**Feasibility and preliminary effectiveness of the eHIS (Homework Intervention Strategy) programme to enhance male condom use: A research protocol**

## Abstract

Background Although condoms are effective in reducing the risk of sexually transmitted infections, (STIs) including HIV, and unintended pregnancy, they are still often not used consistently and correctly. Negative impact on sensation and pleasure, ruining the mood, causing problems with maintaining erection, and condom slippage or breakage are some of the reasons given by men explaining why they do not want to use condoms. Although many interventions promoting condom use exist, some of them delivered online, are complex and time- and resource-intensive. ObjectivesThe eHIS, (Homework Intervention Strategy) adapted from the existing face-to-face Kinsey Institute Homework Intervention Strategy (KIHIS) programme, aims to address these issues by encouraging men to focus on sensation and pleasure when trying different types of condoms and lubricants in a low-pressure situation (on their own, without a partner present). This study aims to assess the programme’s feasibility, acceptability and users’ engagement with the programme, its preliminary effectiveness in increasing condom use frequency and consistency as well as the feasibility of the programme’s evaluation approach, including choice of measures and participant recruitment and retaining strategies (primary outcomes). Secondary outcomes include condom use experience, condom use attitudes, condom use self-efficacy, condom use errors and problems, and condom fit and feel. All of these will be analysed in the context of participants’ demographics, sexual history and previous condom use. MethodsPre-post-test, within-subjects design.Men aged 18-69, living in the UK are recruited through posters, leaflets, social media, and e-mails. Study participants are asked to complete T1 (baseline) measures before entering the eHIS website. After completing the T1 measures they can order a free condoms and lubricants kit and have access to the eHIS website for four weeks. During that time they are asked to practice using different types of condoms and lubricants on their own in a no-pressure situation. Four and ten weeks after T1 participants are asked to complete T2 and T3 measures, respectively. ResultsData collection for the study is completed. ConclusionsIf successful, this brief, home-based and self-guided programme may lead to increased consistent and correct condom use. Online delivery can make the programme an easily accessible and low cost health promotion intervention, which has the potential to reach a wide and diverse audience. If results of the current study show the programme’s feasibility and preliminary effectiveness in changing condom use related outcomes, a larger scale RCT is planned to be conducted.

## Keywords

Condoms, Pleasure, Telemedicine/eHealth, Risk Reduction Behavior, Sexual Behavior, Health Psychology, Behavior Modification

## Introduction

Male condoms remain the single best method of reducing the risk of acquiring sexually transmitted infections (STIs), including human immunodeficiency virus (HIV) [1, 2]. Promotion of correct and consistent use of male condoms as an effective method of reducing the prevalence of STIs was recommended in the Global Strategy for Prevention and Control of Sexually Transmitted Infections: 2006 – 2015 [3]. However, research repeatedly demonstrates that condoms are not used consistently [4-7], and even when used, condom use errors and problems and dislike of condoms are often reported [8, 9]. Condom use errors and problems are associated with reasons men give for not using condoms, such as less pleasurable experience when condoms are used, decreased sensation, poor fit and feel, condom breakage and slippage, and difficulties in maintaining erection [10, 11].

Many previous interventions aimed to increase condom use but few of them focused on pleasure and fit-and-feel [12] and they were also often resource- and time-intensive. Improving fit-and feel should lead to reduction in condom use problems and increase consistent and complete condom use. Internet-based behaviour change interventions, on the other hand, may be cost- and resource-effective [13-15], easily accessible and acceptable by users, especially when focused on sensitive or stigmatising health related issues[16-19], and have efficacy comparable with human-delivered interventions focused on condom use [20, 21].

The eHIS is an online adaptation of the Kinsey Institute Homework Intervention Strategy (KIHIS) [22] combining a focus on pleasure and fit-and-feel in condom promotion with the benefits of an online intervention. In the KIHIS during the session with the instructor men are given the correct condom use instruction and are asked to practice condom application on a penile model. The instructor then encourages them to practice using condoms on their own and rate them, highlighting the importance of pleasure and finding the condom that fits and feels well for an individual. The home-based and practice-oriented approach makes the programme distinct from most interventions in this area, which are mainly delivered face-to-face, during group workshops, or in individual consultations [23-25]. The results of previous pilot studies [22, 26, 27], showed the programme’s potential in improving use experiences, confidence in the ability to use condoms, self-efficacy for condom use, condom comfort, and reduced breakage and erection problems.

