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Adaptation, Development and Evaluation of eHIS Intervention to Enhance Male Condom Use

by

Marta Agnieszka Glowacka

Thesis for the degree of Doctor of Philosophy in Health Psychology Research and Professional Practice

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Abstract

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This thesis presents the process of adaptation, development[1] and evaluation of eHIS intervention to enhance male condom use. Description of theoretical underpinnings of the project is followed by a step-by-step presentation of the development and evaluation process, which was supported by evidence review and feedback from participants at eHIS development stages.

In the systematic review completed within the project different methods of supporting development of technical condom use skills (TCUS) were reviewed and their associations with condom use related behaviours, cognitions and sexually transmitted infections (STIs) were explored. Demonstration, skills rehearsal and self-monitoring were amongst the techniques included in the effective interventions promoting condom use.

Results of the qualitative evaluations of the intervention prototype and its computerised version completed within the project allowed insight into potential users' experience with eHIS, understanding of barriers and facilitators of engagement with the intervention, and identification of its areas requiring further development.

In the final study feasibility and preliminary effectiveness of eHIS were evaluated. Its results indicated potential new target groups (those with less condom use experience and men aged 26 and over). The general acceptance of the intervention approach was high amongst those who completed follow-up questionnaires. The intervention was found to be potentially effective in increasing condom use consistency, reducing frequency of sexual intercourse without a condom being used, improving condom use experience, increasing condom use self-efficacy and reducing condom use errors and problems. The evaluation approach was found to be adequate.

[1] Adaptation and development – henceforth, referred to as 'development'.

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Declaration of Authorship

Print name:	Marta Agnieszka Glowacka

Title of thesis:	Adaptation, Development and Evaluation of eHIS Intervention to Enhance Male Condom Use

I declare that this thesis and the work presented in it is my own and has been generated by me as the result of my own original research.

I confirm that:

1. This work was done wholly or mainly while in candidature for a research degree at this University;
2. Where any part of this thesis has previously been submitted for a degree or any other qualification at this University or any other institution, this has been clearly stated;
3. Where I have consulted the published work of others, this is always clearly attributed;
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Signature:		Date:	

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List of Abbreviations

The list of abbreviations used in the thesis in order of appearance:

STI	Sexually transmitted infection
KIHIS	Kinsey Institute Homework Intervention Strategy
eHIS	online Homework Intervention Strategy
HIV	Human immunodeficiency virus
HPV	Human papilloma virus
NATSAL	the British National Surveys of Sexual Attitudes and Lifestyles
MSM	Men who have sex with men
GP	General Practitioner
GUM	Genitourinary Medicine
NHS	National Health Service
FTF	Face-to-face
TCUS	Technical condom use skills
DIs	Digital interventions
MRC	Medical Research Council
BCW	Behaviour Change Wheel
IM	Intervention Mapping
6SQuID	Six Steps for Quality Intervention Development
PBA	Person-Based Approach
GPR	Guiding principle
BIT model	Behavioural Intervention Technology model
LM	Logic model
CUE model	Condom Use Experience model
PLISSIT model	Permission Limited information Specific suggestions Intensive therapy model
IMB model	Information Motivation Behavioural Skills model
BCTT	Behaviour Change Techniques Taxonomy
TAI	Think-aloud interview
SSI	Semi-structured interview
PIS	Participants Information Sheet
UoS	University of Southampton
RCT	Randomised Controlled Trial
EPHPP	Effective Public Health Practice Project
PVI	Penile-vaginal intercourse
VDU	Visual display unit
BAME	Black Asian and Minority Ethnic

Chapter 1

Thesis Introduction and Rationale

Chapter Introduction

This chapter describes the role of condoms in the prevention of STIs, the importance of consistent and correct condom use and the impact of condom use errors and problems on condom effectiveness. An overview of sexual health education and services provision in the UK is also included, as well as description of Kinsey Institute Homework Intervention Strategy (KIHIS), from which online Homework Intervention Strategy (eHIS) was adapted. The rationale for eHIS's development is presented and the thesis outline is provided.

The Importance of Condom Use

Condom use in the prevention of STIs. Male condoms remain the single best method of reducing the risk of acquiring STIs, including human immunodeficiency virus (HIV) (Cates, 2005; Centers for Disease Control and Prevention, 2011; Crosby & Cates, 2012; Holmes, Levine, & Weaver, 2004; UNAIDS, UNFPA, & WHO, 2009; Warner & Steiner, 2011; Weller & Davis-Beaty, 2002). Not using condoms and a higher number of sexual partners was also found to be strongly related to Chlamydia and human papilloma virus (HPV) infections (Sonnenberg et al., 2013).

Although condoms are relatively easy to use and are widely accessible in the United Kingdom, over 30% of sexually active men aged 25-34, and approximately 12% aged 16-24, engage in unprotected sex (Lader, 2009). In the second wave of the British National Surveys of Sexual Attitudes and Lifestyles (NATSAL), comprising a nationally representative sample, over 80% of men and women aged 16-19 reported using condoms, while in the 40-44 age group this proportion dropped to slightly below 30% and 37% for men and women, respectively (Wellings et al., 2001). In the Natsal-3 survey (Mercer et al.,

2013) 7.6% of respondents in the total sample (16 - 74 years) reported having sexual intercourse without condoms with at least two partners in the last year; in the group 16 to 24 years old this figure was 16.4%. A survey conducted with a large community sample of at-risk (reporting unprotected sex in the past 90 days) adolescents and young adults in the US showed that approximately two-thirds of adolescents did not use condoms consistently during sexual encounters (L. K. Brown et al., 2008). The US Centers for Disease Control and Prevention (2013) reported that condom use among young people investigated in the Youth Risk Behavior Surveillance System declined in 2013 compared to 2003, from 63% to 59%. These data show that despite many efforts promoting consistent condom use (Noar, 2008), there is still much room for improvement.

The importance of consistent and correct condom use. Consistent condom use, however, is not enough to protect individuals from STIs. Research has demonstrated that condoms are often used inconsistently (L. K. Brown et al., 2008; Lader, 2009; Mercer et al., 2013; Wellings et al., 2001), but even when they are used, errors in use are common (Crosby, Sanders, Yarber, & Graham, 2003; Lindemann, Brigham, Harbke, & Alexander, 2005; Sharma, Dave, Sharma, & Chauhan, 1997). Recent research has put more focus on correct and complete condom use, i.e. use from start to finish of a sexual encounter and on the problems related to condom use (Baćak & Štulhofer, 2012; Graham, Crosby, Milhausen, Sanders, & Yarber, 2011; Warner et al., 2008). The World Health Organisation (WHO, 2006) recommends providing explicit information about correct condom use, followed by condom use skills practice as an effective method of reducing the prevalence of STIs.

Condom use errors have been defined as “those behaviours that represent incorrect use of condoms” (Sanders et al., 2012, p. 82). The errors frequently reported in the literature are: inconsistent and incomplete condom use (e.g., late application, early removal), application errors (e.g., not leaving space at the tip, failure to expel air from the condom, unrolling the condom before putting in on, and putting the condom on inside out

before flipping it over), not holding the condom during withdrawal, and incorrect lubricant use (Sanders et al., 2012). Condom use problems are defined as "experiences that may be under less direct behavioural control of the condom user, but may compromise condom use or condom protection" (Sanders et al., 2012, p. 82). Frequently described condom-related problems are condom breakage, slippage and leakage, fit-and-feel problems, reduced sexual arousal, decreased sexual sensation, and erectile difficulties related to condom use (Crosby, Milhausen, Sanders, Graham, & Yarber, 2008; Crosby, Milhausen, Yarber, Sanders, & Graham, 2008; Crosby, Yarber, Graham, & Sanders, 2010; Crosby, Yarber, Sanders, & Graham, 2005; Graham et al., 2011; Graham et al., 2006; Yarber, Graham, Sanders, & Crosby, 2004). Condom use errors and problems were found to increase the likelihood of inconsistent condom use (Sanders et al., 2012).

The impact of condom use errors and problems on condom effectiveness. In addition to increasing the likelihood of inconsistent condom use, condom use errors and problems may reduce condom effectiveness and increase the risk of being exposed to STIs (Sanders et al., 2012), even amongst those who report using condoms consistently (Allman et al., 2009; Dolezal et al., 2013). Condom use problems and condom proficiency have been associated with increased incidence of STIs among men who have sex with men (MSM) (D. Cohen, Dent, & MacKinnon, 1991; Goodall, Clutterbuck, & Flowers, 2012). Receptive anal sex without condoms and delayed condom application were found to be independent risk factors for HIV infection (Calzavara et al., 2003). Condom breakage has been linked to gonorrhea infection amongst male patients of STI clinics (Grimley, Annang, Houser, & Chen, 2005). In a sample of African-American girls recruited in an urban adolescent healthcare clinic, consistent and correct condom use (not simply consistent use) reduced the risk of gonorrhea by 90% and the risk of Chlamydia infection by 60% (Paz-Bailey et al., 2005). Consistent condom use in a group of STI clinic patients was linked to a reduction in risk of gonorrhea and Chlamydia, and eliminated the risk of infection altogether amongst participants who also reported no condom use problems (Warner et al.,

2008). Regarding the effectiveness of condom use in the prevention of unintended pregnancy, there is an 18% failure rate among typical users in the first year of use in comparison to only a 2% failure rate amongst perfect users, i.e. those who use condoms consistently and correctly (Trussell & Guthrie, 2011). This difference highlights the importance of correct condom use for its effectiveness in preventing pregnancy. In view of the heightened risk of contracting HIV/STIs associated with incomplete and incorrect condom use (Calzavara et al., 2003; Paz-Bailey et al., 2005; Sanders et al., 2012; Warner et al., 2008), it is essential to target these problems in interventions promoting condom use.

Sexual Health Education and Services in the UK

Sexual health education. Traditionally sex education in the UK focused on biological development, STI prevention, biologically oriented discussion of reproduction, with time introducing elements of contraception, relationship and interpersonal skills (Reiss, 2005). Although elements of Sexual and Relationship Education are mandatory in state schools in England, Wales and Northern Ireland, and recommended in Scotland (Family Planning Association, 2011b), the areas covered include mainly biological aspects of growing up, information about STIs and HIV/AIDS and topics covering social, psychological and moral aspects of intimate relationship and family (Family Planning Association, 2011b; L. A. Hall, 2009). The depth of the information and other areas that may be covered follow general and vague guidance that allows substantial differences in the content between schools and can be influenced by parents and organisations representing different opinions in local communities. Lack of education about the role of pleasure in relation to sexuality is a noticeable gap in the education programmes (Hirst, 2013; Ingham, 2005; Strange, Forrest, Oakley, & Stephenson, 2006). There is also no evidence that condom use is discussed in the context of users' experience; the focus has been on their preventive role against STIs and pregnancy. At present there is no consistent, pleasure oriented sex education in the UK.

Sexual health services. In the UK there is currently a network of places providing free confidential sexual health services. These include General Practitioner (GP) surgeries, family planning clinics, sexual health clinics, STIs testing clinics, genitourinary medicine (GUM) clinics, pharmacies, sexual assault referral centres and young people's services (NHS, 2018). They provide a range of advice regarding contraception, STI testing, treatment, and prevention as well as sexual health education. Since 1974 condoms have been freely available from the National Health Service (NHS) (Family Planning Association, 2011a). However, despite the services being available, the findings of Natsal-2 (French et al., 2009) reported that 45.1% of men aged 16-44 did not use any contraceptive service for supplies and/or advice within a year prior to the survey.[2]

Despite the range of sexual health services numerous barriers (personal and organisational) in accessing them are consistently reported, particularly in relation to young people's experience. Firstly, men may not feel that they need to use services (Carroll, Lloyd-Jones, Cooke, & Owen, 2012), they may obtain condoms from alternative sources and/or do not see visiting services as necessary especially before they have sex (Parkes et al., 2004; Stone & Ingham, 2003). If they access a service, it is mainly to get free condoms or in a crisis situation (Pearson, 2003).

Another barrier in accessing services are confidentiality concerns (Bender & Fulbright, 2013; Carroll et al., 2012) which may be particularly important in small communities (Craig & Stanley, 2006; Garside, Ayres, Owen, Pearson, & Roizen, 2002). Others may be reluctant to return to a service if they are not satisfied with the staff they met (Carroll et al., 2012; Craig & Stanley, 2006) or with the quality of services (Bender & Fulbright, 2013).

Service proximity, convenience and opening times were found to be linked to service use amongst young people (Carroll et al., 2012; Craig & Stanley, 2006; Parkes et

[2] The recently published results of the Natsal-3 (Tanton et al., 2018) showing that over 75% of participants aged 16-74 (of which 44.4% were men) who reported not using condoms with new or different partners within the last year did not visit a sexual health service further support the need for intervention such as eHIS in the UK.

al., 2004). Although GP surgeries could be the first point of call to discuss any problems related to sexual health, clinical staff (GPs and nurses) tend not to raise the topic of sexual health themselves (Gott, Galena, Hinchliff, & Elford, 2004; Macdowall et al., 2010).

Discussing sexual health topics with specific groups may be another problematic issue. Although there is a growing body of research indicating that people may be sexually active until late adulthood (Eardley et al., 2004; Gott & Hinchliff, 2003; Mercer et al., 2013) and experience a range of sexual health problems (Bacon et al., 2003; Jung & Schill, 2004; Laumann et al., 2004), providing adequate sexual health services and education to middle age and older adults seems to be a particular gap, with the primary focus on young people (Gott, Hinchliff, & Galena, 2004). Middle-aged and older patients were listed amongst those whom GPs did not feel comfortable to discuss sexual health topics with (Gott, Galena, et al., 2004). This is especially concerning considering suboptimal level of sexual health education provided over the last six-seven decades as discussed above.

Personal characteristic, other than age, can also have impact on whether issues related to sexuality are discussed. For example some GPs found it difficult to discuss sexual health topics with people from ethnic minorities or non-heterosexual patients (Gott, Galena, et al., 2004; Hinchliff, Gott, & Galena, 2005). This is consistent with service perceptions from the perspective of these group members. Older gay men's reasons for not disclosing their sexual orientation while accessing healthcare was linked to their perception of their needs not being addressed (Clover, 2006). Another example is provided by a study conducted in east London, in which Bangladeshi men found the existing sexual health services to be culturally insensitive (Beck, Majumdar, Estcourt, & Petrak, 2005).

Addressing gaps in the sex education and barriers to accessing sexual health services. The picture of sex education in schools in the UK seems inconsistent and unsatisfactory. Issues related to sexual pleasure seem to be particularly absent from sex education (Hirst, 2013; Ingham, 2005; Strange et al., 2006). Inconsistent and changing over time sex education may mean that many men, especially older ones, are lacking

adequate knowledge in this aspect. Taking these factors into account it seems justified to make the assumption that men of all ages may have incomplete knowledge and awareness of the reasons for condom use and methods of dealing with condom use related problems. Additionally, barriers in accessing available services may mean that these gaps may not be easily addressed.

In this context and considering the importance of consistent and correct condom use, it seems that a new approach to promoting consistent and correct condom use is needed. Addressing problems that men may experience when using condoms and/or deciding not to use them may have a positive impact on their sexual health and sexual life.

KIHIS – a Novel Approach to Enhance Male Condom Use

Considering the importance of correct and consistent condom use and the impact of condom use errors and problems on health and wellbeing of an individual as well as on the health at the population level, a novel intervention aiming to improve complete, correct and consistent condom use was developed. KIHIS, a brief, self-guided home-based condom use intervention, addresses issues related to condom use errors and problems by focusing on developing positive condom use experience (Milhausen et al., 2011).

The initial brief clinic session with a health educator/nurse focuses on developing correct condom use skills through demonstration, practice and feedback, normalisation of condom use and encourages participants to practice correct condom application and explore different types of condoms in a low pressure situation, at home and without their partners present. This approach was designed to emphasise practising skills to use condoms correctly and increase an individual's focus on pleasurable sensations whilst using condoms (Milhausen et al., 2011).

The home-based and practice-oriented approach makes the KIHIS intervention distinct from most interventions in this area, which are mainly delivered face-to-face (FTF), during group workshops or in individual consultations and are thus resource-intensive (X.

Chen, Murphy, Naar-King, & Parsons, 2011; Free, Roberts, Abramsky, Fitzgerald, & Wensley, 2011; K. Wang, Brown, Shen, & Tucker, 2011). The results of previous pilot studies (Emetu et al., 2014; Milhausen et al., 2011) showed that KIHIS was effective in addressing issues such as poor condom use experiences, lack of confidence in the ability to use condoms, low self-efficacy for condom use, condom discomfort, breakage and erection problems.

Thesis Aims

This thesis presents the research project completed to develop and evaluate eHIS. The first aim was to translate a FTF intervention into the online environment ensuring the closeness to KIHIS and to report on the process and results of the studies completed as parts of it. Evaluation of the intervention feasibility and potential to be effective in changing condom use behaviour and condom use related outcomes was the second key aim of the project. It focused specifically on exploration who would be interested in taking part and whether individuals' characteristics could be linked to the outcomes of the evaluation. An additional aim was to assess the feasibility of the evaluation approach (i.e. recruitment approach, measures completion).

Thesis Outline

This thesis presents the process of development and evaluation of eHIS intervention to enhance male condom use – an online version of KIHIS (Milhausen et al., 2011). It started with the project background and rationale described above. Chapter 2 discusses the initial stages of the development process – the review of the theoretical base of the intervention, its key assumptions and the consideration of the methodological paradigm leading the project. In the following three chapters the individual studies completed within the project are presented. Chapter 3 describes the systematic review of the effectiveness of different methods to develop technical condom use skills (TCUS).

Two qualitative studies in which the prototype and the computerised version of eHIS were evaluated are described in Chapter 4. The evaluation of the feasibility and preliminary effectiveness of eHIS is presented in Chapter 5. Chapter 6 provides a summary of the project and discusses its methodological approach and the implications of its results, as well as the project's strengths and weaknesses. The overview of the chapters with description of the aims of the conducted studies and their contribution to the intervention development process is presented in Figure 1.

Figure 1

The overview of the chapters of the thesis

Chapter 1 Thesis Introduction and Rationale	In this chapter the background and rationale for the thesis are set.
Chapter 2 Development of an Online Version of the Kinsey Institute Homework Intervention Strategy (eHIS) Intervention to Enhance Male Condom Use	In this chapter behaviour change digital interventions are discussed. eHIS's theoretical underpinnings, key assumptions, guiding principles and logic model are presented. The methodological underpinnings of the thesis are discussed.
Chapter 3 The Role of Technical Condom Use Skills Development Techniques in Interventions Promoting Male Condom Use – a Systematic Review	In this chapter the systematic review conducted to explore the effectiveness of various methods of developing correct condom use skills is presented. The review results informed the development of elements of the intervention focused on correct condom use skills.
Chapter 4 A Qualitative Evaluation of a Prototype (Study 1) and a Computerised Version (Study 2) of eHIS	Qualitative evaluations of the intervention prototype and its computerised version are presented in this chapter. Their aims were to explore potential users' perspectives on the intervention and its acceptance. The studies' results influenced the revision of the intervention's guiding principles. They also informed the development of the intervention in terms of amendments to its content and design. Additionally the results of the evaluation of the computerised version verified the accuracy of changes introduced after the evaluation of the prototype.
Chapter 5 An Evaluation of Feasibility and Preliminary Effectiveness of eHIS (Study 3)	This chapter presents the final study which provided information about the feasibility and preliminary effectiveness of the intervention. The results were also used to evaluate the methodological approach to the intervention evaluation. The results of the study allowed the formulation of recommendations for further development of the intervention.
Chapter 6 General Discussion	In this chapter the completion of the research project is discussed. This is followed by the discussion of the thesis contribution to research and practice in the context of the current developments in the digital behaviour change area.

Chapter 2

Development of an Online Version of the Kinsey Institute Homework Intervention Strategy (eHIS) Intervention to Enhance Male Condom Use

Chapter Introduction

This chapter discusses digital interventions (DIs) for changing health behaviour and describes the eHIS development approach. Firstly it provides an overview of behaviour change DIs and discusses their role in addressing health issues and health inequalities. Then behaviour change interventions development frameworks and their relevance for the eHIS development are discussed. This is followed by an overview of the eHIS development process, which includes description of its steps: setting the interventions aims, choosing target groups, formulation of the intervention's guiding principles (GPRs), discussion of the theoretical base of the intervention, logic model (LM) formulation and operationalisation. The chapter also includes the discussion of the methodological approach employed during the project. A brief overview of completed studies closes the chapter.

Digital Interventions for Changing Health Behaviour

DIs appeared for the first time in web-based chat rooms in 1980s to expand with development of the Internet and mobile technologies especially since 2000s (Arigo et al., 2019; Bull, 2012; Noar & Harrington, 2012; WHO, 2016). They address a wide range of health topics from managing existing conditions to promoting preventive health behaviours (Kraft & Yardley, 2009; Marcolino et al., 2018; Mohr, Cheung, Schueller, Hendricks Brown, & Duan, 2013; Wicks, Stamford, Grootenhuis, Haverman, & Ahmed, 2014). According to Cassell, Jackson, and Cheuvront (1998) they "constitute a hybrid channel with the persuasive capabilities of interpersonal communication and the broad reach of mass media" (p. 77).

DIs are expected to easily reach a wide population and are recommended as the best way of reaching young people (WHO, 2006). They offer cost- and resource-effective support for health care issues (Lou, Zhao, Gao, & Shah, 2006; Mauriello, Gökbayrak, Van Marter, Paiva, & Prochaska, 2011; Noar & Harrington, 2012; Pekmezi et al., 2010) and have greater fidelity in comparison to FTF interventions (Solomon, Card, & Malow, 2006). Other advantages of DIs include: anonymity, automated data collection, appeal for technology users, convenience, flexibility, interactivity, customisation and real-time responses (Kaplan & Stone, 2013; Noar, Benac, & Harris, 2007; Noar & Harrington, 2012).

DIs have been found to be easily accessible and acceptable by users, especially with regard to sensitive or stigmatising health related issues (Conn, 2010; L. M. Jones & McCabe, 2011; Moskowitz, Melton, & Owczarzak, 2009; Roffmann, Shannon, & Dwyer, 1997; Saranto, Kivekäs, Kuosmanen, & Kinnunen, 2018; Van Diest, Van Lankveld, Leusink, Slob, & Gijs, 2007). This is consistent with the Natsal-3 survey (Hobbs et al., 2019) results of which indicated that respondents experiencing sexual difficulties used Internet to seek help and/or advice. The efficacy of HIV prevention DIs was found to be comparable to human-delivered interventions in increasing condom use (Noar, Black, & Pierce, 2009) and to have similar or larger effect sizes on impacting condom attitudes and condom communication (Noar, Pierce, & Black, 2010).

DIs can be delivered as web-based interactive interventions, online games, virtual reality, urban games, social media, phone or smart watch apps, with the latter two often integrated with activity or physiological data sensors (Arigo et al., 2019; Bull, 2012; Car, Tan, Huang, Sloot, & Franklin, 2017; K. Chen, Gonsalves, Guaralda, Turkay, & Kerr, 2019; Dunn, Yeo, Moghaddampour, Chau, & Humbert, 2017; Kaplan & Stone, 2013; Kelly, 2016; Noar & Harrington, 2012). Blended or hybrid interventions combining different technologies (e.g. apps and websites) or DIs with non-digital formats are common (Arnab et al., 2013; Daher et al., 2017; Dennison et al., 2014; Soetens, Vandelanotte, de Vries, & Mummery, 2014). They vary in complexity from brief, focused

on single behaviour (Beyer, Lynch, & Kaner, 2018; Little et al., 2015), to complex addressing multiple issues (Cook, Hersch, Schlossberg, & Leaf, 2015; R. Lehto, 2015; Lloyd et al., 2013; Parks et al., 2020).

The heterogeneity of DIs brings the challenge of choosing an optimal format for newly developed ones (Bailey, Mann, et al., 2015; Schueller, Mohr, & Muñoz, 2013; Soetens et al., 2014). Other challenges include cost of design and maintenance and maintaining compatibility with emerging technologies (Borrelli & Ritterband, 2015; Car et al., 2017; Harst et al., 2018; Kelly, 2016; Schueller et al., 2013). On an individual's level DIs need to respond to one's unique circumstances such as fitting with daily life, technology use habits, or addressing users' design and content preferences (M. Jones, DeRuyter, & Morris, 2020; Koivumäki et al., 2017; Saranto et al., 2018; Spooner, Salemi, Salihu, & Zoorob, 2017; Tennant et al., 2015; Wicks et al., 2014).

Role of Digital Interventions in Addressing Health Inequalities

Digital health is recognised worldwide as essential in addressing health inequalities by improving access to health services (WHO, 2016, 2019). Despite DIs' potential to contribute to improving populations' health, structural and societal challenges such as low digital literacy, digital exclusion or digital divide impact their implementation (Gordon & Hornbrook, 2016; Jiang & Liu, 2020; Kontos, Blake, Chou, & Prestin, 2014; Muessig, Nekkanti, Bauermeister, Bull, & Hightow-Weidman, 2015; Philip, Cottrill, Farrington, Williams, & Ashmore, 2017). Those from lower socio-economic and/or more vulnerable groups for example older people, those experiencing mental health issues or living in rural areas are at higher risk of being digitally excluded. Introducing services which are not accessible or usable for parts of population or which replace existing ones may lead to increase of health inequalities and inequities and deeper population segmentation (Azzopardi-Muscat & Sørensen, 2019; Ennis, Rose, Denis, Pandit, & Wykes, 2012; Saranto et al., 2018; Serrano-Santoyo & Rojas-Mendizabal, 2017; Tobitt & Percival, 2019;

Wicks et al., 2014; Yee et al., 2018). To avoid this, new DIs need to be integrated with existing health care systems (Car et al., 2017; Oderanti & Li, 2018) and adopted by health care professionals to reach those who may benefit from them (M. Jones et al., 2020; Traver, Basagoiti, Martinez-Millana, Fernandez-Llatas, & Traver, 2016).

eHIS – an Online Adaptation of KIHIS

Designing widely accessible, acceptable, low cost interventions to promote correct and consistent condom use can lead to improvement in men's condom use skills and experience, and thereby reduce STIs and unplanned pregnancy rates. eHIS - an online adaptation of KIHIS - has the potential to extend reach and accessibility beyond those of the FTF KIHIS intervention. It can provide easily accessible information, practical skills development, and brief information targeting specific problems related to condom use to a wide range of users, regardless of their location. It can address some of the key barriers to accessing sexual health services, namely concerns about confidentiality, anonymity, and embarrassment, reaching those men who would not be willing to attend an FTF appointment. As a self-guided, home-based, non-intrusive intervention, eHIS can with minimum interruption fit into users' daily lives, therefore increasing the chance of its implementation in a real life setting. If successful in improving condom use experience it could complement existing resources and provide an intervention that is unique in the UK setting.

Adaptation of Behaviour Change Interventions between Contexts and Modes of Delivery

Behaviour change interventions are frequently adapted between contexts to meet needs of different populations (C. Brown, Maggin, & Buren, 2018; Castellanos et al., 2020; Escoffery et al., 2018; Nierkens et al., 2013). Adaptation frameworks focus mainly on two issues: selecting interventions to be adapted and understanding their new context

(Escoffery et al., 2019). They also highlight the need to maintain fidelity between versions of interventions and involving members of the new target group and experts to ensure the appropriateness of the adaptation (Escoffery et al., 2018) This can be supported by considering interventions' theoretical underpinnings and understanding of old and new contexts (S. J. Lee, Altschul, & Mowbray, 2008; E. Smith & Caldwell, 2007).

Transferring behaviour change interventions between various modes of delivery is a notably less frequent type of adaptation, usually addressed as a general "materials preparation" category in the adaptation frameworks (Escoffery et al., 2018; Escoffery et al., 2019). Translating an intervention into a new mode of delivery may require creativity and "out of the box" thinking (Schueller et al., 2013). It goes beyond simple verbatim translation and may require further development of an intervention's elements and its structure. This is a multistep, often exploratory process, in which consideration of an intervention‘s content, design, interactive features, intervention intensity, level of exposure, support provided, etc. is essential.

Research on different modes of delivery of various behavioural change interventions (Brigham, Javitz, Krasnow, Jack, & Swan, 2013; Bulik et al., 2012; Frings et al., 2018; Morrison, Hargood, et al., 2014; Preschl, Maercker, & Wagner, 2011; Shingleton & Palfai, 2016) as well as several FTF sexual health promotion interventions adapted for online delivery (Danielson et al., 2016; Lightfoot, Comulada, & Stover, 2007) bring some guidance for the adaptation process. However, none of the studies approached the adaptation process systematically and adaptation of specific elements was not well described.

Behaviour Change Interventions Development Frameworks

There are several frameworks to guide development of behaviour change interventions, for example MRC Complex Intervention (Medical Research Council, 2008), PRECEDE-PROCEED model (Green & Kreuter, 2005), Behaviour Change Wheel (BCW)

(Michie, Atkins, & West, 2014), Intervention Mapping (IM) (Bartholomew, Parcel, & Kok, 2011), or Person Based Approach (PBA) (Yardley, Morrison, Bradbury, & Muller, 2015). All of them aim to comprehensively guide interventions development. Although they vary in the number of steps of the process, all recommend starting with understanding of a problem and/or defining outcomes to be achieved, advise formulation of planned behaviour change mechanism and recommend planning for evaluation of interventions.

The key differences between the frameworks pertain to their focus and the level of details in the offered guidance. The PRECEDE-PROCEED model (Green & Kreuter, 2005) emphasises the importance of understanding socioenvironmental determinants of behaviour. The BCW (Michie et al., 2014), the IM (Bartholomew et al., 2011) and the PBA (Yardley, Morrison, et al., 2015) focus on technical and/or practical aspects of interventions development. The BCW provides the most detailed guidance regarding target behaviour within wider psychosocial context, whilst the IM focuses on operationalisation and practical applications, and the PBA on the central role of users' perspectives. The MRC framework (Medical Research Council, 2008) gives guidance on setting research parameters in piloting phase and includes implementation outside of research context and a long term follow-up stages.

Although the frameworks discussed above provide general guidance for interventions development, their biggest limitation comes from their nature. To be applicable across various contexts, they do not address in detail specific issues such as the heterogeneity of formats or transferability of interventions. None of the approaches discussed above directly addresses how existing interventions should be adapted into a different mode of delivery, and to the author's knowledge there is currently no clear guidance regarding this.

The Person-Based Approach. From the frameworks discussed above the PBA[3] (Yardley, Morrison, et al., 2015) was judged the most appropriate to guide eHIS development due to its flexibility and focus on users' perspectives, which were seen as central for developing a potentially effective and acceptable digital behaviour change intervention. The PBA (Yardley, Morrison, et al., 2015) was formulated to guide health behaviour change interventions development and is complementary to theory-based and evidence-based approaches used in this project. It is seen as particularly useful in development of interventions promoting users' autonomous engagement such as eHIS. It was used to guide development of health behaviour change interventions addressing health issues such as eczema (Santer et al., 2014), asthma, diabetes, (Yardley, Ainsworth, Arden-Close, & Muller, 2015), blood pressure monitoring and management (Band et al., 2017), prescribing antibiotics (Little et al., 2013), and managing dizziness (Essery et al., 2015).

This model was chosen to guide the eHIS development as it provides practical guidance to the process aimed at ensuring its transparency at conceptual and operationalisation levels, while also focusing on developing an intervention that is acceptable and engaging to users. The key principle of the PBA is to understand the way potential users engage with the intervention and implement its guidance in their individual context. The main focus is on developing an acceptable and engaging intervention which delivers positive experience to its users, which in turn increases the chances of achieving the intended behaviour change.

The first element of the PBA is formulation of an intervention's GPRs (Yardley, Morrison, et al., 2015). They "state the key intervention objectives and describe the key features of the intervention required to achieve each objective" (Yardley, Morrison, et al., 2015, p. 4). These principles provide reference to ensure that an intervention's objectives are met throughout its development phases.

[3] Professor Lucy Yardley, who is the author of the approach, was one of the project's supervisors.

