.

Research activities reopened in June 2021 following the third national lockdown. However, the legacy and ongoing impact of COVID-19 on NHS staffing levels, a shift to online SHS provisioning along with the work-from-home directive meant that the original protocol was no longer fit for purpose.[26] The protocol was amended to reflect the new NHS working practices.[27] Specifically, changes included a reduction in direct clinical contact time with trial participants and increased the provision of remote research participation and care delivery (protocol v6).[26]

It was quickly evident, however, that if recruitment remained focused solely within NHS clinical settings, the successful completion of the trial was unlikely. In an attempt to meet the trial objectives, further protocol amendments were made to extend the recruitment routes. The methodology outlined in the final protocol (v9)[26] is presented below.

Methods

A randomised controlled superiority trial was used to compare the effectiveness of HIS-UK, with usual condom information and distribution care. A repeated-measures trial design with baseline measurement, monthly follow-up questionnaires and three STI screening points was employed over a 12-month period.

Setting

The multicentre trial was set up in eight NHS Trusts in England. Fourteen clinical trial recruitment sites (CTRS) were opened at selected integrated sexual health (SH) and genitourinary medicine (GUM) services and university-associated health centres/general practitioner (GP) practices within the Trusts. Trained NHS staff were responsible for the delivery of the HIS-UK research procedures in the CTRS.

In addition, GP practices and SH/GUM services located in 13 of the 15 NIHR Clinical Research Network areas acted as participant identification centres (PICs), and community and educational establishments, youth advisory, information and counselling services and social media platforms were used to advertise the study. Adverts signposted interested young men to the study website where they could complete an expression of interest application (EOIA) for online self-registration (OSR).

The co-ordinating centre for the main trial was located at the Centre for Sexual Health Research, University of Southampton. HIS-UK staff at the University were responsible for the delivery of the research procedures for self-referral participants recruited via PICs and other community advertising routes if a participant did not live within a CTRS catchment area.

Participants

Between June 2021 and February 2023, participants were recruited through opportunistic direct approach in clinical settings. Targeted advertisements and direct text messaging were also used to signpost potential participants to the HIS-UK study website for online eligibility screening and self-registration. Anyone with a penis was eligible if they were aged between 16 and 25 years, UK residents and at risk of STIs through reporting of condom use errors (breakage or slippage) or condomless intercourse with a casual or new sexual partner during the previous 3 months. Exclusion criteria were an allergy to latex, lack of internet access and limited written or spoken English proficiency (sufficient to prevent the following of trial instructions). Recruitment flow charts for clinical and online self-referral are shown in *Figures 1* and *2*.

In CTRS, trained staff directly approached potential participants with the use of study fliers and contact cards. Interested men were either screened for eligibility in clinic or signposted for self-registration via the study website. PICs conducted patient record database searches to identify individuals who met the study eligibility criteria. Potential participants were informed about the study via text message. Over 70,000 text message adverts were sent by PICs, achieving a 10% study website hit rate.

Prior to recruitment, all men viewed a patient information sheet and had the opportunity to ask questions of the CTRS staff or HIS-UK team. Men at CTRS settings were screened for eligibility using a computer-assisted questionnaire administered by *Lifeguide*[27] (*Lifeguide*, www.lifeguideonline.org/ is an interactive web-based intervention software platform and secure validated data management system designed to collect participant information and deliver DIs to support health behaviour change). If eligibility was met, men gave informed online consent and completed the trial registration procedures. Those using the online self-referral route were prompted to complete a screening questionnaire administered by *Qualtrics* (*Qualtrics* is a University of Southampton-approved online survey platform.) and, if successful, made an EOIA. All EOIAs were reviewed by the HIS-UK team who allocated applicants to an appropriate CTRS if necessary (based on postcode) or to the community OSR group. A *Lifeguide* weblink was then shared with potential participants, allowing them to complete the online trial consent and registration procedures.

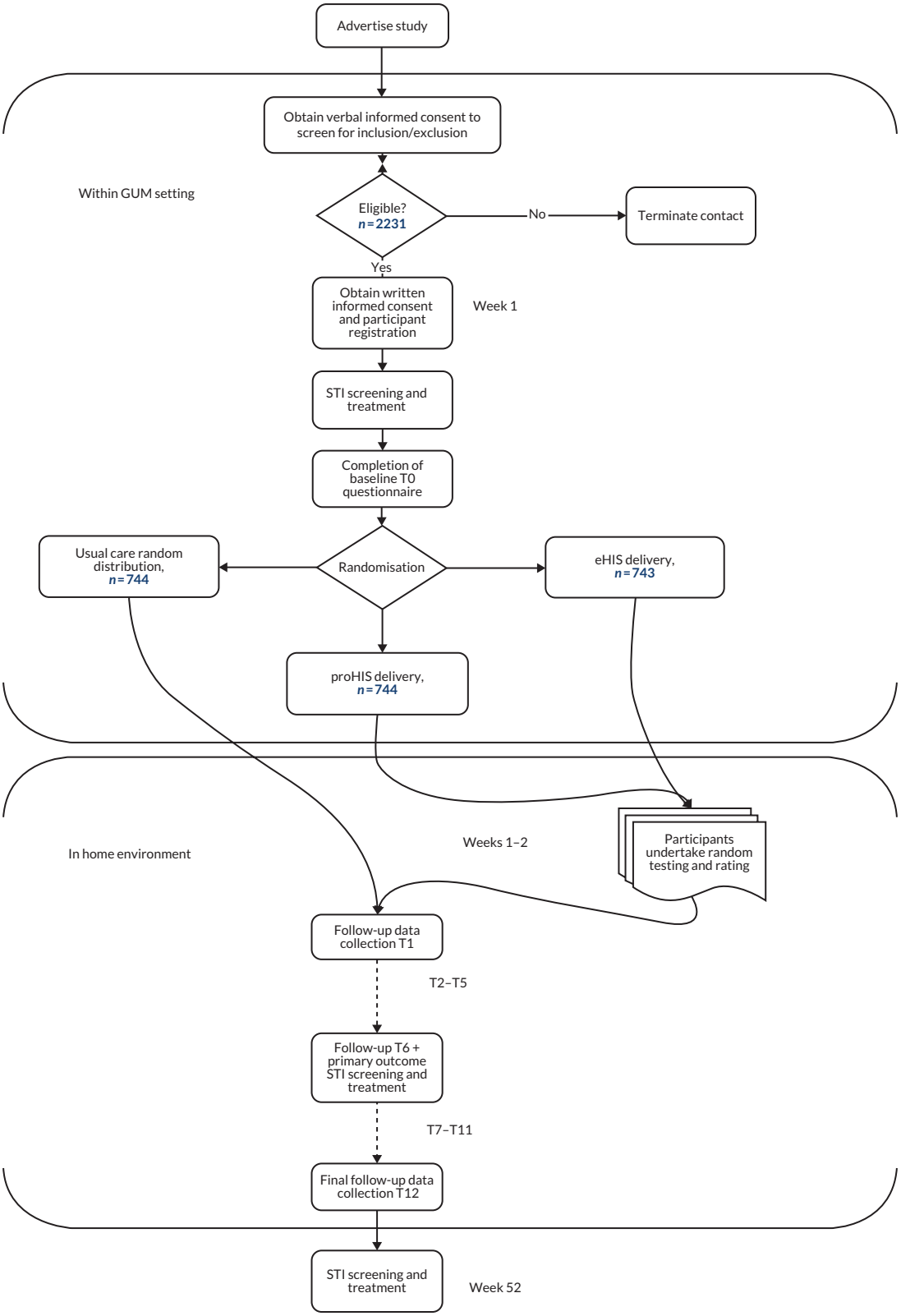

FIGURE 1 Clinical recruitment flow chart.

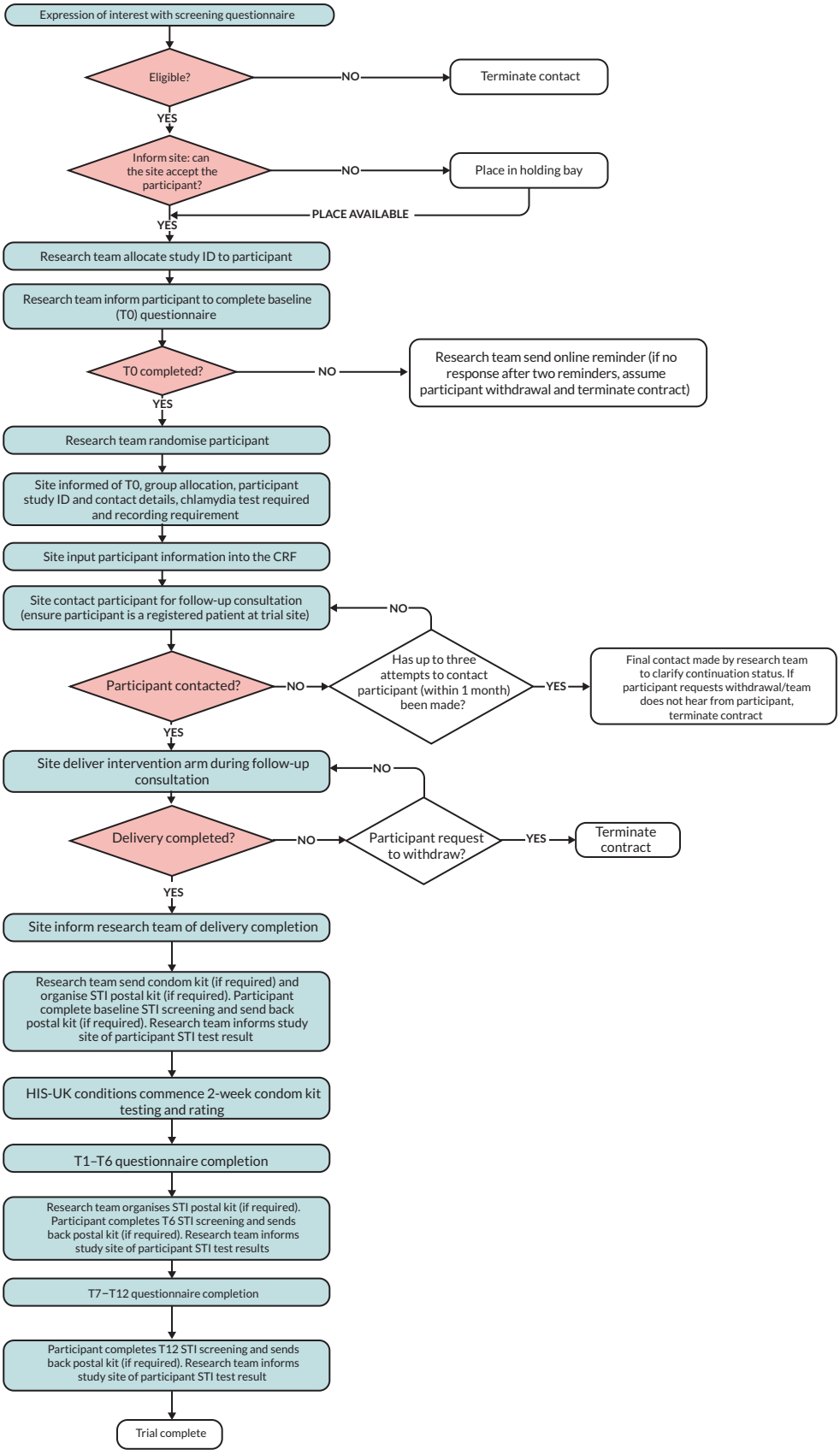

FIGURE 2 Online self-referral recruitment flow chart. CRF, case report form.

Baseline procedures

Questionnaire survey

The baseline self-completion computer-assisted questionnaire (T0) collected basic demographics (age, ethnicity, postcode, sexual orientation, education, employment and housing), indicators of health-related quality of life (HRQoL) and health service resource use. Data were also collected on a series of behavioural, condom use experience, attitudinal, intentions and self-efficacy outcome measures along with details of any partnered sexual activity and condom use that had occurred in the previous 4-week period.

Screening

Chlamydia positivity data were collected at baseline. If a participant had been screened within the previous 28 days, the result of that screening was used. All remaining participants were asked to provide samples for chlamydia detection. Participants who reported sex with other men during T0 were offered triple testing, as per usual clinical practice (urine sample and anal and oral swab); all other participants were asked to provide a single urine test for analysis. If a participant refused a triple test, a single urine test was offered instead. Participants could opt to use a postal screening kit or provide samples in a clinical setting.

Participants were informed of all test results and were treated as per standard care if required.

Randomisation

Trial arm randomisation was actioned through an algorithm in-built to *Lifeguide*. The algorithm generated randomly permuted blocks of varying length (between three and six) per strata to preserve concealment and maintain balance within each recruitment-setting site, with stratification by ethnicity and sexual risk (i.e. eight strata per site).

Participants were allocated to the trial arms at a ratio of 1 : 1 : 1. Investigators, CTRS staff and participants were not blinded to trial-arm allocation.

Intervention delivery and activities

Control group (control) Clinical trial recruitment sites participants randomly allocated to the control received a usual condom distribution care consultation. OSR participants in the control reviewed online safe sex advice and condom information from a selection of NHS, governmental and charitable organisations.

HIS-UK groups (interactive website and health promotion professionals) The HIS-UK intervention comprised three elements:

a. focused condom and lubricant education and training
b. solitary condom and lubricant experimentation
c. online ratings of condoms and lubricants.

Education and training Two delivery models for the HIS-UK education and training were compared: face-to-face delivery by a trained professional (proHIS) and digital delivery by way of an online interactive digital media website (eHIS). The education and training covered the following:

I. condom use information, including the need for, and advantages of, condom testing and self-practice
II. correct condom use; how to apply and remove a condom
III. using condoms for pleasure and how to find the best condom for fit and feel
IV. information about lubricants, their benefits and how to use them
V. advice on condom self-practice and details of condom use exercises to try out at home.

Solitary experimentation and practice Following (a), all HIS-UK participants commenced a 2-week condom/lubricant experimentation and self-practice period using the contents of a HIS-UK condom kit and following the guided home-based exercises. The aim was for participants to practise applying, using (masturbating with) and removing each of the different condoms provided in 'low-pressure' situations (i.e. not in the presence of a sexual partner) and to experiment with the different lubricants. The condoms provided varied by shape, size, material, texture and thickness.

As participants tried out each product, they were asked to focus on pleasurable sensations to build positive associations between condom use and sexual enjoyment.

Condom and lubricant rating After experimentation with each condom/lubricant, participants were requested to complete an online rating and feedback form via *Lifeguide*. The purpose of the rating form was to enable participants to identify the condoms that 'fit and feel' the best and the lubricant of choice. Participants who submitted at least three ratings were able to order further supplies of their choosing.

Follow-up assessment

Monthly questionnaires

All participants were prompted to complete monthly online assessment questionnaires as per baseline (T1–T12). Following submission of each monthly questionnaire,

proHIS and eHIS participants who reported sexual activity in the previous 4-week period were able to order further supplies of their choosing.

Chlamydia screening

At 6 months and 12 months post randomisation, each participant was asked to provide samples for chlamydia detection as per baseline.

Sample size

For the purposes of sample size estimation, the primary health outcome was the test positivity rate of chlamydia at 6 months post randomisation.

The effectiveness of HIS-UK delivered by proHIS and eHIS was planned to be analysed with an overall type I error rate of 5% (2.5% per comparison) and by comparing test positivity among each of the intervention arms with the control (usual care). Data published by the National Chlamydia Screening Programme suggested a test positivity rate of 11% among young men aged 15–24 years in England, who were tested in specialist SHS.[28] The trial was powered to detect a reduction in chlamydia test positivity rates among participants in our intervention arms from 11% to 6% (a 45% reduction) at 6 months post randomisation.

Previous piloting suggested that the intervention was likely to be equally effective across all subgroups (deprivation, ethnicity, sexual orientation and age).[24,25] To have 85% power to detect the projected difference in the analyses requires 476 participants in each of the arms (G*Power 3.1.9.2). To minimise risk to the trial and to reflect 36% attrition at follow-up (observed during our HIS-UK feasibility testing), the aim was to randomise a total of 2231 participants.

Process evaluation

Consistent with Medical Research Council (MRC) guidance and a person-based approach to the evaluation of interventions,[27] a mixed-method design was employed to examine how the intervention was implemented, sources of potential bias, possible mechanisms of change and contextual factors that may have influenced implementation of the intervention.

During early stages of recruitment, CTRS site staff (SS) were asked to provide written and verbal feedback regarding the acceptability of the research design and intervention delivery, ease of recruitment, willingness of participants to be randomised, ease of acquiring STI screening and data transfer and issues of intervention fidelity. Any barriers or issues that arose were incorporated into the amendment process for further refinement.[26]

To measure the process and potential contamination between trial arms, qualitative assessments of the delivery of proHIS and the control arm were undertaken. Within each CTRS, in a 15% random selection of participant cases, the consultation interaction with the SS was identified to be audio-taped and assessed for intervention fidelity using an automated algorithm built into Lifeguide. Participants were required to provide consent for these recordings to take place.