The final content and design of the programme were developed taking into account the feedback from participants provided in the qualitative evaluations of the programme prototype (paper-based) and computerised version of the programme (M. Glowacka, thesis chapter in preparation). It was also consulted with the research team adapting the face-to-face version of the programme to the UK context [27].

Mirroring the KIHIS approach, the eHIS addresses the issues related to condom use errors and problems by focusing on correct condom use, pleasure, and developing positive condom use experience. Participants are encouraged to practice correct condom application and explore different types of condoms and lubricants in a low-pressure situation, at home and without their partners present. Components of the intervention are listed in Table 1 and an example of the eHIS webpage is presented in Figure 1.

Table 1

*eHIS – programme components*

|  |
| --- |
| eHIS components |
| **Core pages**  | programme’s rationale, correct condom use skills review, tips on how to deal with specific condom use errors and problems, information about programme procedure and condom kit content, a home practice guide, condom rating forms, ratings feedback, condoms and lubricants kit order |
| **Optional pages** | masturbation, partner involvement, condoms effectiveness, information where to find support in case of concerns related to condom use, condom use instruction in various formats, example of condom rating form, motivational message (aimed to provide study rational for specific users’ circumstances such as various condom use experience and relationship status or message strengthening programme credibility perception)  |
| **Additional pages** | contact form, reminders cancellation, login, exit, password reset  |
| **Study pages** | Participant Information Sheet, consent statement, screening questionnaire, registration, study questionnaires, charity donation, debriefing sheet, information about uncompleted measures, next follow-up date/completion of the study |
| **Condoms and lubricants kit** | 6 different types of condoms, (2 of each) chosen to give a wide range of sizes, shapes, and materials (latex and non-latex), 2 types of lubricants in 6 single use sachets, a printed correct condom use instructions with a link to the study website. |

Figure 1

*An example of the eHIS webpage*



### Aims and Objectives

The current study aims to evaluate the feasibility of the Internet-based eHIS programme. Evaluation of participants’ engagement with the programme and its acceptability (dimensions of feasibility, primary outcomes) and the potential of the intervention to change targeted behaviour (preliminary effectiveness) can provide a “proof of concept” for the approach used in the intervention [28, 29]. Condom use related variables assessed in this study are: increasing condom use frequency and consistency (primary outcomes), and reducing condom use errors and problems, enhancing condom use experience, increasing condom use self-efficacy, and improving condom use attitudes and motivation (secondary outcomes).

 The study does not target men based on characteristics such as sexual orientation or condom use history as it has not yet been established for whom the eHIS intervention may be the most useful. Therefore, whether the programme’s feasibility and preliminary effectiveness are linked to participants’ demographic characteristics, sexual history or previous condom use variables is also explored.

To inform development of a larger trial, the feasibility of the approach to study evaluation with focus on recruitment effectiveness, measures completion, and attrition rate is investigated. This will help to verify whether the specific study design and approach employed for the evaluation are appropriate and identifies acceptable outcome measures that should be used as measures of its effectiveness in a full-scale randomized controlled trial (RCT) [30]. The results can also help to estimate expected effect size of observed changes, to be used in calculation of the sample size needed for a full scale RCT [31].

### Research questions

This study is guided by the following research questions: Is the eHIS programme feasible? Does the eHIS programme have the potential to be effective in: increasing the frequency of condom use, increasing consistent condom use, improving condom use experience, improving condom use self-efficacy, reducing the number of condom-related errors and problems, changing condom use attitudes to more positive ones, and increasing motivation to use condoms? Is the approach to evaluate eHIS programme feasible? Are the programme and study feasibility, and the preliminary effectiveness of the programme on condom use outcomes associated with participants’ characteristics (demographic, sexual history or baseline condom use variables)?

## Methods

### Study design

The study uses a pre-post-test, within-subject design.