According to the PBA in depth understanding of the potential users and their psychosocial context should be introduced at the earliest stages of an intervention's development. Qualitative methods are recommended to allow in depth exploration of issues relevant for potential users. Although the PBA suggests the use of qualitative research at all stages of intervention development, it allows a flexible approach determined by project-specific factors. Resources, project timeline, and/or intervention characteristics can affect the way an approach is implemented. However, users' perspectives should remain central when making decisions about all aspects of an intervention (Yardley, Morrison, et al., 2015).

Models of Developing Online Behaviour Change Interventions

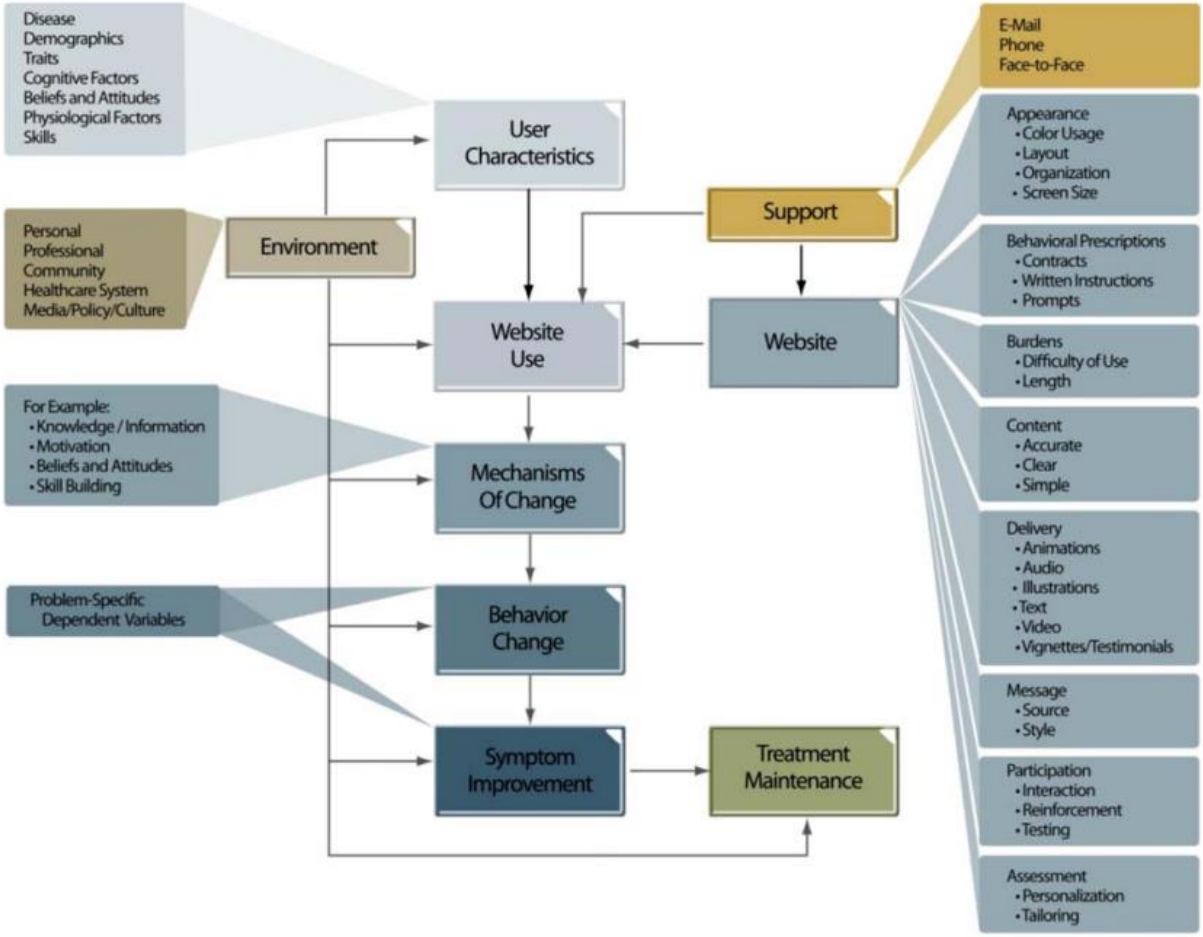
In addition to the PBA framework two models were used to identify the key aspects/considerations essential in development of online behaviour change interventions. The behaviour change model for Internet interventions (Ritterband, Thorndike, Cox, Kovatchev, & Gonder-Frederick, 2009) and the behavioural intervention technology (BIT) model (Mohr, Schueller, Montague, Burns, & Rashidi, 2014) (included at later stages of the project) looked at specific factors important in the development of online interventions. These models added another layer to the intervention development, especially in regards to elements aimed at initiating and maintaining engagement with the intervention.

The behaviour change model for Internet interventions (Ritterband et al., 2009). This model provided a general framework in which the intervention's development was nested. The model was built on the concepts and solutions taken from psychological theories, marketing, website design, research, and clinical experience, and provides an overview of the aspects relevant for developing an intervention website. It states that a sequential interaction between a user and the website influenced by environmental factors will lead to change of behaviour and improved health (Ritterband et al., 2009). According to the model, users' and website's characteristics, as well as available support, can

influence the process. At a more detailed level the model includes aspects of each of the core elements, such as website or support, which can be manipulated to achieve the intended change. An intervention for cancer survivors with insomnia (Ritterband et al., 2012) provides an example of the model's application. The full model is presented in Figure 2.

Figure 2

The model for Internet interventions (Ritterband et al., 2009, p. 20)



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The behavioural intervention technology (BIT) model[4]. The BIT model (Mohr et al., 2014) offers another comprehensive framework to guide development of technology based behaviour change interventions. The model divides the development process into two phases: theoretical and instantiation. In the theoretical phase the purpose of an intervention should be formulated, followed by decision, on conceptual level, how the intended behaviour change could be achieved. In the instantiation phase (operationalisation and technical solutions) the specific elements of the interventions are developed as well as the whole intervention structure and its visual side are considered.

The BIT model adds a meta-level of organisation of the key phases of the intervention development process to the previous model. Inclusion of the BIT model into eHIS LM provided a point of reference to confirm that essential steps of an online intervention development were considered in eHIS development.

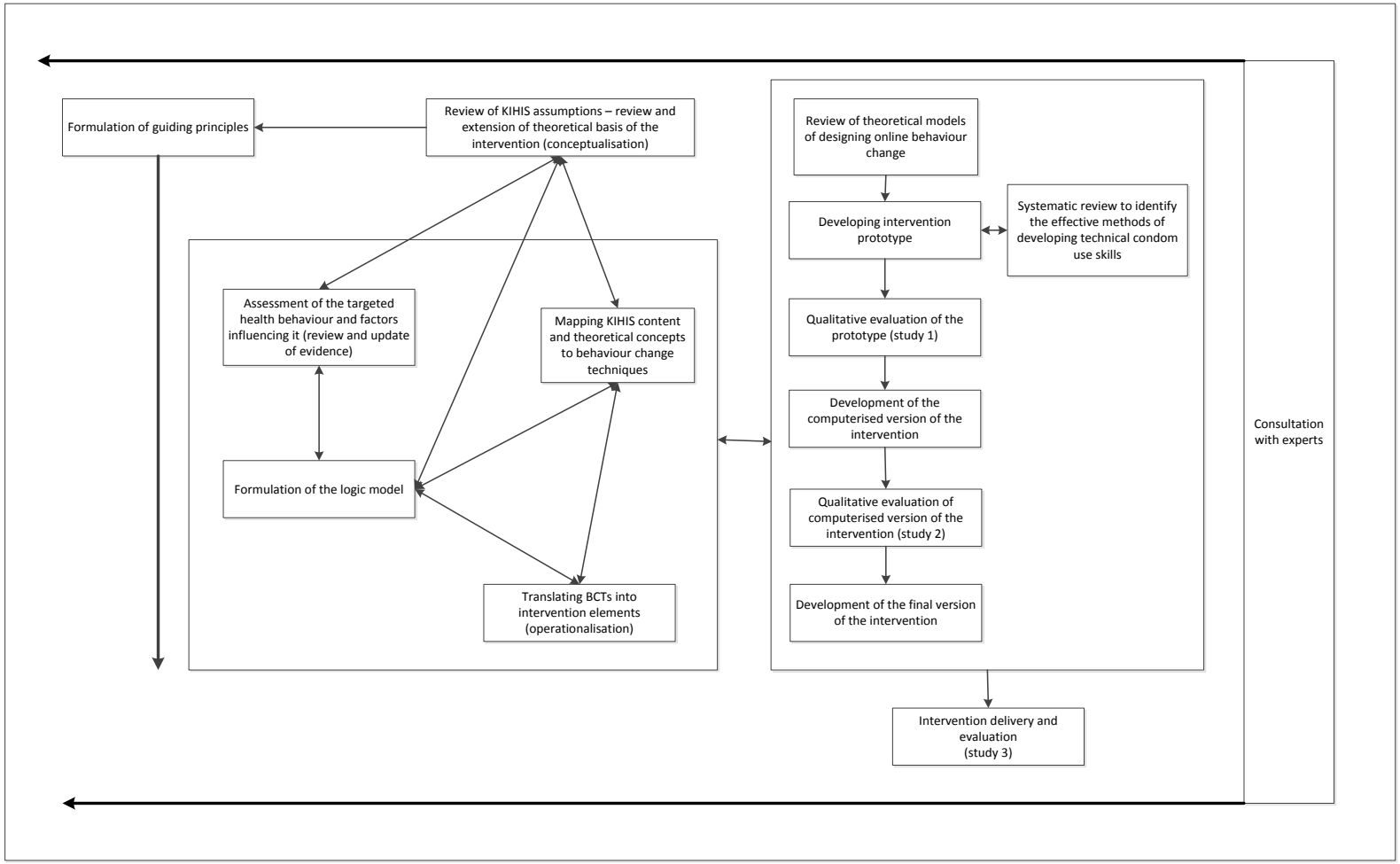
eHIS Adaptation and Development

As the target behaviour, key objectives and target audience were already defined, the eHIS development process started with reviewing them and assessing their relevance for the UK context (as discussed in Chapter 1). To ensure the consistency and transparency of the development process the eHIS GPRs and LM were formulated. This was followed by translating KIHIS into online environment and an evaluation of eHIS. The GPRs and the LM, as well as the intervention's operationalisation level were reviewed and amended where relevant in line with the results of the studies completed within the project and in consultation with the project's supervisors. The process of eHIS development with all completed steps and links between them are visually summarised in Figure 3.

[4] The BIT model uses the term "intervention" for each interaction with the programme, whereas the term "treatment" is used for the entire programme. To maintain consistency in this thesis the term "intervention" is always used when referring to the entire programme.

Figure 3

Key stages of eHIS adaptation, development and evaluation



eHIS objectives. Following the PBA (Yardley, Morrison, et al., 2015) the first step in the intervention development process was to review and briefly re-state the key objectives of eHIS. These were: to improve men's condom use experience to increase consistent condom use, to help them to improve their skills to increase correct condom use and to change condom use related cognitions to be more favourable towards using condoms. These aims were to be achieved by providing men with information regarding improving condom use experience and by encouraging them to explore condoms in search for these which fit and feel well.

Theoretical Basis of eHIS. Linking the intervention elements with theoretical concepts helps to maintain transparency of the intervention at the conceptualisation level and aids in understanding the mechanisms which are theorised to be responsible for behaviour occurring in the first place as well as for its change (Glanz & Bishop, 2010; Lippke & Ziegelman, 2008). This in turn provides a framework for operationalisation and defining the elements of the intervention (Glanz & Bishop, 2010). The evidence also suggests that interventions rooted in a theoretical framework are more likely to impact behaviour change (Noar et al., 2007).

The theoretical basis for the KIHIS intervention were the Condom Use Experience (CUE) model (Sanders et al., 2012) and the Permission Limited Information Specific Suggestions Intensive Therapy (PLISSIT) model (Annon, 1976). The CUE model provides specific suggestions regarding which factors should be targeted to improve condom use experience. The PLISSIT model provides broad therapeutic guidance and a general approach to the problems addressed in the intervention; however, it was judged to be insufficient for formulating a clear LM for a behaviour change intervention. It was decided that including a health behaviour change theory would provide a more comprehensive approach and facilitate formulation of a consistent LM to guide eHIS development.

A review of theories used in the area of AIDS prevention interventions (Noar et al., 2007) did not indicate superiority of any of the 13 reviewed theories over others. The

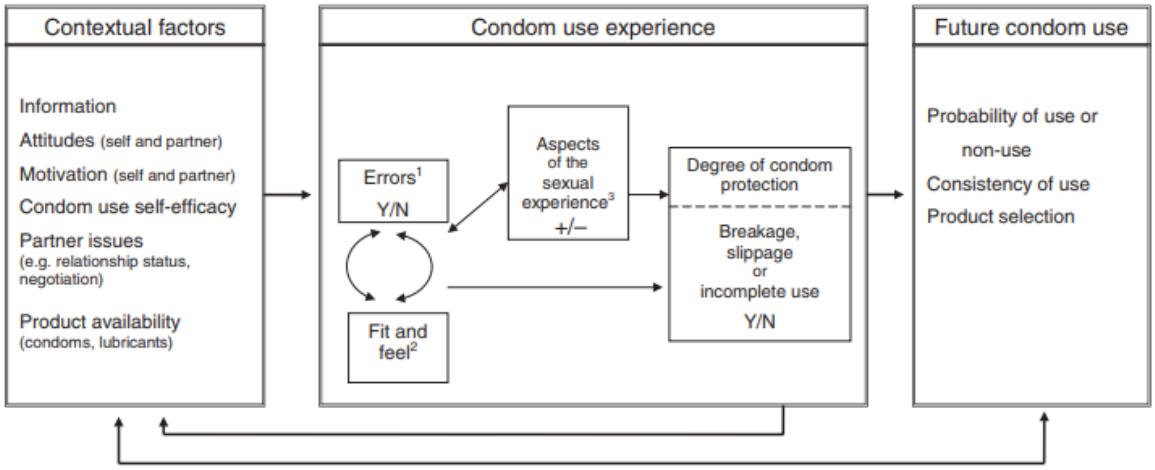
review's author suggested that finding the best fit between the aims of the intervention, a theoretical framework and an intervention specific context may provide the best outcomes. Taking the above into consideration and in consultation with one of the KIHIS' authors (project's supervisor), the Information Motivation Behavioural Skills (IMB) model (J. D. Fisher & Fisher, 1992; W. A. Fisher, Fisher, & Shuper, 2014) was chosen to complement the two models providing theoretical framework for KIHIS to guide eHIS development.

It is also important to note that the models described in this chapter provide the theoretical framework for developing eHIS. However, during the process other models and theories alongside the relevant evidence were used to address specific challenges in relation to development of specific elements of the intervention.

Condom Use Experience (CUE) model. The CUE Model presents possible theoretical relationships between condom use errors and problems and future condom use, based on comprehensive evidence identified in an extensive literature search on condom use errors and problems (Sanders et al., 2012). The model comprises of three key categories: contextual factors, condom use experience, and future condom use. According to this model condom use experience mediates the relationship between contextual factors and future condom use, its consistency, and choice of condoms. Condom use errors and problems, aspects of sexual experience (physical, sensations, and sexual function) and a degree of condom protection linked to breakage, slippage or incomplete use are the interconnected elements of condom use experience. Contextual factors include: information, attitudes, motivation, condom use self-efficacy, partner issues, and product availability. The impact of contextual factors is not only mediated by condom use experience, but can also be directly linked to future condom use. The full CUE model is presented in Figure 4.

Figure 4

The Condom Use Experience (CUE) model (Sanders et al., 2012, p. 93)



The studies included in the Sanders et al. review (2012) demonstrated the links between condom use errors and problems. Some errors may increase the likelihood of problems; for example, not protecting condoms from contact with sharp objects or not squeezing air from the condom tip were found to be associated with condom breakage (Crosby et al., 2007). Fit-and feel problems were found to be linked to condom-associated erection problems, condom slippage, or breakage (Crosby et al., 2010; Crosby et al., 2007; Graham et al., 2006). Condom-related erection loss was associated with condom slippage or incomplete condom use e.g., early condom removal (Graham et al., 2011; Graham et al., 2006; Yarber et al., 2004). Incorrect and incomplete condom use may be associated with individual-level variables such as lack of condom use skills, or low self-efficacy in using condoms (Bell, 2009; L. K. Brown et al., 2008; Crosby et al., 2007; Graham et al., 2006). The links between condom use problems and inconsistent condom use were also reported in a study investigating condom effectiveness (Warner et al., 2008).

The key assumptions of the CUE model also find support in other research not included in the Sanders et al. (2012) review. For example perception that condoms reduce sexual pleasure was found to be associated with inconsistent/no condom use among young

people (Bell, 2009; L. K. Brown et al., 2008). Association between condom use problems and inconsistent and incorrect condom use was found in a study of Graham et al. (2011). On the other hand increasing knowledge about condoms and discussing individual perception of fit and feel could contribute to condom use by men (Nöstlinger et al., 2010).

The PLISSIT model. KIHIS followed the first three aspects of the PLISSIT sex therapy model: permission, limited information, and specific suggestions (Annon, 1976) The model provides guidance how to approach sexual functioning problems, starting from giving permission to feel comfortable with one's experience followed by validation of one's perspective, concerns and feelings. Limited information focused on the problem together with specific suggestions are also included in the model (Annon, 1976). The PLISSIT approach was used previously outside sex therapy as a basis for healthcare model for HIV/AIDS prevention (Rosser, Coleman, & Ohmans, 1993).

The Information Motivation Behavioural Skills (IMB) model of HIV/AIDS preventive behaviour. The IMB model (J. D. Fisher & Fisher, 1992; W. A. Fisher et al., 2014) has been frequently used to investigate factors related to condom use (Cai et al., 2013; Fullerton, Meaney, Rye, & Loomis, 2013; Nöstlinger et al., 2010; Scott-Sheldon et al., 2010; Walsh, Senn, Scott-Sheldon, Vanable, & Carey, 2011; H. Zhang et al., 2011) and to develop sexual health and condom promotion interventions (E. S. Anderson et al., 2006; Cornman, Schmiege, Bryan, Benziger, & Fisher, 2007; Kiene & Barta, 2006; Kudo, 2013; Ybarra, Korchmaros, Prescott, & Birungi, 2015).

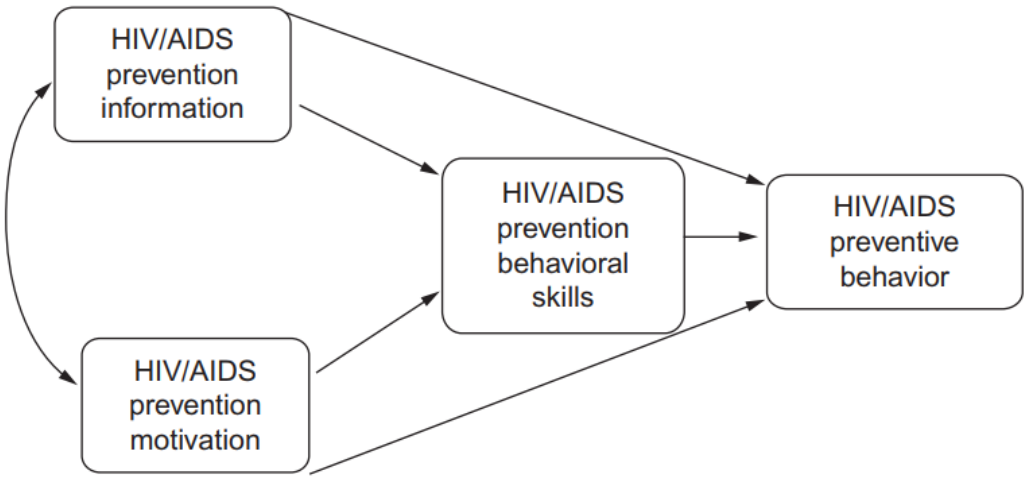
The key assumptions of the IMB model are that individuals need to have information about transmission and prevention of HIV infection, need to be motivated to prevent the infection and need to have behavioural skills to perform a preventive behaviour. Only when these three elements are present behaviour change is possible. The preventive behaviour may be the effect of information and motivation working through behavioural skills or information and motivation may affect some less complex behaviours directly as presented in Figure 5 (J. D. Fisher & Fisher, 1992; W. A. Fisher et al., 2014).

The authors of the model also provide guidance on how the key concepts should be translated into practice, highlighting that the information should be relevant for the preventive behaviour and prescriptive (J. D. Fisher & Fisher, 1992; W. A. Fisher et al., 2014). According to the model two types of motivation should be taken into account: personal motivation represented in the attitudes towards preventive behaviour and social motivation reflecting social norms. The behavioural skills refer to objective skills as well as to self-efficacy. The model also takes into account the personal psychosocial context (J. D. Fisher & Fisher, 1992; W. A. Fisher et al., 2014).

This model was judged to adequately complement the main concepts of the PLISSIT model. Its central concepts were included in the LM to guide the review and development of the components of the intervention.

Figure 5

The Information-Motivation-Behavioural Skills model of HIV/AIDS preventive behaviour. (W. A. Fisher, Fisher, & Harman, 2003)



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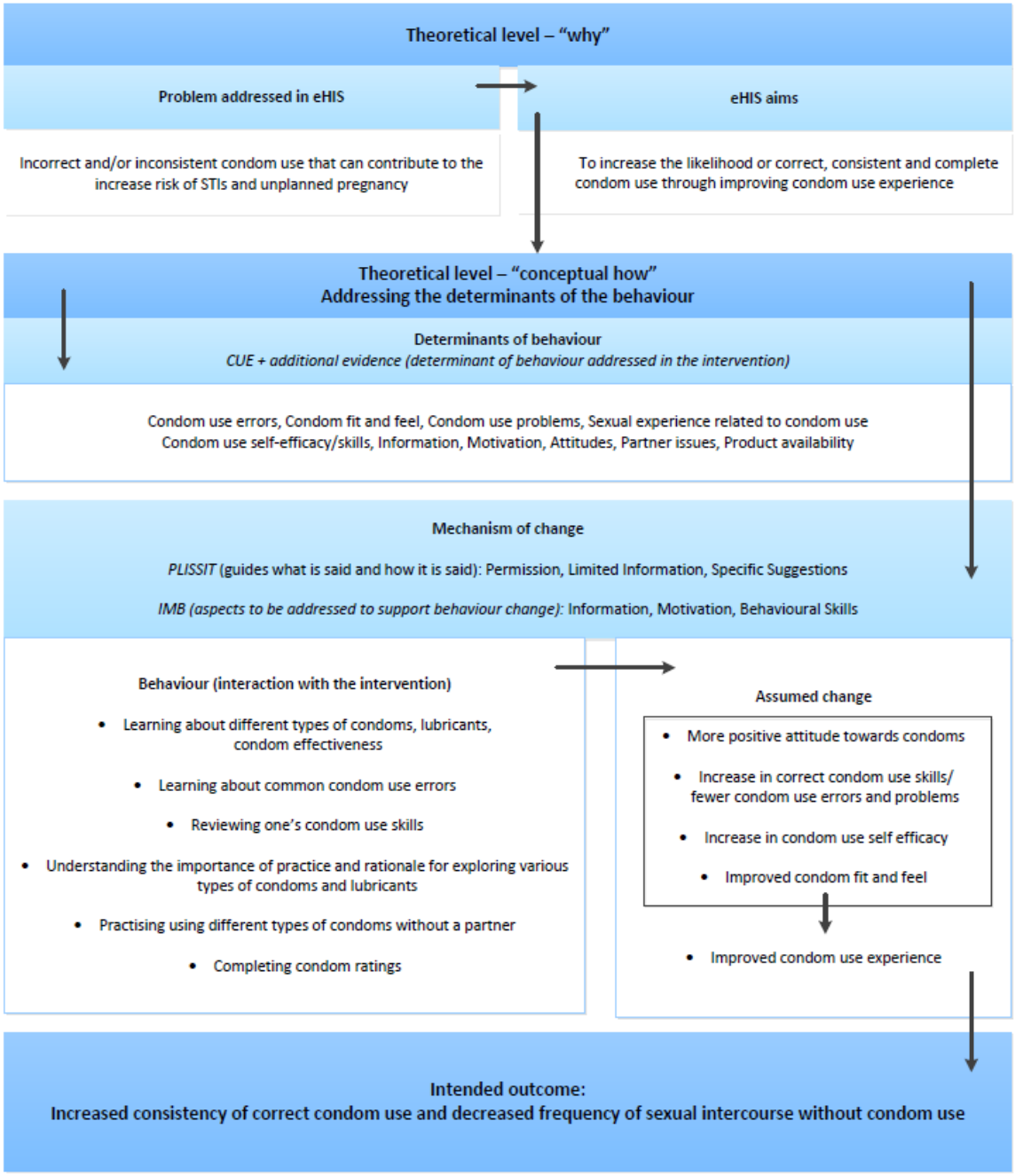
eHIS logic model. The LM was formulated to visually present links between theory, evidence and target behaviour. It presents the mechanisms through which the intervention was assumed to impact specific behavioural and cognitive outcomes. The integrative approach (Reid & Aiken, 2011) combining assumptions of various models to formulate a more comprehensive overview of the theoretical basis of the intervention was followed. The theoretical model of condom use (Sanders et al., 2012) and behaviour change models (Annon, 1976; J. D. Fisher & Fisher, 1992; W. A. Fisher et al., 2014) placed within the context of online behaviour change interventions models (Mohr et al., 2014; Ritterband et al., 2009) are integrated in the LM and linked to expected outcomes. The evidence regarding condom use experience and the findings of previous evaluations of the FTF versions of the KIHIS intervention (Emetu et al., 2014; Milhausen et al., 2011) were also incorporated into the model.

The key assumption of eHIS at the theoretical level is that improving men's condom use experience through reduction of condom use problems linked to incorrect use, condom fit and feel issues and/or condom use self-efficacy will lead to increased likelihood of correct, consistent and complete condom use. The change may be achieved through increasing knowledge about different types of condoms, encouraging use of lubricants, understanding causes of condom use errors and problems, practising using different condoms in non-pressure situation and focusing on sensation and pleasure while using condoms. Completing condom ratings is assumed to bring men's attention to issues related to condom fit and feel and pleasure, therefore move the focus of thinking about condoms from performance to fit, feel and pleasure. The eHIS LM is presented in Figure 6. The LM was reviewed during the intervention development phase and adjusted if relevant in the context of the findings of the qualitative evaluation of the eHIS (see Chapter 4).

Figure 6

Initial eHIS logic model



eHIS guiding principles. After defining eHIS target audience and its objectives the intervention's GPRs were formulated. The GPRs are usually formulated following the theory and evidence based intervention planning stage (Geraghty et al., 2016; Geraghty, Wood, & Hyland, 2010; Yardley, Morrison, et al., 2015). However, experience and findings from previous studies evaluating the intervention can also be used (Band et al., 2017). In the current project the assumptions of KIHIS (Milhausen et al., 2011) and its specific modifications made to the FTF (Emetu et al., 2014) and video (R. A. Crosby, personal communication, 2014) versions were reviewed to identify the eHIS GPRs. The central GPR was "To persuade men that they can improve their condom use experience". To fit with the online format and eHIS "Maintaining men's engagement with the intervention" GPR was added and key features of "Condom use skills development" and "Minimising the intervention intrusiveness" were extended. In further stages of the intervention development (qualitative evaluation of eHIS prototype and its computerised version – Chapter 4) the GPRs and key intervention features were reviewed and amended if appropriate throughout the intervention development process (see Chapter 4). The eHIS initial GPRs are presented in Table 1.

Table 1

eHIS initial guiding principles

Intervention design objectives	Key features
To persuade men that they can improve their condom use experience	To present men with a new perspective on condom use: pleasure- and sensation- oriented as opposed to performance-oriented To provide men with a condoms and lubricants kit to explore at home To ask men to complete a condom rating form directing their attention on pleasure and sensation aspects of condom use To inform about the causes of condom use problems and how to address them
To encourage men to practise condom use without the partner to help them to improve their condom use experience	To provide a rationale for practising using condoms alone
To support men in correct condom use skills development	To encourage men to review their condom use skills[a] To provide information about condom use steps
To maintain men's engagement with the intervention	To ensure content clarity and ease of use[a] To support users' perception of choice[a] Reminders
To minimise the intrusiveness of the intervention	To ensure that the intervention is brief, home based, self-guided, not requiring in person contact[a]

Note. Adapted from Yardley, Morrison, et al. (2015). [a]Added at the initial stage of eHIS adaptation process to adjust the feature to online format.

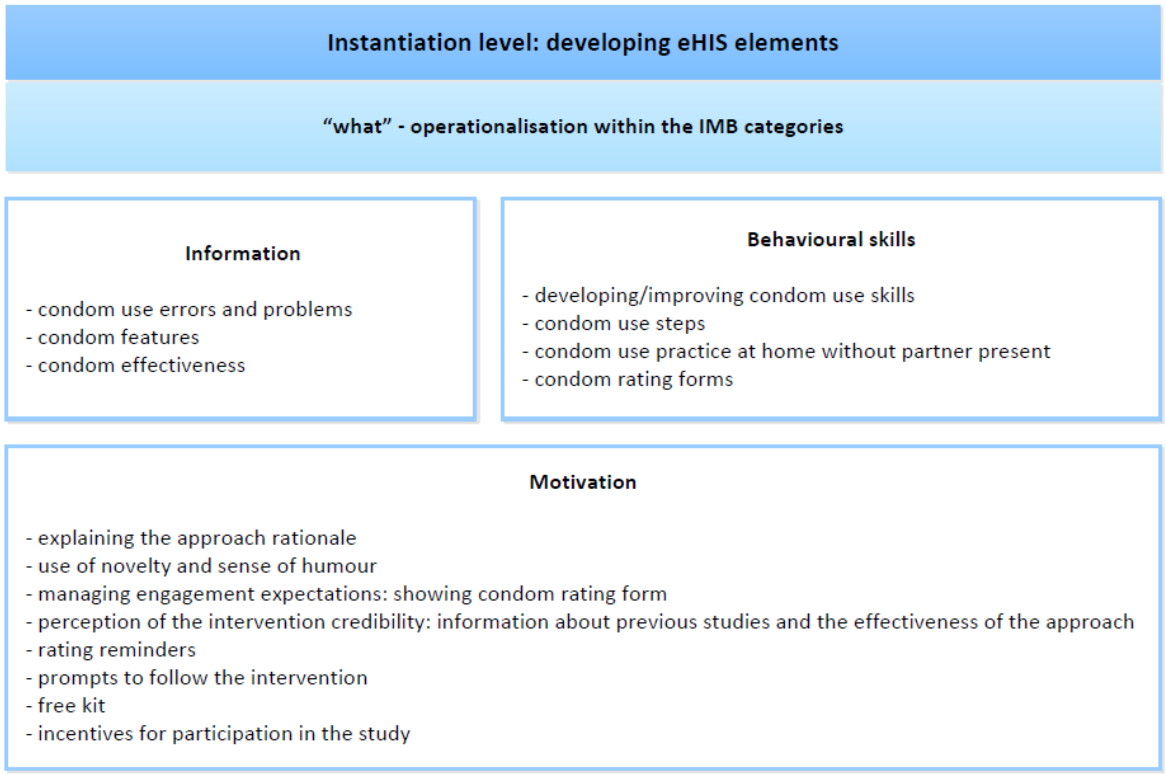
eHIS target audience. KIHIS was designed to target young men (aged 16-21) who were already condom users (Milhausen et al., 2011). However, on the basis of the background review (Chapter 1) it was decided that this intervention could be potentially relevant for men at various ages and with different condom use experience and that it could benefit from. It was generally expected that men who could be interested in the eHIS approach might have had unsatisfactory condom use experience or could consider using condoms in the future. The decision was made to extend the focus of the project and assess,

amongst other aspects, who might be interested in the intervention in the first place (see Chapter 5 for Study 3 results). Therefore the target group was extended to include men aged 18-69 and was not limited to those with specific condom use experience.