At T6 and T12, participants were asked (via Lifeguide) if they were willing to be contacted by the research team and to be interviewed about the trial (by telephone or video call). From those who agreed, 25 participants were purposively sampled to ensure that a range of participant experiences were represented. The purpose of these interviews was to explore trial acceptability, issues of contamination and protocol adherence, costs associated with trial involvement and how and why the intervention may/may not have been beneficial. All participants gave consent for the interviews to be digitally recorded, transcribed and analysed.

Economic evaluation

In line with NICE recommendations to evaluate the cost-effectiveness of an intervention using a cost–utility analysis (CUA), quality-adjusted life-years (QALYs) were collected as outcome measures. While NICE recommends the EuroQol-5 Dimensions, five-level version (EQ-5D-5L) for assessing HRQoL, it is recognised that the measure may not be suitable within economic evaluations of public health interventions, particularly in SH interventions, which have an important psychosocial aspect.[29–32] Therefore, this trial also used the Short Form questionnaire-12 items (SF-12) instrument to assess HRQoL, which has been successfully applied in similar context.[31] Both questionnaires were administered across the three trial arms at T0, T6 and T12.

Beyond the QALY-based CUA approach, the study proposed a cost-effectiveness analysis (CEA) using an incremental cost-effectiveness ratio (ICER). Unlike CUA, which focuses on QALY gained, CEA assesses cost per unit of health outcome, such as cost per case of a chlamydia infection prevented. This approach provides an alternative perspective on the effectiveness and value of the HIS-UK intervention and can be used to guide decisions on whether an intervention provides value for money relative to its costs.

Resource use data were collected prospectively to estimate the costs associated with each trial arm. These costs

encompassed the delivery of the HIS-UK intervention through face-to-face (proHIS) and digital (eHIS) models as well as the cost of usual care. Additionally, costs incurred after receiving the HIS-UK intervention or usual care were considered alongside expenses related to the treatment of STIs and other conditions and any personal costs borne by participants. Unit costs and price data were sourced and applied to each resource use item to calculate an overall cost per participant.

Data were recorded through Lifeguide and other trial reporting mechanisms, including monthly staffing timesheets, screening outcome reports, non-eligibility report forms and site PIC reporting questionnaires. Wider NHS and public sector resource use by participants was collected via the monthly questionnaires, capturing details on medication use, GP and SH clinic visits and engagement with other public sector services. Participant-incurred costs related to trial involvement and receipt of the intervention or usual care, such as time, travel expenses and internet usage, were recorded through Lifeguide usage logs, monthly questionnaires and participant interviews.

Analysis amendment

As a result of the impact of COVID-19, the halt to recruitment activities for 15 months, and the fact that the funder declined to extend the study timeline to cover the lost time, the HIS-UK study was unfortunately unable to recruit the target sample size of 2231 within the reduced time frame or complete the 12-month follow-up with all participants. Considering the shortfall, the original statistical analysis plan (SAP) and economic evaluation were amended accordingly (see further details below).

Results

Between June 2021 and February 2023, 8528 men accessed the trial website and 2387 (28.0%) consented to eligibility screening. In total, 1233 eligible participants were identified and invited to register for the trial. Of those, 725 (58.8%) accepted the invitation, completed the baseline assessments and were randomised to one of the three trial arms (proHIS: 241, eHIS: 243, control: 241). Five hundred and eighty participants received condom care as per randomisation [proHIS: 125 (51.9%), eHIS: 228 (93.8%), control: 227 (94.2%)]. Approximately a third (n = 210, 36.2%) of participants were linked with a CTRS, and 370 (63.8%) were OSR participants.

The final cohort eligible for analysis consisted of 575 of the 580 participants due to participant withdrawal and associated requests for the deletion of any data held. *Figure 3* presents the Consolidated Standards of Reporting Trials diagram.

Measures

Basic demographics and sexual history indicators were collected at baseline along with markers of HRQoL (SF-12 and EQ-5D-5L) and chlamydia screening data. SHS utilisation, STI diagnoses, tested scale and score items along with details of any partnered sexual activity and condom use that had occurred in the previous 4-week period were also collected at baseline and again at monthly intervals. At 6 months post randomisation, markers of HRQoL and chlamydia screening were repeated.

Health-related quality of life

Short Form questionnaire-12 items

The SF-12 is a 12-item version of the Short Form questionnaire-36 items, an appropriate measure to capture the health status of patients when there are constraints on questionnaire length or when the focus is on patient-based assessments of physical and mental health.[32,33] In this study, the physical component summary-12 and mental component summary-12 scores, represented by six items each, were computed and normalised for the SF-12 according to published algorithms. Scores range from 0 to 100, with higher scores indicating better physical and mental health functioning.[33]

EuroQol-5 Dimensions, five-level version

The EuroQol-5 Dimensions (EQ-5D) is a widely used HRQoL measure that assesses an individual's overall health state by considering five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension is evaluated on five levels, indicating the person's health state. This results in a descriptive health profile with scores ranging from 0 to 1, with 1 representing the best possible health state. Additionally, the EQ-5D includes a visual analogue scale (VAS) that allows individuals to rate their own health status on a scale from 0 (worst health) to 100 (best health).[34]

Attitudinal and behavioural scales and scores

Condom use experience scale

Condom use experience was assessed using a seven-item subscale of the validated Condom Barriers Scale,[35] measured on a five-point Likert scale (strongly disagree to strongly agree).

Condom use attitudes scale The *Condom use attitudes scale* was adapted from the Multidimensional Condom

Attitude Scale[35] and was previously used by the Kinsey Institute Homework Intervention study team.[24]

Pleasurable condom use scale The five-item pleasurable condom use scale was created following recommendations and findings from the HIS-UK feasibility study.[24]

Condom use self-efficacy scales Condom use self-efficacy was assessed by an established seven-item measure of self-efficacy (The Condom Use Self-Efficacy Scale) designed to assess ability to apply condoms correctly.[36] Items asked participants how difficult or easy they would find certain actions. A second three-item measure was used to assess confidence in using condoms effectively with partners.

Condom use errors and problems score The condom use errors and problems score was created from the Condom Use Errors and Problems Survey.[37] Participants were asked to report (using a binary yes/no response) whether any of the statement items had occurred or been experienced at last condom use. Participant responses were tallied to give a final score, with a higher score reflective of more reported errors and problems.

Condom use fit-and-feel score Four statement items from the Condom Fit and Feel Scale[38] were used to

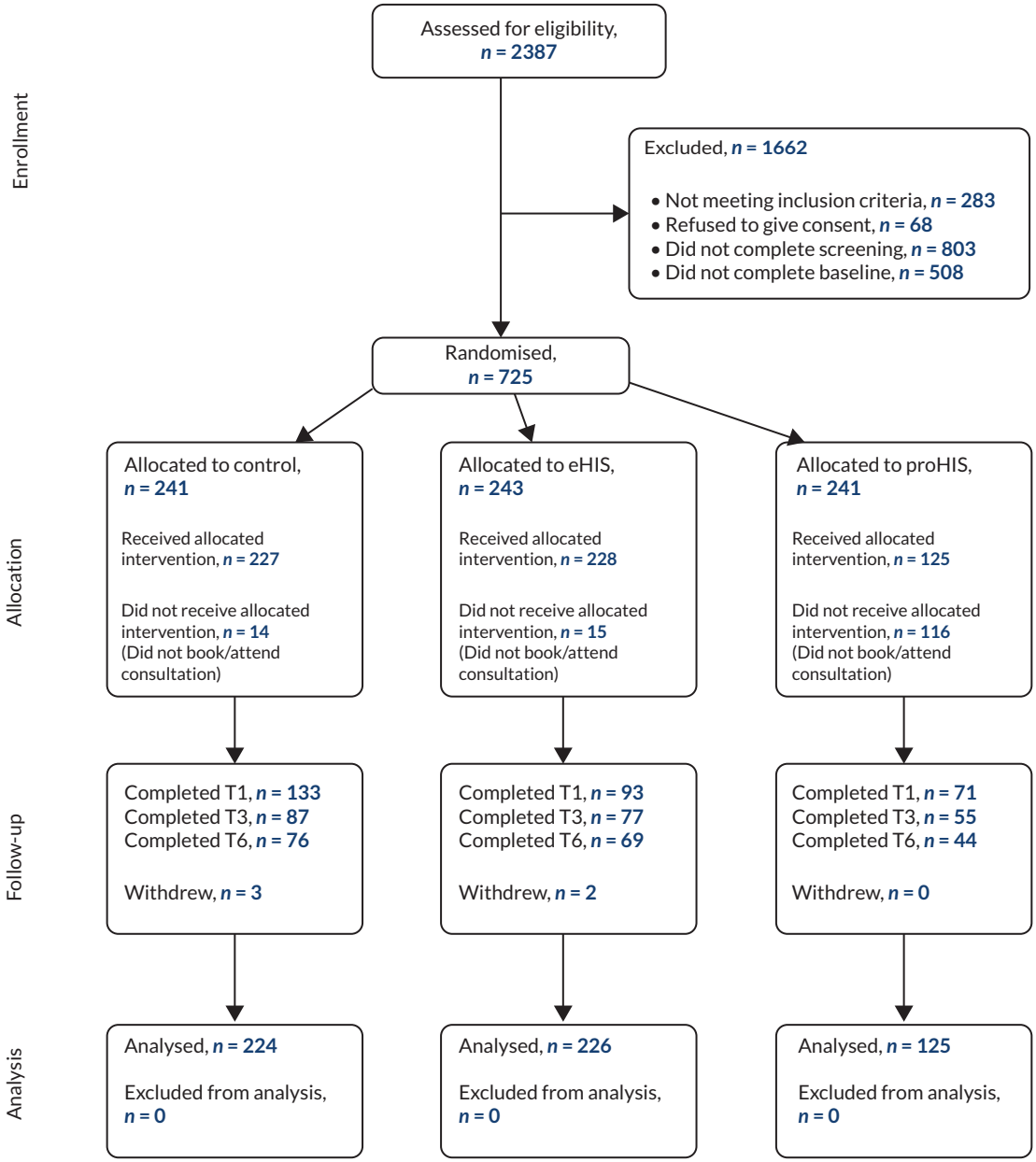

FIGURE 3 Consolidated Standards of Reporting Trials diagram.

explore men's general experiences with condom fit and feel. Responses were provided on a frequency Likert scale (1 – never applies to me to 4 – always applies to me). A second binary measure of any reported fit-and-feel issues at last condom use (yes/no) was also used.

Condom use motivation scale To measure condom use motivation, a single question was used asking participants to report their level of motivation to use condoms with partners by using a five-point Likert scale.

Baseline characteristics

Table 1 presents the demographic characteristics of the sample. The median age of fully recruited participants at randomisation (*N* = 575) was 21.0 years. The majority identified as White (81.2%) and the participant sample was evenly distributed across the social deprivation quintiles [Index of Multiple Deprivation ascribed by postcode (https://opendatacommunities.org/def/concept/folders/themes/societal-wellbeing)].

Descriptive statistics of the sexual history and sexual behaviour baseline measures are shown in *Tables 2–6*. The average number of lifetime sexual partners was 10, 93% of participants had ever used a condom and 30% had previously received a positive STI diagnosis. A third of participants reported having a long-term sexual partner, 19% (*n* = 36) of whom also reported casual sex with others.

At baseline, 86% of participants reported being sexually active during the last 4-week period. Of those who were sexually active, 28% reported sex with a man and 41% reported use of a condom.

Tables 7–11 present the descriptives for the condom scales, acceptance of chlamydia screening, HRQoL measures, participant retention and chlamydia test positivity.

Six per cent of participants did not agree to chlamydia screening. Among those who did, only 58% provided a valid sample (*n* = 312) despite reminders being sent out to return the postal screening kits.

TABLE 1 Demographic statistics and background characteristics by arm and for total sample

Variable	HIS-UK (*n* = 351)	Control (*n* = 224)	Total (*N* = 575)
Age at randomisation (median)	21 IQR: 20–23	22 IQR: 20–24	21 IQR: 20–24
Ethnicity			
White	284 (80.9%)	183 (81.7%)	467 (81.2%)
Black	21 (6.0%)	13 (5.8%)	34 (5.9%)
South Asian	26 (7.4%)	15 (6.7%)	41 (7.1%)
Other	20 (5.7%)	13 (5.8%)	33 (5.7%)
Education and training			
Full-time	175 (49.9%)	97 (43.3)	272 (47.3%)
Part-time	22 (6.3%)	16 (7.1%)	38 (6.6%)
No	152 (43.3%)	111 (49.6%)	263 (45.7%)
Employment			
Full-time	149 (42.5%)	100 (44.6%)	249 (43.3%)
Part-time	93 (26.5%)	62 (27.7%)	155 (27.1%)
No	106 (30.2%)	62 (27.7%)	168 (29.2%)
Social deprivation			
1 – Most deprived	57 (16.2%)	39 (17.4%)	96 (16.7%)
2	76 (21.7%)	53 (23.7%)	129 (22.4%)

continued

TABLE 1 Demographic statistics and background characteristics by arm and for total sample (*continued*)

Variable	HIS-UK (*n* = 351)	Control (*n* = 224)	Total (*N* = 575)
3	85 (24.2%)	41 (18.3%)	126 (21.9%)
4	77 (21.9%)	41 (18.3%)	118 (20.5%)
5 – Least deprived	44 (12.5%)	33 (14.7%)	77 (13.4%)
Highest level of education completed			
GCSE/BTEC level 1–2	46 (13.1%)	34 (15.2%)	80 (13.9%)
A-Level/ BTEC level 3	168 (47.9%)	97 (43.3%)	265 (46.1%)
BTEC professional level 4–7	11 (3.1%)	11 (4.9%)	22 (3.8%)
Degree	94 (26.8%)	55 (24.6%)	149 (25.9%)
Masters	25 (7.1%)	18 (8.0%)	43 (7.5%)
Doctorate	0 (0.0%)	2 (0.9%)	2 (0.3%)
Other	6 (1.7%)	6 (2.7%)	12 (2.1%)
Missing	1 (0.3%)	1 (0.4%)	2 (0.3%)

BTEC, Business and Technology Education Council; GCSE, General Certificate of Secondary Education; IQR, interquartile range.