### Participants

A target sample of 139 participants was recruited and data collection is underway. The sample size was estimated on the basis of calculation of the number of participants required to conduct statistical analysis to evaluate the feasibility of the programme and its preliminary effectiveness, possible high attrition (in the region of 60%), more likely in self-guided interventions [32-36], study resources and numbers of participants recruited to similar studies [31, 37-42]. Inclusion criteria for the study are listed in Table 2.

Table 2

*Inclusion and exclusion criteria*

|  |  |
| --- | --- |
| Inclusion criteria | Exclusion criteria |
| gender: male; | gender: other than male; |
| aged 18-69; | below the age of 18 or aged 70 or above; |
| fluent in English (written and spoken); | not fluent in English (written and spoken); |
| have access to the Internet for the duration of the study; | allergic or sensitive to latex, non-latex condoms and/or lubricants; |
| living in the UK | have difficulties using computers and other VDU |
|  | equipment requiring use of specialist software to access the website content; |
|  | have a learning disability requiring third person support to access and use the eHIS website; |
|  | do not have access to the Internet for the duration of the study; |
|  | living outside of the UK |

### Recruitment

 Participants were recruited through self-referral in response to recruitment advertisements (posters, leaflets, business card adverts, Facebook and Twitter posts and paid adverts, e-mails and UK-wide mailing lists for postgraduate psychology students). The adverts included key phrases such as: test and rate condoms, improve condom use experience, learn more about condoms, focus on pleasure, enjoy using condoms, get free condoms and lubricants kit. To ensure wide reach and reduce the risk of recruitment bias (age and geographical location) where possible, study advertisements were distributed in multiple locations (mainly in England, including universities, colleges, sexual health charities, commercial sector employers, community centres, youth organisations) and in social media (Facebook paid posts addressed to specific age groups, for example 26-35 years, 36-45 years etc. with the UK chosen as geographical location). People from professional and personal networks were also asked to share the advertisements in their locations and through social media. UK wide was also used to share the study advertisements.

### Data collection

Questionnaires and website usage data are used in the study to collect data. The questionnaires were chosen to mirror as closely as possible the measures used in the face-to-face KIHIS [22, 26] and HIS-UK studies [27]. They were reviewed and modified informed by the feedback received in a qualitative evaluation of the programme during its development phase (M. Glowacka, thesis chapter in preparation). Additional measures/items were chosen or developed for this study to allow investigation of the aspects of the programme related to its specific mode of delivery. The data collection schedule is presented in Table 3.

Table 3

*Study measures*

|  |  |  |
| --- | --- | --- |
| **T1** | **T2** | **T3** |
| Eligibility screening questionnaire |  |  |
| Study registration |  |  |
| Motivation to take part in the study |  |  |
| Recruitment information |  |  |
| Background information |  |  |
| Sexual history |  |  |
| STIs and unplanned pregnancya |
| Condom use and sexual activityb |
| Effect on Sexual Experience subscale from Condom Barriers Scalec |
| Correct Condom Use Self-Efficacy Scale (CCUSS) |
| Condom Use Errors and Problems Survey (M-CUES)c |
| Condom Fit and Feel Scaled |
| Multidimensional Condom Attitudes Scale (MCAS) (selected 5 items) |
|  | eHIS Evaluation Survey |  |
|  | Searching for Condom Use Related Information |  |
| Between T1 and T2 Condom Rating Form (maximum 15 entries) |
| Website usage data are collected throughout the period when the website is available to the participants.  |

a at T1 questions are asked about lifetime and last year, at T2 and T3 about the last 4 weeks

b additional questions asked at T1 (see measures descriptions)

c questionnaires displayed only to those who reported that they had used condoms during sexual intercourse over the last 4 weeks

d questionnaires displayed only to those who reported that they had used condoms during sexual intercourse or had practiced using condoms over the last 4 weeks

Eligibility screening questionnaire. The screening questionnaire includes questions assessing the inclusion/exclusion criteria (see Table 2).

Registration. Following screening eligible participants are asked to provide an e-mail address that the study reminders are sent to and an optional phone number if they would also like to receive text messages with study reminders.