Transferring the elements of the existing intervention into online environment. Moving from theoretical to instantiation level (Mohr et al., 2014), the KIHIS content was systematically organised in line with the three IMB model categories: providing information, motivational messages, and skills development (J. D. Fisher & Fisher, 1992; W. A. Fisher et al., 2014). Although the specific eHIS elements could belong to more than one category, for example information about common condom use errors aimed to raise awareness and motivate users to improve their skills; they were assigned to one key category during operationalisation (see Figure 7) to maintain the clarity of the process. The behaviour change techniques taxonomy (BCTT) (v1) (Michie et al., 2013) was used as a reference point.

Figure 7

Initial eHIS operationalisation



The development of the eHIS prototype of the online version started with transferring the specific elements of the KIHIS to the online environment with the minimum degree of change. Materials received from the intervention's authors, including the FTF session script of the original KIHIS intervention (Milhausen et al., 2011), materials of its version adapted for young men who have sex with men (Emetu et al., 2014) and script and DVD version of the intervention (R. A. Crosby, personal communication, 2014) were used to develop the eHIS prototype. The elements of eHIS were systematically reviewed and amended in line with the results of the studies completed throughout the process of the intervention development as discussed in Chapters 3 and 4.

The intervention's prototype development followed the guidance provided by the models described earlier in this chapter (Mohr et al., 2014; Ritterband et al., 2009) and commercial and health information websites development guidance (D. Kim & Chang, 2007; Krug, 2006). Due to resources and time constraints a paper-based prototype was developed in this phase (see Appendix A for examples of eHIS mock webpages). The prototype was purposefully basic to elicit users' preferences (as discussed in Chapter 4) and to avoid overinvesting resources in design at the initial stage.

Content of the kit. The content of the condoms and lubricants kit (henceforth "the kit") was reviewed to ensure a variety of condoms and their availability on the UK market. The kit content also had to be amended due to different brands and types of condoms available in the UK to ensure varied condom use practice experience (no specific brand endorsement). The cost of the kit included in the original study exceeded the resources available in the current project. For that reason six types of condoms (compared to 8 in KIHIS) and two types of lubricants were included in the kit.

Methodological Approach Employed in the Studies Completed within the eHIS Development Process

Pragmatism as a Philosophical Paradigm Leading the Project. Pragmatism, a paradigm developed at the end of the 19th century (Dewey, 2004), guided the methodological approach used in the research project presented in this thesis. Unlike post-positivism or constructivism, which seeks truth through objective, standardised or subjective, individualised methods of inquiry, pragmatism is not interested in the nature of reality and objective truth (Feilzer, 2010). Instead the nature of experience and outcomes of actions are central (Morgan, 2013). In pragmatism the value of knowledge lies in its ability to solve practical problems (Creswell & Clark, 2007; Feilzer, 2010). For that reason the knowledge should be relevant for specific context at a personal and/or societal level. The choice of research method should be guided by their ability to provide answers relevant to the problem (Elkjaer & Simpson, 2011; Morgan, 2013; Onwuegbuzie & Leech, 2006). This may require investigating the problem from different angles, at different levels, which in turn provides support for use of mixed method approach (Feilzer, 2010; Morgan, 2013; Onwuegbuzie & Leech, 2005)

Mixed Method Approach. The aim of the project was to develop an intervention that was based on the theory and evidence applied to provide solutions to a real life problem – how to improve men's condom use experience. Following the assumptions of pragmatism, a mixed method approach was chosen to build evidence to support the intervention development, gain understanding of users' experience with the intervention and gather knowledge essential to design a feasible and effective intervention (Sandelowski, 2000; Yardley & Bishop, 2008; Yardley, Morrison, et al., 2015). This approach is used more frequently in applied sciences (Alise & Teddlie, 2010) and it was found to be effective in behaviour change intervention projects (Gifford et al., 2008; Steinmo et al., 2016; Yardley, Morrison, et al., 2015).

In line with a synergistic approach, both qualitative and quantitative methodologies were treated as equally important, complementary interactive parts which used together can provide new quality knowledge (Creswell, 2009; B. Hall & Howard, 2008; R. B. Johnson, Onwuegbuzie, & Turner, 2007). The mixed method approach allowed inclusion of two different perspectives: subjective experience of intervention users and its quantified evaluation (Östlund, Kidd, Wengström, & Rowa-Dewar, 2011). The former was to ensure the intervention relevance and acceptability (Yardley, Morrison, et al., 2015), whilst the latter was used in the assessment of its feasibility and allowed comparison of results across studies evaluating different versions of the intervention. The quantitative approach was also used in the systematic review (see Chapter 3) which was completed to inform the development of specific elements of the intervention. The results of one type of enquiry provided context for better understanding of the results obtained from the other one (Onwuegbuzie & Leech, 2005; Sandelowski, 1996; Yardley, Morrison, et al., 2015). As stated by Onwuegbuzie and Leech (2005, p. 383) combining qualitative and quantitative approach allowed to "understand phenomena systematically and coherently."

The pattern of using the methods broadly followed the one proposed by Nastasi et al. (2007) for designing, modifying and evaluating interventions. The qualitative and quantitative approaches were used sequentially to fit best the requirements of the specific stages of the intervention development. In the final feasibility study elements of qualitative evaluation were introduced concurrently alongside the quantitative evaluation. However, the choice of specific methodology at subsequent phases of eHIS development was also, to some degree, limited by the project's timeline and resources.

Qualitative methods. Qualitative methods are based on "interpretive" and "constructivist" paradigms (Yardley & Bishop, 2008). Their key assumption is that understanding of a phenomenon can be only "interpreted" or "constructed" within a personal and social, subjective context, as it is not possible to "find" and objective truth. Instead numerous "truths" can exist between and within individuals depending on their

personal circumstances. Without getting insight into them it is not possible to gain understanding of one's experience and offer adequate support to change one's behaviour, cognitions and/or feelings.

Qualitative methods are recognised in social sciences as a valid and valuable method of scientific inquiry (Camic, Rhodes, & Yardley, 2003; Coolican, 2004). The approach found its way to health psychology in the 1970s following development of critical theory (Morrow & Brown, 1994) and social constructivism (Kukla, 2000) and with time gained more prominence (Chamberlain & Murray, 2008). At present these methods are widely used across the discipline. Exploring participants' perspectives is used for example in studies of illness and treatment perceptions and beliefs (A. Cooper, Jackson, Weinman, & Horne, 2005; H. Richards, Reid, & Watt, 2003), management of health conditions (Bair et al., 2009) and to study health preventive behaviour (De Souza & Ciclitira, 2005; Morrison & Yardley, 2009; Mosavel & Genderson, 2016). Qualitative methods are also common in research on behaviour change interventions (see Chapter 4), often as a part of mixed-method approach (Yardley, Morrison, et al., 2015).

In the current project qualitative methods (think-aloud interviews (TAIs), semi-structured interviews (SSIs), observation, open text survey questions) and qualitative coding used to analyse data (Bishop & Yardley, 2015; Joffe & Yardley, 2004) were chosen to provide insight and better understanding of potential users' experience with the intervention (Nastasi & Schensul, 2005; Rathbun, 2008). Qualitative approach allowed to address participants' expectations and reservations as well as make the key messages of the intervention clearer and the intervention itself more acceptable and more persuasive in line with PBA (Yardley, Morrison, et al., 2015) (described below). The approach was employed from the early stages of the process when two qualitative evaluations of the intervention were completed at its development stage (as presented below and in Chapter 5) and maintained until its completion with elements of qualitative evaluation included in the feasibility study (see Chapter 6).

Quantitative methods. Quantitative methods are based on positivist paradigm assuming searching for objectively existing, generalisable and comparable rules and results (Willig & Stainton-Rogers, 2008). The key assumption behind quantitative inquiry is that by using methods based on measurements it is possible to uncover systematic regularities that can be applied across specific group of individuals and in specific types of situations.

This type of inquiry has been commonly used in health psychology from the beginning of its formulation as a separate discipline (Chamberlain & Murray, 2008; Coolican, 2004) to explore wide range of health psychology research questions (Willig & Stainton-Rogers, 2008). Evaluation of the effectiveness of behaviour change interventions uses primarily quantitative tools (such as standardised scales, questionnaires, biological outcomes or quantified assessment of behaviour) (D. Cohen, MacKinnon, Dent, Mason, & Sullivan, 1992; Judah et al., 2009; Milhausen et al., 2011; Wyer et al., 2001) to numerically assess whether any change was observed and whether it was statistically significant.

Use of quantitative methods was judged to be the most appropriate at two stages of the project. First, quantitative approach was employed to investigate the effectiveness of various methods to develop TCUS (see Chapter 3). Analysis of their effectiveness was possible only if the same number of comparable outcomes were being assessed. Second, quantitative approach was primary in the feasibility study (see Chapter 5). This allowed comparison of findings with other studies evaluating different versions of KIHIS (Emetu et al., 2014; Milhausen et al., 2011; Stone et al., 2017), as well as gaining understanding of participants' engagement with the intervention in the context of their characteristics.

Studies Completed Within the eHIS Development Process. Ensuring that condoms are used correctly is one of the key aims of eHIS, as incorrect use has been linked to condom use problems (Sanders et al., 2012). The FTF demonstration, practice and feedback – elements of the FTF KIHIS – needed to be replaced with eHIS feature(s) that would allow users to review correct condom use. Although various formats of condom use

instructions are used in interventions promoting condom use (D. Cohen, MacKinnon, et al., 1992; R. A. Crosby, personal communication, 2014; Hill & Abraham, 2008; Milhausen et al., 2011; Noar et al., 2011; Norton, Fisher, Amico, Dovidio, & Johnson, 2012), the justification for using certain methods is mostly lacking. When it is given, it is mostly focused on engaging participants with the skills training but not on the mechanisms or effectiveness of this training (Noar et al., 2011). To support development of this element of eHIS, a systematic review of the effectiveness of various methods of developing TCUS was completed (Chapter 3).

As guided by the PBA (Yardley, Morrison, et al., 2015), feedback was obtained as soon as it was practical i.e., when the eHIS prototype was developed. The qualitative evaluation was chosen to elicit views of potential users on content, structure, and format of the intervention (see Chapter 4). Participants were also asked about their opinions regarding the content of the kit. The prototype also included mock log-in procedure and a first version of the Participant Information Sheet (PIS) that would be used in the feasibility study. The evaluation at this early stage allowed an exploration of participants' reactions to the intervention approach and experience with the prototype.

Users' experience with the computerised version of the eHIS, which in addition to the intervention pages also included feasibility study pages such as the PIS, baseline measures, charity donation page etc., was explored in a second qualitative evaluation (Chapter 4). This evaluation allowed better understanding of participants' experience with eHIS, its specific components and elements of the planned feasibility study. This evaluation was also important for providing verification of the accuracy of the amendments made to the intervention prototype.

In the final phase of the eHIS development a study assessing feasibility and preliminary effectiveness the intervention (Study 3, Chapter 5) was completed. The study explored eHIS's feasibility, participants' engagement and acceptability of the intervention's content and format. The preliminary effectiveness of eHIS to increase

condom use consistency and reduce frequency of sexual intercourse without a condom being used, reduce the number or condom use errors and problems, and change condom use related outcomes to being more favourable towards condom use were also assessed. Finally, the feasibility of the approach used to evaluate the intervention (e.g. recruitment, measures completion) was also examined.

Consultations with Experts

Throughout the whole process of eHIS development, feedback and advice from experts was sought to ensure that the key principles of the development process were followed and to obtain opinions when decisions were made in the context of contradictory or insufficient evidence. Regular discussion during supervision and annual progress meetings were key sources of guidance and advice. The ability to consult the authors of the original KIHIS intervention helped to clarify any ambiguities during conceptualisation and prototype development phases and ensure that the GPRs of the intervention were followed throughout eHIS development. The project was also discussed with colleagues in the research groups in Psychology department at the University of Southampton (UoS) during seminars or workshops as well as in connection to the intervention development presentations at scientific conferences.

MoSCoW Analysis

The MoSCoW analysis, a management prioritisation method (Bradbury, Watts, Arden-Close, Yardley, & Lewith, 2014; Clegg & Barker, 1994; Kuhn, 2009), was another important stage of the intervention development. Before introducing any changes lead by the results of studies completed within the project and following consultations with the experts, the MoSCoW analysis was completed to decide the priority of changes to be made. Considering the project's timeline and resources the decision was made to categorise the suggested amendments into one of four categories: must have, should have, could have or

won't have. The amendments were then implemented according to their priorities. The assigned MoSCoW categories are presented in Appendix B alongside the presentation of the decision making process which include the review of relevant evidence and expert advice.

Discussion

The tasks at the initial stages of the eHIS development included choice of the framework to guide the process, reviewing the conceptual underpinnings of the intervention and translating the eHIS elements to online format while ensuring the fidelity of the new version of the intervention.

As the adaptation frameworks are focused on general changes, mostly on cultural level, they do not offer much insight into the process of adaptation of interventions between modes of delivery. On the other hand, the behaviour change interventions development frameworks give much weight to the initial exploration of health issues and formulating ideas for new interventions, but they also offer guidance on development of elements of interventions. In this context PBA (Yardley, Morrison, et al., 2015) was selected as it offered the most flexibility and placed potential users' perspectives in the centre. Supporting this framework by the digital behaviour change development models (Mohr et al., 2014; Ritterband et al., 2009) provided a coherent framework for developing eHIS and its specific elements.

The second task was to review eHIS's theoretical underpinnings. Although the key theories and the principles of approach assumed to lead to behaviour change were stated (Annon, 1976; Sanders et al., 2012), explicit links to a behaviour change theory were missing. Introducing the IMB model (J. D. Fisher & Fisher, 1992; W. A. Fisher et al., 2014) and formulating the LM helped to review and understand the mechanisms of intended change. Discussing the LM with one of KIHIS authors confirmed that the conceptual

consistency was maintained when the IMB model was introduced and that the LM itself was accurate.

The next challenge was development of the eHIS prototype in which elements of the FTF intervention were translated to the online environment. Evidence from the field of DIs development and expert advice supported the process. However, due to lack of specific guidance on translating the skills focused elements of the intervention, a decision was made to complete a systematic review (see Chapter 3) to support the process.

Fidelity of the online version of the intervention was achieved by maintaining conceptual consistency between the original KIHIS and eHIS (S. J. Lee et al., 2008; E. Smith & Caldwell, 2007), supported by formulating its LM and GPRs. Grounding the development in the theories and evidence related to condom use, behaviour change, and Internet intervention development was important to ensure conceptual transparency. This in turn aimed to allow making conclusions about the feasibility of translating the intervention into a new format and comparing the potential for effectiveness of interventions delivered in different modes. The transparency of the development process aimed to support replicability and/or further amendments of the process in future iterations of the intervention.

Selecting the pragmatic paradigm and employing mixed-method approach allowed addressing issues essential to the eHIS development in the most accurate way. The selection of methodology for each study depended on the research question(s) and practical issues such as study timeframes and resources. The key rule was seeking the method to yield results which would inform the eHIS development best. The studies completed within the project and their impact on the intervention's development are described in Chapters 3-5.

Conclusions

Nesting the eHIS development in relevant frameworks helped to maintain its methodological rigour. The pragmatic approach ensured the best match between the aims of the specific steps of the project and the results produced to inform the development. Engaging potential users and prioritising amendments in line with evidence and expert advice aimed to support creation of an acceptable and potentially effective intervention. The transparency of the eHIS development from its early stages can support its contribution to the body of knowledge about adaptation of behaviour change interventions between different modes of delivery.

Chapter 3

The Role of Technical Condom Use Skills Development Techniques in Interventions Promoting Male Condom Use – a Systematic Review

Chapter Introduction

This chapter presents the rationale, methods and results of the systematic review investigating different methods of developing TCUS. The implications of the results for designing future condom promotion interventions and wider research are discussed. The discussion of strengths and limitations of the review closes the chapter.

The Role of Technical Condom Use Skills in Condom Use Promotion and STIs/HIV Prevention Interventions

The likelihood of condom use problems and errors can be reduced by enhancing TCUS, i.e. the ability to completely and correctly use condoms (Lindemann et al., 2005; Yarber et al., 2004). Greater condom use skills may in turn lead to better condom use experience and subsequently more consistent and correct use of condoms (Crosby, Milhausen, Sanders, et al., 2008; Sanders et al., 2012). Various techniques of developing TCUS may have different impact on the final skills level. For example, in a study by St. Lawrence et al. (1995), participants who completed condom use skills training demonstrated better condom use skills than the control group which received only information. It is therefore crucial that interventions promoting complete and correct condom use employ the most effective methods of developing and improving these skills.

Already in 1990s researchers underlined the need to teach correct condom use skills, regardless of individuals' self-reported efficacy in this area (Langer, Zimmerman, & Cabral, 1994; Martin, 1990), and this still appears to be an important issue. In the Global Strategy for Prevention and Control of Sexually Transmitted Infections: 2006 – 2015 (WHO, 2006), promotion of correct and consistent use of condoms was recommended as

an effective method of reducing the prevalence of STIs. According to the recommendations, training in correct and consistent use of condoms should be an important part of any intervention promoting condom use (McKay, 2000; WHO, 2006). In the recent review of the Evidence for the UK National Guidelines on Safer Sex Advice (Clutterbuck et al., 2012), developing TCUS was listed among components of successful interventions.

Previous Reviews

The findings of previous reviews have shown that many of the successful interventions promoting condom use and/or focused on HIV/STIs prevention included condom use skills training (Lyles et al., 2007; Scott-Sheldon, Huedo-Medina, Warren, Johnson, & Carey, 2011; Scott-Sheldon & Johnson, 2006). In a review of interactive safer sex websites, 76% of these included some information about condom use (Noar, Clark, Cole, & Lustria, 2006). Active condom instructions and training along with providing condoms were significant predictors of the effectiveness of interventions in modifying condom use behaviours and thus reducing the risk of HIV amongst adolescents (B. T. Johnson, Carey, Marsh, Levin, & Scott-Sheldon, 2003). This demonstrates that the condom use skills component is likely an essential or at least a useful part of an intervention. However, many of the previous wide scope reviews (in terms of populations and types of interventions included, and time period covered) have focused mainly on a general category of behavioural skills training/building in their analyses, that can cover various types of skills such as, for example, personal or self-management, communication, and/or TCUS (Huedo-Medina et al., 2010; B. T. Johnson, Carey, Chaudoir, & Reid, 2006; Manhart & Holmes, 2005; McKay, 2000; Noar, 2008; Noar et al., 2009; Noar et al., 2010; Wetmore, Manhart, & Wasserheit, 2010). This approach does not allow either the importance of TCUS development, or the effect of specific TCUS development techniques used in the interventions, to be properly assessed.

Several previous reviews which attempted to explore the role of specific components, including TCUS training, have been found (Albarracín et al., 2005; Albarracin, Albarracin, & Durantini, 2008; Crepaz et al., 2006; Herbst, Kay, et al., 2007; Herbst et al., 2005; Mullen, Ramirez, Strouse, Hedges, & Sogolow, 2002; Scott-Sheldon et al., 2011). Condom demonstrations and practice-based training were listed amongst the characteristics of effective interventions for people living with HIV (Crepaz et al., 2006). Active condom use skills' training was found to have a significant impact on reducing HIV incidence in interventions aiming to reduce sexual risk (Scott-Sheldon et al., 2011). Herbst, Kay, et al. (2007), reviewing interventions targeting Hispanics in the United States and in Puerto Rico, reported that inclusion of a technical skills component, specifically practice of condom use skills, was associated with reduction of risky sex behaviour. Albarracin et al. (2008) found that condom skills' training was effective in increasing condom use in interventions amongst male participants. Other reviewers reported lack of a significant impact of condom use skills training on changes in condom use (Albarracín et al., 2005), or no evidence of TCUS training being associated with the effectiveness of interventions aiming to reduce risk behaviours among MSM or sexually active adolescents (Herbst et al., 2005; Mullen et al., 2002). Inclusion of behavioural skills training was found to have a negative effect on condom use amongst Latino and Latin American women (Albarracin et al., 2008). One possible explanation for the discrepancies between the conclusions from various reviews is that specific techniques used in condom use training may vary in their impact on the effectiveness of interventions.

Gaps Identified in Previous Literature Reviews

In summary, previous reviews have yielded inconsistent results and do not provide clear answers to the question about the role of TCUS development techniques in promoting consistent, correct and complete condom use and in influencing related factors such as condom use experience, condom use self-efficacy, and condom use errors and problems. In

one review (Albarracín et al., 2005), impact of the interventions on behavioural skills was assessed, but apart from TCUS, this also included negotiation skills, sexual communication etc.

No systematic review of the role of various TCUS development techniques was found, and existing evidence in this area is fragmented. Reviewers have provided information regarding the effectiveness of various TCUS development techniques, but limited to comparison between active and passive condom use skills training (Scott-Sheldon et al., 2011), and listing one or a few TCUS development techniques amongst components of the successful interventions (Crepaz et al., 2006; Herbst, Kay, et al., 2007). Mostly, however, they described one general category of TCUS development (Albarracín et al., 2005; Albarracin et al., 2008; Herbst et al., 2005; Mullen et al., 2002). Moreover, most of these reviews did not include actual condom use skills, complete and correct condom use, condom use experience or condom use self-efficacy amongst assessed outcomes.

With the exception of one review (Scott-Sheldon et al., 2011), all of the reviews had a wider scope than simply condom promotion and investigated complex interventions designed to reduce the behavioural risk of HIV/STIs or even more generally, prevent HIV/STIs. None of the reviews identified focused on simple interventions consisting only of condom use promotion and other condom-related topics. Large systematic reviews, investigating a wide range of factors related to the effectiveness of complex interventions, often do not allow for a detailed investigation of specific behaviour change techniques used. This highlights a need for a review focusing on the role of specific components in the effectiveness of interventions.

A crucial consideration in designing an effective health promotion intervention is the choice of behaviour change techniques used in order to maximise the effectiveness of the intervention (Abraham & Michie, 2008; Michie & Abraham, 2004). Focusing on the effectiveness of a specific component of the interventions contributes to our understanding

of the mechanisms responsible for behaviour change (Michie & Abraham, 2004). Researchers have recommended investigating the role of specific components of interventions as essential for developing more effective interventions in the future (Albarracín et al., 2005; Buller & Floyd, 2012; Edgar, Noar, & Murphy, 2008). There have been several reviews published in the last decade focusing on the impact of specific elements of interventions promoting condom use and/or aiming to reduce STI/HIV infections. Authors have explored topics such as persuasive communication (Albarracín et al., 2003), communication (Edgar et al., 2008), erotisation (Scott-Sheldon & Johnson, 2006), and active versus passive interventions (Albarracín et al., 2005). To date no systematic review has been identified that has comprehensively investigated the role of TCUS development techniques in condom promotion interventions. This review aimed to fill some of the gaps identified in this area.

Aims of the Review

Examining specific TCUS training techniques could help us to understand how these techniques work. This in turn can help to build the links between specific techniques and key concepts of behaviour change theories, adding to the existing body of knowledge (Michie & Abraham, 2004; Michie & Prestwich, 2010). This review focused specifically on the role of TCUS development techniques in improving frequency, consistency, and complete and correct condom use. Links between specific TCUS development techniques and variables related to consistent, complete and correct condom use, such as condom use errors and problems, condom use experience, and condom use self-efficacy were investigated. The optimal mode of delivery for specific techniques was also assessed. As the overall goal of most of the interventions promoting condom use is HIV/STI prevention, the association between TCUS development techniques and new instances of STIs was also explored. The key research questions were:

- *Which TCUS development techniques are associated with the effectiveness of the interventions to promote condom use?*
- *Which TCUS development techniques are associated with an increase in a) frequency and consistency of condom use b) complete and correct condom use?*

The effectiveness of the interventions employing specific TCUS development techniques on other outcomes, which were found to be related to correct and complete condom use (Cates, 2005; Centers for Disease Control and Prevention, 2011; Crosby & Cates, 2012; Holmes et al., 2004; Sanders et al., 2012; UNAIDS et al., 2009; Warner & Steiner, 2011; Weller & Davis-Beaty, 2002) was also investigated. For that reason more specific research questions were formulated:

- *Which TCUS development techniques are associated with a reduction in problems related to condom use?*
- *Which TCUS development techniques are associated with an increase in positive condom use experiences?*
- *Which TCUS development techniques are associated with an increase in condom use self-efficacy?*
- *Which TCUS development techniques are associated with a reduction in STI incidence?*

Research indicates that the mode of delivery can impact the intervention effectiveness (Lustria, Cortese, Noar, & Glueckauf, 2009; Lustria et al., 2013; Webb, Joseph, Yardley, & Michie, 2010) therefore another question explored in the review was:

- *What modes of delivery are used to deliver condom use skills development techniques in successful interventions promoting condom use?*

It was assumed at the outset that it might not be possible to provide answers to all of these research questions, but in these cases the secondary aim of the review was to identify gaps in existing evidence in order to guide further research.

Method

Search strategy. Electronic databases were searched for relevant publications. The list of databases with the search terms sets created for each of them are presented in Appendix C. The search terms were chosen to ensure maximum search sensitivity to find data relevant for the review topic. The search for relevant publications was conducted until 17th March 2013, was updated for studies including adolescents on 1st April 2013, and included all records from the start date of searched databases. The reference lists of the articles identified as relevant for the review were visually examined to identify other relevant publications. The citations of articles already included in the review were searched for relevant studies, retractions and errata, using the Google Scholar citation widget between 4th November 2013 and 9th December 2013. Researchers' professional profiles and websites were searched for supplemental materials, published papers, and recent publications.

Inclusion and exclusion criteria. The studies identified were screened against inclusion and exclusion criteria presented in Table 2. Interventions to promote female condoms use were not included in this review as female condoms are used infrequently and are not widely promoted (Gallo, Kilbourne-Brook, & Coffey, 2012). HIV counselling and testing was found to have impact on reductions in sexual risk behaviours in some of the studies (Fiorillo et al., 2012; MacGowan et al., 1997), especially for HIV-positive participants (Weinhardt, Carey, Johnson, & Bickham, 1999); thus, HIV testing, and pre- and post-testing counselling were treated as constituting additional topics and excluded from the review. Studies presenting male condom as one possible choice from a range of other HIV/STIs prevention methods (including the female condom) were also excluded from the review as the choice may lead to decreased condom use (Farr, Acosta Castro, DiSantostefano, Claassen, & Olguin, 1996; Fontanet et al., 1998).

Table 2

Systematic review inclusion and exclusion criteria

	Inclusion criteria	Exclusion criteria
study design	RCTs, controlled trials (intervention and control group); pre-test and post-test between subjects; pre-test and post-test within subjects	case studies; studies without control or comparison group; studies without pre-test, post-test assessments
study type	quantitative; only original studies	qualitative; economic evaluations; book chapters; thesis
participants	aged above 16 years; any gender; of any sexual orientation; of any HIV/STI status	below the age of 16 years; or if the age range was below and above 16 years , the average age below 16 years
intervention characteristic	studies including only male TCUS development component; condom promotion only interventions; other topics included only to provide the context information for condom promotion (for example basic STIs/HIV information); individual and group level interventions; any type of intervention setting; the intervention was standalone event; any mode of delivery	studies promoting female condom use; studies promoting condom use as one of the alternatives for HIV/STI prevention; topics other than condom use for example: any type of general communication skills, negotiation skills, non-condom specific individual-level skills such as general self-management or relaxation skills, drugs use, HIV testing etc.; structural level intervention (Charania et al., 2011); school based interventions if they were provided as a part of formal/extended school curriculum or other wider social intervention (for example complex programmes for immigrants, homeless etc.); condom distribution only programmes
outcomes	frequency of condom use; consistency of condom use; frequency of condom use errors; complete and correct condom use; frequency of condom use problems; condom use experience; condom use self-efficacy; changes in STI rates	outcomes not presented separately for different groups
publication status	peer reviewed journals	not peer reviewed journals
language	articles published in English; intervention manual and materials available in English	articles not published in English; study manual and/or materials not available in English

The aim of the review guided the choice of study designs; therefore, the decision was made to include studies not using randomised design. The randomised studies were classified as randomised clinical trials (RCTs) if they provided details of the randomisation procedure and it was adequate to ensure that all participants had an equal chance to be allocated to any of the study conditions. If the randomisation procedure was not described sufficiently, or the procedure used could have increased the allocation bias (randomisation by day, session in the clinic etc.), the studies were categorised as controlled trials, as defined in the dictionary for the Quality Assessment Tool for Quantitative Studies by

Effective Public Health Practice Project (EPHPP) (Armijo-Olivo, Stiles, Hagen, Biondo, & Cummings, 2012; Thomas, Ciliska, Dobbins, & Micucci, 2004; http://www.ephpp.ca).

Studies selection. The identified articles' titles and abstracts were screened against inclusion and exclusion criteria. Those studies clearly outside of the scope of the review and those not meeting all inclusion criteria were excluded. The available full texts of remaining articles were read and final decisions on their inclusion for the review were made. This review relied on full text of articles available through UoS resources and free access texts. Authors of articles for which full texts were not available were contacted for assistance with obtaining them. If the information about the intervention content or other essential study details were not sufficient to make the decision about the study's inclusion, authors were contacted for relevant details (e.g., to request study manuals/protocols and/or materials used in the studies). Internet resources were also searched for available online interventions descriptions and materials. Where there was no clear description of the intervention, which would allow ensuring that no other topics than condom promotion or context information were provided, and studies for which the manuals were not available, were also excluded from the review. Moreover, if the information about the results was presented in a form not allowing for the critical evaluation of article conclusions (for example, numeric results of analysis were not presented), articles were also excluded. The decisions were made on the basis of the first exclusion criteria met. All references were managed using EndNote reference manager (Thomson Reuters, 2012).

The data from included studies were extracted following the Centre for Reviews and Dissemination recommendations (Centre for Reviews and Dissemination, 2009), modified to make these more relevant for the review topic. The Data Extraction Form is presented in Appendix D. The content of the intervention/experiment was coded on the basis of the details provided in the description section of the published article, provided manual, or study protocol and available study materials such as programme websites, leaflets etc.

Definitions of terms used in the review. There is a lack of a clear definition of terms used across various interventions promoting condom use. Some taxonomies of strategies and techniques used in sexual health promotion (Galbraith et al., 2011) and behaviour change techniques used in interventions (Michie et al., 2013) are available in the literature; however, these are still under development and do not always provide comprehensive frameworks for all TCUS development techniques. Nonetheless, they do provide some direction for formulating definitions of other techniques. In this review the BCTT (Michie et al., 2013) was used[5] as guidance and as a basis for formulating specific definitions where gaps were identified.

The ability of individuals to use condoms correctly and completely throughout a sexual encounter is referred to as TCUS; these include: using appropriate lubricants, ability to correctly apply and remove condoms, etc. Developing TCUS as one of the intervention components is defined as a general strategy. Specific methods of TCUS development are defined as techniques (Michie et al., 2013). These include components used in interventions such as instructions on how to use condoms completely, instructions on how to use condoms correctly, demonstration, skills rehearsal, feedback, observing other participants practising behaviour and being observed by them, self-monitoring, home practice and behavioural experiments. The coding was in part an open exploratory process in which additional codes were added if needed. Three techniques: being observed by others while practising condom application and removal, observing others practising condom application and removal, and self-monitoring did not match exactly the definitions provided in the BCTT. Although monitoring of behaviours by others without feedback (2.1) seemed similar, it did not exactly reflect the nature of practice in front of other participants and observing their practice. Additionally, it could not be coded together with feedback (2.2), which would not precisely reflect what happened during the sessions in all

[5] The trained coder (Marta Glowacka) completed a half-day workshop "Specifying and describing the content of interventions to improve health: Using a taxonomy of behaviour change techniques" in September 2013 in collaboration with British Psychological Society Division of Health Psychology annual conference, Brighton.

interventions. Similarly, the self-monitoring (2.3) definition provided in the taxonomy did not always reflect the specific nature of self-monitoring taking place while rehearsing skills during a session rather than whilst performing the behaviour in a real life situation. Because of these mismatches between BCTT and techniques described in the interventions, definitions of self-monitoring and monitoring of behaviour by others were modified and a new definition of observation of others performing behaviour was added within the existing framework. Definition of the techniques and relevant BCTT used as a coding scheme are presented in Appendix E.