TABLE 2 Frequencies and percentages of sexual history at baseline by arm and for total sample

Variable	HIS-UK (*n* = 351)	Control (*n* = 224)	Total (*N* = 575)
Number of lifetime sexual partners (median)	10 IQR: 5–20	10 IQR: 4–20	10 IQR: 5–20
Intercourse ever with a man	123 (35.0%)	81 (36.2%)	204 (35.5%)
Intercourse ever with a woman	275 (78.3%)	167 (74.6%)	442 (76.9%)
Intercourse ever with an individual who did not identify as either a man or woman	27 (7.7%)	15 (6.7%)	42 (7.3%)
Previous STI diagnosis	102 (29.6%)	68 (30.6%)	170 (30.0%)
HIV diagnosis	2 (0.6%)	0 (0.0%)	2 (0.3%)
Use of erectile dysfunction medication	21 (6.6%)	19 (8.6%)	42 (7.4%)
Ever used a condom	328 (93.4%)	209 (93.3%)	537(93.4%)
Ever used lubricant	306 (87.2%)	196 (87.5%)	502 (87.3%)

TABLE 3 Frequencies and percentages of current relationship status at baseline by arm and for total sample

Relationship status	HIS-UK (*n* = 351) (%)	Control (*n* = 224) (%)	Total (*N* = 575) (%)
In a monogamous regular/long-term partnership	103 (29.4)	50 (22.3)	153 (26.7)
In a regular/long-term partnership and have casual sex partners	19 (5.4)	17 (7.6)	36 (6.2)
Not in a regular/long-term partnership but have frequent casual sex partners	95 (27.1)	42 (18.8)	137 (23.9)
Not in a regular/long-term partnership but have occasional casual sex partners	123 (35.1)	106 (47.3)	229 (39.9)
Not currently sexually active	10 (2.9)	9 (4.0)	19 (3.3)

TABLE 4 Descriptive statistics of sexual behaviour in last 4 weeks by arm and for total sample

Variable	HIS-UK, *n* = 310	Control, *n* = 185	Total, *N* = 495
Number of sexual partners (median)	1 IQR: 1–3	1 IQR: 1–2	1 IQR: 1–2
Number of episodes of intercourse (median)	5 IQR: 2–10	4 IQR: 2–8.5	4 IQR: 2–10
Intercourse with a man	90 (29.0%)	49 (26.5%)	139 (28.1%)
Intercourse with a woman	226 (72.9%)	137 (74.1%)	363 (73.3%)
Intercourse with an individual who did not identify as either a man or woman	5 (1.4%)	4 (1.8%)	9 (1.8%)
Sex with a regular/long-term partner	150 (48.4%)	83 (44.9%)	233 (47.1%)
Sex with a new/casual partner	223 (71.9%)	145 (78.4%)	368 (74.3%)
Use of a condom	118 (38.1%)	84 (45.4%)	202 (40.8%)
Use of lubricant with any condoms used	62 (52.5%)	40 (49.4%)	102 (51.3%)
Use of lubricant with last condom used	55 (47.4%)	31 (38.3%)	86 (43.7%)
Correct use (start to finish) of last condom used	73 (63.5%)	52 (65.0%)	125 (64.1%)

TABLE 5 Frequencies and percentages of consistency of condom use during episodes of sex occurring within the last 4 weeks by trial arm and for total sample

Variable	HIS-UK	Control	Total
Consistency of condom use (regular partners)	*n* = 58	*n* = 38	*n* = 96
Every act	15 (25.9%)	7 (18.4%)	22 (22.9%)
Infrequent	38 (65.5%)	25 (65.8%)	63 (65.6%)
Never	5 (8.6%)	6 (15.8%)	11 (11.5%)
Consistency of condom use (casual partners)	*n* = 81	*n* = 62	*n* = 143
Every act	20 (24.7%)	18 (29.0%)	38 (26.6%)
Infrequent	61 (75.3%)	44 (71.0%)	105 (73.4%)
Never	0 (0.0%)	0 (0.0%)	0 (0.0%)

TABLE 6 Frequencies and percentages of condom use at most recent sex by trial arm and for total sample

Variable	HIS-UK	Control	Total
Use of a condom at last sex with regular partner	31 (53.4%)	17 (44.7%)	48 (50.0%)
Use of a condom at last sex with new/casual partner	51 (60.7%)	40 (64.5%)	91 (62.3%)

TABLE 7 Descriptive statistics of condom scale and score items by trial arm and for total sample

Variable	HIS-UK	Control	Total
Condom use experience scale			
Seven-item; Likert; mean score (min 1, max 5)	3.47	3.43	3.46
Higher score – more barriers	SD 0.66	SD 0.63	SD 0.65
Condom use attitudes scale			
Five-item; Likert; mean score (min 1, max 5)	3.63	3.68	3.65
Higher score – more negative attitudes	SD 0.75	SD 0.71	SD 0.74
Pleasurable condom use scale			
Five-item; Likert; mean score (min 1, max 5)	2.29	2.25	2.27
Higher score – more positive	SD 0.77	SD 0.74	SD 0.76
Condom use self-efficacy scale			
Likert; mean score (min 1, max 5)			
Higher score – greater self-efficacy			
Seven-item	3.39 SD 0.77	3.41 SD 0.72	3.40 SD 0.75
Three-item	3.35 SD 0.90	3.32 SD 0.98	3.33 SD 0.95
Condom use motivation scale			
Single item; Likert; min 1, max 5	3.07	3.13	3.09
Higher score – greater desire	SD 1.13	SD 1.16	SD 1.14
Condom fit and feel			
General score (condoms used in last 4 weeks)			
Four-item; binary; total score (min 0, max 8)	0.81	0.91	0.91
Higher score – poorer fit and feel	SD 0.88	SD 0.92	SD 1.04
Issues/problems reported at last use *Two-item; binary outcome; (min 0, max 1)*			
Yes	58 (50%)	43 (53.8%)	101 (51.5%)
No	58 (50%)	37 (46.3%)	95 (48.5%)
Condom use errors and problems at last use score			
14-item; binary; total score (min 0, max 14)	4.04	3.66	3.89
Higher score – more errors	SD 2.11	SD 1.82	SD 2.00

max, maximum; min, minimum; SD, standard deviation.

TABLE 8 Frequencies and percentages of acceptance of chlamydia screening by trial arm and for total sample

Variable	HIS-UK (%)	Control (%)	Total (%)
Response to request to provide samples			
Agreed	327 (93.2)	211 (94.2)	538 (93.6)
Declined	21 (6.0)	11 (4.9)	32 (5.6)
No response given	3 (0.9)	2 (0.9)	5 (0.9)
Provision of valid samples			
Yes	199 (60.9)	113 (53.6)	312 (58.0)
No	128 (39.1)	98 (46.4)	226 (42.0)

TABLE 9 Health status and HRQoL indicators at baseline by trial arm and for total sample

Health variable	HIS-UK	Control	Total
EQ-5D-5L	***n = 325***	***n = 206***	***N = 531***
EQ VAS	73.4 SD 16.5	72.7 SD 15.8	73.1 SD 16.2
SF-12	***n = 328***	***n = 215***	***N = 543***
PCS-12	55.5 SD 5.5	55.8 SD 5.2	55.6 SD 5.4
MCS-12	43.6 SD 9.4	42.2 SD 10.4	43.1 SD 9.8
GP prescribed medication	***n = 351***	***n = 224***	***N = 575***
Psychiatric	36 (10.3%)	31 (13.8%)	67 (11.7%)

TABLE 10 Frequencies and percentages of participant retention by trial arm and for total sample

Retention at	HIS-UK, *n* = 351 (%)	Control, *n* = 224 (%)	Total, *N* = 575 (%)
1 month (T1)	164 (46.7)	133 (59.4)	297 (51.7)
3 months (T3)	132 (37.6)	87 (38.8)	219 (38.1)
6 months (T6)	113 (32.2)	76 (33.9)	189 (32.9)

TABLE 11 Descriptive statistics of chlamydia test positivity at baseline and by 6 months post randomisation by trial arm and for total sample

Chlamydia test positivity	HIS-UK	Control	Between-arm absolute difference p.p. (95% CI)	Total
Baseline	*n* = 199 17 (8.54%)	*n* = 113 13 (11.50%)		*N* = 312 30 (9.62%)
By 6 months (T6)	*n* = 76 6 (7.89%)	*n* = 47 6 (12.77%)	4.87 (−5.92 to 15.66)	*N* = 123 12 (9.75%)

p.p., percentage point.

Comparative exploratory analyses explored differences (at 5% level of significance) between participants who provided chlamydia screening data, and those who did not, at baseline (see *Appendix 1*, *Table 21*). The following observations were made:

- Younger participants were less likely to provide baseline screening samples.
- Those of South Asian ethnicity were less likely to engage in baseline screening.
- Those not in employment were more likely to provide samples (note: financial incentive to participate).
- Participants who reported sex with other men and/or with non-binary partners were more likely to provide samples.
- Those with a fewer number of lifetime sexual partners were less likely to provide samples for testing.
- Participants who had previously experienced a positive STI result were more likely to provide samples.
- Those recruited in clinical settings were more likely to be tested.

Outcome analysis

Amendment

The majority of analyses presented in the following section were in the original SAP, with the modification that proHIS and eHIS participants were combined into a single HIS-UK trial arm for comparative purposes due to the recruitment shortfall. Additionally, all repeated-measures analyses were conducted using data from baseline to the 6-month follow-up, rather than extending to 12 months, because of the study's early closure.

One additional post hoc analysis was added to the analysis plan as a result of the protocol changes: a comparison between participants recruited from clinical trial settings (CTRS participants) and those who self-registered online to the trial (OSR) to help explore any potential selection or sampling bias.

Methods analyses were by intention-to-treat (ITT) principles comparing HIS-UK (proHIS and eHIS) with the control. The primary outcome is presented descriptively by trial arm. A logistic regression model of chlamydia test result at follow-up was also fitted to examine the intervention effect after adjusting for chlamydia test result at baseline and the stratification factors of recruitment (site, ethnicity and sexual partnering/risk).

For continuous secondary outcomes, linear mixed-effects models were used. These models included the following fixed covariates: time (questionnaire month), trial group (HIS-UK/control) and the stratification factors of recruitment. Additionally, a time by trial group interaction term was also tested for. Repeated measures within individual participants were accounted for using a random effect. For binary outcomes, logistic regression models were fitted using generalised estimating equations with an autoregressive-1 correlation structure. From each model, the estimated intervention effects between the HIS-UK and the control are presented [i.e. difference in estimated marginal means (EMM), or odds ratios (ORs) as appropriate] along with their corresponding 95% confidence intervals (CIs) and *p*-value from a test of no intervention effect. In the analyses, time is referred to as an ordered categorical variable since it was not measured at evenly spaced intervals for each participant and contained the intervention between two of the time points (baseline–T1). All analyses were performed using IBM SPSS Statistics version 29.0.1 [IBM Corporation, Armonk, NY, USA (IBM SPSS Statistics from version 19 onwards)].

Missing data

The procedures for handling missing data in the secondary analyses were as follows:

1. Participants who provided a baseline measure of outcome but failed to provide any postintervention monthly outcome data were not excluded from the respective analyses following ITT principles.
2. Multiple imputation methodology was used when required for all user-missing outcome measures among eligible participants in each analysis.
3. A mixed-model approach was used to handle unbalanced data. Unequal repeats of monthly outcome measures (T1–T12) among eligible participants in each analysis (system missing due to not applicable, i.e. not using a condom during a month).

Participant retention

Post baseline, half of all participants (52%) completed at least one follow-up questionnaire. A third of participants (n = 189) reached the primary end point at 6 months post randomisation completing the T6 questionnaire.

Comparative analyses were conducted to explore distinctions and potential attrition bias (at 5% level of significance) between participants exclusively involved in baseline and intervention activities and those who continued to contribute additional data during the follow-up period (see *Appendix 1*, *Table 21*). Participants who were not in paid employment demonstrated greater

engagement with the follow-up activities than men in employment, possibly having more time and being influenced by the study incentives. Additionally, men engaging in sexual activities with other men or individuals identifying outside the traditional gender binary were more likely to offer follow-up data than cisgender men who reported sex with women only. Finally, participants randomised to the control were more likely to engage post baseline than HIS-UK participants.

Similar bivariate analyses were performed to investigate the differences between participants who reached the primary end point at 6-month follow-up and those who did not. Cisgender men who reported sexual activity exclusively with women were less likely to complete the T6 follow-up questionnaire compared to men who reported sex with men and/or non-binary individuals. All other comparisons showed no variation.

Primary health outcome

Chlamydia test positivity

At the primary end point, the absolute difference in chlamydia test positivity rates between HIS-UK and the control was −4.9 percentage points (95% CI: −15.66 to 5.92); 7.9% for HIS-UK participants and 12.8% for the control.

Variation in chlamydia test positivity was evident between participants recruited through the two distinct strategies, as indicated in *Tables 12* and *13*. At the primary end point, the absolute difference between the two arms for individuals recruited from or allocated to clinical settings (CTRS) was 8.3 percentage points (95% CI: −7.36 to 23.98). Specifically, rates were 7.7% for HIS-UK participants and 16.0% for the control. For community OSR recruits, the differences were more modest, with a 1% percentage point variance observed at 6 months post randomization (95% CI: −13.71 to 15.68). Notably, the rates stood at 8.1% for HIS-UK participants and 9.1% for the control.

Comparative analyses were again conducted to explore the differences between participants who provided chlamydia screening data at baseline only and those who provided data both at baseline and during follow-up (see *Appendix 1*, *Table 21*). No statistically significant differences were observed.

Table 14 displays the parameter estimates derived from the logistic regression models for chlamydia test positivity at follow-up. As shown, the odds of receiving a positive test at follow-up were reduced by 55% for HIS-UK participants as compared to the control (reference) after accounting for baseline chlamydia screening, ethnicity, recruitment site and sexual risk (95% CI: 0.113 to 1.805; $p = 0.261$). This reduction, however, was not statistically significant. Similar reductions were also evident for the CTRS and OSR subsamples; again, neither were shown to be statistically significant.

Secondary outcomes

The secondary process outcomes, through which the primary outcome is likely to be realised, reflect condom competency and enjoyment. Indicators modelled included the condom attitudes and opinion scales items (see further details above), behavioural measures of condom use (condom use during last month, condom use at last intercourse and consistency of condom use during the previous 4 weeks) and lubricant use (during last month and at last condom usage).

Attitude and opinion scale responses were collected monthly from all participants; as such, all 575 participants provided at least one response. Behavioural measures were collected monthly from among eligible participants only. For example, 340 participants reported sex with a regular partner within the previous 4 weeks on at least one occasion during the trial period and provided condom use data.

Comparisons between the HIS-UK arm and the control based on EMM are displayed. EMM provided a way to understand the average effect of an independent variable (i.e. the intervention) while holding other variables constant. In this context, the EMM shows the average score on the outcome of interest for participants in each of the trial arms. These means are estimated while accounting for the influence of other variables in the model, such as ethnicity, recruitment site and sexual risk.

Odds ratios are presented in *Table 16*. These describe the effect of an independent variable (in this case, the HIS-UK intervention) on the odds of an outcome occurring after controlling for all other factors in the model. An OR > 1 indicates an increased odds of the outcome, and < 1 indicates a decreased odds.

Attitudes and opinions

Table 15 displays the intervention arm and the intervention arm by time interaction fixed effects derived from the linear mixed-effects models determining the attitudinal scale items measured by the monthly questionnaires. As shown, a significant interaction effect between the intervention arm and time was observed for all the scale items; consequently, the EMM by trial arm and time displayed in *Figures 4–8* should be considered.

TABLE 12 Descriptive statistics of chlamydia test positivity among CTRS participants at baseline and by 6 months post randomisation by trial arm and for total sample

Chlamydia test positivity	HIS-UK	Control	Between arm absolute difference p.p. (95% CI)	Total
Baseline	*n* = 106 13 (12.26%)	*n* = 54 8 (14.81%)		*N* = 160 21 (13.13%)
By 6 months (T6)	*n* = 39 3 (7.69%)	*n* = 25 4 (16.00%)	8.31 (−7.36 to 23.98)	*N* = 64 7 (10.94%)

p.p., percentage point.

TABLE 13 Descriptive statistics of chlamydia test positivity among OSR participants at baseline and by 6 months post randomisation by trial arm and for total sample

Chlamydia test positivity	HIS-UK	Control	Between arm absolute difference p.p. (95% CI)	Total
Baseline	*n* = 93 4 (4.30%)	*n* = 59 5 (8.47%)		*N* = 152 9 (5.92%)
By 6 months (T6)	*n* = 37 3 (8.11%)	*n* = 22 2 (9.09%)	0.98 (−13.71 to 15.68)	*N* = 59 5 (8.47%)

p.p., percentage point.

TABLE 14 Home-based intervention strategy UK intervention parameter estimates (ORs) for chlamydia test positivity at 6 months post randomisation for the total, CTRS and OSR samples[a]

Participants	*N*	OR (95% CI)	*p*-value
Total		0.452 (0.113 to 1.805)	0.261
CTRS (clinical)	210	0.454 (0.085 to 2.432)	0.356
OSR (community)	370	0.393 (0.030 to 5.118)	0.476

a Logistic regression model included: trial group, chlamydia test positivity at baseline, ethnicity, site, sexual risk.

TABLE 15 Selected tests of fixed-effects for the continuous secondary attitudinal scale outcomes[a]

Outcome variable	*N*	Trial arm	Trial arm by time
Condom use experience scale *Higher score – more barriers*	575	$F = 12.805$, $df = 1$, $p < 0.001$	$F = 8.419$, $df = 6$, $p < 0.001$
Condom use attitudes scale *Higher score – more negative attitudes*	575	$F = 26.070$, $df = 1$, $p < 0.001$	$F = 7.624$, $df = 6$, $p < 0.001$
Pleasurable condom use scale *Higher score – more positive*	575	$F = 27.696$, $df = 1$, $p < 0.001$	$F = 9.082$, $df = 6$, $p < 0.001$
Condom use self-efficacy scale *Higher score – greater self-efficacy*			
Seven-item	575	$F = 4.445$, $df = 1$, $p = 0.035$	$F = 2.679$, $df = 6$, $p = 0.014$
Three-item (partners)	575	$F = 8.512$, $df = 1$, $p = 0.004$	$F = 5.221$, $df = 6$, $p < 0.001$
Condom use motivation scale *Higher score – greater desire*	575	$F = 5.078$, $df = 1$, $p = 0.025$	$F = 3.744$, $df = 6$, $p = 0.001$

a Linear mixed-effects model for repeated measures with unbalanced responses. Factors included: trial group, ethnicity, site, sexual risk, time, time × trial group.

A higher score on the *condom use experience scale* and the *condom use attitudes scale* is indicative of increased barriers and more negative attitudes. As illustrated, the EMM scores for both scale items exhibited a significant and enduring decrease among HIS-UK participants, following the delivery of the intervention post baseline. In comparison, little change was observed in the EMM scale scores post intervention delivery among the control.