 Background information questionnaire. At baseline (T1) participants provide background information such as ethnic background, education, employment, relationship status, first part of the postcode, and computer use proficiency. The ethnic background question categories were adapted from the Census for England [43].

Sexual history. At T1 participants are asked about their current sexual activity (they can choose one answer from options: Sex with one partner only, Frequent sex with different partners; Infrequent sex with different partners, Occasional sex with different partners; Not sexually active, Other), gender of their sexual partners (they can choose one of the options: Women, Men, Women and men, I have never had sex) [44] and number of sexual partners.

STIs and unplanned pregnancy. At T1 questions about lifetime and last year STIs diagnoses and unplanned pregnancies are asked. At T2 and T3 participants provide information about STI diagnoses and unplanned pregnancies in the last four weeks.

Condom use and sexual activity. To assess the frequency and consistency of condom use at T1-T3 participants are asked about the number of episodes of penile-vaginal, penile-anal or penile-oral intercourse in the last 4 weeks, number of partners in the last 4 weeks, and the number of times a condom was used during penile-vaginal, penile-anal or penile-oral intercourse in the last 4 weeks, and whether they practiced using condoms in the last four weeks. Participants also provide reasons for using condoms (they can choose multiple reasons from: I did not use condoms, to avoid sexual transmitted infections, to avoid HIV/AIDS, to please my partner, to make sex more pleasurable, to make sex last longer, so my partner would not get pregnant, to practice, other) and the type(s) of condoms used in the last four weeks (latex, non-latex, I don’t know what kind we used, not applicable (I did not use condoms)). Additionally, at T1 they are asked whether they were taught how to use condoms, and if so, where did they learn to use condoms from (multiple choice from: Leaflet attached to the condom pack, leaflet given to me, watching condom use demonstration (video), watching condom use demonstration (live), practicing how to use condoms correctly instructed by somebody else (i.e. during sex education/in the clinic etc.), erotic/porn movie, erotic/porn magazine, have not learnt how to use condoms), and whether they had ever used condoms or practiced using them without a partner present.

Condom use experience. This questionnaire is only displayed to those who report that they had used condoms during sexual intercourse over the last 4 weeks (T1, T2, T3). The Effect on Sexual Experience subscale from the Condom Barriers Scale [45, 46] is a seven-item scale which measures participants’ condom use experience at T1-T3, including condom fit and feel, condom mood interruption, and condom impact on climax or orgasm and on the relationship with sexual partner. Items are rated on a five-point scale (1 = strongly agree to 5 = strongly disagree). Higher scores indicate better condom use experience. In previous research this subscale showed good internal reliability (α = .74 [22], α = .81 [26]).

Condom Attitudes. Five items chosen from the Multidimensional Condom Attitudes Scale (MCAS) [47]assessing pleasure associated with condoms are used to assess attitudes toward condoms at T1- T3 [26]. Items are rated on a seven-point scale (1 = strongly disagree to 7 = strongly agree), with higher scores indicating more positive condom use attitude (3 items are reversed scored). An option of “neither agree nor disagree” for item number (4) was added because of participants’ feedback in the qualitative study evaluation eHIS programme website (M. Glowacka, thesis chapter in preparation). The subscale showed good reliability in the previous study evaluating the KIHIS programme [26], with α = .81.

Condom use self-efficacy. At T1-T3 participants’ perception of their condom use ability (e.g., finding condoms that fit properly, keeping condoms from drying out during sex) are measured by seven items adapted from the Correct Condom Use Self-Efficacy Scale (CCUSS) [22, 48]. These items are rated on a five-point scale (1 = very difficult to 5 = very easy). Higher scores indicate greater correct condom use self-efficacy, which is associated with fewer condom use errors and problems [49]. This scale was demonstrated to have good internal reliability in previous studies (α = .72 [22] α = .70 [49], α = .82 [27]).

Condom use errors and problems. The survey is only displayed to those who report that they had used condoms during sexual intercourse over the last 4 weeks (T1, T2, T3). The 17-item Condom Use Errors/Problems Survey (M-CUES) [50] assesses condom use errors and problems experienced during the last condom-protected sexual event. Respondents are asked about the presence or absence (yes/no) of problems and errors such as condom breakage and slippage, issues with fit and feel, incomplete or incorrect use of condoms, and loss of erection associated with condom use. Separate condom use error and problems scores are calculated, with higher scores indicating more condom use errors and problems. The CUES has good face and content validity [50].