Techniques such as developing condom negotiation skills or condom erotisation were classified as additional condom-related content. Any type of general communication or negotiation skills, or non-condom specific individual-level skills, such as general self-management or relaxation skills, were considered to be additional components fulfilling exclusion criteria and therefore not relevant for the purposes of this review. The only exception was made for basic HIV/STI information providing contextual background for condom promotion. The categories of other condom-related and context topics were developed in the process of content analysis, by grouping all the topics found in the interventions; these are presented in Appendices F and G. Mode of delivery refers to different ways of delivering specific techniques e.g., verbal, written, visual, direct (i.e. FTF) or indirect (i.e. video) and level of delivery refers to individual or group.

The data extraction forms and coding sheets were completed for each included study and reviewed by the supervisor. Any uncertainties in the process of study selection, data extraction, quality assessment, and techniques identification were discussed and/or consulted with experts in the area of the review and with the supervisor. The specific TCUS development techniques, other intervention components, and theories used to guide interventions development were coded only if they were explicitly stated in available materials.

Quality assessment. The quality of studies included in the review was assessed using the Quality Assessment Tool for Quantitative Studies (EPHPP, 2010; Thomas et al., 2004). The tool was listed amongst six best quality assessment tools for systematic reviews and is suitable for assessment of randomised and non-randomised studies (Deeks et al., 2003). It was also recommended by Jackson and Waters (2005) for systematic reviews in health promotion and public health interventions. It assesses the studies across six categories: selection bias, study design, confounders, blinding, data collection methods and withdrawals and dropouts, and presents the results in three categories: strong, moderate and weak. Two more items help to guide the judgment of intervention integrity and method of analysis used. The tool was demonstrated to have good content validity and inter-rater reliability (Thomas et al., 2004). Regarding confounders, the tool manual did not provide clear guidance for the assessment of pre-test post-test within group design. It was agreed to rate this item as "weak" in this situation. The copy of the quality assessment tool and tool dictionary are presented in Appendices H and I respectively.

Data Analysis and Synthesis

Due to a small number of studies included in the review and high clinical heterogeneity (West et al., 2010) e.g., very small number of studies assessing the same outcomes using different assessment tools and the diversity of TCUS development techniques employed in interventions, narrative synthesis was chosen as the most optimal approach to analyse the findings of the review (Centre for Reviews and Dissemination, 2009; Gough, Oliver, & Thomas, 2012). The descriptive synthesis of the included studies was performed, including study design and procedures, study quality, sample characteristics, and intervention characteristics. The frequencies of use of all of the TCUS development techniques, other condom-related techniques, and additional techniques/topics were calculated. The effectiveness of interventions was assessed by counting votes for each significant change in the outcome in expected direction (Gough et

al., 2012). If no significant results were reported, the intervention was classified as not effective in changing an outcome. The intervention was classified as potentially harmful if significant results were reported but the direction of change was opposite to the expected one. If a few different measures were used to assess the same outcome, and only some of them showed significant change, the intervention effectiveness on this outcome was classified as "inconclusive".

The analysis of patterns between the use of specific TCUS development techniques and the significant results on the outcomes analysed in the review was undertaken. The impact of possible confounders such as baseline condom use and/or experience, intervention setting, participants' gender and ethnicity, intervention format, inclusion of other condom-related, additional topics, intervention facilitator, length of session, condoms provision and choice, as well as study quality were reviewed. Patterns of possible moderating effects of mode of delivery of specific techniques were analysed. Effect sizes were extracted or calculated where possible. A table of condom use skills development techniques was prepared, together with their mode of delivery, and information about significant results on specific condom use related outcomes.

Narrative Synthesis

Eighteen articles were found describing studies meeting the inclusion criteria for the review. Fourteen of them were found through the electronic database search, one was identified through a search of citations of included articles, and one was received from the authors (in press at the time of the review). Two articles were found during an online material search for other studies.

Study characteristics. Most of the studies clearly stated that their main aim was to promote condom use, specifically to change condom use related behaviours and/or cognitions; some focused explicitly on improving condom use skills. In three of the studies the formulated aims focused also on STIs/HIV prevention; however, the content of the

interventions consisted of TCUS development and other condom related topics. Only two studies met the strict RCT criteria and twelve of the studies included in the review were categorised as controlled trials. Four studies used pre-test post-test design, with within-subject comparison.

The maximum follow-up period varied between the studies from immediate assessment to one-year follow-up. This was linked to the study type and outcomes assessed. The shortest follow-ups featured in simple studies assessing skills acquisition. The studies assessing behavioural and cognitive outcomes had on average approximately 2.1 month long follow-ups compared to those which reported medical records review, with approximately 6 months. The number of follow-up assessments was similar across the studies with on average one assessment for medical records review and approximately 1.5 for behavioural and cognitive outcomes. Five studies had two follow-ups and only one study featured three. In six of the included studies participants were rewarded with money for completing the assessments, and in three they received credits for their university course. The most frequent settings were educational institutions (universities, colleges, school), followed by sexual health and/or family planning clinics. Two articles described studies conducted in the community setting and one was conducted in prison. The large majority of the studies were conducted in the US, with two articles presenting the results of studies conducted in Thailand, two in Canada and one each from Uganda and the UK.

Quality assessment and risk of bias. The quality of the studies included in the review assessed using EPHPP (Thomas et al., 2004) varied from weak to strong, with all of the categories being equally distributed. None of the studies achieved a “strong” rating in the assessment of the blinding procedure used in the studies, because in most cases the description of blinding procedure was not presented. This made the assessment of the risk of detection bias, caused by interviewer/researcher’s knowledge about participants’ allocation to specific condition, or participants responding in line with their expectation regarding the aim of the study, often not possible. The risk of detection bias could also be

elevated due to the methods used to collect the data. The quality of the majority of the studies was rated as "moderate" in the data collection methods section due to using proxy indicators or self-reports of behaviour, such as new STI rates or reported condom use, respectively. Detection bias was also increased by using mostly complete cases rather than intention to treat analysis in the assessment of the intervention impact. The studies rated as "weak" were most often placed in this category due to relying on volunteers, which led to high risk of selection bias. Other factors raising the risk of detection bias were lack of a comparison group and/or not controlling for possible confounders. Two weaknesses of most of the included studies, not included in the EPHPP final rating, were not providing clear description of inclusion/exclusion criteria and not describing control procedures used to ensure the accurate and consistent implementation and the integrity of the interventions. The latter, in connection with knowledge about the participants' allocation, could lead to performance bias caused by favouring one of the conditions. Another source of bias could be the lack of clear description of conditions that could be defined as previous exposure to similar interventions (Pannucci & Wilkins, 2010). It seems possible that participants could have been previously exposed to some form of condom promotion, especially in the clinic settings. The summary of the studies' description with quality rating is presented in Appendix J.

Sample characteristic. The sample size varied across the studies with the smallest sample of $N = 32$ (Milhausen et al., 2011) and the largest $N = 1{,}006$ (D. Cohen, Dent, MacKinnon, & Hahn, 1992) at enrolment. At the longest follow-ups the total number of participants was $N = 4{,}447$. The sample sizes for specific outcomes were: frequency and consistency of condom use $N = 2{,}260$, condom use skills $N = 736$, condom use errors and problems $N = 28$, condom use experience $N = 58$, condom use self-efficacy $N = 710$, and new STI rates $N = 2{,}543$. Although the age range reported in the studies spanned five decades, the majority of the participants were in their late teens and twenties. In eight of the studies the mean age was below 20 and in another four was between 20 and 30. Ten

studies included both male and female participants, six targeted male and two only female participants. In the mixed gender studies the average proportion of male participants was slightly higher than female, but it varied across studies. One study conducted in the US specifically targeted African-American males; this ethnic group constituted two-thirds to 90% of the sample in four other studies. In five studies at least 2/3 of the group was described as White. The samples where the majority of participants were African-American were recruited for clinic-based studies and for one study conducted in prison, whereas those with a majority of White participants were mostly recruited at universities and colleges. The two ethnic groups least represented across the studies conducted in the US were Hispanic (in five studies) and Asian (listed in four studies), with proportions of 20% and 17% of the samples, respectively. One study conducted in the UK described all participants as British. Two studies conducted in Thailand and one conducted in Uganda did not report ethnicity of participants.

At baseline less than half of the participants from clinic samples described in two studies used condoms at last intercourse. Sixty to ninety-six per cent of participants in four of the studies conducted in educational institutions reported having prior experience using condoms, compared to between 11% and 50% of the participants recruited in clinics. In two other studies participants recruited at universities reported using condoms in 50-60% of sexual intercourses. A quarter of the participants from the Thai village community study had ever used condoms in comparison with approximately 40% in the Uganda urban sample. The baseline condom use amongst participants is reported across the studies using different measures and is not described in a consistent manner; thus it is difficult to compare baseline condom use related behaviours across the samples.

In a prison sample and two clinic samples, approximately 1/3 of the participants had had more than 2 sexual partners recently. In the other two studies the average number of partners was between 2-3 (period covered between last 3 months and a year). In most of the samples recruited at educational institutions (excluding those in which being sexually

active was an inclusion criterion) between 45% and 95% of participants were sexually active. Only four studies reported the sexual orientation of participants; one was targeting only heterosexual and one only homosexual males and one clinic and one school study reported predominantly heterosexual samples (97.5 – 100%). In five studies approximately one third to two thirds of the clinic samples reported previous STIs. Categories with various degree of detail were used to describe participants' relationship status; it was therefore difficult to make comparisons between samples. In the studies providing this information between six and eighty five per cent participants were married, and between ten and over sixty per cent were in a steady or serious relationship. The detailed characteristics of the samples are presented in Appendix K.

Interventions description – characteristics. Eighteen studies describing 23 conditions were included in this review. This review includes analysis of 21 conditions, henceforth referred to as interventions. The difference in numbers occurred due to the analysis approach used by Norton et al. (2012) – the impact of intervention on frequency and consistency of condom use was assessed for all three conditions together. Because the same TCUS techniques were used in all of them, the decision was made to describe and analyse them together. The detailed characteristics of interventions with complete content description are presented in Appendix L.

All of the interventions comprised only one session which lasted between 10 and 180 minutes. Two interventions additionally included a 2 week period of practice at home. Thirteen interventions were conducted in a group setting with facilitator(s), four individual interventions were led by facilitators, three consisted of individual leaflet reading and one was video based. The facilitators were mainly health educators, and less frequently research staff or personnel trained specifically for the study. On one occasion the intervention was facilitated by lay health advisors and on another one by trained community members.

The theoretical background of the intervention was explicitly indicated in only nine of the interventions. Four of the behaviour change theories, namely IMB (J. D. Fisher & Fisher, 2002), Bandura's social learning theory (Bandura, 1977), PLISSIT model (Annon, 1976) and Theory of Planned Behaviour (Ajzen, 1991), were used twice each across the interventions. The Health Model (Rosenstock, 1966), Theory of Reasoned Action (Ajzen, 1985) and lay health advisor model (Eng & Parker, 2002) were each used in only one intervention.

Frequencies of techniques. In ten conditions only one TCUS development technique was used; the remaining eleven interventions used between two and eight different TCUS development techniques. Across all of the interventions demonstration of proper condom use was most frequently used, six times as the only technique and nine times in combination with other techniques. Penile models, proxy models, fruit, or facilitators' hands were used for demonstrations. In only one intervention demonstration was the explicit focus on condom failure prevention. The second most popular techniques were instruction of correct condom use and skills rehearsal, used in nine interventions each. The details provided in descriptions of correct condom use instructions varied between the interventions, from describing between five and ten different steps of correct condom use to just mentioning that instruction on correct use was given. The role of adding water-based lubricants to improve condom use experience and/or prevent condom breakage was mentioned explicitly in four studies, whereas avoiding using oil-based lubricants was underlined in three interventions. Only one intervention described a review of steps for correct condom use after skills rehearsal (E. A. Smith & Dickson, 1993) and another one provided re-demonstration with the emphasis on correct use (Hayden, 1993). In interventions providing the description of skills rehearsal participants practised on penile or proxy models, and on one occasion on fruit. Two interventions employed a condom race (with blindfolds and timed) to practise correct condom application and removal. In the condom races participants, divided into small groups, were asked to put a

condom on a model and take it off as quickly as possible. The first team in which all participants completed the task won (Elkins, Dole, Maticka-Tyndale, & Stam, 1998; Hayden, 1993). Practice in most interventions was usually limited to single condom application and removal; however, in one study participants had a chance to practise before the race (Elkins et al., 1998), and in another one they practised until achieving mastery (Crosby, DiClemente, Charnigo, Snow, & Troutman, 2009). A group setting allowed participants in six interventions to observe others practising condom application and removal. In further eight interventions they were also observed by others while practising, and in four participants were given feedback on their performance. Four interventions described participants focusing on monitoring their own performance during practice. Only two mentioned providing instructions to use condoms from the beginning to the end of sexual intercourse. Home practice done during masturbation and behavioural experiment were also used in two interventions.

Other condom related topics and context topics. Only four interventions did not include any other topics than developing TCUS. All the other interventions covered between one and ten additional condom related topics. The most frequently used were condom use experience (nine interventions), condom negotiation and communication (eight interventions), condom use as protection from STIs/HIV (eight interventions), condom knowledge including the display of various condom types (six interventions) and condom use preparatory skills (five interventions). Nine interventions also allowed time for questions and discussion of condom-related topics. Condom erotisation, condom familiarisation, barriers to condom use and solutions, condom use misconceptions, condoms and relationships, and advantages of condom use were relatively infrequently covered (only in between two to three interventions each). In six interventions free condoms were provided to participants, and in three of them participants had the chance to choose and try various types of condoms and lubricants. Additionally, prizes were given in three interventions (prize draw entry, gift certificate, condom key chains and small cash

rewards). Hayden (1993) mentioned prizes for winning the race as a component of the intervention; however, it was not clear if they were given in the particular intervention described. In one intervention social recognition was also used as a reward, as the winning team was to enter the condom race at between villages level (Elkins et al., 1998).

Although only interventions that focused on condom use were included in the review, some of them consisted of additional topics providing context for the condom promotion. The context topics were found in eleven interventions. Most frequently risk awareness was raised by presenting the infection rates, alongside the basic information about STIs/HIV transmission and prevention.

Analysis of association of TCUS development techniques and specific outcomes. Of the studies included in the review most assessed only one of the outcomes in the scope of the review; only two (Crosby et al., 2009; Emetu et al., 2014) assessed three, and one assessed four outcomes (Milhausen et al., 2011). The results of the analysis of associations of TCUS development techniques and specific outcomes are summarised in Appendix M.

Frequency and consistency of condom use.[6] Data for frequency and consistency of condom use were available for 10 interventions. This outcome was assessed using various measures such as self-reports of condom use at last sexual intercourse, frequency of unprotected sexual intercourse, frequency of condom use, consistency of condom use, percentage of condom use during sexual intercourse and a condom use index ("frequency of condom use (…) divided by frequency of intercourse occasions, multiplied by 100" (E. A. Smith & Dickson, 1993, p. 5)). All measures used different recollection periods (from four weeks to 6 months) and various points of reference to assess frequency (never-always, last five sexual intercourse events etc.).

[6] The terms 'frequency' and 'consistency' were not used exclusively in the included studies, and as both measures are related, data were often presented for just one of them. For this reason the data about frequency and consistency of condom use are analysed together for the purpose of this review.

The interventions using single TCUS development techniques did not result in any significant changes in frequency or consistency of condom use, or frequency of unprotected sex. Amongst the interventions using combinations of various TCUS development techniques, one showed a significant increase in condom use during last sexual intercourse (Crosby et al., 2009), and one an increase in frequency of condom use (Orr, Langefeld, Katz, & Caine, 1996). However, both of them failed to achieve significant results on other measures of frequency and consistency of condom use e.g., in changes in the frequency/number of unprotected sex events (Crosby et al., 2009) and in condom use during last sex (Orr et al., 1996). For that reason their results on this outcome were categorised as inconclusive. Only Emetu et al. (2014) demonstrated significant increases in consistency of condom use accompanied by reduced frequency of unprotected sex (*d* = .98). All of the interventions showing any significant results used three TCUS development techniques – demonstration, skills rehearsal and self-monitoring. However, demonstration and skills rehearsal and their combinations were also used in the intervention that did not show a significant impact on the discussed outcome. The distinctive characteristics of the successful interventions were skills rehearsal until mastery (Crosby et al., 2009), and home practice together with behavioural experiments (Emetu et al., 2014). Self-monitoring was also a technique found only in interventions reporting some significant results (Crosby et al., 2009; Emetu et al., 2014). The other apparent difference between successful and ineffective interventions was format of delivery (individual in the former and group in the latter).

Correct condom use. The impact of five interventions on correct condom use was assessed using three different observational checklists. Two interventions (Lindemann & Harbke, 2013; Lindemann, Harbke, & Huntoon, 2012) used the Measure of Observed Condom Use Skills (MOCUS) (Lindemann & Brigham, 2003; Lindemann et al., 2005); two others used 9-item (Crosby et al., 2009) or 11-item (O-Prasertsawat & Koktatong, 2002) checklists. The two interventions in which the effectiveness of instruction from

condom packages was investigated were unsuccessful in improving condom use skills (Lindemann & Harbke, 2013; Lindemann et al., 2012). Those using demonstration, skills rehearsal (O-Prasertsawat & Koktatong, 2002), or a combination of various techniques, including demonstration and skills rehearsal until mastery (Crosby et al., 2009), showed significant improvement in correct condom use skills. The effect size in interventions successfully improving condom use skills was in the medium to large range, not indicating advantage of one technique over the others. Despite the different quality of studies, the evidence supports the superiority of demonstration and practice over simple written instructions. However, numerous other factors apart from TCUS development techniques may have contributed to the observed differences. The ineffective interventions were conducted with both male and female participants, whereas the successful ones were targeting males only. In both of Lindemann's studies (Lindemann & Harbke, 2013; Lindemann et al., 2012) the majority of the sample was White, compared to Asian and Afro-American samples in three successful studies. All of the successful interventions were delivered FTF and facilitated, while ineffective interventions were those delivered FTF by facilitators, leaflets and video interventions.

Complete condom use. Data on complete condom use (from the beginning to the end of sexual intercourse) were not available in any of the included studies.

Condom use error and problems. The study of Milhausen et al. (2011) was designed to target condom use errors and problems and was the only one in which these outcomes were assessed. This intervention used home practice and behavioural experiment (trying various types of condoms while masturbating and rating the experience) alongside instructions for complete and correct use, demonstrations, skills rehearsal, monitoring practice by others, feedback, and self-monitoring. Significant changes were reported on specific items of Condom Use Errors/Problems Survey (Crosby, Graham, Milhausen, Sanders, & Yarber, 2011a).

Condom use experience. Two interventions showed inconsistent results in improving condom use experience, with Milhausen et al. (2011) reporting significant improvement, while this result was not repeated in Emetu et al. (2014) study. The results reported by Emetu et al. (2014) were not significant for the total Condom Use Experience Scale (Doyle, Calsyn, & Ball, 2009; St. Lawrence et al., 1999) and the only significantly lower score was found for one item – "condom decreasing sensation". Although both interventions were testing the same approach, there were some differences between specific TCUS used. In Emetu et al. (2014) participants did not practise condom application and removal during the session with the researcher. The other differences between the two interventions included: sexual orientation of participants (Emetu et al. (2014) – homosexual; Milhausen et al. (2011) – heterosexual), participants' ethnicity (Emetu et al. (2014) 50%; while Milhausen et al. (2011) almost 100% white), facilitator (researcher vs. health educator) intervention setting and recruitment procedure.

Self-efficacy in condom use. The impact of interventions on self-efficacy in condom use was assessed in five studies (Elkins et al., 1998; Emetu et al., 2014; Hayden, 1993; Hill & Abraham, 2008; Milhausen et al., 2011), and only one of them (Hayden, 1993) did not show significant results. Printed leaflets (Hill & Abraham, 2008) with instructions were found to be effective as well as interventions using an experiential approach. The only difference was visible in the effect size with small (d = .28) for written instructions (Hill & Abraham, 2008) and medium to large (d = .41 to d = 1.93) effect sizes for interventions employing demonstration, skills rehearsal, home practice and behavioural experiment (Emetu et al., 2014; Milhausen et al., 2011) and feedback (Milhausen et al. (2011). This may suggest that interventions using active and varied TCUS development techniques may have greater potential for changing participants' self-efficacy in condom use. However, one of the interventions (Hayden, 1993) also used multiple active techniques but did not show significant effects. All of the successful interventions were conducted in different settings and different formats, with various ethnic and social groups,

and with both genders. Interventions were guided by different theories, but they did not distinguish between effective and ineffective interventions; neither did quality of the studies, nor follow-up length. Three of the successful interventions (Emetu et al., 2014; Hill & Abraham, 2008; Milhausen et al., 2011) included other condom related topics, but one (Elkins et al., 1998) did not.

New STI rates. New STI rates were assessed for seven interventions conducted in a clinic setting (D. Cohen et al., 1991; D. Cohen, Dent, et al., 1992; D. Cohen, MacKinnon, et al., 1992; Crosby et al., 2009; Orr et al., 1996) and one in prison (Beltrami, Farley, Hamrick, & Cohen, 1998). The main assessment tool was a review of medical records of participants. Only three of the interventions (D. Cohen et al., 1991; D. Cohen, MacKinnon, et al., 1992; Crosby et al., 2009) were successful in reducing the new STI rates. In D. Cohen, MacKinnon, et al. (1992) participants were given printed pamphlets with condom use instructions. Condom use demonstration was used in another effective intervention (D. Cohen et al., 1991). The most effective (*OR* = .32) was also an intervention using a combination of TCUS development techniques including instruction, demonstration, practice until mastery, feedback and self-monitoring (Crosby et al., 2009). However, these results do not give a clear indication of contribution of specific TCUS development techniques in reducing new STI rates as demonstration and skills rehearsal were also used together in interventions that did not show significant reductions in new STI rates, and the same was reported for interventions using only skills rehearsal. The results reported in D. Cohen, Dent, et al. (1992) also suggested that one of the interventions, which included brief demonstration amongst other components, could have harmful effects on female participants, increasing their risk of new STI. None of the other characteristics were distinctive for successful interventions.

Mode of delivery. In interventions using only printed materials increase in self-efficacy (Hill & Abraham, 2008) and decrease in new STIs rates were reported (D. Cohen, MacKinnon, et al., 1992) but no significant change were reported in condom use skills and

frequency and consistency of condom use. In only one intervention a video was used to demonstrate condom use and this intervention did not report significant results.

FTF interventions in which only demonstration was used reported significant change in condom use skills, but no significant change in condom use frequency and consistency. The impact on new STI rates was inconclusive amongst 4 studies with only one of them (D. Cohen et al., 1991) reporting significant reduction on this outcome. FTF interventions using a mix of TCUS development methods reported significant improvement in condom use skills. Reported results of changes in frequency and consistency of condom use, condom use self-efficacy and new STI rates differ between the studies in regard to their significance.

Interventions employing multiple modes of delivery and multiple TCUS development techniques reported significant improvement in condom use self-efficacy in two versions of the same intervention (Emetu et al., 2014; Milhausen et al., 2011) and mixed results on condom use experience and condom use frequency and consistency. Significant change on single items on condom use errors and problems were reported in the study measuring them (Milhausen et al., 2011).

Discussion

The role of TCUS development techniques. Available evidence does not allow clear indication of which of the TCUS development techniques are linked to the interventions effective in changing outcomes investigated in this review; however, some patterns of possible association emerged during the synthesis of the results.

The TCUS techniques most frequently included amongst components of effective interventions were demonstration, skills rehearsal and self-monitoring. They were found on their own or amongst other techniques in interventions successful in increasing condom use frequency and consistency (Crosby et al., 2009; Emetu et al., 2014), improving correct condom use skills (Crosby et al., 2009; O-Prasertsawat & Koktatong, 2002), increasing

condom use self-efficacy (Elkins et al., 1998; Emetu et al., 2014; Milhausen et al., 2011) or reducing new STI rates (D. Cohen et al., 1991; Crosby et al., 2009). These findings are consistent with previous reviews, where active condom use skills training and TCUS development techniques such as demonstration and practice were found to be components of interventions effective in reducing sexual risk and improving condom use (Crepaz et al., 2006; Herbst, Kay, et al., 2007; Scott-Sheldon et al., 2011). Inclusion of live demonstration was found to enhance the effectiveness of group-level interventions for MSM (Herbst, Beeker, et al., 2007). Condom use demonstration and practice was found to improve condom use skills, with the latter reported to have a more pronounced effect than only demonstration in multi-topic interventions targeting men in substance abuse treatment (Calsyn et al., 2010).

Feedback was one of the least frequently described TCUS development techniques and was not characteristic for either effective or ineffective interventions. It might be possible that this is an element which, if not central for the intervention, is the one assumed to be an obvious part and not included in the intervention descriptions. For example it might be implicitly assumed if monitoring behaviour by others or skills rehearsal are described. The possible lack of details of the interventions limits the conclusions of the review.

Correct condom use. Interestingly, no consistent links were found between providing correct condom use instruction and significant changes on any of the outcomes assessed in this review, especially condom use skills. El-Ibiary and Youmans (2007) suggested that the level of complication of instructions provided may be crucial for their effectiveness, as some of the instructions require a good level of education to be understood and therefore may not be as effective for users with lower levels of literacy. However, it does not seem to be the case for the interventions included in this review in which correct condom use was assessed, as both were conducted with university students.

It might be as in case of feedback above that the instructions are not mentioned explicitly as distinctive element of the intervention.

Self-efficacy. On the basis of available evidence limited conclusions can be made about the impact of specific TCUS development techniques on increasing condom use self-efficacy. Some techniques seem to have greater potential of changing this outcome; however, further research is needed to explore the links between specific TCUS development techniques and condom use self-efficacy. A possible explanation of positive impact of interventions regardless of the TCUS development techniques employed might be that contact with any of them may lead to increase in subjective confidence in the ability to use condoms during future sexual intercourse. It is noteworthy that the follow-up period for the successful interventions was relatively short (from immediate to maximum six weeks) and in case of the very short follow-ups real-life difficulties might not have a chance to occur and possibly undermine an individual's confidence in his/her skills level. In previous research those reporting high levels of perceived condom use skills were found to largely overestimate their skills (Langer et al., 1994).

One distinctive technique, namely the condom race, led to inconsistent results. The lack of significant change in the study of Hayden (1993) may be related to relatively high levels of participants' self-efficacy at baseline. The results of the second study using this method support this explanation, as taking part in condom races significantly improved condom use amongst those who had very limited experience with condoms and low self-efficacy in using them (Elkins et al., 1998).

Condom use experience. Condom use experience was explored in only two studies (Emetu et al., 2014; Milhausen et al., 2011), yielding inconsistent results. Both of the studies used the same approach; however, they differ in the TCUS development techniques they used and targeted different populations. For these reasons it was not possible to decide whether the reported differences were related to any of these two aspects or additional

factors such as facilitator's skills. Research controlling for factors other than intervention content would be required to clarify the inconsistencies found.

Although promising, the results of the studies of Emetu et al. (2014) and Milhausen et al. (2011) should be interpreted with caution as they were within subjects pre-test post-test pilot studies with small sample sizes of 30 and 28 participants, respectively. Due to these limitations the evidence to support the claim about the effectiveness of approach and specific TCUS development techniques used is not strong.

Condom use errors and problems. Limited evidence exists regarding possible impact of different TCUS development techniques on condom use errors and problems as these were investigated in only one study using multiple techniques and modes of delivery (Milhausen et al., 2011). Despite promising results, due to sample size (as discussed above) which limited available analysis methods, complexity of the intervention and the fact that these outcomes were not assessed in any other study, it was not possible to make a conclusion about impact of these techniques.

New STI rates. Although previous reviews indicated that active condom use skills training and demonstration and practice may be linked to reduction in new STI rates (Crepaz et al., 2006; Scott-Sheldon et al., 2011), similarly as in case of self-efficacy, no patterns of links between specific TCUS and new STI rates were found. For new STIs it might be that the link between this outcome and specific TCUS development techniques used in the intervention is moderated by other factors. The CUE model (Sanders et al., 2012) indicates that condom use errors and problems impacting condom use experience, and frequency and consistency of condom use could moderate this association. The mechanism described by the model finds support in the results of Goodall et al. (2012) who reported the association between condom use problems and higher number of self-reported STIs. If the model predictions regarding the direction of interactions between specific variables are correct, it may not be possible to see the associations between TCUS

development techniques and new STIs without assessing a wide range of possible behavioural moderators (Herbst, Beeker, et al., 2007).

Mode of delivery. The was no consistent pattern linking effectiveness of the interventions with their mode of delivery. However, an observation was made that developing TCUS may be most effective in an individual format, with time for multiple practices allowing mastery of the skills. Two TCUS development techniques intrinsic to interventions in group settings – being observed by others while practising condom use application and observing others during their practice – were more often present in the ineffective interventions. This finding is in line with the results of a previous review where condom use skills training was found to be less effective on a group level than in one-to-one interventions (Albarracín et al., 2005). In one group intervention (Elkins et al., 1998) when specific feedback was given, the group setting did not seem to have a negative effect. This result, however, should be treated with caution, as the outcome assessed was self-efficacy, found to improve in interventions employing different types of techniques.

The possible explanations of lower effectiveness of the interventions in group setting may include factors such as: more attention being paid to the reactions of observers, not having enough time and opportunity to focus on own experience, lack of opportunity to try more than one time and correct one's own errors and/or time and peer pressure. The explanation of some of these factors comes from social, personality and learning psychology. Mere presence or "choking under pressure" effects may be responsible for lower effectiveness of group level interventions (Baumeister, 1984; Blascovich, Mendes, Hunter, & Salomon, 1999; Butler & Baumeister, 1998). This may be especially relevant for potentially embarrassing behaviour such as condom use (Bell, 2009; S. G. Moore, Dahl, Gorn, & Weinberg, 2006). Learning procedural tasks which should be almost automatic to be effective requires repeated practice (T. D. Lee, Swanson, & Hall, 1991), the possibility of which is limited in group interventions. Also, the types of goals may

affect the learning, with mastery goals being found linked to psychological safety (Ashauer & Macan, 2013).

Limitations of included studies. Although the review findings can be used to indicate some TCUS development techniques that are linked to effective interventions, the results should be treated with caution due to numerous limitations of the included studies. Study design issues, validity and reliability of measures used and approach to data analysis are factors weakening the strength of evidence. A narrow choice of settings and samples constrains the external validity of the findings, whereas variety of assessed outcomes limits the possibility of comparing the results amongst the studies included in the review.

Quality of studies design and follow-up. A number of studies did achieve strong ratings, which may be related to the fact that studies which had lower quality of reporting were not included in the review as they did not provide sufficient data to meet inclusion criteria. A large number of studies excluded from this review due to insufficient or unclear intervention descriptions support this explanation. Moreover, the tool used in this review to assess the quality of the studies is less strict than, for example, the Cochrane assessment of bias (Higgins & Green, 2011) resulting in more high quality ratings. One third of studies, mostly experimental or small non-randomised pilot studies, were given a "weak" rating and the evidence they provided should be treated with caution.

Although the majority of the studies included were described as randomised, only two (Crosby et al., 2009; Hill & Abraham, 2008) provided description of adequate randomisation strategies to ensure that all the participants had equal chances to be allocated to each of the conditions. Others used randomisation by session, day of the week etc. or did not provide detailed enough description to assess the adequacy of the procedures employed. The randomisation approaches were often determined by practical issues, especially in the clinic settings; however, this could introduce selection bias and lower the reliability of the results.

Despite the limitations related to design and sample size, the current review purposefully did not exclude pilot or small scale non-randomised studies, as one of the aims was to describe the widest possible repertoire of TCUS development techniques. Excluding these types of studies could lead to missing some new or less popular approaches to teaching TCUS and limiting wider insight in the field (van Teijlingen & Hundley, 2001). This was the case for studies of Hayden (1993), Elkins et al. (1998), Emetu et al. (2014) and Milhausen et al. (2011), in which TCUS development techniques such as skills rehearsal (the condom race), home practice, and behavioural experiment were introduced. All of the pilot studies, except Hayden (1993), demonstrated significant changes in some of condom use related behaviours and cognitions, contributing to the development of knowledge about the role of specific TCUS techniques and highlighting potential directions for future research and development of programmes promoting condom use.