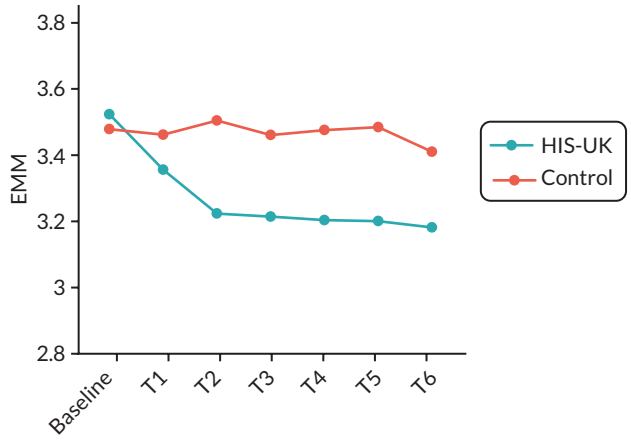

FIGURE 4 Condom use experience scale EMM by trial arm and time.

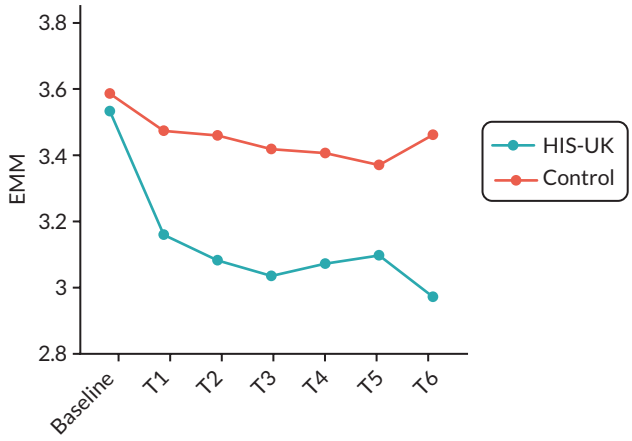

FIGURE 5 Condom use attitudes scale EMM by trial arm and time.

A higher score on the two self-efficacy scales reflected greater condom confidence. As illustrated in *Figure 6*, HIS-UK participants reported increased and sustained confidence in their ability to use condoms effectively post baseline and intervention arm delivery (T1–T6) after controlling for all other factors as compared to the control.

Likewise, a marked and statistically significant impact of the HIS-UK intervention over time was observed for responses to the *pleasurable condom use scale* and *condom motivation scale*. Participants expressed heightened and sustained agreement that condoms can increase enjoyment of sexual experiences, following delivery of HIS-UK (*Figure 7*). Furthermore, HIS-UK participants' desire to use condoms with their sexual partners remained consistent during the follow-up period (T1–T6), while motivation declined among the control (*Figure 8*).

Behavioural

The impact of the HIS-UK intervention on the behavioural measures was more limited, with fewer noticeable effects observed.

Table 16 displays the intervention effect for selected binary behavioural outcome measures, expressed as the OR parameter estimates from the generalised estimated repeated logistic regression equation model. *Table 17* displays the intervention arm EMM score differences from the linear mixed models determining two behaviour score items.

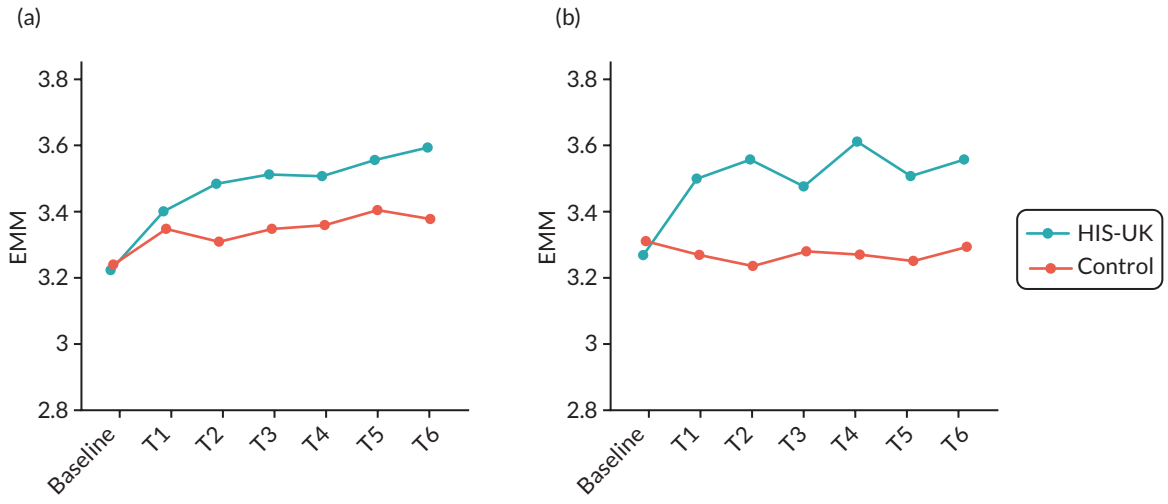

FIGURE 6 Condom use self-efficacy scale EMM by trial arm and time. (a) Seven-item scale. (b) Three-item scale.

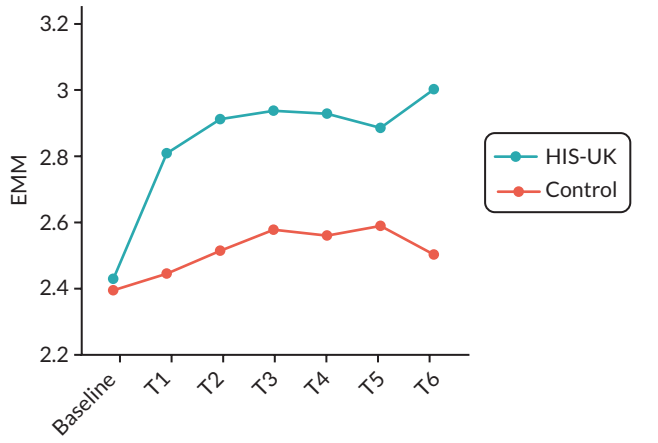

FIGURE 7 Pleasurable condom use scale EMM by trial arm and time.

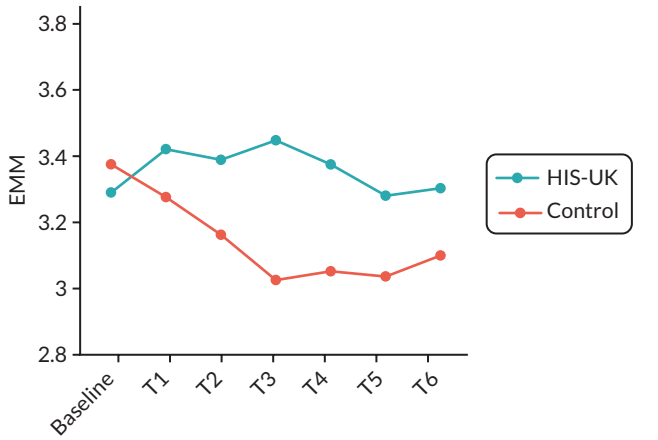

FIGURE 8 Condom use motivation scale EMM by trial arm and time.

As illustrated by *Table 16*, modelling showed a strong interactional effect of the intervention arm with time for usage of condoms with sexual partners during the previous 4-week period (Wald $\chi^2 = 27.79$, $df = 6$, $p < 0.001$). As illustrated in *Figure 9*, in the first month post intervention, condom use among sexually active participants in the HIS-UK arm peaked, exhibiting a heightened likelihood of condom use during the month compared to the control. This effect diminished, however, with time and usage was at a similar level between the groups at T4 onwards.

Figure 10 displays the percentage of condom use at last sex by partner type, at each time point. When the data were modelled, no apparent intervention effect or time-by-intervention interaction was evident (see *Table 16*). Furthermore, no intervention effect was seen when consistency of condom use with casual partners, as measured by the binary outcome of irregular condom use during the month versus usage at every act, was modelled [OR: 1.198 (95% CI: 0.663 to 2.167), $p = 0.549$].

As expected, there was, however, a significant time effect for the behavioural outcomes of condom use at last sex with a casual partner and consistency of condom use with casual partners (see *Table 16*); condom use and consistency of use were more likely at every month post intervention as compared to baseline (reference category). This was due in part to the effect of our study participant recruitment eligibility

TABLE 16 The HIS-UK intervention parameter estimates (ORs) for selected binary behavioural outcomes occurring during last 4 weeks[a]

Outcome variable	*N*	Estimated intervention effect HIS-UK vs. C-group (95% CI)[b]	Time, *p*-value[c]	Trial arm by time[c]
Condom use in last month	532			$\chi^2 = 27.787$, $df = 6$, $p < 0.001$
Condom use at last sex with regular partner	192	1.378 (0.820 to 2.315), $p = 0.225$	0.445	–
Condom use at last sex with casual partner	248	1.208 (0.836 to 1.747), $p = 0.314$	< 0.001	–
Consistency of condom use with casual partners (always vs. irregular)	237	1.198 (0.663 to 2.167), $p = 0.549$	< 0.001	–
Correct use (start to finish) for last condom used	308	1.211 (0.796 to 1.844), $p = 0.371$	0.879	–
Condom fit and feel issues (last use)	311	0.725 (0.470 to 1.120), $p = 0.148$	< 0.001	–
Lubricant use (in last month)	313			$\chi^2 = 12.55$, $df = 6$, $p = 0.051$
Lubricant use with last condom used	312	1.511 (0.967 to 2.361), $p = 0.070$	0.281	–

a Generalised estimating equation model for a repeated-measures logistic regression with factors: trial group, ethnicity, site, sexual risk, time, time*trial group.
b OR of model parameter estimates.
c Wald chi-square.

TABLE 17 Estimated effect (EMM difference) of the HIS-UK intervention and tests of fixed-effects for selected behavioural score outcomes[a]

Outcome variable	*N*	Estimated intervention effect HIS-UK vs. control (95% CI)[b]	Trial arm by time
Condom use errors and problems score *Higher score – more errors*	537	−0.459 (−0.886 to −0.033), $p = 0.035$	$F = 2.765$, $df = 6$, $p = 0.012$
Condom fit and feel score *Higher score – poorer fit and feel*	537	−0.095 (−0.300 to 0.110), $p = 0.363$	$F = 1.878$, $df = 6$, $p = 0.082$

a Linear mixed-effects model for repeated measures with unbalanced responses; factors included: trial group, ethnicity, site, sexual risk, time, time*trial group.
b Pairwise comparison based on EMM.

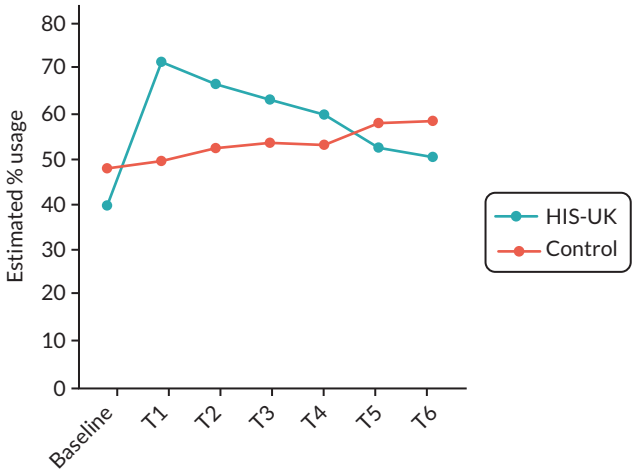

FIGURE 9 Estimated percentage usage of condoms during last month by trial arm and time.

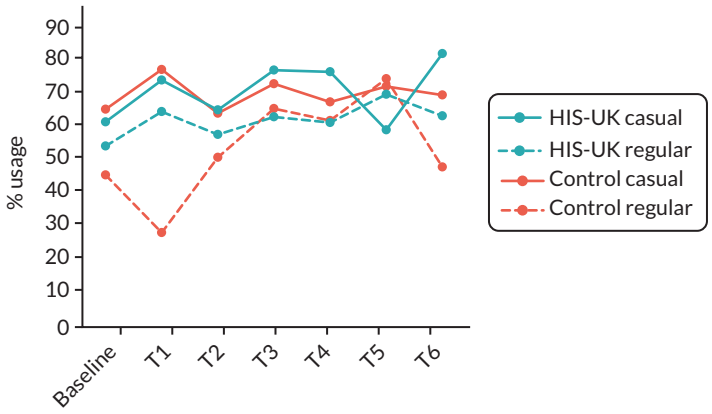

FIGURE 10 Reported percentage condom use at last sex by partner type, trial arm and time.

requirement of the recent occurrence of condomless sex with a casual or new partner.

Figure 11 shows there was also a significant effect of time (Wald $\chi^2 = 27.88$, $df = 6$, $p < 0.001$, full data not shown in *Table 16*) on condom comfort. The model revealed a consistent decline in the likelihood of participants reporting poor fit and feel of their last condom from baseline to T6. There was no apparent effect of HIS-UK (OR: 0.725, 95% CI: 0.470 to 1.120, $p = 0.148$), as the decline was evident among both trial arms.

Figure 12 depicts the effect of HIS-UK on the usage of lubricants at monthly intervals post intervention delivery. The likelihood of lubricant being used was greater among the HIS-UK participants than the control during the months following intervention delivery (Wald $\chi^2 = 12.55$, $df = 6$, $p = 0.051$). Furthermore, the odds of lubricant usage

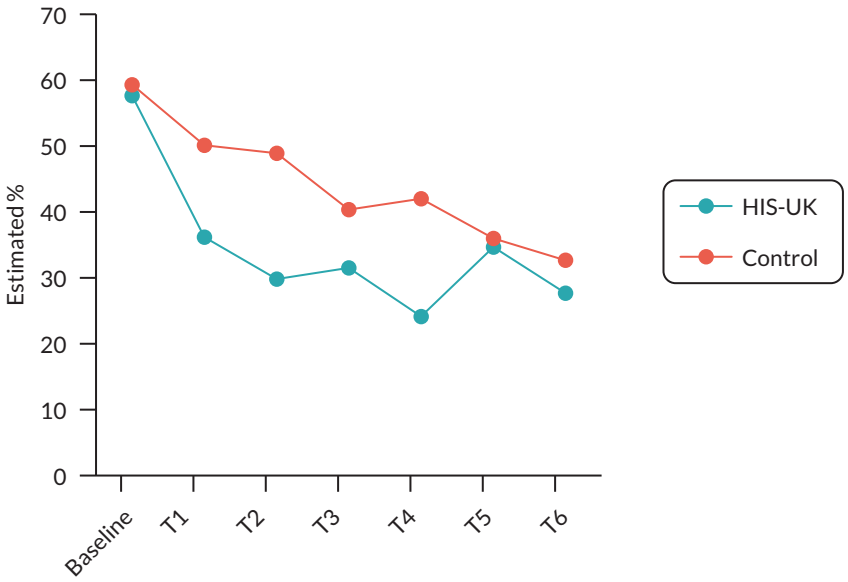

FIGURE 11 Estimated percentage reporting poor fit and feel of last condom used by trial arm and time.

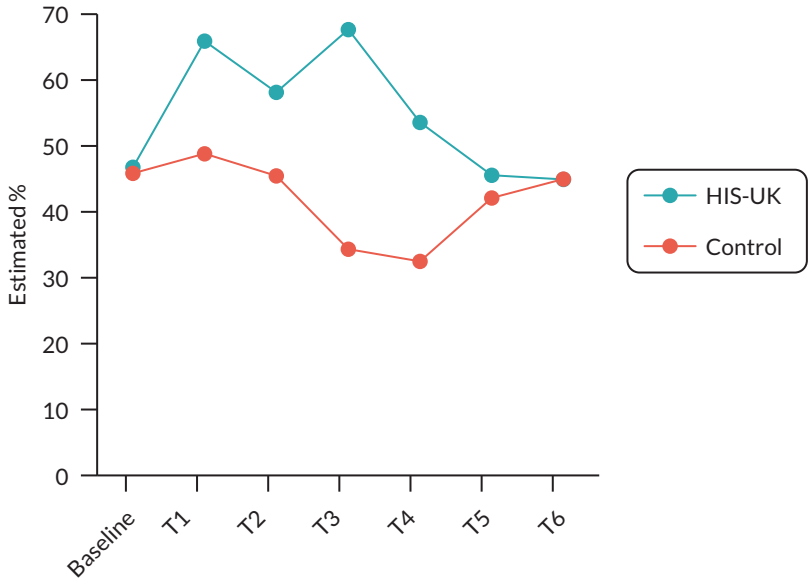

FIGURE 12 Estimated usage of lubricant during last month by trial arm and time.

at last condom usage were 51% higher among HIS-UK participants than the control (95% CI: 0.967 to 2.361, $p = 0.070$), although not proven statistically significant at the 5% level.