The CUES was modified in line with feedback received from participants in the qualitative study evaluating the eHIS website (M. Glowacka, thesis chapter in preparation) and from materials developed for the HIS-UK feasibility study [27]. The form of the questionnaire was simplified, as was the scale instruction and item wording. An item asking about checking a condom expiry date was added to the scale to make it consistent with the condom use instructions given in the programme. To make the recollection of events easier the recall time was changed from “last 3 times the condom was used” to “last time you used a condom”.

Condom Fit and Feel Scale [51]. The questionnaire is only displayed to those who report that they had used condoms during sexual intercourse or practiced condom use over the last 4 weeks (T1, T2, T3). This 14-item scale is completed at T1-T3. Items include “Condoms fit my penis just fine” and “Condoms are too long for my penis.” Answers are given on four-point scale (1 = never applies to me and 4 =always apply to me) with some items being reversed scored. An overall score is obtained; higher scores indicate more negative experiences with condom fit and feel. Scale validity and reliability have been demonstrated previously (α = 0.60–0.86 [52]).

Condom rating form. Participants are asked to complete this form after each condom use practice. In the first part of the form they give information about which condom they used during a practice session and whether they had used it before. They indicate what type of sexual activity the condom was used for, whether they stopped testing it before putting it on and if yes, what was the reason. In the second part of the rating form participants rate condoms on different aspects of fit and feel. They are also asked about the use of lubricant and their preference for using the particular condom in the future. Participants are expected to complete at least 6 condom rating forms; a maximum of 15 ratings can be completed across the time when participants have access to the programme’s website. The condom rating form was adapted from materials used in previous studies evaluating the face to face version of the programme [22, 26, 27] and modified in line with feedback received in the qualitative evaluation of the programme’s computerised version (M. Glowacka, thesis chapter in preparation).

 eHIS Evaluation Survey. This survey assesses the acceptability of the programme’s content and format at the first follow-up (T2). The eHIS evaluation survey was developed for this study to explore participants’ opinions about the programme and the website. A literature search of previous studies using questionnaires to evaluate eHealth interventions, treatment preferences, and measures used to evaluate websites’ content and usability [42, 53-60] and themes identified in the qualitative phase of the eHIS website development (M. Glowacka, thesis chapter in preparation) were used to define key categories and guided items development.

 The 24 item survey assesses agreement or disagreement (from strongly disagree to strongly agree) with statements related to relevance of the programme for the issues covered, personal relevance, completeness of the information and advice given, willingness to follow the advice given, trustworthiness, clarity of the content, and programme use enjoyment, website usability, including questions about its structure, navigation, information, and organisation, and website aesthetics. Participants also have a chance to share their preferences regarding the programme’s content and design in open text entry questions, as well as provide additional qualitative feedback. For the item “The amount of the information on the page was…” the responses are “just right,” “too much,” and “not enough.”

Searching for Condom Use Related Information. This is a 3-item questionnaire developed for this study that is completed at T2 only. Participants are asked whether they searched for additional condom use information when they had access to the eHIS website and if yes, where they searched for the information (multiple choice: social media, NHS website, other health information websites, sexual health clinic, GP surgery, youth centre, friends, other) and what type of information it was (multiple choice: correct condom use instruction, advice on dealing with condom use problems, information about different types of condoms, information about different types of lubricants, other). Answers to these questions together with the answers from the eHIS evaluation survey will be used to assess the programme completeness and credibility (dimensions of acceptability).

Website usage data will be also used as a measure of participants’ engagement with the programme [31, 35, 39, 61], the eHIS website logs are used to analyse participants’ activities on the website e.g., time spent on the website, number of visits, and specific pages seen by participants.

Whether participants ordered the condoms and lubricants kit and the number of completed condom rating forms are used as measures of engagement with the programme alongside participants’ self-reports on the specific items in the eHIS evaluation survey.