Most of the studies reported that significant changes in condom use related behaviour and cognitions occurred in a relatively short time post intervention. The majority of these studies used single follow-up, four immediately after the intervention and another four up to a month after the intervention. However, there was no information regarding dynamics of the change, nor data about long-term behaviour modification. Shorter follow-ups may provide better accuracy of behaviour recall but at the same time they may miss some behaviours that do not frequently occur (Schroder, Carey, & Vanable, 2003). A possible solution to that problem could be to conduct a few consecutive follow-ups that could reduce the risk of recall error in the longer term, and not miss "low-frequency" behaviours (Schroder et al., 2003).

Choice of samples and settings – generalisability. Most of the studies included were conducted in the US, with two distinctive groups of participants, namely public STI clinic patients or students. Ethnic differences between these two groups were also apparent. The large proportion of interventions presenting significant results across various outcomes

were targeting only male participants (Crosby et al., 2009; Emetu et al., 2014; Milhausen et al., 2011; O-Prasertsawat & Koktatong, 2002). All these factors in combination with the young age of the majority of participants reduce the generalisability of findings outside these very specific settings and groups.

There are many groups that are not represented in the existing research, mainly those who are not labelled as high risk groups, i.e. they are middle age or older, heterosexual, professionals and not STI clinic patients. Recent research shows that many people are sexually active until late adulthood (Mercer et al., 2013) and they face sexual health risks specific for various life stages, such as divorce or widowhood, and finding new sexual partners (Goddard & Leviton, 1980; Gott & Hinchliff, 2003; Idso, 2009; Rich, 2001; Sherman, Harvey, & Noell, 2005; K. P. Smith & Christakis, 2009). Another group not well represented across the studies included are people living in rural areas, without good access to STI clinics and living a distance from academic centres. Only one study from Thailand (Elkins et al., 1998) focused specifically on this group, but the approach used (engaging village leaders and organising community wide events) may be difficult to implement in rural settings in the other parts of the world, specifically western countries, due to different structure and organisations of communities.

Identification of all these gaps leads to the question about the implementation of successful interventions in wider settings with different ethnic and age and with both gender groups. It is especially important as the prevalence of different types of condom use problems may also vary between countries (Dodge, Reece, Herbenick, & Schick, 2010), highlighting the need for development of different condom use skills. It is possible that specific strategies or techniques are only effective in some populations and/or contexts. For instance, condom use skills training was found to be effective in countries other than the US, and in studies which targeted men rather than women (Albarracín et al., 2005; Albarracin et al., 2008; Herbst, Kay, et al., 2007). Special attention should be given to

promotion of condom use and developing TCUS with various groups across the whole life span.

Choice of outcomes. The choice of outcomes is critical for assessment of the effectiveness of the interventions. Two outcomes - frequency and consistency of condom use, and new STI rates - were most frequently used across the studies, with the latter assessed only in clinic settings. In comparison, none of the studies assessed complete condom use. Correct condom use was also not widely chosen as an outcome. In five interventions it was assessed by observation of condom application and removal and only one (Milhausen et al., 2011) assessed condom use errors and problems. Lack of assessment of complete and correct condom use increases the risk of overestimating the proportion of protected sexual intercourse events (Dolezal et al., 2013). This in turn may cause overestimation of the frequency and consistency of condom use and underestimation of the impact of the intervention on outcomes e.g., new STI rates (Steiner et al., 1994). Only Milhausen et al. (2011) asked about correct condom use in real life situations. This reduces the ecological validity of the interventions (Coolican, 2004) and raises the question of whether the improvement in skills presented on a model in a research/training environment will translate into behaviour during sexual activity with a partner.

Considering that complete and correct condom use are essential for the effectiveness of condoms (see Chapter 1) participants' condom use skills should be assessed more often. Using this measure together with new STI rates perhaps could better show the links between specific TCUS development, complete and correct condom use and STI rates. This in turn could shed some light on possible reasons in differences of new STI rates changes between the studies, especially when condom use frequency improved without reduction in new STI rates (Orr et al., 1996).

Another outcome that was omitted in most of the interventions was condom use experience. As discussed above only two studies (Emetu et al., 2014; Milhausen et al., 2011) used this to assess the effectiveness of the intervention. Including this outcome in

future studies would be in line with the approach advocating more focus on the subjective experience (Rosser, 1990) which, according to the model of Sanders et al. (2012), is essential for consistent, complete and correct condom use. Assessing the experience could provide further evidence regarding the nature of links between TCUS, subjective perceptions of condom use experience and complete, correct and consistent condom use.

Methods of assessment. Most of the studies used validated scales to assess condom use experience or self-efficacy; however, they were often modified for the purpose of the study (Elkins et al., 1998) or only some subscales were used (Emetu et al., 2014; Milhausen et al., 2011). This raises the question about the reliability of the assessment as these modifications or use of subscales only make the comparison of the results across different studies difficult, or even impossible.

Another issue is the use of self-reports for the assessment of all but two outcomes. Self-reports are prone to two main types of reporting bias. Firstly, social desirability may lead to providing answers perceived by respondents to be expected by the researcher (Cordero-Coma & Breen, 2012; P. Fleming, 2012; Geary, Tchupo, Johnson, Cheta, & Nyama, 2003; van de Mortel, 2008). Secondly, they rely on the recollection of past events which can be affected by "length of the reference interval, the level of measurement, and the frequency of behaviour being assessed" (Schroder et al., 2003, p. 2). Self-reports of condom use were found to be the most accurate for recall periods between 3 and 6 months (Jaccard, McDonald, Wan, Dittus, & Quinlan, 2002). Alternative methods that increase the reliability of measurement, such as coital dairies, daily diaries and/or increasing the number of follow-up measures, each covering relatively shorter periods of time, could reduce the risk related to inaccurate recollection and omission of less frequent behaviour (Graham, Crosby, Sanders, & Yarber, 2005; McAuliffe, DiFranceisco, & Reed, 2007; Schroder et al., 2003).

Two outcomes most frequently assessed across the studies – frequency and consistency of condom use and new STI rates – were assessed using measures that raise

questions about the actual information they elicit and their accuracy for the assessment of the effectiveness of the intervention. The variety of measurement methods used to assess condom use frequency and consistency made the comparison of results between studies difficult and often not possible. Graham et al. (2005), in their review of various methods of condom use assessment, underlined the limitations of all the methods used in the studies included in this review. For example, the consistency of condom use was sometimes measured using percentage of condom use during sexual intercourse or a condom use index. The latter gives an elegant way to compare results; however, it carries the risk of losing the information about actual number of risk behaviour occurrences and can lead to underestimating the real effect of the intervention (e.g., in some cases of decreased number of intercourse events) or, in cases of increased number of sexual events, overestimating the change. Discussing frequency measures Graham et al. (2005) underlined the need to differentiate between times when condoms were used and number of unprotected sexual intercourse events. The authors argued that the second measure is a more accurate measure of risk. Summarising the results becomes even more problematic when various recall periods, various reference points (last sexual intercourse, last five penile-vaginal intercourses (PVIs) etc.), different types of partners (casual, steady etc.) and inconsistency in the terminology used (last sex, last penetrative vaginal events etc.) are added to the picture. In only two studies (Hill & Abraham, 2008; Kajubi et al., 2005), condom use was assessed separately for different types of partners. The specific characteristics of sexual contact, for example “vaginal”, “penetrative with female partner” etc., was given to participants in a third of included studies. To be able to formulate conclusions it is important to ensure that the same behaviour is assessed for all participants (Graham et al., 2005).

Additionally, in most of the studies conducted in clinics, participants were asked about the number of sexual partners, whereas at universities they were mostly asked only whether they were sexually active. For participants, the way the questions are framed may

lead to reflection over their behaviour and constitute an intervention itself (Godin, Sheeran, Conner, & Germain, 2008; Levav & Fitzsimons, 2006; McCambridge & Kypri, 2011). It may also affect the participants' perception of relevancy of the intervention to themselves and in this way may affect its effectiveness. This could explain the higher proportion of significant results in the clinic-based interventions compared to the non-clinic ones.

All participants recruited in the clinics were sexually active and had had the negative experience of STI. Not all non-clinic participants were sexually active and they might have had lower motivation to change their condom-related behaviour, as it was not relevant for them at the time of the intervention.

Other challenges are related to using new STI rate as the measure of effectiveness of behaviour change interventions. One is the implicit assumption that behaviour change leads directly to changes in STI rates. In the case of high prevalence and/or highly infectious STIs, even a very low proportion of unprotected sexual intercourse may lead to infection (Graham et al., 2005; Pinkerton, Chesson, Crosby, & Layde, 2011). On the other hand Schachter and Chow (1995) underlined that the less than perfect validity of diagnostic tests for STIs (e.g., test for Chlamydia trachomatis) may lead to underestimation of the effects of interventions, especially in the case of small intervention groups and low prevalence of STIs. Another issue is whether participants' medical records provide accurate data. It is possible that when experiencing new symptoms participants used a different clinic. Additionally, in the reviewed studies the assessments included different STIs – some of these may stay asymptomatic for long periods; therefore even participants with previous STIs may not be motivated to visit a clinic. These factors could lead to overestimation of the effect of the interventions.

Analysis method. None of the studies included a mediation analysis of the impact of factors such as improving actual TCUS on observed behaviour change, nor discussed the possible impact of specific components of the intervention on its overall effectiveness. Only the O-Prasertsawat and Koktatong (2002) study provided insight into the

effectiveness of different TCUS development techniques comparing the effectiveness of two of them. The complete cases analysis used in the majority of the studies increases the risk of overestimation of the effects of the intervention. Only the interventions which did not include any other development components than TCUS (Lindemann & Harbke, 2013; Lindemann et al., 2012; O-Prasertsawat & Koktatong, 2002) provide the strongest evidence about the impact of specific techniques on intervention effectiveness. However, these studies assessed only one outcome in the scope of this review – correct condom use skills.

Strengths of the review.

TCUS development techniques. The strongest point of this review is showing the wide range of TCUS development techniques used in interventions promoting condom use ranging from more traditional (e.g., providing leaflets including instructions or demonstration) to more recent approaches incorporating behavioural experiments. It shows that translating recommendations to include behavioural skills training (Clutterbuck et al., 2012; WHO, 2006), or more specifically, TCUS development, can be done in different ways, and some of the techniques may have greater potential of contributing to the positive effects of the intervention than others. Although the available evidence is limited, it points towards possible links between the use of specific techniques, and the interventions' effectiveness. These findings are in line with the results reported in multi-topic/complex interventions investigating various TCUS development techniques (Calsyn et al., 2010; Lindemann et al., 2005). This is particularly important as the problem of choosing the best available technique of developing TCUS seems to be often overlooked by researchers, public health practitioners, and even condom manufacturers (Oberne & McDermott, 2010).

Identifying gaps. As predicted at the stage of formulating review questions, it was not possible to answer all of them. However, this review provides valuable knowledge about gaps in existing evidence. Firstly, it highlights the limitations of current knowledge and directions of future research. In particular, it shows that for further progress in condom

promotion and more effective HIV/STIs prevention, it is essential to step back from large and complex multi-topic interventions and find the best way for delivering specific components, in this case developing TCUS. Secondly, findings of this review can also enhance critical evaluation of the content of existing, and guide the development of future interventions.

Time perspective on TCUS development techniques. The review also shows how the approach to promote condom use and develop TCUS has changed in the last two decades. There is visible shift from a simple didactic style through enhancing information based interventions by practice towards incorporating personal experience and pleasure into condom use. The review findings reflect the general change in sexual health education and promotion as the latter approach, although already proposed nearly 30 years ago (Rosser, 1990), has been recently attracting more attention from researchers and practitioners (Ingham, 2005; Philpott, Knerr, & Boydell, 2006).

BCTT research contribution. This review also contributes to the research on applications of BCTT (Michie et al., 2011; Michie et al., 2013). It was found that the current taxonomy does not cover all techniques, especially those specific to the behaviour that may be presented and observed during the intervention session, but not easy or possible to observe or present in real life situations.

Limitations of the review.

Finding relevant studies. The first challenge of the review was finding the balance between broadness of the search and its sensitivity. Reading full texts was in most cases essential to find relevant studies due to components of the intervention, even the key ones, often not being indicated in the title, abstract or keywords of papers. Another difficulty arose from great inconsistency in terms used in the studies' descriptions. There were studies with "condom promotion" in the title, but the components were targeting mainly topics other than condom use related to HIV prevention. Some other studies focused on

HIV prevention in the title and abstract, whereas the intervention was focused in major part or exclusively on condom promotion.

Another difficulty was caused by the variety of terms describing condom use and their definitions used in studies. Safer sex is sometimes used as interchangeable with condom use (Noar et al., 2011), or to describe other non-condom use behaviours (Kissinger, Clark, Dumestre, & Bessinger, 1996). Sometimes users of this term refer to sexual intercourse without penetration and sexual intercourse when condom is used (Waldby, Kippax, & Crawford, 1993) or even to drug and alcohol use and knowledge about sexual partners' history (DiIorio, 2010). The same is true for "HIV prevention" – it can cover different topics, not necessarily including teaching TCUS (e.g. Thurstone, Riggs, Klein, and Mikulich-Gilbertson (2007)). Condom use counselling is another ill-defined term that can refer to varying content, from providing basic information that condoms should be used consistently, with condom use demonstration or without, to complex issues related to alcohol and drugs use, or gender imbalance.

Descriptions of interventions. The greatest limitation of this review stems from insufficient descriptions of the interventions' components. As discussed above it is unlikely that skills rehearsal or demonstration were provided without instruction on correct condom use, but the available descriptions are very limited in this part. The analysis of components of the intervention described in the available manuals gives the impression that some components might be seen as obvious, therefore not described. For that reason the role of other, better described components, may be unduly weighted in the results of this review. This weakness of the review at the same time constitutes one of its strengths, underlining how limited available evidence is. Exploring the role of specific TCUS and their combinations in an experimental setting could be one possible solution to this problem.

Lack of detailed description of interventions' components and delivery may also raise the question about their integrity and the possibility of their replication. Searches for

the details of interventions revealed another problem that can largely limit the body of available evidence. Requests for details of interventions from researchers resulted in a very low response rate, and often the protocols, manuals and/or materials used in the interventions were no longer available. This makes any future analysis of those interventions' content and results impossible.

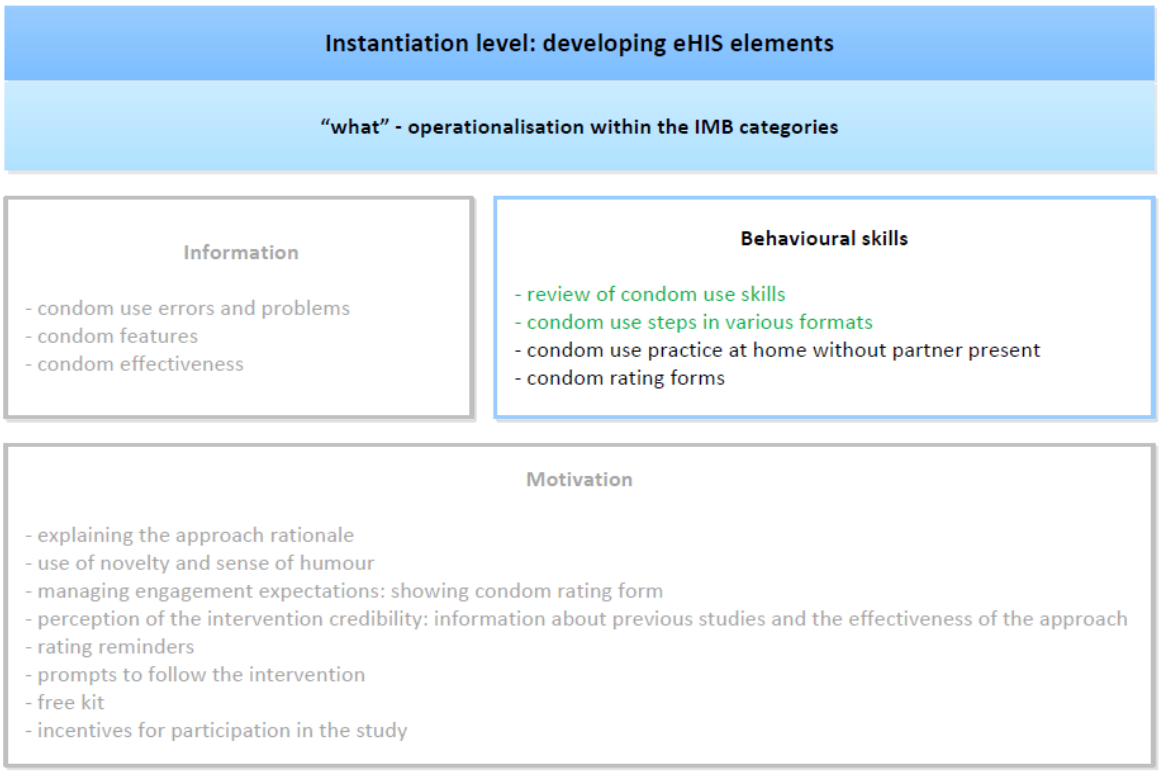
Limited ability to detect patterns and limited generalisability of findings. Low number of studies and a wide range of outcomes did not allow undertaking a meta-analytic comparison and could lead to inability to detect existing patterns between TCUS development techniques and specific outcomes. Available data did not allow conducting mediation analysis, limiting the review to a descriptive synthesis of existing evidence. Detection bias was the type of bias most frequently found across all the studies included in the review; together with a high risk of allocation bias in over one third of the studies it could affect the overall results of analysis.

Findings of this review are also limited in their generalisability. Small number of studies diverse in terms of designs, quality, and measures of specific outcomes negatively affect the possibility of generalisation of their results.

Contribution to the aims of the thesis. One of the challenges of translating an FTF intervention into an online based, self-guided one was creating a method to support the review of correct condom use skills, in the absence of a possibility of providing immediate feedback on them. The systematic review highlighted demonstration, skills rehearsal and self-monitoring as the TCUS development techniques most frequently found in interventions effective in increasing condom use frequency and consistency and improving correct condom use skills. Based on these results supported by theory, evidence and experts' advice, a condom use video demonstration and skills review were included in eHIS (see Figure 8).

Figure 8

Changes at the operationalisation level following the systematic review



The aim of the video was to replace the demonstration by a health professional during the initial meeting. The skills review was introduced to compensate for the lack of hands-on practice with feedback, one of the methods found to be most likely to contribute to developing TCUS. Users were encouraged to review their own condom use skills by recalling condom use steps accuracy as a substitute for FTF immediate feedback.

Recall has been found to be more difficult than recognition and consequently related to better knowledge of various subjects such as health promotion or political knowledge (Hollander, 2014; M. S. Lim, Gold, Bowring, Pedrana, & Hellard, 2015; Waller, McCaffery, & Wardle, 2004). The skills review could also enhance learning in line with a "testing effect" (Rowland, 2014), and as an interactive element could increase users' engagement (Kraft, Drozd, & Olsen, 2009). This approach was assumed to trigger the actual review more accurately than the task used before based on recognition of given condom use steps (Noar et al., 2011).

Conclusions and Recommendations

This review provides an overview of the various TCUS development techniques used in condom promotion studies. In its findings it complements previous reviews contributing to a better understanding the role of specific TCUS development techniques in promoting correct condom use and revealing some gaps in the existing evidence.

Although TCUS development techniques are used in many interventions promoting condom use to prevent HIV/STIs and unplanned pregnancy, there is very little knowledge about which of them are the most effective. Some patterns of association between use of specific techniques and the effectiveness of the interventions were identified indicating demonstration, self-monitoring and skills rehearsal as techniques with the most potential for changing condom related behaviour and/or cognitions. The findings also show that written instruction most commonly used, e.g., included in each condom package, may not be sufficient to improve the correctness of condom use. However, at present the available evidence does not allow making any statements about the causal links between TCUS development techniques and condom use related outcomes assessed in this review.

The majority of the studies focused on the investigation of changes in condom use frequency and consistency; however, these measures are not sufficient to assess the actual level of protection when using condoms due to possibility of incorrect and incomplete use. The greatest challenge for future research in this area is to investigate the associations between specific TCUS development techniques and change of behaviours and cognitions contributing to the condom effectiveness; these are complete and correct condom use, and related to them condom use problems and condom use experience. Another challenge for future research is to link the use of specific TCUS development techniques and biomarkers such as new STIs.

It was also not possible to comprehensively answer the question about the most effective modes of delivery for specific techniques. However, some tentative suggestions

about the superiority of guided individual skills rehearsal over practice in a group setting can be made. Again, an investigation of the various modes of delivery, such as video or online interventions, could reveal the benefits and limitations of specific modes used to deliver different TCUS development techniques.

Future research should improve the quality of studies and their reporting. Providing detailed and unified description of all behaviour change techniques included in the intervention is necessary to allow comparing content and related results across various studies. To improve the generalisability of findings diverse samples need to be recruited - including in particular older age individuals and various socioeconomic groups. Greater methodological discipline to reduce biases, particularly allocation and detection biases, is also necessary to produce stronger evidence.

Chapter 4

A Qualitative Evaluation of a Prototype (Study 1) and a Computerised Version (Study 2) of the eHIS

Chapter Introduction

The rationale behind the two qualitative evaluations of eHIS at various stages of its development, followed by the studies aims and research questions are presented. The results of the evaluation and discussions of their implications for the intervention development are also included. Finally the strengths and limitations of the studies are discussed as well as wider implications of the findings.

Background

The importance of users' perspectives in an intervention development. In intervention development it is crucial to ensure that its core principles are well communicated; equally important is its relevance and acceptability for users. According to the PBA (described in Chapter 2), users' perspectives are crucial in developing interventions which will be feasible, acceptable and effective (Yardley, Morrison, et al., 2015). This approach highlights the need for involving users from the earliest stages of intervention development. Qualitative evaluation of an intervention allows insight into their experience with the intervention, understanding of the content, relevance of the intervention for personal circumstances and preferences for information provision and design features (Atkinson et al., 2009; Carroll et al., 2002; Dickerson et al., 2013; Fleisher et al., 2008; Hightow-Weidman et al., 2011; Linke, McCambridge, Khadjesari, Wallace, & Murray, 2008; Steele, Mummery, & Dwyer, 2007; Stinson et al., 2010; P. Trivedi & Wykes, 2002; Yardley, Morrison, Andreou, Joseph, & Little, 2010).

The information gained from users' perspectives and understanding of their needs and expectations can help to adjust the intervention content and guide choice of specific

information to be included and how it is presented, improve ease of use of various features and suggest additional ones (Carroll et al., 2002; Dorfman et al., 2010; Linke et al., 2008; Stinson et al., 2010; Yardley et al., 2010). For example the feedback from users of an Internet-based arthritis self-management programme helped researchers to discover functional errors and improve the website use experience (Stinson et al., 2010). The usefulness of making changes was demonstrated in the process of developing a HIV prevention intervention – users' experience improved after changes were made to a website guided by their feedback (Hightow-Weidman et al., 2011). In the longer term, involving users in the development of the intervention may contribute to higher intervention use satisfaction and lower attrition and increase chances for an intervention being effective (Schneider, van Osch, & de Vries, 2012; Yardley, Morrison, et al., 2015).

Qualitative testing during intervention development. Placing participants' perspectives in the centre of an intervention process as postulated by the PBA (Yardley, Morrison, et al., 2015) and also supported by other research (Campbell et al., 2000; C. M. Johnson, Johnson, & Zhang, 2005) leads to gaining insight into users' experiences with the intervention and their preferences and concerns is possible using a qualitative approach. It is important that in an intervention development process attention is paid to discovering aspects important for users and to better understanding their experiences with interventions (Linke et al., 2008; Yardley, Morrison, et al., 2015; Yardley et al., 2010). In-depth qualitative testing of the interventions goes beyond the traditional usability testing focused primarily on ease of use of the website navigation, functionality, and preference for the design (Yardley, Morrison, et al., 2015; Yardley et al., 2010).

Qualitative evaluation can be undertaken at any stage of intervention development; however, it is recommended that user testing be employed in the early stages of intervention development (Fernandez, Insfran, & Abrahão, 2011; Gould, Boies, & Lewis, 1991; Gould & Lewis, 1985; Krug, 2006; Yardley, Morrison, et al., 2015). This increases the chances of detecting problematic areas and directs further development. Early feedback

can improve the intervention development process on various levels and at all of its stages. For example, feedback from women with low income living in rural areas informed development of a nutrition education website developed for them from the stage of setting the website name through content development to usability testing (Atkinson et al., 2009).

In summary, early stage users' involvement can help to guide modifications already at the prototype stage to ensure that planned intervention aims are clearly communicated to the users. It also significantly reduces the likelihood that changes would need to be made at later stages, thus reducing resources and time required (Krug, 2006). Evaluation at later stage allows verification of whether the changes made in response to users' feedback met their objectives.

Qualitative evaluation in eHIS development process. Two qualitative studies evaluating first the eHIS paper-based prototype and then the computerised version of the intervention were completed to inform its development. The information gathered from the studies, together with the results of a review of evidence and experts' advice, guided eHIS development (for details see Chapter 2).

Study 1 - Evaluation of the eHIS Prototype

Aims and objectives of evaluation of the eHIS prototype. The first qualitative evaluation was completed at the stage of developing the prototype of eHIS. Its main aim was the exploration and understanding of users' experiences and its specific aspects such as the clarity of information, relevance of the content, and engagement with the intervention.

The study key research questions were:

- *How did participants engage with the intervention?*
- *Did participants understand the aim of the intervention, its content and procedure?*
- *What was participants' overall experience with the intervention?*
- *Was web-based eHIS acceptable for users?*

To inform the eHIS development it was also important to explore:

- *Which aspects of the intervention were identified by the participants as requiring change or improvement?*
- *Which aspects of the intervention were valued most by the participants?*
- *Which aspects of the intervention were valued least by the participants?*

Participants were also specifically asked about their opinions about guided home practice and the sample kit that accompanied the website prototype.

Method.

Recruitment. Participants were recruited between May and September 2014 through self-referral in response to posters at the UoS and public advertisement boards in Hampshire. The study was also advertised through posts on Facebook and Twitter, through the PsyPAG mailing list addressed to participants from South England and at the UoS Psychology eFolio platform. A Southampton based youth organisation No Limits helped with recruitment. The researcher (Marta Glowacka) travelled for the sessions if it was not possible or convenient for participants to attend a session at the UoS. Due to a low response rate, recruitment was extended by accessing potential participants through personal and professional networks. Family, friends, work colleagues and other known professionals were asked if they were willing to share the advertisement with their networks. This recruitment approach helped widen networks and increased the diversity of the sample. The study advertisements are presented in Appendix N. The participants were offered £15 to thank them for participation or they could receive study credits if they were Psychology students at the UoS and the travel costs reimbursement.

Recruitment was conducted until data saturation, the point where "further data collection and analysis are contributing nothing new" (Chamberlain, Camic, & Yardley, 2004, pp. 74-75), was achieved. The number of sessions estimated on the basis of previous research (Carroll et al., 2002; Faulkner, 2003; Virzi, 1992) to be sufficient to reach data

saturation was accurate – it achieved by the 11th session. However, as two more sessions were already scheduled these were also conducted.

Participants reflecting the characteristics of potential intervention users who met the inclusion criteria (Table 4) were recruited. Any individuals who would need specific intervention adjustments or special session arrangements to accommodate their needs (persons having a learning disability (Rotondi et al., 2007), or having hearing or visual impairments (Krug, 2006)) were excluded from the study (see Table 3) as such adjustments and arrangements exceeded the scope and resources of the project.

Table 3

Study 1 inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
male; aged 18-69 fluent in English (written and spoken); use male condoms; do not use condoms regularly or stopped using condoms for reasons other than allergy to latex, non-latex condoms and/or lubricants; lack of confidence in using condoms, or are considering using condoms in the future; not allergic or sensitive to latex, non-latex condom and/or lubricants	not fluent in English; below the age of 18 or above age 70 or more; allergic or sensitive to latex, non-latex condom and/or lubricants; have visual or hearing impairment; have a learning disability

Study procedure. Men indicated their interest in taking part by accessing the online study information sheet (Appendix O), giving consent for screening (Appendix P) and completing the screening questionnaire (Appendix Q). Men also had the option of a phone call to receive study information (Appendix R), give consent for screening and complete the screening questionnaire (Appendix S). Study procedure is presented in Figure 9.

At the beginning of the session men were asked to sign the consent form (Appendix T). Printed copies of the screening questionnaire and study information sheet were also available at the beginning of the session. During the session participants were asked to

"speak aloud" their thoughts (Appendices U – V) as they went through paper mock-ups of the webpages (for examples see Appendix A) and later to answer questions about the intervention (Appendix W). The sample kit was also provided and condoms from the kit could be used for practice on a penile model during the session. At the end of the session participants received a printed copy of the debriefing sheet (Appendix X). Ethical approval from the Psychology Ethics Committee at the UoS was obtained.

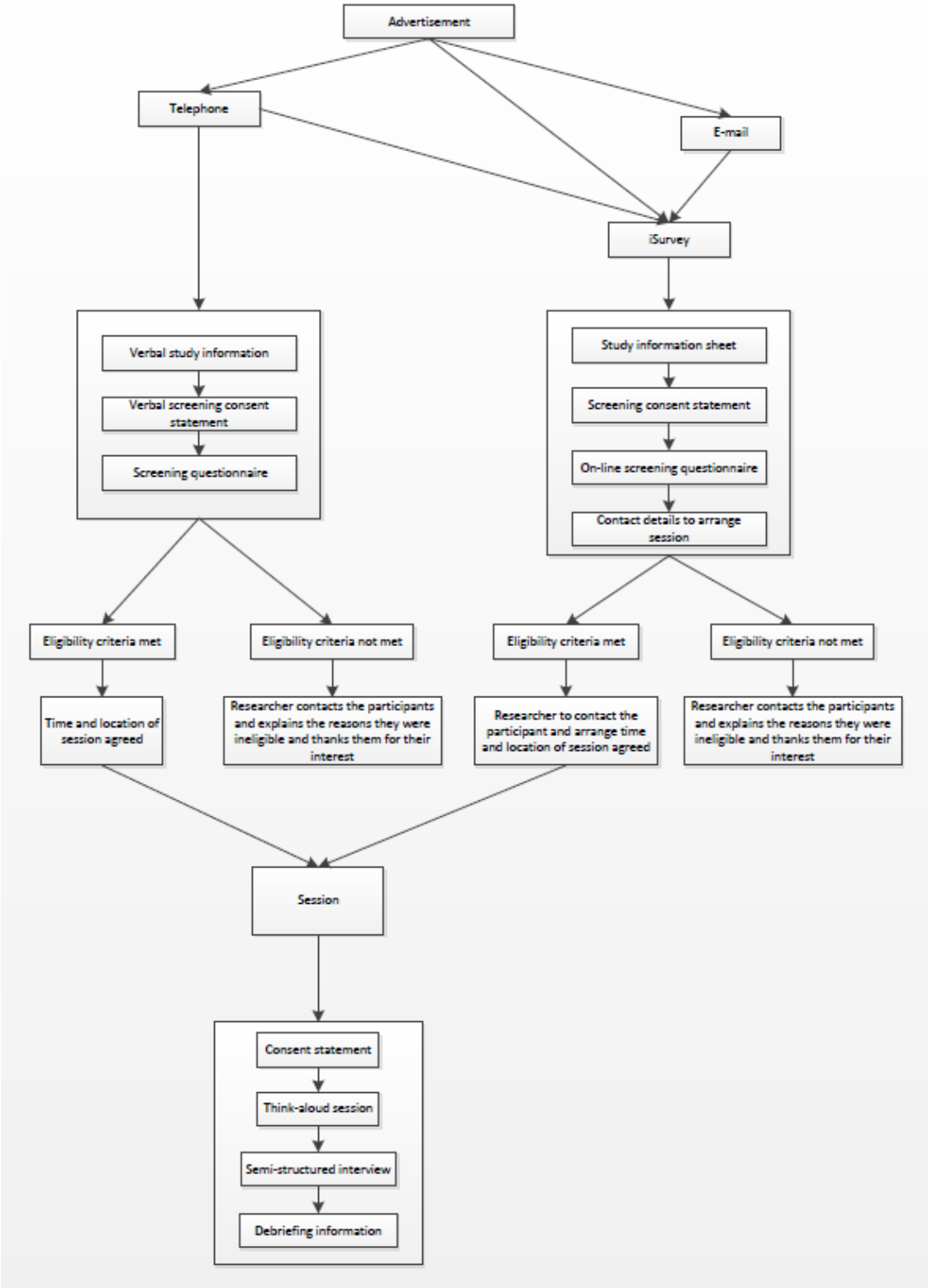
Data collection.