Linear mixed-effect models were fitted for the two behavioural scores measures of condom use errors and problems and condom fit and feel. After controlling for ethnicity, recruitment site and sexual risk, the average condom use error score was significantly lower among the HIS-UK participants than the control (EMM diff: −0.459, 95% CI −0.886 to −0.033, $p = 0.035$) with a clear intervention by time interaction ($F = 2.76$, $df = 6$, $p = 0.012$). *Figure 13* illustrates a marked and consistent decline in condom use errors after baseline among the HIS-UK participants.

An intervention by time interaction trend was also observed for the fit-and-feel scoring of condoms used during the last month ($F = 1.88$, $df = 6$, $p = 0.082$). As shown in *Figure 14*, discomfort scores remained high in the few months post baseline among the control prior to declining. This compares to the HIS-UK participants who reported improved and sustained condom comfort following intervention delivery up to T5.

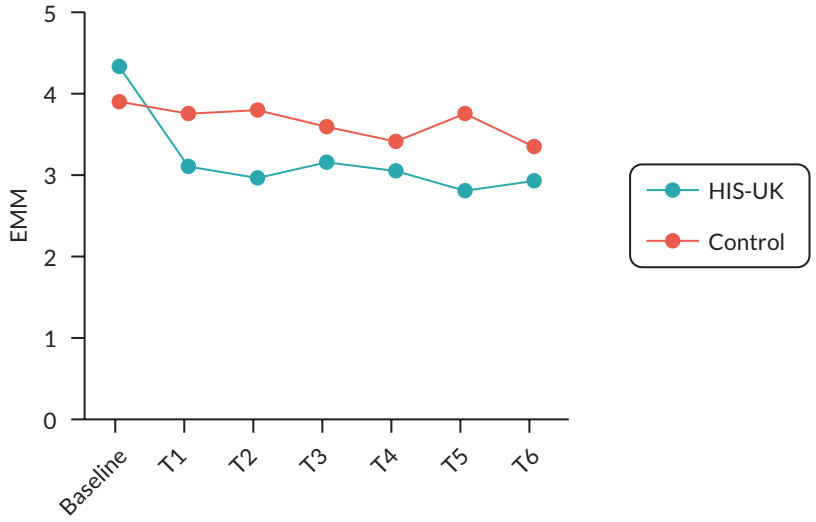

FIGURE 13 Condom use errors and problems score EMM by trial arm and time.

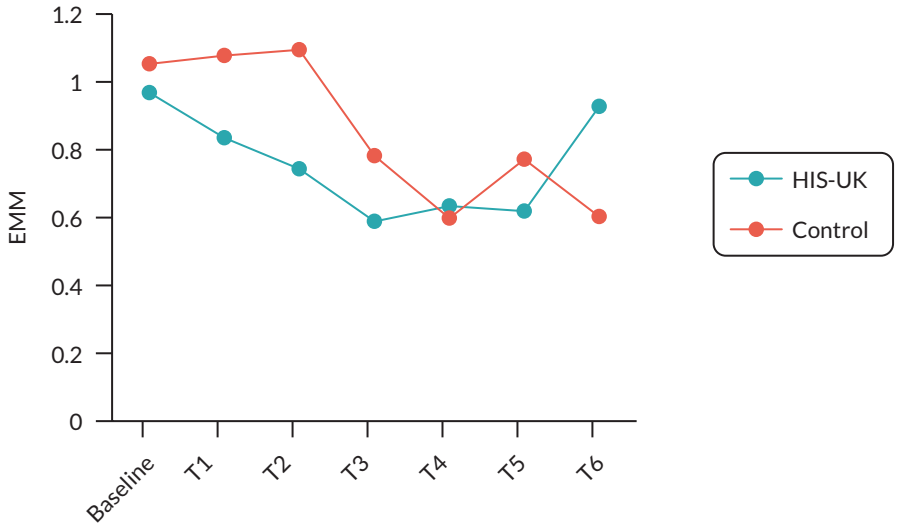

FIGURE 14 Condom fit and feel issues during the last month, EMM by trial arm and time.

Health economic analysis

The economic analysis considered the costs and outcomes associated with the three arms of the trial. This involved evaluating the costs and benefits of the two delivery models for the HIS-UK intervention (proHIS and eHIS) as compared with usual care. If proHIS and/or eHIS were seen to be effective in improving the competency for consistent and correct condom use and in reducing the incidence of STIs, there are likely to be important cost implications for the healthcare sector, for the wider public sector and for society.

Methodology

A comprehensive economic evaluation of the HIS-UK intervention was initially intended, integrating both CUA and CEA, to ensure that both quality-of-life improvements and specific health outcomes were considered when determining its value for money. However, due to the premature closure of the HIS-UK trial, recruitment challenges and diminished participant follow-up, a basic economic assessment was conducted instead. A simple descriptive analysis of costs and outcomes was performed from the perspective of the NHS. The analysis entailed a comparison of costs and outcomes between the two intervention arms and the control, with a focus on the costs associated with the delivery of proHIS and eHIS compared with the control. A series of one-way deterministic sensitivity analyses were carried out on the per-participant costings. These included: (1) reducing the follow-up condom supply distribution within HIS-UK to a collection service (i.e. c-card scheme); (2) including the health service costs for

treating all positive chlamydia cases occurring during follow-up and (3) including broader societal costs associated with participant time, with the assumption that foregone leisure time was valued at 40% of the median hourly wage for a 18- to 21-year-old male.[39] Costs and outcomes were then assessed in a disaggregated manner for each intervention arm to establish whether any clear differences were evident based on the data available. We examined the costs and consequences for all three arms. The analyses were based on the health outcome of chlamydia test positivity.

Resource use and cost definition

Specially designed posters, fliers, advertising cards, intervention delivery packs, online educational materials and HIS-UK condom kits were used at all clinical locations to promote recruitment and provide the equipment necessary for participation and trial delivery. The educational materials and condom kits were considered to be an essential part of the intervention and were included in the costing estimates. The online education materials (delivered during eHIS) were assumed to be reusable over a period of 3 years before becoming outdated, and as such, all design and editing costs were annuitised for 3 years at an interest rate of 5%.

The HIS-UK intervention was designed as an 'add-on' to the safe sex advice and condom information delivered during a usual condom distribution care consultation. As such, the estimated costs for proHIS included costs for a staff member (healthcare assistant) to deliver the additional HIS-UK education and training, plus the cost of the HIS-UK condom kit and monthly postal supplies of condoms and lubricants for a duration of 6 months. The estimated costs of eHIS were limited to the costs of a staff member providing a weblink for the HIS-UK educational website and the provision of a HIS-UK condom kit and additional monthly postal supplies. For the control, the time for a healthcare assistant undertaking a usual condom distribution care consultation was included along with the provision of usual condom supplies, plus additional supplies (e.g. c-card, in-person collection) over a 6-month follow-up period.

In all cases, it was assumed that the time taken by the HIS-UK participants to engage in the guided home-based condom exercises was forgone leisure time and would not impact on health service costs. However, it is recognised that this assumption may not apply to all participants. Some individuals may have had to forgo productive work hours, affecting the true economic cost of the intervention.

Results

Table 18 contains the information on health service costs for each intervention arm.

In the trial, the average cost per delivery of the proHIS intervention was £30.26, which was twice the cost of eHIS (£15.88) and three times greater than the control (usual care) at £10.03. The eHIS intervention was approximately 50% more expensive than the control.

Effectiveness was measured as the absolute difference in chlamydia test positivity (i.e. 4.9 percentage points). The ICER for proHIS was therefore £412.86 per case prevented, and for eHIS, £119.39 per case prevented, as compared to usual care.

The 95% CI for effectiveness ranged from 15.7% to −5.9%. Therefore, in the best-case scenario (greater effectiveness, e.g. a 15.7 percentage point absolute reduction in positivity), the ICERs would be £129.19 for proHIS and £37.37 for eHIS.

A cost sensitivity analysis explored different intervention conditions, such as removing postal distribution, adding the treatment costs for positive chlamydia cases and considering participant time as an economic cost. These adjustments led to variations in per-participant costs across the three arms, with proHIS remaining the most expensive intervention (*Table 19*). For the results on the ICER, see *Table 20*.

Qualitative process evaluation

A mixed-methods approach was used to examine how the intervention was implemented, possible mechanisms of impact and contextual factors that may have influenced implementation of the intervention.

Two researchers conducted the one-to-one semi-structured interviews. Data were analysed using a codebook approach to thematic analysis.

Results

Five audio recordings between SS and participants were taken. During the blind review of these recordings, intervention fidelity was observed in all instances.

Twenty-five interviews were conducted with participants aged 18–25 years (mean n = 22). This included 17 from the HIS-UK arm and 8 from the standard care arm. Eleven

TABLE 18 Health service costs for intervention arms

Trial arm	Resources used	Cost item	Unit cost (£)	*N*	Total cost (£)
proHIS	Staff training	Per site	54.00	9	486.00
	Consultation	Per pt	12.00	125	1500.00
	HIS-UK condom kit	Per pt	4.66	125	582.50
	Follow-up postal supplies[a]	Per pt.p.m	3.88	313	1214.44
Total					3782.94
eHIS	Staff training	Per site	3.00	9	27.00
	Consultation	Per pt	1.80	226	406.80
	On-line training[b]	Per year	341.25	1	341.25
	HIS-UK condom kit	Per pt	4.66	226	1053.16
	Follow-up postal supplies[a]	Per pt.p.m	3.88	454	1761.52
Total					3589.73
Control	Consultation	Per pt	6.00	224	1344.00
	Condom supplies	Per pt	1.20	224	268.80
	Follow-up supplies (c-card)[a]	Per pt.p.m	1.20	529	634.8
Total					2247.60

pt, per patient; pt.p.m, per patient per month
a 6-month follow-up.
b Includes costs for the first year of the design elements of the online education materials, annuitised at 5% for 3 years.

TABLE 19 Costs sensitivity analysis

Trial arm	Original value (£)	Revised value (£)	proHIS: total cost (average per participant)	eHIS: total cost (average per participant)	Control: total cost (average per participant)
Base case			£3782.94 (£30.26)	£3589.73 (£15.88)	£2247.60 (£10.03)
(a) Removal of postal service	3.88	2.33	£3297.79 (£26.38)	£2886.03 (£12.77)	
(b) Addition of chlamydia treatment		121.00	£4387.94 (£35.10)	£3710.73 (£16.42)	£2973.60 (£13.28)
(c) Addition of participant time[a]		5.00 ph	£5657.94 (£45.26)	£6979.73 (£30.88)	£3614.90 (£16.14)

a Estimated 2 hours for HIS-UK home-based exercises, 1 hour per consultation, 1 hour for online HIS-UK training, half-hour c-card.

TABLE 20 Incremental cost-effectiveness ratio of sensitivity analysis[a]

Scenario	proHIS ICER (per case prevented) (£)	eHIS ICER (per case prevented) (£)
Base case	412.86	119.39
(a) Removal of postal service	333.67	55.92
(b) Addition of chlamydia treatment	445.30	64.08
(c) Addition of participant time	594.29	300.82

a Absolute difference in chlamydia test positivity at 4.9 percentage points.

were recruited from the community (proHIS *n* = 4, eHIS *n* = 6, standard care *n* = 1) and 14 were recruited in-clinic (proHIS *n* = 4, eHIS *n* = 3, standard care *n* = 7). Four main themes were identified: (1) perceived benefits of online versus in-clinic recruitment; (2) perceptions of the educational content; (3) benefits of the kit: novelty, variety and convenience and (4) acceptability of condom testing and monthly questionnaires.

Perceived benefits of online versus in-clinic recruitment

Participants considered the positives and negatives of online and in-clinic participation, with the majority favouring the online route. Online was valued for convenience, the familiarity of a home setting and the possible outreach to those who usually avoid a SH clinic. However, other participants considered that the distance would lead to disengagement and distraction, risking long-term information retainment. Additionally, there was apprehension among some about the potential for misdiagnosis, as healthcare providers might struggle to obtain a comprehensive understanding of health status without an in-person assessment.

Perceptions of the educational content

Perceptions of the educational content were influenced by the trial arm and the level of prior knowledge pre- study. Participants who had received comprehensive education, such as sex education classes, tended to benefit less from the intervention materials than participants who were not as equipped with prior knowledge. Participants with greater prior knowledge admitted to skipping certain sections or considering the information to be common sense. This appeared to be particularly the case for eHIS, where some participants noted that they had seen the content shown in the animations when younger.

However, other participants found that the content helped to consolidate prior knowledge. This was particularly the case for the proHIS condom demonstration, where participants noted that it was useful to observe how a condom should be applied. The success of this element may have been aided by the face-to-face component where participants could learn in a safe non-judgemental environment, away from a group setting.

Some participants also described the addition of new skills and knowledge beyond their school sex education classes. The introduction of pleasurable condom use and methods to boost enjoyment, such as using different types of condoms and lubricants, were more unfamiliar. Positive ways to enjoy condoms subsequently challenged previously held negative attitudes toward condoms.

Standard care participants also described the study as an opportunity to reflect on their current condom use behaviours and attitudes. For some participants, this promoted condom awareness and condom use. In general, standard care condom education and training were regarded as limited. A small supply of condoms (typically of one brand), and occasionally some lubricants, was provided to participants. However, one participant did describe the provision of condoms in waiting areas and consultation rooms across clinic settings.

Benefits of the kit: novelty, variety and convenience

The condom kit was the standout benefit for participants due to the number and variety of condoms and lubricants provided. The intervention encouraged exploration; therefore, participants were able to experiment with brands, shapes and sizes in a low-pressure environment to identify the best condom for fit and feel. For some cases, this challenged pre-existing negative views regarding condoms and their use. The benefits of the kit equally extended beyond the study, with participants using the bag for travelling and praising its accessibility and solution when not having a condom present.

Participants noted the novelty of the shape and size condom measurers, with one participant describing this kit feature as ‘mind-blowing’. This ruler-like tool aimed to give participants a visual understanding of how their penis size/shape corresponded to different condoms. This again questioned participants’ previously held condom size beliefs, pointing participants in the direction of better-fitting condoms.

The importance of lubricants was also acknowledged, with participants distinguishing between water- and silicon-based. Participants particularly valued the addition of information regarding their use in the shower, for example establishing types that were non-greasy and waterproof. However, there was still some confusion between the two different types of lubricants, for example, in one interview, a participant described how water-based lubes could break condoms. These errors may largely be due to some participants skipping the lubricant section due to having no interest. Some participants may not necessarily have been fully aware of why this topic was important and how it may impact pleasurable condom use for themselves and their partner post study completion.

The kit resources were also provided in a ‘washbag’ style kit, removing the typical condom retail boxes. This meant participants could not refer to a description of the condoms, a factor that proved problematic for more

ambiguous-named types. For example, 'magnum' could be considered as large or flavoured. It is advisable that future research provides a booklet in the kit to describe each condom to save participants having to guess or look up separately.

Finally, some participants noted the possible issue with the 2-week time frame for self-practice and rating. Due to the large supply, some were overwhelmed and felt they did not have the time/energy to test all the condoms, a factor that may have resulted in missed feedback. However, when asked if this time frame should be lengthened, most said 2 weeks was sufficient.

Acceptability of condom testing and monthly questionnaires

Initially, participants questioned the importance of self-practice in rating the condoms and regarded practicing with a partner as effective. However, upon realising the number of condoms to test and the limited time frame, participants realised that this would not be feasible and self-testing would be the most efficient option to identify fit and feel. Some participants, however, felt that the importance of the self-practice was exaggerated and saw no difference to practicing with a partner.

The most notable area for improvement reported by participants was the follow-up monthly questionnaires. In general, these were described as repetitive and tedious, with question familiarity resulting in participants putting answers 'in the middle'. It was therefore suggested to have automatically pre-filled questions each month with the ability to edit if required. Some questions also appeared to be more tailored to some participant groups than others.

Discussion/interpretation

Principal findings

Chlamydia test positivity

At baseline, an overall chlamydia test positivity rate of 9.6% was observed. At the primary end point, the absolute difference in chlamydia test positivity rates between HIS-UK and the control was −4.9% (95% CI: −15.66 to 5.92); 7.9% for HIS-UK participants and 12.8% for the control. The odds of receiving a positive test at follow-up were 55% lower for HIS-UK participants as compared to control participants (95% CI: 0.113 to 1.805; $p = 0.261$) after accounting for baseline chlamydia screening, ethnicity, recruitment site and sexual partnering risk. While this reduction was not statistically significant, it merits consideration in the context of public health interventions aimed at preventing STIs.