The feasibility of the study evaluation approach will also be assessed in the context of the recruitment information, motivation to take part in the study, specific outcome measures completion, and attrition rate. At T1 participants are asked how they heard about the study, what were their reasons to take part (a multiple choice question) and whether they took part in any study in the programme’s development stage. Measures acceptance is assessed on the basis of proportion of participants’ completing specific scales and providing answers to their specific items. Attrition will be assessed on the basis of completion rate of baseline and follow-up questionnaires.

### Study procedure

Following the link or QR code from the advertisement individuals are directed to the study website, where they are first presented with the Participant Study Information Sheet. Participants indicate their consent to take part and for their data they provide to be used for research purposes by ticking a box next to the consent statement. They then complete the eligibility screening measure; if eligible, they are directed to the study registration page and then to the T1 measures. If ineligible, they are thanked for their interest in the study.

Next, participants can access the core eHIS website and are able to order a condom kit to be sent by post or collected from the University of Southampton within 3 working days from placing the order. They have 4 weeks, counting from the date they completed the T1 measures, (hereafter “start point”) to practice condom use at home and complete condom rating forms after each practice event. Four weeks from the start point the website is no longer available to participants and at that point participants are asked to complete T2 measures; ten weeks after the start point they are asked to complete the final T3 measures.

Participants receive one e-mail reminder and one optional text reminder on the day T2 and T3 measures are due to be completed. They also receive 2 e-mails and an optional text per week for the duration of home practice (during weeks 2, 3 and 4) reminding them to complete condom ratings. The condom rating reminders are automatically cancelled for the particular week if at least one rating is completed; all reminders are automatically cancelled if at least 4 ratings are completed. Participants have the option to cancel e-mails and/or text messages when they visit the programme’s website regardless of the number of ratings reminders. An overview of the study procedure is presented in Figure 2. Ethical approval from the Department of Psychology Ethics Committee at the University of Southampton was obtained. The study is registered in the Research Registry, Unique Identifying Number researchregistry2325.

Figure 2

*Study procedure*



### Incentives

After completion of each set of study measures participants can choose one of three charities for 50p donation. After completion of the T3 measures participants receive a £5 Amazon voucher. Psychology students at the University of Southampton have the option to claim up to 32 research credits for participation.

### Data analysis

Feasibility of the programme and the evaluation approach will be assessed through analysis of programme engagement, acceptability, recruitment and retention rates. Descriptive statistics will be used to describe the study population, feasibility of the evaluation approach, engagement with the programme and its acceptability. The preliminary effectiveness of the programme will be assessed through evaluation of the change on primary and secondary condom use related outcomes. Within group comparison will be undertaken to assess whether there are any differences between specific subgroups (for example, those who complete the study and those who drop out, those reporting improvement on various dimensions of condom use and those who do not report change) on characteristics such as demographic variables, sexual history and/or baseline condom use-related variables where sufficient data will be available. The results of the preliminary effectiveness results will be used to calculate the effect size of changes in condom use related outcomes. SPSS software v.21.0 [62] will be used for data analysis.

## Results

Recruitment for the study is completed and data collection was completed by the end of July 2017.

## Discussion

It is expected that this study will provide preliminary information about eHIS feasibility, specifically engagement with the eHIS programme, its acceptability and potential to improve condom use frequency and consistency, reduce condom use errors and problems, improve condom use self-efficacy, improve condom use experience, and improve condom use attitudes. These findings can further direct the programme’s content and procedure improvements. The results of an exploratory evaluation may support the need for further programme development and/or indicate the need for conducting a large scale RCT and provide valuable guidance regarding its optimal design [39, 63]. The findings are expected to have scientific and clinical implications, advancing knowledge about the feasibility and preliminary effectiveness of the novel approach to promote consistent and correct condom use and potentially contributing to the development of a tool that could be used in sexual health promotion practice.

## Conflict of interest

To avoid promoting a specific brand of condoms the choice of condoms included in the condom kit was made from those available in the UK shops and/or on the Internet on the basis of their features (size, shape etc.) to provide a variety of choice (essential for the study). There is no particular brand endorsement in any part and at any stage of the programme.

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