Screening questionnaire. The screening questionnaire included questions reflecting the inclusion/exclusion criteria, demographics (age, education, occupation), and perceived level of proficiency with computers. Participants were also asked if they were condom users, and if yes, whether they used condoms correctly and consistently, whether they felt confident using condoms, and whether they had experienced any condom use problems (see Appendix Q).

Think aloud interview. The TAI approach was used as a primary method of gathering information about participants' experience with the intervention's prototype. They were asked to "speak aloud" their thoughts as they went through it. TAIs are a well-established method of exploring users' interactions with computer software and online programmes, including computerised health interventions and assessment tools (Atack, Luke, & Chien, 2008; Fleisher et al., 2008; Jaspers, 2009; Yardley et al., 2010). They allow elicitation of users' understanding of the content of the website, as well as exploration of their views regarding available functionalities and website navigation (Cotton & Gresty, 2006; Hagen et al., 2008).

Figure 9

Studies 1 and 2 procedure



The researcher had an option to use feedback cues, elicit clarification, and support participants' progress (Boren & Ramey, 2000). This approach was found to yield similar results to a strict "no interaction" approach (Ericsson & Simon, 1998), seemed more natural, and facilitated task completion (Krahmer & Ummelen, 2004). The TAIs script and prompts (communication tokens) (Krug, 2010) are presented in Appendices U and V.

Semi-structured interview. To complement the data from TAIs participants were asked to participate in a brief SSI. The SSI allowed to gather information in a systematic way, at the same time being open to the details important for the participants (Wilkinson, Joffe, & Yardley, 2004). In previous studies developing e-health interventions (Fleisher et al., 2008; Stinson et al., 2010) this method provided useful information, complementing that gained through TAI. The questions included in the SSI focused on participants' general experience with eHIS, their preferences, and suggestions of changes to the intervention (see Appendix W).

Observation. During the TAIs observation notes focusing on participants' non-verbal reactions were made. Correct condom application and removal skills on a condom demonstrator (wooden non-anatomical penile model) of the participants who opted for optional practice were also observed. Observation allows recording of data that might otherwise be missed (Aitken, Marshall, Elliott, & McKinley, 2011). It is often used to complement the data gathered through TAIs and/or interviews as it can provide contextual data allowing clarification of ambiguous statements (Farzanfar, Finkelstein, & Friedman, 2004; Hinchliffe & Mummery, 2008; Ozok, Wu, Garrido, Pronovost, & Gurses, 2014; Stinson et al., 2010).

Data analysis. The data gathered in the screening questionnaires were used to present the characteristics of the participants. The TAIs were audio-recorded and transcribed verbatim. The notes from the observation were reviewed and added to the transcripts if they were judged to be important for analysis. The transcripts were coded for relevant pages of the intervention prototype for clarity of the analysis. Observation notes

about condom practice during the session were summarised and included in the final analysis. The quotes used in the analysis were "cleaned" of repetitions, hesitation, and interjections such as "yeah," "erm" etc.; grammatical mistakes were corrected and phrases were transferred into sentence format (Braun & Clarke, 2006).

Thematic analysis of the transcripts was conducted (Bishop & Yardley, 2015; Braun & Clarke, 2006; Joffe & Yardley, 2004; Yardley et al., 2010). This is a well-established method of analysing the qualitative material previously employed in usability testing research (Følstad & Hornbæk, 2010; Stinson et al., 2006; P. Zhang & von Dran, 2001). The thematic analysis followed the approach described by Braun and Clarke (2006, pp. 202-203). The themes were identified primarily on the basis of data gathered during TAIs, and data gathered during SSI were used as complementary.

The research questions indicated general areas of interest of the evaluation; however, participants' perspectives led the analysis. The transcripts were read for familiarisation and notes for code candidates were taken (Appendix Y). The first three TAI transcripts were trial coded on paper to create an initial coding structure (Appendix Z) and identify initial theme ideas in relation to four a priori categories: website content, design, functions, and general experience. Additional data-derived codes relevant for the research questions were also identified. In the following step all transcripts were moved to NVivo 10 software (QSR International, 2012). The TAI transcripts were divided into "meaning units;" the first two transcripts were coded and the initial themes were proposed (Appendix AA). The transcripts were reviewed and changes to code definitions were made to improve their precision. Following this, transcripts were recoded where needed. Minor amendments to coding to improve its clarity were carried into writing up phase.

Developing themes and adjusting codes was a dynamic process accompanied by data recoding, repeated when required until the fit between the proposed themes model/structure and data was satisfactory. Some parts of the transcripts, that were initially coded in an "additional" category and were not included in the theme structure, were added

in the final stages of the analysis, after their importance for understanding participants' experience was reviewed (i.e., beliefs and previous experience). These stages of the data analysis are presented in Appendix AB and the final themes are presented in the "Results Summary and Analysis" below.

A coding manual was developed and continuously reviewed and updated, followed by recoding of appropriate parts of the transcripts when required (see Appendix AC for the final version). The manual also includes additional codes related to technical issues, errors etc. which were not used in the current evaluation but were used to organise data.

Throughout the analysis process the codes and theme candidates were reviewed and discussed with the project supervisor at all steps of the analysis. Reliability of coding was assessed by the researcher and supervisor both coding some of the transcripts.

The SSIs were also audio-recorded and transcribed and summarised. As the interviews were conducted to complement the TAIs, only new comments and opinions that were not presented during the TAIs were included in the final analysis.

Participants. The screening survey was completed by 24 people (one man completed the survey twice); five were excluded as ineligible (four women, one did not disclose their gender). Six participants withdrew after completing the screening (two explicit withdrawals and four no further contacts). Thirteen men completed the study. None of the participants reported to be allergic to latex or to have any type of disability that could be a barrier to participate. All participants perceived themselves as competent computer users.

The mean age of participants completing the study was $M = 32.08$, $SD = 12.03$ (range 19-61). They represented a well-educated group at different stages of their professional life. Four of the participants experienced condom use problems, reporting eight different problems between them. Participants' characteristics and details of their condom use are presented in Table 4.

Table 4

*Study 1 participant characteristics and their condom use experience (*N = *13)*

Participants characteristic[a]			
Highest level of education completed	A2/A-levels (2), Degree/BSc (3), Masters/MSc (6), PhD (2)		
Occupation	IT (2), Retired (1), Retail (1), Researcher (1), Clerical Assistant (1), Design/marketing (1), Student (6)		
Participants condom use experience			
	Yes	No	Don't know/ Not always
Use condoms (13)	12	1	
Use condom each time you have sexual intercourse (12)	6	6	
Use condoms correctly (12)[b]	11	1	0
Feel confident using condoms (12)[c]	10	1	1
Plan to use condoms in the future (9)[b]	6	---	3
Ever experienced any condom use problems (13)	4	9	
Condom use problems experienced (4)	split condoms (2), broke (2), desensitisation, lack of feeling, diminished erection when condom is on, condom sort of bunching up so it is not covering the shaft		

Note. [a] *n* presented in brackets. [b] questions with 'don't know' answer option. [c] questions with 'not always' answer option.

Results summary and analysis. Three themes intertwining across other themes were identified in the analysis: "Clarity," "Beliefs and experience," and "Engagement." Other identified themes were: "Personal relevance," "Relevance for the problem," "Personal preferences," "Breaking points and facilitators" and "Privacy, safety and security" (Figure 10). All of the themes were connected through their links to the engagement with the intervention. Details of the themes and their relationships are described below.

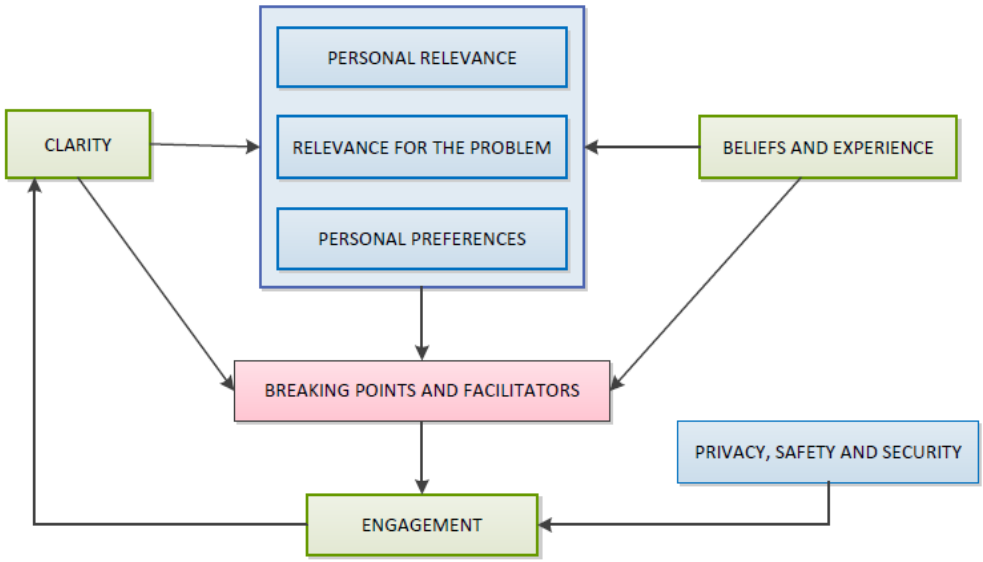
The intertwining "Clarity" theme reflects participants' understanding of the aims of the intervention, its content, procedure and the purpose of specific elements. The issues covered in this theme are fundamental, as problems in communication between the intervention and its users on any level (from design and navigation to understanding its aim) seemed to have an impact on users' overall experience and in turn on the engagement with the intervention and judgments regarding its potential effectiveness.

"Beliefs and experience" is the second intertwining theme identified. During the TAIs participants often spontaneously revealed theirs beliefs about condoms and lubricants and linked their personal condom use experiences to the content. They also presented their assumptions about other men's experiences and beliefs which could impact future users' engagement with eHIS. Beliefs and experience seemed to have an impact on judgment of the content and the engagement with the intervention.

The intertwining theme "Engagement" describes how participants interact with eHIS. It focuses on how engagement was affected by or affected other identified aspects of participants' experience with the intervention and how this contributed to the overall experience with the intervention.

Figure 10

Model of participants' experience with eHIS prototype



To some degree these three themes intertwine with others and are best understood within that context; therefore, they are presented in the paragraphs describing other themes or separately when it is clearer, to maintain the consistency of the analysis.

"Clarity" – What was clear. Judgment of the intervention's clarity varied between participants, with some having a good understanding of its aims, content, and procedure and others struggling to understand some of these aspects. Elements most often noted as being easy to understand were the aims of the intervention and the idea of home practice. Understanding the skills review instructions, the home practice guide, and the study procedure appeared to be challenging for most of the participants.

When talking about the aims of the intervention a few of the participants [2, 6, 13][7] referred to its research purpose, whereas others focused more on practical goals such as finding the right condom [4, 6, 7], its right size [9], or a broader aim of encouraging condom use [1, 13]. Participants also indicated more general aims such as HIV prevention [6] and promotion of safer sex [7].

Participants showed good understanding of the purpose and the form of the PIS [12, 11], noting "You know what you're launching yourself into in terms of being a participant." [4], and showing good understanding of its research purpose: "You have to have all the information there (…) for the study to be valid." [13]. When they commented on the clarity of the page explaining the next stage of the intervention their feedback was positive [10, 13].

Most of the participants commented on the registration process using descriptions such as "easy," "obvious," "straightforward," "simple," or "clear," as illustrated by participant 7's comment: "You're not getting confused as where to go, it's really straightforward you know you've got two options register or log in, it couldn't really get much simpler than that." However, the registration procedure was not entirely clear with group allocation being confusing for some. The kit collection and delivery information was seen overall as clear and straightforward. Some of the participants demonstrated good understanding of the intervention and condom ratings procedures [4, 7, 6, 13]. "Straightforward" was the word used to describe the condom ratings form and the

[7] The numbers in the square brackets (1 to 13 Study 1 and 1 to 9 Study 2) refer to the specific participants. In cases of 3 or more participants having similar opinions, references to a few of them are given as examples.

understanding of its purpose was good across participants. Participant 2 identified the main rationale behind it, saying “It walks you through a number of items to think about, which otherwise you have never thought [about].”

Participants demonstrated good understanding of eHIS rationale [10, 4, 6, 11]. As participant 4 said, “That’s good to bring that into awareness otherwise it’s (…) just use a condom and that’s the end of the story.” Explaining the content of the kit and raising awareness of the available products were well understood [2, 3, 6, 7], as demonstrated in participant 3’s comment: “That’s educational because I suppose you wouldn’t be like trying out too many different types of condoms, you wouldn’t think about it too much.” The kit content was clear for most of the participants.

Perception of the elements aiming to develop condom use skills varied among participants. Some of them described the condom use steps as “clear” and “straightforward”. The purpose of including a video was also clear, as participant 13 commented: “I think the video demonstration helps a lot because from images alone you may not fully get what you’re trying to do.” Some of the participants understood the aim of the skills review [1, 3, 13, 6], stating accurately that “It’s sort of a revision tool.” [1] and highlighting its purpose – “It forces you to slow down and read properly rather than just see the whole picture.” [4].

The home practice rationale was mostly well understood. Participants focused on its specific aspects such as mastering skills [1, 2, 11], exploring personal condom preferences [13], or gaining confidence [5]. Participant 2 noted “The reason why you practice alone at home, and how this helps is because (…) you get the familiarity with the gestures.” Another participant commented: “If they find they don’t like that [condom] they can try one of the others first and same with the lubricants if they’ve used them before or not” [13]. Many participants stated that understanding the home practice was “easy,” “clear” or “obvious” or easily rephrased the procedure description [2, 3, 4, 5, 12].

Participants showed mainly good understanding of the content and purpose of the "Overcoming problems" section e.g., "If you have any issues at this stage you get some guidance into overcoming problems." [11]. Participant 7 grasped the purpose of the links to the manufacturers' websites: "It's also got links there to the variety of products available, so after trying what's in my package here I can go on and try things from around the web give them a go."

Impact of engagement on clarity. A direct link between two of the intertwining themes was evident. The lack of clarity in different aspects of eHIS contributed to more negative experiences and could decrease engagement. However, participants' engagement with the intervention also contributed to the level of their understanding of the content. Those who paid more attention more often asked for clarification and confirmation. Misunderstandings described in the "Clarity" theme on the other hand, were related to skim reading or skipping pages [11,12, 1, 3, 13]; for example, participant 11 said, "I should have read all the information on previous page to know what it is all about before I sign in." In another example, not reading pages' content resulted in two participants mistakenly understanding that water, not water-based lubricant, should be used: "Adding water to a condom is not something that I thought about." [12].

Sometimes participants shared their opinions about the study or the intervention elements or procedure before they reached the relevant information, which resulted in concerns or incorrect assumptions [2, 3, 13]. Participant 11 believed that the practice should start at the stage of going through condom use steps and that the partner should be involved:

> If the gentleman [is] with his girlfriend, and I'm going to sit in front of this and have a look, let's see, maybe they think it's fun, maybe add fun element to it, so it would be fun to both boy and girl to be clicking.

"Personal relevance". A perception of eHIS relevance for personal circumstances seemed to be significant for the overall intervention experience, especially for initiating

engagement with it. For this reason opinions regarding the intervention's relevance for participants and their perception of eHIS target group were isolated as a separate theme.

(Not) relevant for me. The key elements in judging the relevance of the intervention were participants' own condom use experience and declared confidence in condom use skills. Participants mentioned some errors they made [9, 1] and problems they experienced [1, 13, 2, 11, 7]. Condoms' interference and erection difficulties seemed to be the most worrying problems. Participant 2 said: "[Using condoms] ruins the whole thing (…) the pressure when you put it [on] causes me to lose erection sometimes."

Participants who reported experiencing condom use problems saw eHIS as a chance of finding solutions [2, 11], or answering their questions and easing their concerns [7]. Declared lack of condom use problems [5, 10] or not believing that they could happen [11] was linked to judging the "Overcoming problems" section as not personally relevant.

Half of the participants underlined that the intervention was not relevant for them. The reasons they gave included that it would have been relevant for them when they were younger, less experienced [10,7], or at a different stage of life [5]. Masturbation, which is an essential part of home practice, was sometimes perceived as an activity of younger men, not practiced in later life [10, 1].

Having the confidence in the knowledge and experience participants already had, especially in their condom use skills, was related to perceiving the intervention as personally irrelevant [11, 10, 12, 8]; as participant 10 commented "I'm inclined to kind of breeze over this because I already feel like I don't need to look at this [condom use steps]." Interestingly, of the three participants who decided to practice condom application during session, two of whom declared at least moderate confidence in their condom use skills, none completed all nine steps correctly. They made between two and four errors when applying or removing condoms. One of the participants believed that spillage was an inevitable part of the condom use. As he demonstrated condom use, he commented:

> We're trying to pinch the end and try not to have the content of the end leaking back down the shaft as you are taking it off, which I always find a little bit difficult (…) if I was removing that in a real life, the way it's squeezed at the end, would mean I've almost got the condom off the penis and I'm gonna end up with fluid all over my hand. [1]

Already having a favourite brand of condoms was also a reason for not seeing the need to explore the intervention [10]. Participant 13 said the practice would be relevant if it included the condoms he had not tried before. Having a partner putting a condom on for some of the participants was another reason for judging the condom use steps as irrelevant [1].

Relevant for others. Although many participants did not perceive the intervention as relevant for them they indicated groups that in their opinion could benefit from it. As participant 7 explained:

> People who don't know the benefits of condoms and just dismiss them because they don't like using them… (…) This might be a good programme for them to sway their views and maybe change their minds and help promote safe sex.

Participants described possible target groups as those not having knowledge, skills or confidence in using condoms, or overestimating the ease of using condoms [8, 7, 9, 12]. On a few occasions participants made assumptions that others would not know things which were obvious for them [1, 2, 13, 8]; as participant 8 said "I don't think a lot people would know that the condom has to be on the penis from start to finish." They also suggested that others might lack knowledge that correct condom use was a condition for protection [11], overestimate their skills [6], not be aware of different types of condoms [13], lack knowledge of some of the condom use steps [11], or not understand the rationale behind them [2, 13]. Participant 2 said: "Everybody knows the standard routine, but I'm 100% sure that most people don't have knowledge of the rationales behind it." Participants also listed errors others could make, for example using Vaseline as a lubricant [1] and/or

not checking condom expiration date [13, 6, 9]. Participant 13 said “It says that a wallet is not a good place, but a lot of people I know do keep them in wallets, so I assume that’s not particularly common knowledge I’m not saying I don’t know that though.” Other problems men might experience were loss of feeling and problems with arousal when using condoms [7].

Some participants also pointed out that relationship status might determine whether the intervention might be relevant for some people depending on their relationship status [12]. Others focused on stereotypical risk groups such as gay men [13] or people at higher risk of acquiring STIs [5]. Several participants pointed out that one of the phrases was heterosexual centred, which could give the impression that eHIS was not suitable for homosexual men [1, 10, 3, 2], and this could discourage gay men from taking part.

Links between perception of relevance and engagement. It was observed that participants seeing the intervention as irrelevant skipped quickly through the content. On the other hand, those who perceived it as highly relevant for themselves, especially because of experienced condom use problems, had more intensive interaction with the prototype and gave more comments regarding all of the intervention’s elements.

“Relevance for the problem”. This theme focuses on judgment about whether the intervention is a relevant and effective response to the issues related to condom use. It also includes participants’ perception of the intervention’s credibility and trustworthiness. Judgment of the intervention’s usefulness was linked to maintaining engagement with it.

(Not) relevant for the problem. The intervention’s content was generally seen as relevant for its aims, these being developing or improving correct condom use skills and improving condom use experience. As participant 4 explained: “I think that’s good because often you just don’t really think about it too much and don’t spend a lot of time [unclear] make sure that you’re using the thing correctly.” However, opinions about the specific intervention elements varied.

Almost all of the arguments supporting the intervention's rationale were seen as standard and relevant, although participants highlighted different ones as the most relevant, and/or very important e.g., fit and feel issue [10, 4] or the health warning [13]. Participant 13 commented on the rationale for correct condom use: "This is a very important message to get across, because I know a lot of people might think if it's before their first time, they might think 'oh how hard can it be to put one on.'" Participant 6 pointed to the relevance of the link between using condoms, relaxation, and enjoying sex.

Some information such as possibility of incorporating putting condoms on as a part of foreplay [11], or the condom breakage and slippage prevention [2, 7, 13] were seen as helpful in dealing with condom use related problems. Participant 13 commented: "That's also important, because a lot of people may think that the size only affects the amount of fun they have not realising that it can possibly lead to breaking." Some participants underlined that the intervention information was satisfactory for participants' questions and expectations [6, 7].

Opinions about relevance of other elements of the intervention were mixed. Although condom use steps were often seen as relevant, [7, 11, 9, 3] one of the participants believed that there was no need for one, as everyone reads the instruction attached to the packet: "It's self-explanatory" and it cannot be done incorrectly [8]. Others did not see finding the top of a condom or checking expiration date as necessary [1, 9]. As participant 9 explained: "I thought that since I buy it from store they're in good condition." Some participants saw incomplete use information as relevant [1, 6], but for others it was an "alien concept" [10, 13].

The relevance of condom use problems section was not always obvious [8, 11, 4]. "Condoms may interfere with arousal/erection" page was the one that triggered the most diverse opinions. It was seen as a relevant issue [2, 4, 13] that might also be of concern to others [2]. Some saw the connection between focusing on pleasure and reducing interference [9], but others completely rejected this idea [11]. Suggestion to check

condoms manufacturers' websites for the variety of condoms available was seen as not relevant for the problem and not practical [11] or helpful [7].

The condom ratings were seen as standard, reasonable [12], comprehensive [5, 6, 9], and useful to find favourite condoms [8]. However, "This condom is too thick" item was judged to be not relevant for condom use experience, as participant 1 explained:

> "This condom is too thick." I'm not sure I could say condom is too thick or too thin. It's more about how it feels. (…) I would say this condom reduces the sensation too much or reduces feeling too much.

A few participants pointed to the relevance of the educational and personal preferences aspects of testing a variety of condoms [2, 3]. Asked in SSIs about the home practice idea, they saw it as appropriate [10, 7]. As participant 10 said: "It's not a silly thing to do though, not at all, it's a good idea (…) I think it's healthy." Participant 2 was already familiar with practice during masturbation for "Being comfortable with the condom on and at some point not even caring that you have the condom on." He accurately described the main point of trying various condoms: "The moment you realise that there is a difference between each type of condom you use and the experience you get, that already changes it." Participant 13 highlighted the aspect of practicing without a partner: "It's probably better first (…) to practice on your own get a feel of what you're doing and then move on to the partner if you wish." However, some participants did not see the relevance of practice to their specific problems [11] or for improving skills [8]. In the SSI Participant 8 said: "I think it's pretty pointless practising on your own to be honest."

The selection and number of condoms and lubricants were mostly judged to be adequate [13, 2]. However, there was a suggestion to include additional brands and/or more condoms for a wider range of experience [2]. Participants' beliefs about the purpose of different types of condoms had an impact on their judgment of the available selection. Some believed that all condoms were the same [8, 1] or that various condom's features might serve other than fit and feel purposes. As participant 1 explained:

> I presume those standard condoms are meant to give adequate protection. With thicker ones I don't know if it's meant to be if you are engaging in more risky practices or whether, it's [pause] just a sort of marketing thing to make people more at ease. (…) I always cynically considered that different sizes of condoms were a marketing trick for people with ego issues, but I have read recently that I am wrong about that.

A few participants believed that non-latex condoms were only for those with latex allergy [1, 13]. Talking about lubricants participants thought that they were mainly used for anal sex [10], that using them could be related to bacterial infections [1], or that the lubricants included in the packet were female products [1, 11].

Real life. Some elements of the intervention were criticised for not being relevant to the real life situation, for example that demonstration on the model is easier than actually putting a condom on [1]. In the comments about the skills review, participants highlighted that there are various scenarios of sexual intercourse not reflected on the page [11,8]. The idea of trying various condoms was criticised by participant 8, who said "I don't think one is gonna be like a preferred condom. I think you just gonna use what's available to be honest." Participant 2 also questioned the idea of practising without the partner present as not relevant for having sex with a partner:

> One issue here is 'without the pressure of sex with the partner' things are gonna change dramatically when the pressure is added. It's like playing football in the backyard or playing it on stadium with 60 thousand people watching you; you don't make the same decisions.

Good luck with that. Perception of relevance of eHIS and its elements was sometimes linked to perception of the intervention's potential effectiveness. Negative opinions about the relevance of some elements were accompanied by lack of belief in its effectiveness. This was sometimes linked to the personal experience of specific condom use problems and participants' belief that there was nothing they could do to change it [11,

2, 1]. Participant 2 explained "I don't have solutions for myself so I do not know how this can be overcome. (…) It's complicated, really isn't sure simple." Even more critical was participant 11, whose comment on the tips was: "It doesn't help me at all."

Participants shared views that it would be difficult to changes people's opinions [6], especially those who already had had negative experience with condoms [4]. Critical opinions were also voiced about the effectiveness of practice in gaining confidence [2], developing condom use skills [8] and finding the right condom size [6].

Alongside negative views about the intervention's potential effectiveness, on a few occasions (more frequently in SSIs) participants said that it already gave answers, eased concerns [7], taught new things [1] added to their knowledge [4], challenged their condom use practice [10] or was helpful [8]. As participant 5 explained:

> I think it reinforces key messages well but without being fussy. (…) Men mostly want to have good sex and if they can be persuaded that actually using condoms can be fun as well as a sensible thing to do, [pause] and that you can have fun experimenting with different types [pause] I think generally men will buy into that.

Credibility. One of the concerns raised was lack of information to support eHIS credibility. A clear affiliation of the intervention's authors shown in logo, name of institution etc. from the very first page was expected. The importance of this can be illustrated by participant 11's comment:

> "Condom intervention" I would not know immediately who's the organisation behind (…) intervention maybe to support more use of it, or maybe to make a research about it, or maybe some religious organisation who doesn't want people to use condom so I don't know at this point.

For some of the participants knowing that the intervention referred to evidence was enough to judge it credible [7, 2]. As participant 2 [SSI] said: "There's authority in the sense that this information you can trust, comes from a reliable source." For those who did not agree with eHIS message, lack of references gave an argument to undermine the

credibility of the evidence [11]. As participant 5 said, referring to the study claiming no difference between sex with and without condom, "It could have after all been carried out on behalf of Durex."

Regardless of the intervention affiliation and evidence supporting the arguments some of the participants declared they would check new information in Google or on the NHS website [11, 10]. Participant 10 said in the SSI:

> Probably if I was doubtful about some of the things I might have read and what the recommendations are (…) using something like an NHS website (…),because of the status that it has within our healthcare system and providing appropriate information.

Links between the "relevance for the problem" and other themes. Those who reported experiencing condom use problems were more critical regarding the relevance of the content and possible effectiveness of the intervention. Interestingly, those who said that they would use eHIS for educational purposes, but did not report experiencing condom use problems, were more positive towards the content and had more positive beliefs about its effectiveness.

The perception of the relevance and credibility of the information were identified as contributors to the engagement with the intervention. The parts that were seen as relevant prompted participants to think about their own condom use [10, 1, 7]. Some of the participants would use the tips as a precautionary measure, as, participant 13 explained "I'd read the third one ['Condoms may break or slip'] (…) if that happens then you have to make sure you do everything." He also would refer back to eHIS in case of fit and feel problems.

The credibility of the information was predicted to have an impact on the future users' engagement with the intervention. According to participant 2:

> (…) if you tell me I'm gonna learn about how to use condoms correctly and [unclear] a lot of tips about it but from a source of authority, not just like random

> websites and stuff like this, so I know that this is actually from studies and scientifically proven (…) then I'll be much more willing to participate, cause I would think it's quite a lot in it for me.

On the other hand, lack of clarity regarding relevance of the information might lead to disengagement with the intervention, as explained by participant 3: "I don't know how important it [links to condom use problems] is, so if I was going through this quickly I would probably click next, sadly."

"Breaking points and facilitators." This theme gathers together the aspects of the intervention which could directly impact engagement with it, and hence potentially support or hinder its effectiveness. Perceived eHIS demands and strong disagreement with the content were identified as engagement breaking points, whereas interest and emotional reactions could result in either enhanced or reduced engagement with the intervention.

Intervention demands. The volume of the intervention was mentioned as one of its aspects that could be demanding. Pieces of text that were too long [13, 8, 6, 7], required long concentration [1], and/or good memory [9] and being too much to process at a time [3] are the examples. The intervention was seen as challenging to go through in one go. As participant 11 said, "I would definitely not go for the whole website when it was live as I do now. Probably stopped and come back." Participant 3 also commented on the issue of volume when he reached the "Overcoming problems" section:

> I think by the time I get to the right hand column my brain seems to be tired from taking in the instructions on the left, so at this stage I'm not really fully concentrating on it. [pause] I think it's a bit much (…) instructions to come on the one page.

Large volume of text was indicated as a reason to skip pages [6, 7, 8, 9, 2]. Participant 3 said "When I'm looking on the Internet and I see a lot of text then I just don't read it." Participant 12 predicted that others might be less engaged than him: "I would probably read the entire of the first sheet but I know that a lot of people probably wouldn't."

Another demand mentioned by participants was task difficulty, an example of which was the skills review [1, 11, 6], as participant 1 explained:

> I don't know, because having just read through the steps which should be familiar to me, having heard this sort of thing before, I'd struggle a bit to know where I begin if I was faced [with] that page and what to do.

The study and the intervention procedure also seemed to be confusing at times especially the frequency of practice [3, 8, 11, 6], or study timeline [8].

Another demand mentioned by participants was the inconvenience linked to taking part in the intervention, for example receiving e-mails every evening [2, 9]. Participant 2 commented that "At 10 pm is quite late actually to masturbate to be honest, especially during the week, because if you have work at 7 in the morning you're not able to go to sleep until 12 at least." During SSIs participants suggested reducing the frequency of reminders to increase their acceptance [6, 13]. There were also concerns voiced about the possible complications with providing condom ratings and their reliability [10, 9]. Lack of clarity regarding the study procedure could contribute to the perception of inconvenience, as participant 4 explained:

> I'm not sure if it helps to understand how easy this [is] to give feedback on the website. I suppose it's fairly straightforward because obviously if it's something you need to do quite quickly afterwards and do online rating. I guess as long as it's not too time involving or you [unclear] think too much about things, it's something you can do quite easily, it's an easy form to fill in.

eHIS intensity was also brought up as a possible reason for users disengaging. This, however, was mostly based on misunderstandings regarding the procedure. For example, although there was no expectation that participants would practice every day for the duration of the study, some believed this was the case:

> My overall impression is that it's a bit intense on a daily basis and I probably need more flexibility than what is provided (…) I'm assuming that I will have to (…)

> participate in the study every day for two weeks, which feels a bit much and [it] may make me not want to do it. [3]

Disagreement. Only strong disagreements beyond simple statements about the lack of relevance for the topic were categorised as disagreement. It was isolated as a code as understanding how strong disagreements would instantly impact the interaction with the intervention and potentially precipitate complete disengagement was essential for the intervention development.