As anticipated, the test positivity rate at baseline was higher among participants recruited from the CTRS in comparison to the OSR recruited through community advertising and direct text messaging (CTRS: 13.1% vs. OSR: 5.9%). By the 6-month follow-up point, the difference in test positivity rates between the trial arms among the CTRS-recruited participants was −8.3 percentage points (95% CI: −23.98 to 7.36); 7.7% for HIS-UK and 16.0% for control. By contrast, among the OSR group, the disparity was one percentage point (95% CI: 13.71 to 15.68); 8.1% for HIS-UK and 9.1% for control.

The higher baseline rates among CTRS-recruited participants and the subsequent divergence in test positivity rates at the 6-month follow-up highlight the influence of recruitment strategy on baseline risk measurements and intervention outcomes. The observed differences underscore the need for tailored strategies in reaching at-risk populations and optimising the effectiveness of interventions based on recruitment channels.

Condom use

At baseline, 40.8% of participants reported condom use during the previous month, with a slightly lower prevalence in the HIS-UK arm (38.1%) compared to the control (45.4%). After controlling for the stratification factors, in the initial months post intervention delivery, sexually active participants in the HIS-UK arm exhibited a heightened likelihood of condom use during the month compared to the control, evidenced by a significant intervention by time interaction (Wald $\chi^2 = 27.882$, $df = 6$, $p < 0.001$) and indicating a dynamic effect that goes beyond the baseline differences. This finding suggests that the HIS-UK intervention induced a positive change in condom use behaviour over the observed period, underscoring the potential efficacy of the intervention in promoting sustained safer sexual practices.

Consistent condom use

At baseline, 50.0% of participants reported condom use during their last sexual encounter with a regular partner (HIS-UK: 53.4% vs. control: 44.7%). In the case of casual partners, 62.3% reported condom usage (HIS-UK: 60.7% vs. control: 64.5%), suggesting a potential recognition of increased risk in more transient relationships.

Following the intervention, monthly reports of condom use at last sex in the context of regular partners exhibited variability, ranging from 56.9% to 69.0% within the HIS-UK group and from 27.3% to 73.7% within the control.

Condom usage at last sex with casual partners was typically higher, ranging from 58.3% to 81.3% within the HIS-UK arm and from 63.3% to 76.5% within the control arm. After controlling for ethnicity, sexual partnering risk, recruitment site and time during modelling, there was no apparent effect of the HIS-UK intervention on the likelihood of condoms being used during the last sexual encounter, with either regular partners or casual/new partners.

Participants were also asked to report their consistency of condom use with any casual or new partners during the preceding 4-week period. At baseline, slightly over a quarter of participants (26.6%) reported consistent condom use during every sexual act. Monthly responses were modelled comparing consistent use with irregular use, but no discernible intervention effect was observed.

The absence of a marked intervention effect on the consistency of condom use with regular or casual partners raises questions about the nuanced impact of the HIS-UK intervention in influencing these specific aspects of sexual behaviour and underscores the need for a comprehensive understanding of the multifaceted factors influencing condom use dynamics beyond the direct effects of the intervention.

It is important to note, however, that individuals who volunteer to participate in a study about condoms are likely to already have an inherent interest is using them, and the control group in this trial did receive usual NHS condom care.

Correct condom use

Correct condom use at last usage was assessed by way of two measures: (1) complete coverage, denoting the consistent use of a condom from start to finish (with no unprotected penetration) and (2) the condom use errors and problems score. The odds of achieving complete condom coverage were seen to be 21% greater among HIS-UK participants in comparison to the control (OR: 1.211, 95% CI: 0.796 to 1.844, $p = 0.371$); however, this difference was not statistically significant.

The examination of condom use errors and problems uncovered a significant intervention effect favouring the HIS-UK arm. Participants who received the HIS-UK intervention reported fewer errors and problems than the control, as reflected by a negative estimated mean difference [EMM difference: −0.459 (95% CI: −0.886 to −0.033), $p = 0.035$]. Notably, a significant interaction effect between the intervention and time was also observed ($F = 2.76$, $df = 6$, $p = 0.012$). This dynamic aspect underscores the need for longitudinal assessments in understanding the sustained impact of SH interventions beyond immediate postintervention outcomes.

Condom use experiences

Measures of lubricant use and condom comfort (fit and feel) were used to assess the effect of the HIS-UK programme on lived condom use experiences.

The likelihood of lubricant being used during the month was greater among the HIS-UK participants than the control following intervention delivery with an associated significant intervention by time interaction (Wald $\chi^2 = 12.55$, $df = 6$, $p = 0.051$). Furthermore, the odds of lubricant usage at last condom usage were 51% higher among HIS-UK participants than the control (OR: 1.511, 95% CI: 0.967 to 2.361, $p = 0.070$). The observed increase in the odds of lubricant use among HIS-UK participants, both at last condom usage and more generally, sheds light on the program's potential impact in promoting a more positive condom use experience. Use of an additional lubricant has been shown to reduce the occurrence of condom breakage and irritation while simultaneously enhancing sensitivity and overall pleasure during sexual activity.[40]

Conversely, the analysis of condom fit and feel experiences is more complex. While there was a consistent decline in reporting poor fit and feel of the last condom used from baseline to T6, indicating an overall positive trend, the absence of a discernible HIS-UK programme effect raises questions about the specific factors driving this decline. The intervention arm by time interaction effect for general fit-and-feel scoring based on all condoms used during the previous month evident during the initial 3 months post intervention delivery adds a layer of complexity, possibly suggesting potential variability in participant recollection or in the program's impact across different measures of condom satisfaction and the ability of the tools used to accurately measure this. Further exploration to unravel the intricacies of measuring intervention outcomes in real-world scenarios is therefore warranted.

Condom attitudes and opinions

The HIS-UK intervention was shown to have a robust positive effect on condom-related beliefs and perceptions. The significance of this influence is underscored by the observed interaction effect between the intervention arm and time, highlighting the dynamic nature of attitudinal shifts over the course of the study.

Examining specific attitudinal scale items, the HIS-UK intervention demonstrated a statistically significant positive effect across all dimensions as demonstrated by the following fixed-effects interactions (trial arm by time):

condom use experience $F = 8.419$, $df = 6$, $p < 0.001$; *condom use attitudes* $F = 7.624$, $df = 6$, $p < 0.001$; *pleasurable condom use* $F = 9.082$, $df = 6$, $p < 0.001$; *condom use self-efficacy* $F = 2.679$, $df = 6$, $p = 0.014$; *condom use self-efficacy with partners* $F = 5.221$, $df = 6$, $p < 0.001$; and *condom use motivation* $F = 3.744$, $df = 6$, $p = 0.001$. This comprehensive impact signifies a meaningful transformation in participants' perspectives and beliefs regarding condoms.

Compared to the control, participants who received the HIS-UK intervention demonstrated noteworthy improvements in their attitudes towards condoms. After receiving the educational and training components of the programme, they exhibited significantly more positive perceptions of condoms and identified fewer barriers to their use. Additionally, they expressed a greater level of agreement that condoms can be enjoyable and are able to enhance sexual experience and pleasure. Men who underwent the intervention also reported increased confidence in using condoms correctly and effectively with their partners. Moreover, these men expressed a sustained desire to incorporate condoms into their sexual encounters with their partners.

In summary, the HIS-UK intervention demonstrated a profound influence on participants' condom-related attitudes, mitigating barriers, fostering positive perceptions and instilling greater confidence in condom use. The sustained positive impact over time highlights the program's effectiveness in shaping long-term changes in beliefs related to SH behaviour change.

Cost-effectiveness

In this trial, the average cost per delivery of the three intervention arms were as follows:

- proHIS £30.26
- eHIS £15.88
- usual care £10.03

The observed cost differences primarily stem from the inclusion of an extensive range of condoms and lubricants in the HIS-UK condom kits as well as the monthly distribution of supplies in HIS-UK via the postal service, both of which elevate the intervention costs. Notably, eHIS demonstrated lower staffing costs compared to proHIS and usual care, owing to its online delivery format. Re-evaluating components such as the use of the postal service and product price points could further enhance the cost-effectiveness of the HIS-UK intervention.

While both proHIS and eHIS represent higher costs per participant than usual care, they show promise in terms of cost-effectiveness. In particular, eHIS demonstrated the most favourable cost-effectiveness, with an ICER of £119.39 per case prevented, significantly lower than proHIS at £412.86 per case prevented. Moreover, in the best-case scenario, the ICER for eHIS drops to £37.37, further emphasising its superior value for money. In comparison, the cost of treating a single case of chlamydia has been estimated at £506,[41] which is higher than the cost per participant for both intervention arms, suggesting potential cost savings for the NHS in preventing infections through both delivery models of the HIS-UK intervention. However, we fully recognise the impact that COVID-19 has had on the delivery of this research and on our ability to draw firm conclusions about the relative cost-effectiveness of the HIS-UK intervention when delivered through proHIS and eHIS. Further research would be beneficial to more fully examine resource use and health outcomes for both proHIS and eHIS, particularly over the longer term, to enable more robust economic analyses to be undertaken.

Process analysis

The HIS-UK trial was positively received by many participants and exceeded expectations. Participants valued the condom kit and the new material linked to pleasurable condom use. However, the study appeared the most beneficial for participants who had limited prior knowledge and equally understood how the information provided would be of value in the future. To further encourage experimentation and exploration, it may prove beneficial for clinics to broaden their range of condoms to attract a wider group of men to use condoms. This may in turn reduce STIs and unplanned pregnancy.

Reflections/limitations

As previously noted, the HIS-UK trial faced significant challenges and disruption due to the COVID-19 pandemic and its legacy, ultimately leading to the trial's premature end. To align with the trial's original objectives, many amendments were actioned over the course of the study.[26] Some of these amendments bolstered the trial, yielding valuable insights for the conduct of similar research in the future. Conversely, certain changes, though essential to striving toward the original goals, ultimately undermined the trial by diminishing its power to detect impact and assess effectiveness. These modifications also introduced potential sources of bias, affecting the internal and external validities of the findings.

In the initial proposal, the trial was designed to be conducted within clinical settings, specifically in SH and GUM settings. The study design involved training healthcare staff to identify and enrol study participants, with all chlamydia screening samples collected and

processed on-site. The recruitment strategy was carefully tailored to target individuals at the highest risk of chlamydia infection, and the study was adequately powered to detect a reduction in chlamydia test positivity among SHS users, from 11% to 6%. The introduction of community-based recruitment (OSR) and GP text message invitations, while necessary to increase participation in response to the challenges posed by COVID-19, likely introduced selection bias, as this broader recruitment pool included individuals at lower risk of infection. Consequently, the chlamydia positivity rate among participants was lower than originally anticipated, reducing the trial's ability to detect a meaningful effect – the assumptions made by the original power calculations were no longer suitable for the data collected. This shift in recruitment also impacted generalisability, as the final sample differed from the originally intended high-risk population.

Additionally, the initial plan to recruit participants face to face within SHS settings minimised the risk of attrition bias, as recruitment and intervention delivery were designed to occur within a single consultation. The post-COVID-19 amendments, which introduced self-registration and remote intervention delivery via telephone and video consultations, led to a substantial reduction in intervention adherence. This was particularly evident in the proHIS arm, where the requirement for participants to book a follow-up online consultation for intervention delivery led to significant dropout despite the dedicated efforts of staff to follow up with participants. This had the potential to introduce attrition bias, as those who did not complete the intervention may have systematically differed from those who did, potentially affecting outcome estimates.

Lastly, the decision to offer postal chlamydia screening kits led to a lower-than-expected screening completion rate. While participants initially consented to provide samples for screening via postal kits, a substantial proportion failed to return them despite receiving multiple follow-up reminders. This introduced measurement bias, as the missing screening data could systematically differ from those who completed the test. Had all samples been collected in clinical settings as initially proposed, it is likely that screening completion rates would have been higher.

Despite the many challenges faced, efforts were made to mitigate bias where possible, such as maximising participant follow-up and incorporating multiple recruitment strategies. However, the unavoidable changes introduced by the pandemic ultimately impacted the study's internal validity and power, limiting the extent to which findings can be confidently generalised to the originally intended high-risk population.

Headlines

Box 2 presents a summary of the conclusions.

BOX 2 Conclusions

In comparison to the control arm, men who underwent the HIS-UK education and training programme:

- reported a more favourable attitude towards condoms and perceived fewer barriers to their usage
- showed a greater tendency to recognise that condoms can enhance pleasure and contribute to a more fulfilling sexual experience
- reported increased confidence in their proficiency to use condoms correctly
- reported fewer instances of errors and problems during condom use
- expressed a greater desire to incorporate condoms into their sexual encounters
- exhibited an increase in condom use and showed a greater propensity to use additional lubricant
- had a 55% lower likelihood of chlamydia test positivity at follow-up (not statistically significant).

The HIS-UK intervention, particularly the eHIS model of delivery, demonstrated strong cost-effectiveness, offering potential savings for the NHS.

Chlamydia test positivity

- Baseline chlamydia test positivity rate: 9.6%.
- HIS-UK participants showed a 4.9 percentage point reduction compared to the control at the primary end point.
- Odds of a positive test at follow-up were 55% lower for HIS-UK participants, though not statistically significant.
- Baseline rates were higher among clinic-recruited participants; there was significant divergence in test positivity rates at 6 months, emphasising the impact of recruitment strategy.

Condom use

- Baseline condom use: 40.8%.
- HIS-UK participants exhibited a statistically significant increase in condom use post intervention, emphasising intervention-induced positive changes in condom use behaviour.

Consistent condom use

- Baseline rates for last sexual encounter with regular partners: 50.0%.
- There was no apparent intervention effect on consistent condom use or usage at last sex with regular or casual partners.

Correct condom use

- Odds of achieving a complete condom coverage was 21% greater in HIS-UK participants, though not statistically significant.
- HIS-UK participants reported significantly fewer condom use errors and problems.

Condom use experiences

- Statistically significant increase in the odds of lubricant usage at last condom usage among HIS-UK participants.
- Consistent decline in poor condom fit-and-feel reports from baseline to T6, but no apparent programme effect.

Condom attitudes and opinions

- Robust positive effect of HIS-UK intervention on condom-related beliefs.
- Significant improvement in attitudes towards condoms, perceived barriers and heightened perceptions of enjoyment and pleasure.
- HIS-UK participants expressed increased confidence in condom use with partners and a sustained desire to incorporate condoms into sexual encounters.

Cost-effectiveness

- Both HIS-UK deliver models (ProHIS and eHIS) were more cost-effective than usual care, with the potential to offer savings to the NHS.
- Online delivery offers superior cost-effectiveness with £120 per case prevented compared to £410 for proHIS.

Overall impact

- The HIS-UK intervention demonstrates a comprehensive and sustained positive influence on participants' condom-related attitudes, behaviours and experiences, highlighting its effectiveness in fostering long-term changes in SH behaviour.

Impact, learning and implications for decision-makers

The HIS-UK study has already exerted a tangible influence on the condom supply practices of several NHS Trusts. Notably, there has been a shift towards offering a more diverse range of condoms and condom sizes along with the introduction of online ordering services, with the option for supplies to be either collected from distribution points or delivered through the post. This adaptation reflects a response to the evolving needs and preferences of service users, enhancing accessibility and choice in condom procurement.

Ease of access to correct-fitting condoms directly impacts individuals' ability to protect themselves and their partners from STIs. When condoms are readily available, affordable and distributed in a stigma-free manner, it encourages their consistent and correct use. This, in turn, contributes to a reduction in the transmission of STIs. Ensuring wide accessibility to correctly fitting condoms is not only a public health imperative but also a vital component of a comprehensive strategy to promote safer sexual practices, protect individuals' health and minimise the societal burden of STIs.

One of the major barriers to condom use is negative attitudes. These attitudes can encompass a range of sentiments, such as reluctance, discomfort or resistance and may stem from various factors, including cultural, social or personal influences and past experiences. Addressing poor condom use attitudes is essential for promoting safe sexual practices and reducing the risk of STIs. The HIS-UK intervention has demonstrated its ability to not only increase condom use but also positively influence the perceptions of condoms. Without improving attitudes towards condom use among young people, the likelihood of achieving higher condom usage remains considerably constrained.

Condom failure can occur due to various reasons, including incorrect use (such as improper placement, unrolling or removal), condom damage from improper handling or sexual activity and slippage or leakage from poor fit. Notably, the HIS-UK intervention has shown its capacity to reduce instances of condom errors and problems. Furthermore, the use of a water-based lubricant is associated with several benefits, including a significant decrease in condom failure rates due to reduced friction while not increasing condom slippage. Lubrication also enhances the overall sexual experience by reducing discomfort and increasing pleasure and can make it easier to put on condoms, reducing the chances of incorrect application. HIS-UK has been shown to increase lubricant usage among men, a valuable practice that contributes to safer and more enjoyable sexual experiences. Together, these accomplishments are anticipated to contribute to the reduction in STIs by enhancing the effectiveness of condom use and the protection they provide.