The first trigger for disagreement [2, 11] was reference to a study that did not find difference in pleasure and arousal between those using and not using condoms (Hensel, Stupiansky, Herbenick, Dodge, & Reece, 2012). This finding was judged as inaccurate and the original study's methodology and generalisability were challenged:

> I don't believe it. I think it's not true. From experience I can tell you that this research doesn't represent the whole scope. People who found that people, how many people? every person? five people? ten thousand people? it doesn't represent me. (…) I want information to support me with the use, not just try academically to convince me something which is not true. I would challenge this research if I could. [11]

Participant 11 also strongly disagreed with the content of the "Condoms interfere with sexual arousal" page, which he described as "nonsense."; he said:

> How is this relevant (…) to the use of condom? [To] the problem that I have? I have a problem, it interferes, but they tell me to concentrate on the sensation, [it] will solve the problem with interference, don't understand the logic. (…) I want something to support me with the use not just try academically to convince me something which is not true.

Another point of disagreement was the statement "condoms today are sexy and fun to use." As participant 2 noted:

> [laughs] this statement 'condoms today are sexy and fun to use' I don't know about that. I probably wouldn't agree with any of them, any of the two sexy and fun to use. I don't find them particularly sexy and I definitely don't find them fun to use. (…) Why do you need to have this here? What is this supposed to tell me? (…) I don't know what to make of it.

All of these points triggered passionate comments. Participants mostly expressed the feeling of their personal experiences being invalidated. These negative comments were linked to more negative opinions about the relevance of other elements and the overall potential effectiveness of the intervention [2, 11].

Emotional reactions – "mighty hell welcome to the condom intervention study" [1]. The emotions that were triggered by the intervention seemed to have an impact on the participants' experience with eHIS. Annoyance was the most frequently expressed negative emotion [11] in response to disagreement (as described in previous paragraph), repetition of some statements, similarity of items in the ratings form [11, 1], information obvious or lacking relevance for experienced problems [11]. It is worth to note that strong negative emotions were expressed by only one participant.

In contrast to the above, some participants reported feeling "good" and "happy" while going through eHIS [3]. There was some excitement about the kit too [5]. Elements which participants found amusing and to which they responded with humorous comments and laughter were for example home practice idea [12, 3, 1] or eHIS rationale. A good illustration of this was participant 2's comment "'Common sense says that you need equipment that works for you', it's a funny statement [laughs] (…) [laughs] I got it, this is makes me laugh." The opening statement of the intervention (the same that triggered strong disagreement for the other participant) made other participant [3] laugh.

Laughter was a frequent reaction while participants were going through the intervention website prototype. It was a response to eHIS approach, unexpected, new information [2, 1] or home practice idea [2, 3]. Some participants laughed when they

expressed confusion [1, 3, 8, 9], read about condoms characteristics [1, 10], looked at the condom use steps [6, 7, 8] or at the kit [3, 5].

Interestingly, although a couple of participants seemed slightly embarrassed at times, none of the participants explicitly reported being embarrassed during the session. Some, however, mentioned that some parts of the intervention, such as the rationale [12] or kit collection [2, 7], might be embarrassing. Participants linked this prediction to their earlier experience of being embarrassed during school demonstrations of condom use [7, 1]. However, there were also suggestions that eHIS could help avoid the embarrassment and awkwardness when obtaining and trying to use condoms [5, 13], as participant 5 explained: "Probably [would] have helped me overcome some embarrassment if I had tried them on my own." In the SSI participant 12 pointed out that practicing on your own may be "a bit embarrassing":

> [I] mean some of the stuff is a bit embarrassing, but then that goes with the territory. If you [are] doing a study on [laughs] sexual behaviours it's gonna be a little bit embarrassing for people. But no, I wouldn't say it's like horrendously embarrassing. It's just there are some things that would make you giggle, you know wooden penis. (…) I don't think it's going to put anyone off if they already volunteered for the study knowing what it's about.

Other participants shared concerns regarding possible embarrassment in the context of lack of anonymity when providing details for the kit delivery [9] or reflecting on the condom carrying tip [1]. As participant 1 explained: "You don't really wanna be seen to be carrying them. [pause] Still seems to be a silly taboo about just having them with you." Placing the UoS logo [1, 11] on the kits was suggested to avoid embarrassment by linking the kit with research as "It's such a tiny little thing [condom] that can cause great load of embarrassment." [1].

Participants' rare comments on possible emotional reactions of potential users to the intervention were focused mainly on negative ones. In addition to embarrassment, and

annoyance mentioned above [1, 3] the risk of "feeling like a failure" in the case of being unable to find the right condom [5] was also brought up.

Some participants indicated that amusement, excitement, and feeling good about the intervention were linked to stronger engagement with it [3, 5]. As participant 5 commented, "I like the emphasis on fun; it doesn't feel stuffy so I think if I started at the beginning on this I would work through to the end." Interestingly, none of the participants demonstrating negative emotions declared that they would leave the intervention at any point.

Interest. The ability of the intervention to gain and maintain participants' interest was central for engagement with eHIS for all participants. Novelty of the intervention approach was a prerequisite of interest. Information contradicting participants' existing beliefs also triggered interest; as participant 13 noted, "That interests me actually. I didn't know that that was true. I thought that it was true that it felt better without a condom, but interesting to see." On the other hand, coming across known information was linked to quick loss of interest and disengagement.

Participants expressed most interest in elements new for them [1, 2, 6, 10,11, 13, 4,]. This can be illustrated by participant 1's comment: "I wasn't aware about the possibility of mixing lubricant with condoms that might make a difference in terms of sensation". Those who did not report condom use related problems were more interested in improving fit and feel and reducing breakage and slippage, and those who reported some problems showed more interest in condoms interference and dislike of the sex with condoms topics.

The approach, stressing the need for experimentation, and the kit containing products new to the participants, triggered curiosity [1, 4, 10, 11]. As participant 10 commented: "It's an interesting point about different types of condom you might use." Participants also compared eHIS to their earlier education or other sources of information [1, 7, 10].

Although infrequent, there were some declarations of lack of interest [11, 12]. For example, participant 12 [SSI] commented on the intervention: “Looks a bit boring, but then I don’t know whether that’s an issue.” Other elements mentioned as uninteresting were parts of the “Overcoming problems” section [9, 11] and skills review [11].

Interest and engagement. Lack of novelty and/or interesting content could lead to decreased engagement. Information perceived as standard or obvious and confidence in knowing condom use steps were linked to breezing over or skipping pages without reading the content [2, 6], as explained by participant 4: “A lot of men take [information] for granted so don’t actually read things properly.” Interest, on the other hand, seemed to be the strongest force behind engagement with the intervention, even despite the lack of perceived personal relevance; as participant 10 explained:

> I’ve probably already got a preference and that I’ve got one [condom] already [unclear] that I normally use. But it’s an interesting suggestion and maybe it’s something to look at again and it’s an opportunity to do that so for me that’s not a bad thing.

Participant 3 [SSI] said that novelty was the factor influencing his engagement with the intervention: “I didn’t know that before, and makes me kind of interested, it increases my interest in trying out the condoms and the lubes as well.”

Exploring the condom kit or clicking on links in the “Overcoming problems” section were almost always triggered by curiosity [1, 9, 10, 11, 12]. A few participants reported that the new approach to condom use provoked them to think differently about condom use experiences. As participant 2 said, “Makes you think about the things you never thought of.”

Novelty and clarity. Novelty was sometimes associated with lack of message clarity and some level of uncertainty that cause participants to seek confirmation that their understanding was accurate. The purpose of the skills review confused some participants who expected a traditional test with feedback as illustrated by these comments “It’s also a

way of testing people's memory but there's no way of knowing how well they did?" [6] and "How does this website know what I'm thinking?" [11].

Novelty could also lead to misunderstandings. One of the participants assumed that the "condom box" mentioned in one of the links, was a box in which condoms are sold, which in turn led to his comment about possible disadvantages of carrying it: "The issue with the condom box (…) [it] might be a bit (…) too prominent to carry anywhere convenient like a pocket or something." [13]

"Personal preferences." The "Personal preferences" theme describes participants' explicitly stated intervention's likes and dislikes. It was assumed that suggested changes were the reflection of participants' preferences; therefore they were also included in this theme. Preferences include opinions about preferred level of information detail, language, content format and organisation, and website design. It also includes participants' ideas of new elements that could be added to the intervention. All of these topics are organised in three subthemes: "Like it, don't like it," "This is how I'd like it to be" and "Design."

Like it, don't like it. The subtheme "Like it, don't like it" reflects participants' explicit preferences regarding the intervention. Only a few participants shared their preferences clearly during the TAIs, with most of them voiced in SSIs, and there was not one specific element liked by most of them. Some of the mentioned included: clear and simple presentation and format of the information [3, 4, 10], the non-judgmental approach [5], privacy [7], home practice idea [7], variety of condoms to and lubricants to try [1, 4 SSI], focus on personal preferences [1 SSI], details and adequacy of information [9, 11, 13 SSI] or design [2, 6, 12 SSI]. Participant 5 [SSI] particularly liked the sense of humour:

> I liked the smiley faces actually, I liked the [unclear] little bits with a little bit of sense of humour. (…) All the messages were good and I liked the thing, but I think the humour is nice and it makes it, seem more conversational or personal.

Most opinions about the kit were also positive [4, 10]. Participants liked its discreetness [6, 1, 7, 11, 12, 13] or possibility of trying a variety of free condoms [12, 3].

During the SSIs only one participant [8] declared that he did not have any preferences regarding the intervention.

There were mixed opinions about reminders which some judged useful [11, 2, 7, 10, 1, 9, 6], whereas others were not enthusiastic about them [6, 8], raised issues of confidentiality and privacy [7, 1] or asked to phrase the reminders in a friendly way. As participant 5 explained "I think as long as it was phrased in a conversational way, which didn't feel like [pause] having a doctor tapping you on your shoulder, then it would probably be fine." Interestingly, the participant who said he would not be happy with the e-mails said he would not opt-out [8 SSI].

There were also mixed views on the rating form – liked by some [2 SSI], it also was criticised, as participant 11 said "Change completely the questionnaire [it is] too long, not engaging repeating question, (…) very difficult for me to type in quickly and go forward."

Fewer elements were identified as ones participants disliked. Critique was related to the intervention message perceived to be "forced" [2] and asking people to do something they would not like to do [6, 11]. Other examples of elements triggering negative comments were lack of detailed information [1, 2, 4 SSI], design issues [6, 9, 10, 13 SSI], strong emphasis on health and safety, insufficient emphasis on comfort and fun [4 SSI], and too large focus on "shortcomings of condoms" [1 SSI] or the strawberry condom in the kit. Participant 2's comment on it was: "It looks horrible and feels horrible, smells bad, who the hell wants to suck on that?" None of eHIS elements were indicated in SSIs as ones to be removed.

This is how I'd like it to be. This subtheme describes participants' suggestions for how the intervention should be changed to improve users' experience. These suggestions were divided into five categories. Four of them relate directly to information: clarity and style, expected level of detail, format, and order of content presentation. The fifth includes participants' ideas of elements to be added to eHIS.

Rephrase. Difficulties with understanding the message of the intervention were raised by many participants and were mostly due to unclear, difficult, or too "academic" language. Many participants asked for clarification when a message was vague or not explicit. For example the word "intervention", although often used in the behaviour change field, appeared to be confusing for participants [1, 5, 12] guessing that it was "something to do with promotion of condom use" [7, 11] or serve some sort of research activity [11].

Participants asked for clarity of content to be improved [11, 2, 4] by rephrasing [1, 11], being more concise [2, 1] using bullet points [12, 13, 6] avoiding academic jargon [2], avoiding repetition [11], or being more explicit [2, 5, 9].

Opinions about the level of explicitness were divided. Commenting on the home practice guide participant 7 said that it was "a bit too literal", whereas participant 5 said: "Obviously being quite explicit in talking about practising, I wonder if you actually wanted to be a bit more explicit and say anything about masturbation."

Participants expected that aspects which they perceived as important would be emphasised more. For example, participant 4 said "Might need to emphasise a bit more (…) how important the fit is, cause if it's just uncomfortable thing or is that important for the performance and (…) the usage of the condom." Others suggested toning down the message [2] to for example: "I think (…) 'you will **almost certainly** find something you like' [pause] you don't want someone to feel a failure if they don't find something." [5].

All language issues and especially its clarity described above had an impact on participants' experience and in turn on their engagement with eHIS. The biggest emphasis was on making the language of the intervention simpler, as messages perceived as too complicated were skipped.

Detail. It was noted that sometimes information was not sufficient or detailed enough and this could affect clarity. Participants asked for more in-depth arguments explaining the intervention's rationale [2, 1], references to its sources [2, 13, 5], more detailed description of study procedure [11, 13, 5], condom use steps [SSI: 1, 11, 10, 2, 13].

There were suggestions to include a more detailed description of the kit content [2, 9, 11], to "(…) make me assess much better why is it that I'm trying more condoms." [2]. Participant 2 further explained:

> What's the difference between using this one this one and this one? (…) I get this one is ribbed but like this one and this one [points to different condoms], what's the difference between them? To me it's not clear at this point in time.

In participants' opinions adding more details would also make the content easier to understand and the condom ratings more reliable [5, 2, 1, 13].

Most criticism of the intervention was directed at the "Overcoming problems" section not being detailed enough [1, 7, 2, 4, 11, 12, 13]. The information was seen as general, and not explaining the mechanisms of possible condom use problems well enough. As participant 1 said:

> I would expect to see more about, I feel like a condom is loose or I feel like a condom is strangling the base of my penis, which is what I feel with them all, those sorts of more specific things. (…) Just to be more specific rather than generic. To show at least with some examples that there are specific solutions.

Two of the participants underlined that they would expect more complex explanation of the mechanisms underlying problems they experienced, e.g., psychological processes linked to specific errors etc. [2, 11]. As participant 11 commented: "I want to find answer why it doesn't fit. Did I do this, or do I have any psychological pathway."

Some of the participants asked for the intervention to be linked even more explicitly to STI prevention by highlighting their consequences [2, 7] and for the arguments to be "more daunting or alarmist." [2]. A similar view was presented by participant 7: "I think maybe a page on STIs, on what the risks of them actually are (…) have maybe pages that outline what will happen if you do catch them. That would be a good idea."

Not all participants requested more details. When asked in the SSIs about whether they would like to add something to the intervention, a few participants said that there was no need for any additions [6, 8, 9, 2 SSI]; as participant 9 commented, "It's clear and detailed every step of it (…)." Moreover, participant 7 [SSI] advised against adding more details "If you add more pages it may become too complicated, and people may lose interest half way through if you're just reiterating the same things."

Participant 1 made suggestions to include more reassurance regarding data security, while for another the information about it was far too detailed [2]. Other comments regarded the content being too detailed related to the PIS [11], arguments supporting correct and complete condom use [3, 9], and home practice [7].

Organisation. The common expectation was that some information about the intervention would be placed on its entry page [10, 4, 5, 6]. As participant 3 said, "'Welcome to the condom intervention' [laughs] I don't really know much about. I suppose there could be a small bit more of information what type of intervention it is." Lack of this information could impact engagement, as explained by participant 9: "I will be reluctant to log in because I don't know what to expect out of it." There was also an idea to make some information optional for those interested in specific topics [7 SSI].

Also the organisation of content within specific pages was commented on with suggestions to put relevant and important [11] or more useful [9] content first. A suggestion was also made to change the intervention's procedure, as explained by participant 2: "You'll be much better to start from the website, then follow up with the receiving the condom kit then use to practice condoms at home and probably then go back."

Organisation of the content seemed to impact how well it was understood. For example, information about the study procedure was split across the website and this seemed to cause confusion, which could be avoided if the information was introduced earlier [2, 9] or if there were reminders added [3].

For some the idea of home practice was introduced too late [1, 3]; as participant 1 said: “I was a little bit unclear what it meant by home practice. It sort of talks about it right at the end which is a bit late really.” Moving it forward was suggested to improve understanding and ease users’ concerns as soon as possible in relation to “Overcoming problems” section.

Organisation of the content could affect intervention engagement. According to some of the participants, explaining the purpose of the home practice and condom kit at earlier stages could motivate users to take part in the intervention [2, 9]. As participant 9 explained,

> Probably this one with the practice should come before to be sort of motivation, why it is necessary to have the kit and all that. You should say ‘you shouldn’t be embarrassed about different sizes and all of that and you should try to get the best fit and all of that’ and afterwards come with the solution which is the bag.

Some participants declared that content repetition would make them skip parts of the intervention [12, 5]. As participant 5 explained:

> So these are the pictures from the previous page repeated. (…) I think if I’m just seeing the pictures I’ve previously seen on the previous page, I think I’ll be rushing through ‘yes I’ve seen that, yes I’ve seen that.’ I don’t think I’d read it again.

Format of presentation of information. Format change suggestions focused on two ideas: replacing text with images [11, 9, 6] or adding images to illustrate the text [2, 9]. This should improve processing of the information [6] or bring the content to real life, as participant 2 explained: “You can have a visual representation of a condom that has been used for some while, so basically have the intercourse for like three four five minutes.” There were also opinions that the video [13, 3, 9] or a PowerPoint presentation [11] could be used in explaining condom use steps.

There were comments that the intervention’s format was not engaging, as participant 6 commented: “Again it’s just an information slide so it’s not really telling me

to do anything apart from read digest and move on." Some participants expected more interaction [7, 9], especially in skills review:

> I was expecting sort of interaction, (…) to have like a panel of the whole pictures and then take those ones drag them there and then see if that's correct or not (…) get an X or something like that, more like a play. [9]

New ideas. During the TAIs participants spontaneously shared their ideas about new elements that could be included in the intervention. Including printed intervention information in the condom kit was the most frequent suggestion [1, 10, 11, 2]. According to participant 2, this would improve engagement with the intervention: "Having something with substantial information on it will guarantee that somebody will look on it and will read through it." The other suggestions pertained to the condom ratings form; for example, adding questions about using condoms for oral sex [5] or rating the lubricants [11].

Among other ideas were including information about: condom myths [13], highlighting the importance of developing partner's correct condom use skills [13] or information about what to do in emergency situations such as condom breakage [7] or allergy [9]. Despite no mention of this anywhere in the intervention, some participants assumed that they would receive some kind of feedback of the ratings they completed [6, 7, 8]. There was also a suggestion to include the partner's experience in the condom ratings [13]. An example of suggestions made in SSI was adding an FAQs section [7, 11]. More examples of new ideas are included in Appendix B.

Design. Across all the aspects of the intervention there was most agreement in judgments of the website mock-ups design (appearance and navigation). The first impression was mostly negative, with participants pointing out that the entry page was very "blank" [4, 5], "plain" [12], "basic" [7], "Spartan" [1] or "not too colourful so it's not really grabbing my attention." [13]. Participants welcomed the introduction of colour in the core part of the intervention [3, 13, 4]. A clear, "uncluttered" layout [3] and a menu on the final page [11] were also judged positively. Having many elements on one page was

sometimes seen as confusing, overwhelming or not easy to process [10, 9, 11, 6]. As participant 11 commented, "I see it is says 'nine steps to correct condom use.' (…) I don't think it's designed very well. Should I start one two three four? [points vertically], or one two three four five? [points horizontally]." However, there were also participants who liked these pages design [5, 6]. For example participant 6 said: "[I] think it's set up quite well, so you just have got the pictures of everything, so you can visually link the two between the pack and what's on the webpage."

Although many participants liked the images [1, 10, 3, 4], there were opinions that they were not always appropriate [10], fit for purpose [13] or that their quality was not good enough – "boring photograph, bad pictures, they are very dark, uninspiring." [11].

Other participants highlighted other elements of design that they considered were not entirely clear. These included elements such as: confusing navigation between pages and sections [3, 8, 4, 11], confusing design of the entry page, and setting an account [1, 2, 11, 9].

Design and engagement. Design may seem a secondary issue to the purpose of the study; however, there were comments that bad design could be one of the reasons for not engaging with the intervention [1, 11, 9], as illustrated by participant 11's comment: "The layout at the moment is very bad because it's based only on text, it is not formatted in short tables. (…) I would never be interested in reading something like this." Lack of clear navigation was also a reason behind lower engagement; as participant 3 said,

> I would leave it for now because I can't remember anywhere clearly where it's back. (…) If I knew exactly where (…) to look over something then I may do it, but having to click back to find the page, to find the out the answer I wouldn't do that.

On the other hand, good clear design encouraged engagement [13, 3]. As participant 3 said: "I like things with not too much text, I like the amount of text that's on this and it makes me want to read it."

Participants suggested numerous changes to improve the intervention's website look, for example redesigning entry and registration pages [1, 6, 10, 13], adding more colour [2, 9] and more appealing pictures [3, 1, 11]. In the SSI participant 11 suggested employing a professional designer to achieve a "sexy" and "colourful" website.

Privacy, safety and security. The final theme identified focuses on the perception of privacy, safety, and security. Although this theme did not appear across all sessions, the perception of how much privacy the intervention would provide and how safe would be using it was important for some of the participants.

Participants generally liked the idea of eHIS being delivered online [7, 5]. They underlined that it was touching on intimate issues therefore required privacy and assurance that the experience would not be shared with others [10, 6, 7]. Participants appreciated the anonymity provided by the website [1, 7]. Some liked the discrete package of the kit [1, 7, 13]. Both options for collection and delivery were also seen as supporting privacy by, on one hand, not risking the embarrassment of having the packaging to be sent home [10], and on the other hand avoiding embarrassment in the case of collection [13, 7]. Participant 10's comment illustrates this issue well:

> I think the collection idea is very good because that makes it a bit more anonymous. Perhaps if I was living with family or something and I was taking part in this, and I was getting deliveries, then that could be awkward if they were asking what it was.

The challenges to protecting privacy were raised in relation to registration [10] or opening the package in the presence of others [13, 6].

Another aspect raised in the context of the online intervention was users' data security. Participants pointed out that there should be reassurance that confidentiality would be maintained and that their data would be secure [1, 5].

Overall experience and intervention acceptance. When participants were asked during the SSIs about their overall experience of using the intervention prototype it was described as positive by all but one participant [11]. They used words such as "interesting,"

"fun," "reasonable," "straightforward," "smooth," and "without any issues" [1, 3, 5, 12, 4, 7, 9]. Many of them also pointed out that there was nothing "frustrating," "boring," "embarrassing," or "uncomfortable" [2, 9, 12, 13, 2]. The areas affecting the overall experience or identified as needing improvement were similar to those indicated during TAIs.

Despite statements that the intervention was not always personally relevant, most participants declared in SSIs that they would use it themselves. There were a few definite "yes" answers [2, 8, 9]. Participant 2 said "I would definitely use it, it's a difference, it's a very good one." Some declarations of interest were followed by conditions which mirrored the comments made during TAIs, such as: having time [1], the intervention being less intense [1], more flexible [3], or partner being involved [4, 11, 1]. Other examples of factors that would motivate participants or future users to take part were: free condoms [3, 13], more engaging, interactive features [11], or links to social media [11]. Participant 11 shared the view that demands were too great and the gain in terms of intervention access and receiving the kit might have not been enough to motivate people to take part.

Some said that they would not use eHIS themselves because did not see the need [5, 10, 12, 7]. However, they would consider taking part if they were younger and/or did not have experience using condoms [5, 7, 10], were having casual sex [5], were starting a new relationship [5], or starting using condoms after some time [7]. There were also some participants not entirely decided about whether they were willing to try the intervention. Participant 13 said:

> I'm quite comfortable with my use. (…) I may use it to experience some other brands without having to pay like ten quid for a box. I might not like any of them and also just I guess it's a refresher in case I have forgotten something.

Discussion. The primary aim of the study to explore participants' experience with eHIS was met and the experience model (Figure 10) was formulated. The experience with the intervention was positive for most of the participants and they accepted its general aim

– improving condom use experience – as valid and important. They liked eHIS novel approach and judged its key elements (home practice, trying various types of condoms and completing condom rating forms) as practical and relevant for the problem. Participants had very positive opinions about the kit which was seen to increase motivation to take part. Many participants were enthusiastic about trying the intervention themselves.

Already a single contact with the prototype during the study session allowed some participants to reflect on their own condom use and get reassurance that problems they may experience can be overcome. Participants also accepted the format of the intervention and liked the privacy of the online delivery.

Although none of the intervention's elements were completely rejected, some triggered discomfort or, occasionally, strong negative reactions. These elements included the intervention's rationale and some information in the "Overcoming problems" section. Their implications for the intervention development will be discussed in the following paragraphs.

Improving experience and engagement. Sharing their experience, participants highlighted issues that discouraged their engagement with the intervention. Some of these would require straightforward changes e.g., reassuring users about data safety, improving navigation, reorganising content, or making design more attractive. It is important to address those issues as even if they do not seem primary for the intervention aim they may affect users' decision to disengage at the initial contact (Danaher, McKay, & Seeley, 2005; Pengnate & Antonenko, 2013; Sillence, Briggs, Harris, & Fishwick, 2007c). Changes regarding volume and intensity of the intervention would be in line with eHIS GPR of being brief.

Improving clarity. Although the general aim of eHIS and a large proportion of its content were understood well, the issue highlighted by all of the participants and affecting their experience was lack of content clarity. This affected judgment of intervention's relevance, demands (especially the intervention's intensity) and procedure. On the other

hand the well understood parts were characterised by a minimum amount of simple text presented on one page, often with points visually separated, and by uncluttered design. These are the same features as those preferred by men in a study investigating gender differences in online information processing (Arcand & Nantel, 2012). Adjusting information presentation alongside the participants' comments and evidence guidance should make the preferred pattern consistent across the intervention and improve future users' experience.

Simplifying the language to make the information more accessible so that users with lower literacy levels could benefit from the intervention would be an essential change (Abraham & Kools, 2011; Birru et al., 2004; El-Ibiary & Youmans, 2007; Plimpton & Root, 1994). Different levels of health literacy could be addressed, for example by using various formats of presenting information (Meppelink & Bol, 2015). Special attention would need to be paid to introducing novel information and the skills review instructions as these, although valued, were often unclear.

Participants' complaints regarding information length, level of difficulty and burden on memory and attention were also linked to the way the content was organised. Improving it could reduce the perception of the study's burden (Brünken, Steinbacher, Plass, & Leutner, 2002; Mayer & Moreno, 2003; Moreno, 2006; van Merriënboer & Sweller, 2010).

Condom use skills perception. About half of the participants did not see eHIS as personally relevant because of confidence in their skills and/or lack of experience of condom use related problems. This could be explained by high confidence with one's condom use skills being related to low level of worry about health risk, which was found to be linked to less engagement in searching and processing health information in hypertension (Sillence, Briggs, Harris, & Fishwick, 2007b).

Although it is possible that participants' perception of being competent condom users was accurate, there is also a risk that they might have overestimated their skills. As

shown during the condom use practice, declared confidence in own competence might not reflect actual skills. This observation is in line with previous research in which perceived condom use self-efficacy was not supported by actual skills (Langer et al., 1994), and perceived knowledge about condom use was not often related to actual knowledge (Crosby & Yarber, 2001). For some of the participants confidence in skills can be linked to lack of awareness of some errors they were making (Allman et al., 2009); as when assuming that spillage during removal was inevitable when using condoms.

Many participants suggested that potential users of the intervention would be men less skilled, less knowledgeable, less experienced, or less confident in comparison to themselves. This perception of own skills versus others may be explained by "self-enhancement" (J. D. Brown, 1986) or "negative-others" (Wills, 1981) biases in which own skills are judged to be higher than others. Similar biases were found in studies investigating the judgments of own driving skills and related risk (Matthews & Moran, 1986; McKenna, Stanier, & Lewis, 1991).

According to the Social Desirability Model (Meston, Heiman, Trapnell, & Paulhus, 1998), self-presentation bias can also play a role in disclosing information that could be perceived as embarrassing or threatening to self-esteem (Catania, 1999). Previous findings on inaccuracy of self-reports of condom use (Lust & Bartholow, 2009) and misreporting often found in surveys investigating sensitive topics (DiFranceisco, McAuliffe, & Sikkema, 1998; Tourangeau & Yan, 2007) also support the possibility that own condom use skills may be misreported. This explanation seems probable as some of the participants who stated the lack of the intervention's personal relevance, but later declared willingness to take part in eHIS if it was available.

Personal relevance. The intervention aimed to be applicable to men regardless of age, relationship status or sexual orientation. Despite this, participants pointed out phrases which could suggest exclusion of gay men or people in casual relationships. In the process

of reviewing the content of the intervention it should be ensured that the language used is inclusive.

Being in a steady relationship was related to being less or un-interested in the intervention. There was also a tendency to see the target audience as young men, without experience in using condoms, gay men, or people in higher STI risk groups. This is consistent with biased perception of others being more at risk of contracting HIV/STI and of underestimation of one's own risk as reported in previous studies (Seal & Agostinelli, 1996). Interestingly, in the current study participants expressed openness to engage with the intervention if their life circumstances changed. Raising the awareness of eHIS availability and emphasising its novel approach could therefore be beneficial to those who do not see its immediate relevance.

Masturbation. There was some uneasiness around trying different types of condoms during masturbation seen as an activity of younger men. There are some likely reasons why the idea of practising without a partner triggered such a strong resistance. Although masturbation is reported at all life stages (DeLamater & Moorman, 2007; Fortenberry et al., 2010; Gerressu, Mercer, Graham, Wellings, & Johnson, 2008) and is common even amongst those in steady relationships, this is a topic infrequently discussed with a partner (Aldridge, 1983). By many men it may still be seen as complementary to or compensating the lack of partnered sex, not relevant for steady relationship or even a form of infidelity (Das, 2007; Flank, 2013). In some cultures negative presentations of masturbation as a substitute to partnered sex or as impairing fertility also contribute to negative perceptions (Gerressu et al., 2008; K. S. Hall & Graham, 2014; Madanikia, Bartholomew, & Cytrynbaum, 2013). For these reasons masturbation might be a sensitive topic and lack of its acceptance might be linked to willingness of some participants to take part in the intervention only under condition that their partner was involved. However, there might still be instances when the intervention based on masturbation will not be acceptable for some potential users.

Embarrassment. Embarrassment is one of the strongest barriers to overcome in sexual health promotion (Hine & Oakeshott, 2001; Richardson et al., 2010). Reducing the embarrassment is important as it could take participants' attention away from the focus on pleasure, and might reduce eHIS's effectiveness. Normalising condom use as behaviour being a natural part of sexual intercourse and emphasising benefits of the intervention could also be an effective way of addressing sources of embarrassment such as condom use information or practice.

Contradicting beliefs and experience. Encountering information that contradicted personal condom use experience and/or beliefs led to negative reactions and in consequence negative judgment of the information for some of the participants. This reaction was consistent with the results of an experimental study investigating judgment of the arguments related to participants' strong beliefs (Edwards & Smith, 1996). However, there were also participants who responded to information discordant with their beliefs with curiosity. The differences in judgment of the information contradicting beliefs might be linked to individual differences in knowledge perception. For example in a study of students' beliefs about knowledge individuals who believed in personal interpretation and personal experience had less trust in the information than those relying on authorities and critical evaluation of evidence (Strømsø, Bråten, & Britt, 2011). Methods of addressing users' beliefs and encouraging them to consider alternative approach whilst not triggering resistance should be investigated.

Trust and intervention credibility. A number of participants indicated that one of the strengths of the intervention was the provision of credible and scientifically supported information; others wished for more indications of the intervention's credibility. Interestingly, none of the participants explicitly stated that lack of credibility would cause them to disengage with eHIS; however, the emphasis that they put on the lack of its indicators suggests that credibility was an important feature of the intervention.

The changes suggested by participants are consistent with guidelines for building website credibility highlighting the need for presenting affiliation and authors' expertise (Fogg, 2002). Website features and clarity were also previously found to impact perception of health information websites (Rains & Karmikel, 2009; Sillence, Briggs, Fishwick, & Harris, 2004; Sillence et al., 2007c; Ye, 2011).

Another issue related to the intervention's credibility highlighted by participants was their willingness to check the information provided on other websites (e.g., the NHS one) while they were using the intervention. Although advisable, it could impact the planned evaluation of the intervention (Chapter 5). The methods of strengthening the perception of the intervention credibility should be explored.

It is worth noting, however, that previous research findings are inconsistent regarding the role of credibility. A systematic review of persuasive features in web-based alcohol and smoking interventions concluded that website credibility was important for users' engagement (T. Lehto & Oinas-Kukkonen, 2011), whereas a review of factors influencing engagement with eHealth found mixed results, especially in judgment of the credibility of scientific evidence (Hardiker & Grant, 2011).