The HIS-UK aims to provide a range of condoms and lubricants to young men to test and try out in the absence of a sexual partner as a means of promoting sexual education and preparedness. This strategy not only

imparts knowledge but also equips men with the essential tools for responsible sexual behaviour. It enables them to gain familiarity with the correct usage and advantages of both condoms and lubricants, thereby empowering them to make informed decisions about their SH.

Unfortunately, due to COVID, the HIS-UK study was unable to fully recruit to the trial in the time available. As such, the study was insufficiently powered to draw firm conclusions regarding its impact on chlamydia test positivity rates. Despite this limitation, a promising trend emerged as HIS-UK participants exhibited a notable 4.9 percentage point reduction compared to the control group at the primary end point (and 8.3 percentage points among those recruited from clinical sites). Although this reduction was not statistically significant, it is noteworthy and warrants careful consideration in the realm of public health interventions targeting the prevention of STIs. The contextual importance of these findings lies in their potential implications for refining and optimising future interventions despite the unprecedented challenges posed by the global health crisis.

Recommendations for future research

Priority areas for future condom research to promote STI prevention with young men are discussed below.

Tailored condom design and development

Research should focus on developing condoms that are not only effective in preventing STIs but also cater to the specific needs and preferences of young men. This includes investigating novel materials, sizes and textures that enhance comfort, sensation and overall user satisfaction.

Behaviour-change interventions

In-depth studies on the effectiveness of behavioural interventions, such as educational programs (like HIS-UK) and counselling, are needed to encourage the consistent and correct condom use among young men for the reduction of STIs. These interventions should address physical, psychological and social barriers to condom use. It is a regret that the no-cost extension to the HIS-UK timeline to cover the months lost to COVID-19 was not granted by NIHR in this regard.

Condom promotion and marketing

Investigate innovative strategies for promoting condoms to young men, including digital and social media campaigns, peer-driven approaches and partnerships with influencers who can help destigmatise condom use and make it a socially acceptable, and pleasurable, choice.

User experience and satisfaction

Conduct research to understand the factors influencing young men's satisfaction with condom use, including aspects like comfort, pleasure and ease of use. This information can guide the development of condoms that meet user expectations and improve overall sexual experiences.

Engagement with partners and stakeholders

From the outset, a commitment was made to foster a collaborative and dynamic partnership with our valued stakeholders and partners. It was recognised that their insights, expertise and experiences were deemed essential to the success of the study.

Monthly newsletter updates

Transparent and regular communication was deemed important. To that end, monthly newsletter updates were provided, offering an overview of research progress. These newsletters kept stakeholders informed about the latest developments, findings and milestones. Encouragement was given for feedback and input.

Dedicated study website and e-mail

The study website was designed as a dedicated hub for accessing essential information about the research. The website served as a central resource, providing updates, publications and an opportunity to connect with the research team. It was designed to be user-friendly and accessible to all partners and stakeholders.

Active involvement in research design and delivery

Stakeholders' perspectives and expertise were considered to be invaluable in shaping the trajectory of the research, particularly in view of the challenges the study faced. They were invited to actively engage in the design and delivery of the research. Regular feedback and advisory panels and committees were hosted to ensure that their input was fully integrated.

Dissemination to partners and stakeholders

The HIS-UK study, conducted amidst the challenges posed by the COVID-19 pandemic, has generated valuable insights into effective behaviour change SH interventions and research methodology. Despite encountering recruitment hurdles, the study has identified noteworthy results that warrant strategic dissemination. We aim to use a multifaceted approach to sharing the findings with partners and stakeholders, including the following:

- Research articles – Comprehensive research articles, detailing the HIS-UK study's methodology, lessons learned, results and implications, will be submitted to peer-reviewed journals. These articles will serve as valuable contributions to the academic discourse surrounding SH research and behaviour change interventions.
- Presentations – Presentations will be delivered at relevant conferences and seminars, providing an opportunity to share the HIS-UK study findings with researchers, healthcare professionals and policy-makers. These sessions aim to foster discussions and facilitate knowledge exchange within the research and public health communities.
- Social media posts – Strategic social media posts will disseminate key highlights and takeaways across various platforms. This approach ensures that the research is accessible to a diverse audience, including the general public, advocacy groups and healthcare professionals.
- Video – Informative videos and animations summarising the HIS-UK study findings will be produced. This dynamic visual content aims to convey the significance and impact of the study in an accessible format.
- Podcasts – Podcast episodes will delve into specific aspects of the study, featuring discussions with researchers and experts. This format provides a conversational exploration of the findings, catering to audiences who prefer audio content.
- Infographics – Condensed and visually appealing infographics distilling complex findings will be shared across various platforms. These infographics aim to summarise key statistics, trends and implications from the HIS-UK study.

Patient and public involvement

During an 18-month period of developing and assessing the feasibility of proHIS, funded by MRC-Public Health Intervention Development, consultations had been conducted with 15 young men via in-depth interviews and group workshops to gather their insights on the intervention design, intervention materials (including the HIS-UK logo, kit contents such as condom and lubricant types, and data collection tools and methods using the Lifeguide system, text messages and e-mails). The development and feasibility study had also included an advisory group with young male representatives who played an influential role in various aspects of the study, particularly in designing the recruitment strategy and providing recommendations post study completion.

The digital version of the intervention (eHIS) was developed and tested as part of a PhD project at the University of Southampton.[25] During eHIS development, a qualitative evaluation was conducted with 22 young men who provided input on content, format and design through a 'think-aloud' study format. They offered feedback after pre-testing online information and guidance pages.

In preparation for the final HIS-UK RCT, feedback was sought from young men who had been part of the proHIS advisory group for the feasibility study. This feedback had an important impact on participant recruitment and retention plans and plans for dissemination to young men. Additionally, feedback was obtained from 33 men who had participated in the proHIS trial, focusing on the revised design, randomisation and the collection of biological samples for chlamydia testing.

During the HIS-UK trial, we recruited various patient and public involvement (PPI) advisory representatives who brought both youth worker and SH promotion experience to the team. Their insights, particularly on recruitment, randomisation, STI data collection and communication, influenced the final proposed research design as well as the protocol changes.[26] For instance, their advice on the use of online booking systems for video consultations to expand community recruitment routes was particularly valued by the research team.

The PPI played an active role in all stages of the HIS-UK study, sitting on our various committees and providing insightful advice on design, management, study website content, participant information and communication, study advertisements, eHIS on-line training web pages, participant interviews and project findings and impact dissemination. The involvement of young men in all the stages has ensured that the study reflects their peers' concerns and interests.

Dissemination to participants

The PPI played a vital role in shaping our participant dissemination strategy. As part of our strategy, we will be sharing our findings through an animated video and an infographic, both of which will be accessible via our study website.

Equity, diversity and inclusion

In our commitment to equity, diversity and inclusion, we strove to create an environment where every individual, regardless of their background or identity, feels valued and supported. Our mission was to ensure that all stakeholders, from team members to research participants, were treated with respect and had equal opportunities.

The study employed a comprehensive array of advertising materials, employing a variety of terminology to ensure inclusivity and avoid stigmatisation. It was consistently emphasised that participation was open to anyone who identified as possessing male anatomy (a penis); in essence, they needed to own a penis to evaluate condom fit and feel.

All informational materials and communications were thoughtfully crafted to be accessible to individuals with a reading ability akin to that of a 12-year-old. However, it is important to note that the eHIS online educational resources and follow-up questionnaires were exclusively available in the English language. Proficiency in understanding and adhering to trial instructions in English served as an eligibility criterion for participation.

Capacity strengthening

Individual

Our commitment to individual growth and development has been evident through a range of initiatives. We have provided our team members and partners with opportunities for skills enhancement, knowledge acquisition and professional growth. These activities have been designed to empower individuals, fostering their expertise and competence. Through mentorship and training, we have invested in equipping the research team with the tools they need to excel in their roles.

Institutional

In parallel, we recognise that the strength of our institution directly correlates with our ability to achieve meaningful outcomes. Therefore, we have undertaken comprehensive efforts to strengthen our institutional capacity. This includes enhancing collaboration and communication and optimising resource allocation. These measures have been instrumental in ensuring our institution's sustainability and resilience. By fortifying our institutional foundation, we aimed to create an environment conducive to innovation, collaboration and effective research delivery.

Additional information

CRediT contribution statement

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Data-sharing statement

All data supporting this study will be openly available from the University of Southampton repository at researchdata@soton.ac.uk; https://doi.org/10.5258/SOTON/

Ethics statement

ISRCTN registration: 11400820 (23/10/2019); South Central – Oxford B Research Ethics Committee number: 19/SC/0486 (04/11/2019); IRAS ID: 255684 (HRA approval 19 November 2019).

Information governance statement

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Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/GJNS1528.

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Trial registration

This trial is registered as ISRCTN11400820 (23/10/2019)

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Award publications

This synopsis provided an overview of the research award *Evaluating the Home-based Intervention Strategy (HIS-UK) to reduce new chlamydia infection among young men aged 16–25 years by promoting correct and consistent condom use: What is the cost effectiveness of two different delivery models (face-to-face and digital delivery)?*

Other articles published as part of this thread are: Bedford R, Towler L, Stone N, Graham CA. Evaluating the Home-Based Intervention Study (HIS-UK) to improve condom use skills and experience: a qualitative study. *Int J Sex Health* 2024;**36**:515–28. https://doi.org/10.1080/19317611.2024.2382246

Stone N, Graham CA, Bremner S, McGrath N, Bedford R, Brown K, *et al*. Evaluating the Home-based Intervention Strategy (HIS-UK) to reduce new chlamydia infection among young men aged 16–25 years by promoting correct and consistent condom use: findings from a randomised controlled trial. *BMC Health Serv Res* 2024;**25**:1607. https://doi.org/10.1186/s12913-024-11911-2

For more information about this research please view the award page (www.fundingawards.nihr.ac.uk/award/17/54/06).

Additional outputs

Stone N, Bedford R, Newby B, Brown B, Jackson L, Bremner S, *et al*. Reducing new Chlamydia infection among young men by promoting correct and consistent condom use: protocol for a randomized controlled trial. *JMIR Res Protoc* 2022;**11**:e35729. https://doi.org/10.2196/35729

Graham CA. *Evaluating the Home-Based Intervention Strategy (HIS-UK) to Reduce New Chlamydia Infections among Young Men Aged 16–25 by Promoting Correct and Consistent Condom Use*. International Academy of Sex Research Annual Conference, Berlin, July 2024.

Graham CA, Stone N, Bremner S, McGrath N, Bedford R, Brown K, *et al*. Conducting an RCT of a sexual health intervention during the COVID-19 pandemic and Mpox outbreak: lessons learned (under review). 2025.

About this synopsis

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List of abbreviations

CEA	cost-effectiveness analysis
CI	confidence interval
CTRS	clinical trial recruitment sites
CUA	cost–utility analysis
DI	digital intervention
EHIS	interactive website
EMM	estimated marginal means
EOIA	expression of interest application
EQ-5D	EuroQol-5 Dimensions
EQ-5D-5L	EuroQol-5 Dimensions, five-level version
GP	general practitioner
GUM	genitourinary medicine
HIS-UK	home-based intervention strategy
HRQOL	health-related quality of life
ICER	incremental cost-effectiveness ratio
ITT	intention to treat
KI-HIS	The Kinsey Institute Homework Intervention Strategy
MRC	Medical Research Council
NICE	National Institute for Health and Care Excellence

NIHR	National Institute for Health Research
OR	odds ratio
OSR	online self-registration
PIC	participant identification centre
PPI	patient and public involvement
PROHIS	health promotion professionals
QALY	quality-adjusted life-year
SAP	statistical analysis plan
SF-12	Short Form questionnaire-12 items
SH	sexual health
SHS	sexual health service
SS	site staff
STI	sexually transmitted infection
VAS	visual analogue scale

References

1. UNAIDS. *UNFPA, WHO and UNAIDS: Position Statement on Condoms and the Prevention of HIV, Other Sexually Transmitted Infections and Unintended Pregnancy*. 2015. URL: www.unaids.org/en/resources/presscentre/featurestories/2015/july/20150702_condoms_prevention (accessed 14 December 2023).
2. Gov.UK. *Campaigns to Protect Young People from STIs by Using Condoms*. 2017. URL: www.gov.uk/government/news/campaign-to-protect-young-people-from-stis-by-using-condoms; www.publichealth.hscni.net/news/choose-protect-yourself-always-use-condom (accessed 14 December 2023).
3. Hatherall B, Ingham R, Stone N, McEachran J. How, not just if, condoms are used: the timing of condom application and removal during vaginal sex among young people in England. *Sex Transm Infect* 2007;**83**:68–70. https://doi.org/10.1136/sti.2006.021410
4. Sanders SA, Yarber WL, Kaufman EL, Crosby RA, Graham CA, Milhausen RR. Condom use errors and problems: a global view. *Sex Health* 2012;**9**:81–95.
5. Graham CA. Condom use in the context of sex research: a commentary. *Sex Health* 2012;**9**:103–8.
6. Graham CA, Crosby R, Sanders S, Milhausen R, Yarber WL. Condom-associated erection problems: a study of high-risk young Black males residing in the southern United States. *Am J Mens Health* 2016;**10**:141–5.
7. Newby KV, Brown KE, French DP, Wallace LM. Which outcome expectancies are important in determining young adults' intentions to use condoms with casual sexual partners?: a cross-sectional study. *BMC Public Health* 2013;**13**:133.
8. Albarracín D, Johnson BT, Fishbein M, Muellerleile PA. Theories of reasoned action and planned behavior as models of condom use: a meta-analysis. *Psychol Bull* 2001;**127**:142–61.
9. Armitage CJ, Conner M. Efficacy of the theory of planned behaviour: a meta-analytic review. *Br J Soc Psychol* 2001;**40**:471–99.
10. Anstee S, Shepard J, Graham CA, Stone N, Brown K, Newby K, Ingham R. Evidence for behavioural interventions addressing condom use fit and feel issues to improve condom use: a systematic review. *Sex Health* 2019;**16**:539–47.
11. Public Health England. *Health Promotion for Sexual and Reproductive Health and HIV: Strategic Plan, 2016 to 2019*. 2015. URL: www.gov.uk/government/publications/sexual-and-reproductive-health-and-hiv-strategic-action-plan (accessed 14 December 2023).
12. Clutterbuck DJ, Flowers P, Barber T, Wilson H, Nelson M, Hedge B, *et al.*; Clinical Effectiveness Group of British Association for Sexual Health and HIV (BASHH) and British HIV Association (BHIVA). UK national guideline on safer sex advice. *Int J STD AIDS* 2012;**23**:381–8.
13. NHS England. *Next Steps on the NHS Five Year Forward View*. 2017. URL: www.england.nhs.uk/next-steps-on-the-nhs-five-year-forward-view/ (accessed 14 December 2023).
14. National Institute for Health and Care Excellence. *Sexually Transmitted Infections: Condom Distribution Schemes*. 2017. URL: www.nice.org.uk/guidance/ng68 (accessed 14 December 2023).
15. National Institute for Health and Care Excellence. *Reducing Sexually Transmitted Infections*. 2022. URL: www.nice.org.uk/guidance/ng221/resources/reducing-sexually-transmitted-infections-pdf-66143830628293 (accessed 14 December 2023).
16. National Institute for Health and Clinical Excellence. *Sexually Transmitted Infections and Under-18 Conceptions: Prevention*. 2007. URL: www.nice.org.uk/guidance/PH3 (accessed 14 December 2023).
17. Free C, Ian R, Abramsky T, Fitzgerald M, Wensley F. A systematic review of randomised controlled trials of interventions promoting effective condom use. *J Epidemiol Community Health* 2011;**65**:100–10.
18. Scott-Sheldon LA, Fielder RL, Carey MP. Sexual risk reduction interventions for patients attending sexually

transmitted disease clinics in the United States: a meta-analytic review, 1986 to early 2009. *Ann Behav Med* 2010;**40**:191–204.

19. Long L, Abraham C, Paquette R, Shahmanesh M, Llewellyn C, Townsend A, Gilson R. Brief interventions to prevent sexually transmitted infections suitable for in-service use: a systematic review. *Prev Med* 2016;**91**:364–82.
20. Carey M, Senn T, Vanable P, Coury-Doniger P, Urban M. Brief and intensive behavioural interventions to promote sexual risk reduction among STD clinic patients: results from a randomized controlled trial. *AIDS Behav* 2010;**14**:504–17.
21. Milhausen RR, Wood J, Sanders SA, Crosby RA, Yarber WL, Graham CA. A novel, self-guided, home-based intervention to promote condom use among young men: a pilot study. *J Men's Health* 2011; **8**:274–81.
22. Emetu RE, Marshall A, Sanders SA, Yarber WL, Milhausen RR, Crosby RA, Graham CA. A novel, self-guided, home-based intervention to improve condom use among young men who have sex with men. *J Am Coll Health* 2014;**62**:118–24.
23. Graham C, Ingham R. Feasibility study of the Kinsey Institute Homework Intervention (KIHIS-UK) to promote correct and consistent condom use, RCUK. *Impact* 2017;**2017**:75–7.
24. Stone NC, Graham CA, Anstee S, Brown K, Newby K, Ingham R. Enhancing condom use experiences among young men to improve correct and consistent condom use: feasibility of a home-based intervention strategy (HIS-UK). *Pilot Feasibility Stud* 2018;**4**:63. https://doi.org/10.1186/s40814-018-0257-9
25. Glowacka M, Yardley L, Stone N, Graham C. Feasibility and preliminary effectiveness of the eHIS (Homework Intervention Strategy) programme to enhance male condom use: a research protocol. *JMIR Res Protoc* 2018;**7**:e1.
26. Stone N, Bedford R, Newby B, Brown B, Jackson L, Bremner S, *et al*. Reducing new chlamydia infection among young men by promoting correct and consistent condom use: protocol for a randomized controlled trial. *JMIR Res Protocol* 2022;**11**:e35729. https://doi.org/10.2196/35729
27. Yardley L, Morrison L, Bradbury K, Muller I. The person-based approach to intervention development: application to digital health-related behaviour change interventions. *J Med Internet Res* 2015; **17**:e30.
28. National chlamydia screening programme (NCSP): annual data. URL: www.gov.uk/government/statistics/sexually-transmitted-infections-stis-annual-data-tables (accessed 14 December 2023).
29. Curtis LA, Burns A. *Unit Costs of Health and Social Care 2016*. Personal Social Services Research Unit; 2016. URL: www.pssru.ac.uk/project-pages/unit-costs/unit-costs-2016/ (accessed 14 December 2023).
30. National Institute for Health and Care Excellence. *Guide to the Methods of Technology Appraisal*. 2013. URL: www.nice.org.uk/process/pmg9/chapter/foreword (accessed 14 December 2023).
31. Herdman M, Gudex C, Lloyd A, Janssen MF, Kind P, Parkin D, *et al*. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;**20**:1727–36.
32. Ware J Jr, Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. *Med Care* 1996;**34**:220–33. https://doi.org/10.1097/00005650-199603000-00003
33. Soh SE, Morello R, Ayton D, Ahern S, Scarborough R, Zammit C, *et al*. Measurement properties of the 12-item Short Form Health Survey version 2 in Australians with lung cancer: a Rasch analysis. *Health Qual Life Outcomes* 2021;**19**:157.
34. EuroQol Research Foundation. *EQ-5D-5L User Guide*. 2019. URL: https://euroqol.org/publications/user-guides (accessed 14 December 2023).
35. St Lawrence JS, Chapdelanie AP, Devieux JG. Measuring perceived barriers to condom use: psychometric evaluation of the Condom Barriers Scale. *Assessment* 1999;**6**:391–404.
36. Crosby R, DiClemente RJ, Wingood GM, Sionean C, Cobb BK, Harrington K, *et al*. Correct condom application among African-American adolescent females: the relationship to perceived self-efficacy and the association to confirmed STDs. *J Adolesc Health* 2001;**29**:194–9.
37. Crosby RA, Graham CA, Milhausen RR, Sanders SA, Yarber WL. *Condom Use Errors/Problems Survey: Handbook of Sexuality-Related Measures*. 3rd edn. New York: Routledge; 2011.
38. Reece M, Dodge B, Herbenick D, Fisher C, Alexander A, Satinsky S. Experiences of condom fit and feel among African-American men who have sex with men. *Sex Transm Infect* 2007;**83**:454–7.
39. Office for National Statistics (ONS). *Employee Earnings in the UK: 2023*. Statistical Bulletin; 2023. URL: www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/bulletins/annualsurveyofhoursandearnings/2023 (accessed 14 December 2023).

40. Kennedy CE, Yeh PT, Li J, Gonsalves L, Narasimhan M. Lubricants for the promotion of sexual health and well-being: a systematic review. *Sex Reprod Health Matters* 2022;**29**:2044198.

41. Turner K, Adams E, Grant A, Macleod J, Bell G, Clarke J, Horner P. Costs and cost effectiveness of different strategies for chlamydia screening and partner notification: an economic and mathematical modelling study. *BMJ* 2011;**342**:c7250.

Appendix 1

Comparative analyses

Comparisons between groups were made on the following variables:

- age
- ethnicity
- education
- employment
- deprivation
- sexual partnering/ risk
- previous STI diagnosis
- ever use of condoms
- number of lifetime sexual partners
- recruitment method (clinical vs. community)
- trial arm.

Summary

TABLE 21 Evidence of statistically significant variation in variables by selected comparison groups

	Engagement in study follow-up vs. non-engagement	Primary end point reached vs. not reached	Provision of T0 screening data vs. non provision	Provision of T0 and T1–T6 screening data vs. T0 only
Age	–	–	***	–
Ethnicity	–	–	***	–
Education	–	–	–	–
Employment	***	–	***	–
Deprivation	–	–	–	–
Sexual partnering/ risk	***	***	***	–
Previous STI diagnosis	–	–	***	–
Ever use of condoms	–	–	–	–
Number of sexual partners	–	–	***	–
Recruitment method	–	–	***	–
Trial arm	***	–	–	–

*** indicates a significant difference at the 5% level of significance.

Baseline only versus follow-up

Two hundred and ninety-seven participants engaged in the study post baseline (51.7%), and only 278 participants completed the baseline activities (48.3%).

Significant differences (5% level) between the participants who completed baseline activities only and those who engaged in follow-up are outlined below. For all other comparisons, no differences were observed.

In paid employment

Crosstab

			In paid employment (TO)			
			Yes – part-time	Yes – full-time	No	Total
Questionnaire completion post TO	No	Count	81	132	63	276
		% within in paid employment (TO)	52.3%	53.0%	37 5%	48.3%
	Yes	Count	74	117	105	296
		% within in paid employment (TO)	47.7%	47.0%	62.5%	51.7%
Total		Count	155	249	168	572
		% within in paid employment (TO)	100.0%	100.0%	100 0%	100.0%

Chi-square tests

	Value	df	Asymptotic significance (2-sided)
Pearson χ^2	11.034[a]	2	0.004
Likelihood ratio	11.133	2	0.004
Linear-by-linear association	7.299	1	0.007
N of valid cases	572		

a 0 cells (0.0%) have expected count < 5. The minimum expected count is 74.79.

Sexual partnering/risk

Crosstab

			Sexual risk (TO)		
			Low	High	Total
Questionnaire completion post TO	No	Count	192	86	278
		% within sexual risk (TO)	53.2%	40.2%	48.3%
	Yes	Count	169	128	297
		% within sexual risk (TO)	46.8%	59.8%	51.7%
Total		Count	361	214	575
		% within sexual risk (TO)	100.0%	100.0%	100.0%

Chi-square tests

	Value	df	Asymptotic significance (2-sided)	Exact sig. (2-sided)	Exact sig. (1-sided)
Pearson χ^2	9.090[a]	1	0.003		
Continuity correction[b]	8.577	1	0.003		
Likelihood ratio	9.135	1	0.003		

	Value	df	Asymptotic significance (2-sided)	Exact sig. (2-sided)	Exact sig. (1-sided)
Fisher's exact test				0.003	0.002
Linear-by- linear association	9.075	1	0.003		
N of valid cases	575				

a 0 cells (0.0%) have expected count < 5. The minimum expected count is 103.46.
b Computed only for 2 × 2 table.

Trial arm

Crosstab

			HIS-UK intervention group		
			No	Yes	Total
Questionnaire completion post TO	No	Count	90	188	278
		% within HIS-UK intervention group	40.2%	53.6%	48.3%
	Yes	Count	134	163	297
		% within HIS-UK intervention group	59.8%	46.4%	51.7%
Total		Count	224	351	575
		% within HIS-UK intervention group	100.0%	100.0%	100.0%

Chi-square tests

	Value	df	Asymptotic significance (2-sided)	Exact sig. (2-sided)	Exact sig. (1-sided)
Pearson χ^2	9.806[a]	1	0.002		
Continuity correction[b]	9.278	1	0.002		
Likelihood ratio	9.854	1	0.002		
Fisher's exact test				0.002	0.001
Linear-by-linear association	9.789	1	0.002		
N of valid cases	575				

a 0 cells (0.0%) have expected count < 5. The minimum expected count is 108.30.
b Computed only for 2 × 2 table.

Retention to primary end point

One hundred and eighty nine of the 575 participants (32.9%) reached the primary end point and completed the T6 questionnaire.

Participants who reported previous intercourse with men and/or intercourse with an individual who did not identify as either a man or woman were significantly more likely to reach the primary end point of the study than participants who reported sex with women only. For all other comparisons, no differences were observed.

Sexual partnering/risk

Crosstab

			T6_done	Yes	Total
Sexual risk (TO)	Low	Count	264	97	361
		% within sexual risk (TO)	73.1%	26.9%	100.0%
	High	Count	122	92	214
		% within sexual risk (TO)	57.0%	43.0%	100.0%
Total		Count	386	189	575
		% within sexual risk (TO)	67.1%	32.9%	100.0%

Chi-square tests

	Value	df	Asymptotic significance (2-sided)	Exact sig. (2-sided)	Exact sig. (1-sided)
Pearson χ^2	15.824[a]	1	< 0.001		
Continuity correction[b]	15.102	1	< 0.001		
Likelihood ratio	15.616	1	< 0.001		
Fisher's exact test				< 0.001	< 0.001
N of valid cases	575				

a 0 cells (0.0%) have expected count < 5. The minimum expected count is 70.34.
b Computed only for 2 × 2 table.

Provision of screening data

Participants were grouped as follows:

- no provision of screening data (*n* = 263)
- provision of screening at baseline (*n* = 312)

and

- provision of screening at baseline only (*n* = 190)
- provision of screening data at baseline and follow-up (*n* = 126)

No provision versus provision at baseline

A two-way comparison between participants who provided screening data at baseline and those who did not was initially conducted. Significant differences (5% level) are outlined below. For all other comparisons (listing above), no differences were observed.

Ethnicity

Crosstab

			Ethnic group				
			White (British/Irish/ other)	Black (Caribbean/ African/mixed)	South Asian (inc mixed)	Other	Total
Provided screening at TO	Not provided	Count	209	12	27	15	263
		% within ethnic group	44.8%	35.3%	65.9%	45.5%	45.7%
	Data provided	Count	258	22	14	18	312
		% within ethnic group	55.2%	64.7%	34.1%	54.5%	54.3%
Total		Count	467	34	41	33	575
		% within ethnic group	100.0%	100.0%	100.0%	100.0%	100.0%

Chi-square tests

	Value	df	Asymptotic significance (2-sided)
Pearson χ^2	8.362[a]	3	0.039
Likelihood ratio	8.422	3	0.038
Linear-by-linear association	1.555	1	0.212
N of valid cases	575		

a 0 cells (0.0%) have expected count < 5. The minimum expected count is 15.09.

Sexual partnering/risk

Crosstab

			Sexual risk (TO)		
			Low	High	Total
Provided screening TO	Not provided	Count	180	83	263
		% within sexual risk (TO)	49.9%	38.8%	45.7%
	Data provided	Count	181	131	312
		% within sexual risk (TO)	50.1%	61.2%	54.3%
Total		Count	361	214	575
		% within sexual risk (TO)	100.0%	100.0%	100.0%

Chi-square tests

	Value	df	Asymptotic significance (2-sided)	Exact sig. (2-sided)	Exact sig. (1-sided)
Pearson χ^2	6.642[a]	1	0.010		
Continuity correction[b]	6.203	1	0.013		
Likelihood ratio	6.681	1	0.010		
Fisher's exact test				0.012	0.006
Linear-by-linear association	6.630	1	0.010		
N of valid cases	575				

a 0 cells (0.0%) have expected count < 5. The minimum expected count is 97.88.
b Computed only for 2 × 2 table.

Age

Crosstab

			Age group			
			16–19	20–22	23 +	Total
Provided screening at TO	Not provided	Count	73	94	96	263
		% within age group	57.5%	39.5%	45.7%	45.7%
	Data provided	Count	54	144	114	312
		% within age group	42.5%	60.5%	54.3%	54.3%
Total		Count	127	238	210	575
		% within age group	100.0%	100.0%	100.0%	100.0%

Chi-square tests

	Value	df	Asymptotic significance (2-sided)
Pearson χ^2	10.792[a]	2	0.005
Likelihood ratio	10.800	2	0.005
Linear-by-linear association	2.771	1	0.096
N of valid cases	575		

a 0 cells (0.0%) have expected count < 5. The minimum expected count is 58.09.

In paid employment

Crosstab

			In paid employment (TO)			
			Yes – part-time	Yes – full-time	No	Total
Provided screening at TO	Not provided	Count	61	129	71	261
		% within in paid employment (TO)	39.4%	51 8%	42.3%	45.6%
	Data provided	Count	94	120	97	311
		% within in paid employment (TO)	60.6%	48.2%	57.7%	54.4%
Total		Count	155	249	168	572
		% within in paid employment (TO)	100.0%	100.0%	100.0%	100.0%

Chi-square tests

	Value	df	Asymptotic significance (2-sided)
Pearson χ^2	7.058[a]	2	0.029
Likelihood ratio	7.069	2	0.029
Linear-by-linear association	0.206	1	0.650
N of valid cases	572		

a 0 cells (0.0%) have expected count < 5. The minimum expected count is 70.73.

Previous sexually transmitted infection diagnosis

Crosstab

			STI diagnosis ever (TO)		
			Yes	No	Total
Provided screening at TO	Not provided	Count	56	202	253
		% within STI diagnosis ever (TO)	32.9%	50.9%	45.5%
	Data provided	Count	114	195	309
		% within STI diagnosis ever(TO)	67.1%	49.1%	54.5%
Total		Count	170	397	567
		% within STI diagnosis ever (TO)	100.0%	100.0%	100.0%

Chi-square tests

	Value	df	Asymptotic significance (2-sided)	Exact sig. (2-sided)	Exact sig. (1-sided)
Pearson χ^2	15.449[a]	1	< 0.001		
Continuity correction[b]	14.734	1	< 0.001		
Likelihood ratio	15.721	1	< 0.001		
Fisher's exact test				< 0.001	< 0.001
Linear-by-linear association	15.422	1	< 0.001		
N of valid cases	567				

a 0 cells (0.0%) have expected count < 5. The minimum expected count is 77.35.
b Computed only for 2 × 2 table.

Lifetime sexual partners

Crosstab

			Lifetime sexual partners grouping				
			1–4	5–9	10–19	20 +	Total
Provided screening at TO	Not provided	Count	74	63	58	61	256
		% within lifetime sexual partners grouping	56.1%	43.8%	44.3%	39.9%	45.7%
	Data provided	Count	58	81	73	92	304
		% within lifetime sexual partners grouping	43.9%	56.3%	55.7%	60.1%	54.3%
Total		Count	132	144	131	153	560
		% within lifetime sexual partners grouping	100.0%	100.0%	100.0%	100.0%	100.0%

Chi-square tests

	Value	df	Asymptotic significance (2-sided)
Pearson χ^2	8.1 33[a]	3	0.043
Likelihood ratio	8.127	3	0.043
Linear-by-linear association	6.341	1	0.012
N of valid cases	560		

a 0 cells (0.0%) have expected count < 5. The minimum expected count is 59.89.

Recruitment method

Crosstab

			Group allocation		
			Group 1 (clinical)	Group 2 (community)	Total
Provided screening at TO	Not provided	Count	45	214	263
		% within group allocation	23.4%	58.5%	45.7%
	Data provided	Count	160	152	312
		% within group allocation	76.6%	41.5%	54.3%
Total		Count	205	366	575
		% within group allocation	100.0%	100.0%	100.0%

Chi-square tests

	Value	df	Asymptotic significance (2-sided)	Exact sig. (2-sided)	Exact sig. (1-sided)
Pearson χ^2	65.757[a]	1	< 0.001		
Continuity correction[b]	64.353	1	< 0.001		
Likelihood ratio	68.467	1	< 0.001		
Fisher's exact test				< 0.001	< 0.001
Lmear-by-linear association	65.642	1	< 0.001		
N of valid cases	575				

a 0 cells (0.0%) have expected count < 5. The minimum expected count is 95.59.
b Computed only for 2 × 2 table.

Provision at baseline only versus provision at baseline and follow-up

A two-way comparison between participants who only provided screening data at baseline and those who provided data at baseline and follow-up was conducted. No significant differences (5% level) were observed.