Information provision. One of the intervention's demands some of the participants highlighted was the volume of information to process. However, opinions regarding this aspect of the intervention varied across participants and seemed to be related to personal preferences for information provision and interest in specific topics. Some participants suggested inclusion of additional and more detailed information, whilst others were happy with current content. Similar individual differences were found in a study evaluating an intervention for cold and flu self-care (Yardley et al., 2010). Ways to address varied information provision needs should be explored.

Addressing fear appeal expectations. Suggestions to add more extensive STIs and unwanted pregnancy risk and consequences information was a type of additional information that needed special consideration. Although fear-based communication might

be effective in health communication (Witte, 1992; Witte & Allen, 2000), providing extensive information about the consequences of not using condoms during sexual intercourse would go against the GPR of eHIS to focus on sensation and pleasure. However, in the light of participants' opinions and recent research reporting that young men wanted more information about STIs (Tanton et al., 2015); how additional information could be incorporated into the intervention without increasing the volume of the intervention and losing the focus on pleasure and personal preferences could be explored.

Solution expectations. When participants' expectations for specific and detailed advice regarding overcoming condom use related problems were not met they were strongly dissatisfied. The solution expectations need to be addressed in the intervention because they might affect engagement with the intervention and its effectiveness. This is the case in sex therapy, where dealing with clients' unrealistic expectations regarding methods and outcomes of "solving" sexual functioning problems is essential for therapeutic success (Althof, 2002; McCabe, 2001; B. W. McCarthy & Fucito, 2005).

However, providing specific detailed problem solving focused information would contradict the intervention's approach, which requires focus on pleasure and sensation. This could also be potentially harmful as focusing on finding solutions and having "perfect" performance may limit pleasurable experience and exacerbate existing problems (Barlow, 1986; McCabe, 2005; Sanders, Hill, Crosby, & Janssen, 2014; Wiederman, 1998). On the other hand, lack of expected information, and the perception that the information given is "too basic," could lead to perception of information as being not reliable or patronising and result in future users disengaging with the intervention.

Interest. Curiosity was frequently brought up as a trigger for engaging with the intervention. Participants who found the content interesting declared that they would pursue the intervention even when they did not find it personally relevant. Similarly, novelty was found to be one of the factors influencing engagement with an online diabetes

intervention (Harle, Downs, & Padman, 2008) and was amongst the strengths of a computerised STIs/HIV intervention (Mackenzie et al., 2007).

Intervention atmosphere. Positive atmosphere and fun were indicated as features improving participants' experience with the intervention. Its non-judgmental nature was identified as a contributor to engagement. This is consistent with evaluations of a computerised STIs/HIV prevention intervention (Mackenzie et al., 2007). Positive reactions to the intervention were usually triggered by details making the website friendlier (like "smiley faces") or content that was seen as amusing. However, the interpretation of the comments about amusement needs to be made with caution, as humour may be a response to embarrassment (Fink & Walker, 1977). Ensuring a positive atmosphere to enhance users' interest and enthusiasm should be, in addition to reducing the sources of negative experience as discussed above, a challenge for the intervention's development.

Participants' new ideas. Incorporating participants' ideas into the intervention would be another way of improving their experience. However, some of the participants' suggestions contradicted the intervention's approach or might not be feasible. For example, involving a partner in practice goes against the idea of practising without the pressure inherent in the partnered situation (Milhausen et al., 2011) and inclusion of female condoms is beyond the scope of the intervention. Suggested inclusion of online forums, links to social networks or sharing the results of the ratings with others, are also not feasible as they would be problematic due to moderation and confidentiality issues (O. McCarthy et al., 2012).

Intervention focus. The study allowed the discovery of additional issues that should be improved in eHIS development. Despite its intentions, the impression some participants had was that the fun and pleasure aspect of the intervention seemed to be overlooked, and the health and possible condom use problems aspects emphasised too much. For some participants there was too much emphasis on the drawbacks of condoms

which created an impression that using condoms may be more difficult than it should be. These issues need to be reviewed and, if necessary, corrected.

Contribution of the Study 1 results to the aims of the thesis. Results of Study 1 allowed insight into potential users' perspectives on aspects of eHIS important for them with personal relevance, relevance for the problem, breaking points and facilitators of engagement being central (as depicted in the experience model, Figure 10). Novelty and humour were indicated amongst the strongest facilitators of engagement with the intervention. On the other hand perception of the intervention's demands and perception of practice during masturbation were the elements of eHIS less accepted by some of the participants. Content and procedure clarity and design issues were highlighted as requiring improvement.

These results informed the process of the development of a computerised version of eHIS using LifeGuide software (Hare et al., 2009). First, the GPRs were reviewed in the context of the participants' experience model (Figure 10) and amended to reflect the users' perspective and needs more adequately (see Table 5). The key change was the inclusion of improving perception of credibility as an aspect that should be present across the intervention. Other changes pertained to increasing engagement with the intervention and reducing its interference with users' daily life.

Table 5

New and extended eHIS guiding principles following Study 1 results

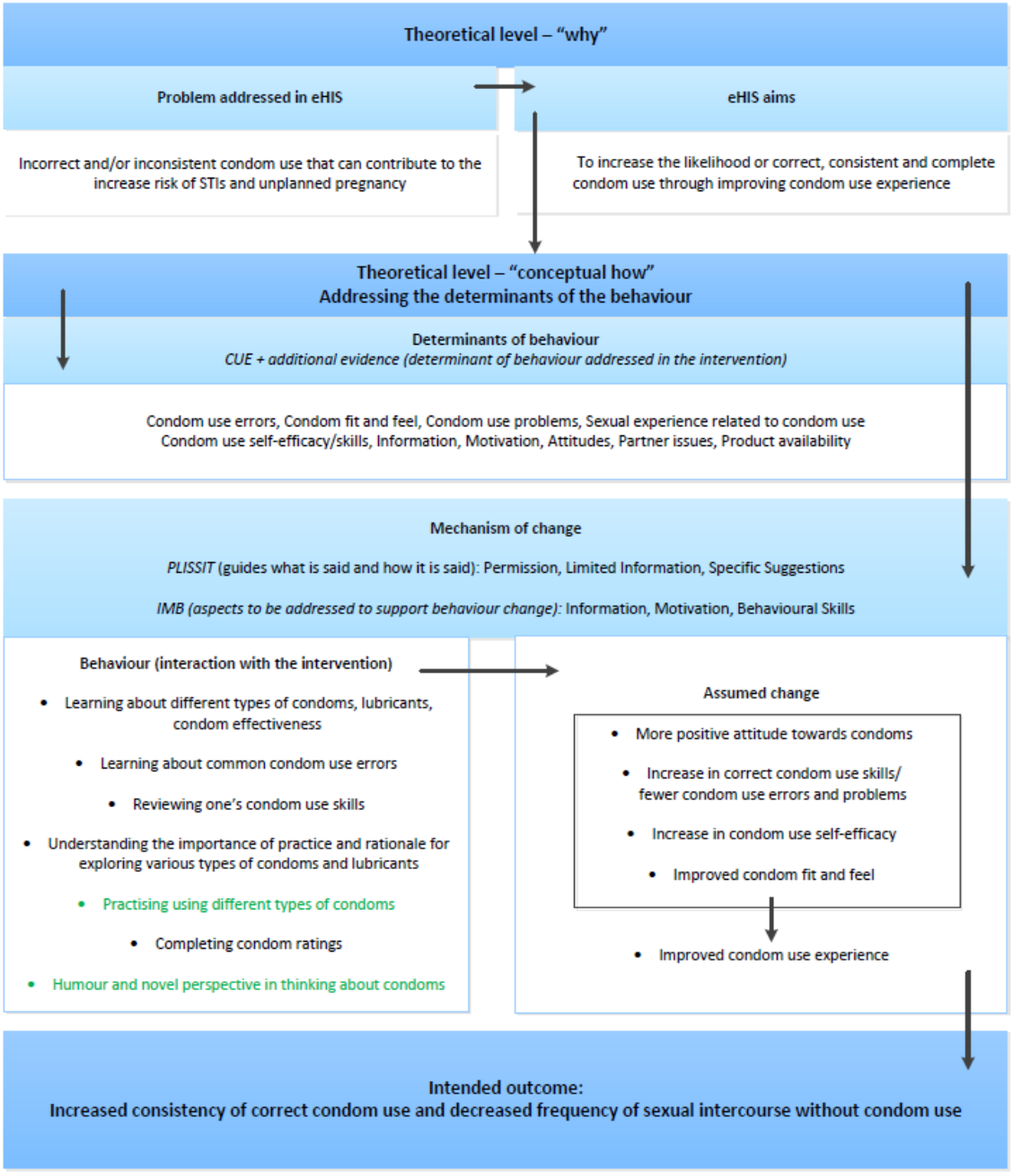
Intervention design objectives	Key features
To maintain men's engagement with the intervention[a]	To include summative feedback on condom ratings To make design attractive and inducing curiosity
To minimise the intrusiveness of the intervention[a]	To ensure that the intervention is not seen as too demanding or interfering with daily life
To ensure users that the information provided in the intervention is perceived as credible[b]	To provide information about previous research and academic affiliation

Note. Adapted from Yardley, Morrison, et al. (2015). [a]an existing GPR extended, [b] a new GPR added.

The study results were judged to be generally in line with the assumed working mechanism of eHIS as presented in the LM. The minor amendment to the LM was moving the focus to condom use practice, leaving the practice without a partner present as a recommended option. Another amendment was highlighting the role of humour and novel approach in thinking about condoms and facilitating the intended behaviour change (see Figure 11).

Figure 11

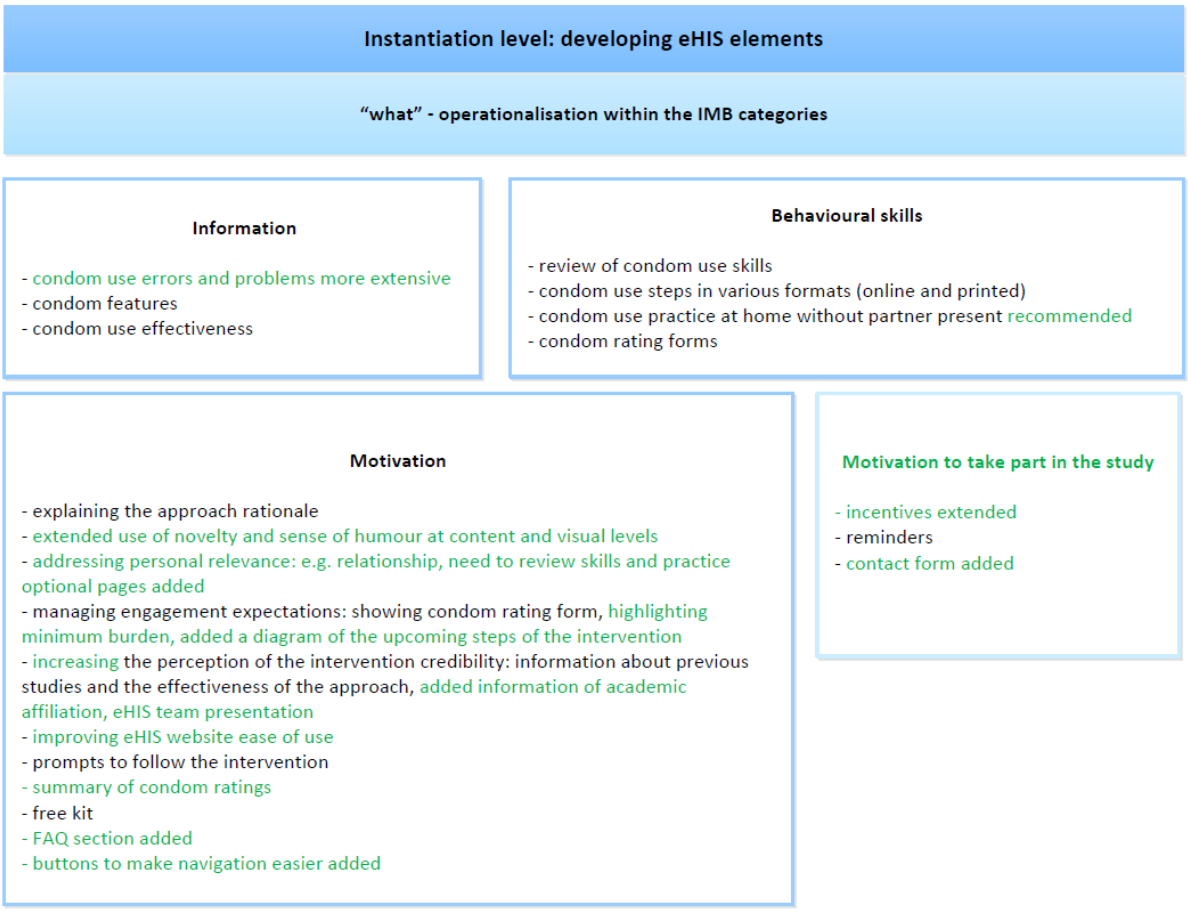
Amendments to the logic model following Study 1



In the next step, a systematic analysis of participants' feedback was undertaken to ensure the transparency and consistency of the process of amending the intervention and/or introducing new elements. Feedback from participants was organised around the themes included in the participants' model of experience (Figure 10) and analysed in the context of evidence and experts' advice to identify possible solutions to issues which emerged from the analysis. The changes to the intervention's operationalisation are presented in Figure 12. The examples of the amended webpages are presented in Appendix A and the process of implementation of the evaluation results is presented in Appendix B.

Figure 12

Changes at the operationalisation level following Study 1



The amendments focused mainly on: improving the clarity of the content, emphasising the intervention message, simplifying the intervention and study procedure, and making the intervention more interesting and friendly through use of novelty and making the website design more attractive. To increase the perception of the intervention relevance participants' concerns or personal circumstances, such as being in a relationship or being an experienced condom user, were addressed by providing additional information, reiterating or clarifying the key points of the intervention, or strengthening the motivational components. For example optional pages raising awareness of common condom use errors or normalising the idea of practising condom use during masturbation were added. The condom rating form was amended to improve its usability and the kit content was reviewed to reflect participants' preferences. Changes that were not implemented were annotated with the rationale for the decision, for example when they contradicted eHIS GPRs (e.g. fear appeal – focusing intervention message on negative consequences of not using condoms).

Study 2 – A Qualitative Evaluation of the eHIS Computerised Version

Aims and objectives of the evaluation of eHIS computerised version. Mirroring Study 1, experience with computerised version of eHIS, and specifically relevance of its content, understanding of its message as well as engagement with the intervention and its acceptability were investigated. The study aimed to answer the same research questions as Study 1 (p. 109). Additionally Study 2 aimed to verify whether the changes made in response to participants' feedback on the prototype led to improved experience with the intervention. The planned feasibility study pages were included in the evaluation to assess whether any part of study website would cause participants to leave before reaching core pages and to assess participants' perception of study information and study measures.

Method.

Recruitment. Recruitment took place between February and April 2016 and the same approach was used as in Study 1 with minor amendments to the advertisements' wording and layout (Appendix AD). On the basis of existing literature (Krug, 2006) it was assessed that approximately 6 participants would need to be recruited to test the computerised version of the intervention. However, if a high level of changes were required there would be a possibility of running a second round of testing, recruiting another 6 participants. Recruitment criteria in Study 2 (Table 6) were in key points the same as in Study 1, but adjusted to reflect the use of computers during the sessions.

Table 6

Study 2 inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
gender: male; aged 18-69; fluent in English (written and spoken); male condom use: use condoms; or do not use condoms regularly or stopped using condoms; or lack confidence in using condoms, or experience condom use related problems and/or difficulties; or are considering using condoms in the future; not allergic or sensitive to any type of condoms (latex or non-latex) and/or lubricants comfortable using computers	gender: other than male; below the age of 18 or age 70 or above; not fluent in English (written and spoken); allergic or sensitive to any type of condom (latex or non-latex) and/or lubricants; have difficulties using computers and other visual display unit (VDU) equipment; have visual or hearing impairment; have a learning disability

Study procedure. Study procedure followed the same schedule as in Study 1 (see Figure 9). Study documents are presented in Appendices U – V and AE – AK. The content of the eHIS computerised version comprised revised intervention web-pages (examples in Appendix A). Additionally, pages with baseline measures were included. Participants were informed that the answers given might be recorded for technical purposes only, but none of the answers were scored and should not be "real" answers. Minor amendments were made

to the intervention between TAIs in cases of straightforward changes such as presenting text in bullet points. As in Study 1 ethical approval from the Psychology Ethics Committee at the UoS was obtained.

Data collection. The same methods of data collection were used as in Study 1 (p. 112). However, some modifications were made to the screening questionnaire (Appendix AF) and SSI (Appendix AK) to improve clarity of questions and gather data deemed relevant in the context of Study 1 results (relationship, ethnic background).

Data Analysis. The method of data analysis used was the same as in Study 1. The coding manual developed in Study 1 was used for initial coding of transcripts using NVivo 10 software (QSR International, 2012). Additional code candidates were created and fragments of transcripts were re-coded when required. The coding manual was reviewed to reflect the changes in coding structure and some of the code definitions were amended to eliminate overlap with new codes and/or reflect participants' experience more precisely in the context of new data. Same as in Study 1, developing and amending codes and themes was repeated until the fit between themes' model and data was satisfactory (Appendix AL) and refining codes and recoding relevant parts of transcripts was continued into writing up phase. The final version of the coding manual is presented in Appendix AM. The model of the experience with the intervention formulated in Study 1 was reviewed and amended accordingly. Study 2 data analysis and the model of participants' experience with the eHIS computerised version are presented below.

Participants. The screening survey was completed by 16 people. Two did not met the eligibility criteria, one did not provide contact details and four did not respond to arrange the interview. Nine participants were interviewed until data saturation was achieved (Chamberlain et al., 2004).

Participants varied in their relationship status and ethnicity, but all were students. Their mean age was $M = 23$, $SD = 9.43$ (range 18-48). A third of them reported feeling confident using condoms. Two thirds of participants used condoms and the same

proportion reported condom use problems. Many of the problems were related to condoms interference with sexual intercourse. All perceived themselves as competent computer users. Participants' characteristics and their condom use are presented in Table 7.

Table 7

*Study 2 participants' characteristics and their condom use experience (*N = *9)*

Participants characteristic[a]				
Ethnic background	White British (4), Indian (1), Black (1), White American (1), British (1), White (1),			
Highest level of education completed	A-Levels (7), BTEC Extended Level 3 (1), MPhil (1)			
Currently in relationship	Yes (6)		No (3)	
Type of relationship	Long-term (3), Stable (1), Banter (1), Healthy (1)			
Participants condom use experience				
	Yes		No	
Use condoms	6		3	
Use condom each time you have sexual intercourse (vaginal or anal)	3		4	
Use condoms correctly	6		1	
Ever experienced any condom use problems	6		2	
Condom use problems experienced	loss of erection and enthusiasm (2), condom breakage (1), not enough stimulation due to condom thickness (1), long to put on (2), condom drying out (1), condom being uncomfortable (1), less pleasure during sex (1), ruins mood (1), loss of interest (1), reduced libido (1), past partner allergic (1)			
Feel confident using condoms	Yes (3)	No (2)		Unsure (2)
Plan to use condoms in the future (if not using them at the moment)	Yes (2)	No (1)	Don't know (1)	Not applicable (5)

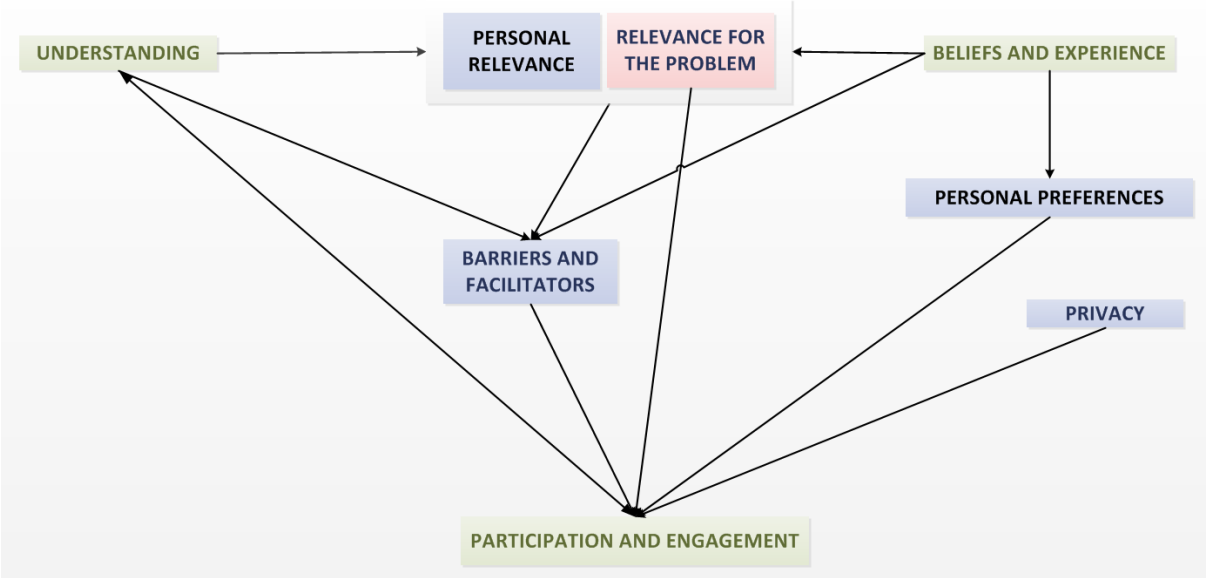
Note. [a]*n* presented in brackets

Results summary and analysis. The model of participants' experience with computerised version of the intervention is presented in Figure 13. The participants' experience with the computerised version of eHIS fit broadly within the model formulated for participants' experience with the intervention prototype. Key themes remained very similar with minor changes to their labels to more accurately reflect themes' content (described below). The new amended labels were "Participation and engagement",

"Understanding", "Barriers and facilitators" and "Privacy". Some connections between themes were also adjusted. Although the general model was almost identical, the content of the themes was different, and in a few cases substantially different. As in previous analysis there were three key themes intertwining with each other and other themes were identified: "Understanding", "Beliefs and experience" and "Participation and engagement".

Figure 13

Model of participants' experience with the computerised version of eHIS



"Beliefs and experience". Personal beliefs and experience is an intertwining theme which describes a personal filter through which the intervention's approach and its format were judged. On a few occasions participants referred to their own skills, knowledge and experience with condoms when commenting on eHIS, especially its personal relevance or relevance for the condom use problems. They often compared using the intervention to their experience when they used other websites. The latter was a reference point for judging the intervention's usability, attractiveness and its format. Examples of these are included when other themes are presented.

"Understanding". This theme was intertwined with others, especially perception of the intervention relevance and experience of barriers and facilitators. Good level of understanding enabled participants to make accurate judgments about various aspects of the intervention.

The level of clarity of the study documents and the intervention pages was good across the website, as demonstrated by overall good understanding and explicit comments about clarity of the study information [1, 3, 5, 6, 7, 9], wording of the items in the questionnaires [4, 5, 8], intervention content [4, 5, 7] procedure [3, 5, 9], or the purpose of the rating form [7]. For example, participant 5 shared his opinion about the PIS "The vocabulary is very accessible. (…) It's straight to the point. So you have the questions you have the answers that gives a good idea of what the project is about." Participants' understanding of the wording and the purpose of study measures was generally very good [1, 3, 6]. They very rarely asked for clarification or displayed confusion while going through the intervention, and after finishing none but one had further questions.

Most of them also easily identified the key messages of eHIS. As participants said: "[It's] giving you incentive by saying that you can enjoy it [using condoms] rather than it's just to prevent pregnancy and STIs etc." [1] and "You're more inclined to use it [condom] if you feel more knowledgeable about it" [2]. Participant 6 very accurately summarised the rationale behind practising using condoms without partner present saying:

> I think the fact that it's saying to truly get a feel of which condom is right for you, should put it on your own. I think it's a really good idea because if it was in front of the partner it's very unlikely that you're just going to have the condom on and just feel it for what it is without doing something else pretty immediately after. Whereas I think if you're on your own then you can gauge whether it's good or not.

Participants also demonstrated good understanding of the purpose of almost all elements of the intervention.

Understanding of the visual metaphors was also good as demonstrated by participant 6: "That picture is quite clever because it sort of suggests about the different types and stuff and how there's different types of fruit and there's the condoms stuff so it gets a little subtle." Participants had a good grasp of the key principles of the intervention and purpose of the elements.

Not clear. Although not frequently, some problems with the content clarity were reported with some of the study and the intervention procedure elements that were seen as clear by others. Some indicated that frequency of condom ratings and reminders [3], follow-up completion timeline [8] or whether non-users should answer questionnaires about condom use [6] were not entirely clear. Other unclear points included: using UoS credentials for logging in [2], some items in the screening questionnaire (visual impairment, learning disability) [7, 8], ambiguous response options, timeframe of events in some of the questionnaires [2, 4, 5, 6, 8], the idea of active and non-active buttons (see Appendix A, Figure A2) [4, 9], or what "eHIS" stands for [9]. Three of the participants highlighted that the links to optional information did not always reflect precisely the content of the page they were leading to [3, 5, 6].

Some parts were well understood by some of the participants, but appeared not be entirely clear for others. Comments about the kit content were divided, with some participants not being sure what would be included [3, 6, 7], and others stating that the information given was clear [5]. Participant 3 understood that the users would be expected to pick their preferred condoms to be included in the kit on the basis of their photo on the webpage. Similarly, the idea of practice without a partner was not fully clear for some [5, 8] and well understood by others [3, 6, 9]. There was a concern voiced that inexperienced condom users may not understand the idea of practice [9]. The overall condom use steps were seen as clear [5], with only one point, avoiding spillage, highlighted as unclear [5].

"Understanding" links to other themes. Participants felt that sufficient and clear information allowed them to adequately judge the demands of the intervention and study.

The link between clarity and engagement was more complex, as perception of clarity seemed to foster engagement [2], but at the same time content seen as easy and obvious could lead to lower engagement, as participant 3 explained: "It seems to be quite clear and there is nothing that I'm really being held back. I think I am getting the full picture, so I tend to skip over."

"Participation and engagement". The engagement theme focuses on the participants' interaction with the intervention, including visiting specific webpages, comments regarding motivation to continue with the study/intervention or leave it and/or actively engaging with the content. It also covers participants' opinions about engaging in the feasibility study. Engagement seems to be determined by all other aspects of participants' experience.

Aspects of engagement. Participants' engagement had two inseparable aspects: participation in the study and engagement with the intervention. Most of the participants saw the study information and/or the study measures as an integral part of the intervention. There were comments [5, 6] that completing the measures themselves triggered reflection on their condom use practices and related issues – "They made me think." [5] – gave a new perspective, and/or a chance to learn something new about condoms.

The level of engagement with specific sections of eHIS varied across participants. Most of them paid some attention to the core pages' content, in particular the condom use skills review and the intervention procedure. The optional pages were visited less frequently and one of the participants stated that he would not explore them at all [4].

None of the participants used the buttons to access again the parts of the intervention they had already seen. Some opened links in new tabs [3]. After reaching Main Menu a couple of participants declared that they could come back to some of the parts at a later time [1, 4], others felt that they had understood everything well and did not need to explore further [6], yet others explored the available options to ensure that they had not missed anything [2, 5]. Participants showed interest in the FAQs section [8, 9] and the

next steps of the intervention [7, 8]. Another participant declared lack of interest throughout the intervention, but he explained that he would still explore the options:

> I don't wanna be caught up in forgetting about things so maybe take a bit more time (…) sussed out when you're gonna contact me again I'd also pay a lot of attention to when I'd be done as well [7].

During SSI two of the participants spontaneously shared their opinions regarding recruiting participants for the future study. Participant 7 predicted that there might be some difficulties in reaching men in general public with the information about the study. Participant 4 recommended use of social media and/or e-mails for advertising. He said: "If someone gives you a little leaflet you think oh that's quite a good idea then you put it in your bag and never really use it because you're not on your laptop."

Change. There were comments that after going through eHIS participants changed their outlook on condom use related issues, would reconsider their own practice, or learnt something new while they were going through the pages. One participant said: "I thought I was relatively well educated on the subject but I'm learning a lot of things I didn't know" [6]. These comments were mostly linked to the new perspective on condom use practice and/or novel information [3, 6, 8, 9 SSI]. As another participant explained commenting on condom use rating form:

> That's good you get to see the form afterwards, just to see it's what you're in for, so that you know what to look for, and feel for when the condom's on. So seeing this I would probably think more about the thickness of it and how well [it] unrolled, when I wouldn't really know a thing about that before. [3]

Engagement and other themes. Direct links between engagement with eHIS and all other aspects of the participants' experience were observed [1, 3, 5, 6, 7, 8], especially with novelty of the intervention approach and some information and perception of personal relevance or problem relevance (both described below), especially when visiting optional webpages. These are described in specific themes sections below.

Interest was directly linked to the engagement with some participants declaring that they would skip or skim read through the parts covering familiar topics, not seeming very interesting, not personally relevant or which were not seen as important (mainly PIS, eHIS entry and rationale, skills review) [3, 6, 7]. Participant 2 said he would skim through most of the pages to reach the part he was interested in. Another participant declared that he usually completed questionnaires going through them as quickly as possible [7]. Participants did not mind answering even sensitive questions when completing the questionnaires [5, 7, 9] and some highlighted that this was because they were relevant for the study topic [7, 9].

The information about the study was linked to participants being more willing to complete study measures. As participant 2 explained: "I think the information page is quite good, makes you feel more like answering these questions. Anyone that would be on it by now surely wouldn't mind since they have been informed enough."

The elements which main aim was to facilitate study participation or engagement with the intervention were also seen as adequate for their role. These were showing how the rating form would look like [6, 9], the information about risk and benefits provided in the PIS [7], and FAQs section [8]. Other facilitators of engagement were clarity of the information provided [2, 6, 7] and friendly atmosphere [2, 5, 7]. The website design (layout, images) [2, 3, 5, 7] and format [2, 3, 4, 5, 7] played an important role in attracting participants' attention.

The organisation of the content [4, 2, 5, 7] and navigation [5] also contributed to maintaining participants' engagement. Interestingly, the material incentives, although welcomed, were not seen as direct motivators to engage with the intervention. Participants also had some new ideas (described below) regarding how to improve the intervention to make it more attractive to them and possibly encourage their engagement. Participants highlighted that they would approach eHIS as any other website, for example skim read, focus on visually highlighted points [3] or browse through pages [5].

"Personal relevance". This theme describes participants' opinions about eHIS relevance for themselves and other men. During the TAIs this theme occurred only occasionally.

Relevant for me. Already at the stage of completing questionnaires participants highlighted that displaying only the questionnaire items that were relevant for them would make their experience more personal [5, 6]. Others suggested adding options to the questionnaires and condoms rating form that would more accurately reflect their experience, for example "not applicable" or "other" options [3, 5, 6].

Two of the participants explicitly stated that eHIS was personally relevant for them [5, 8]. As participant 8 explained: "I think this testing thing (…) actually convince me more of it because I'm just using the same brand and they've been just not good." One participant commented that eHIS would have been relevant for him when he had first started using condoms [6].

Interestingly, when asked directly in SSI whether they would use the intervention themselves, five of the participants answered "yes" [2, 3, 4, 5, 8]. Other participants stated conditions under which they would consider using eHIS: initial experience with the intervention, if they "felt like [I] didn't have enough knowledge of condoms" [6], if they were using condoms [9], if they were younger [7].

Target audience. Participants also made suggestions that eHIS would be appropriate for younger less experienced men [7, 9], possibly in a school setting [7, 2] or at a university [2]. These opinions were linked to the perceived basic level of the intervention; as participant 7 explained: "It seems more like maybe something directed towards school kids, something they could sign up to get free condoms, with them get information that's related to safer sex."

Personal relevance and other themes. Perception of the content to be personally relevant contributed to willingness to engage with the intervention [5, 7, 8]. The perception

of personal relevance seemed to be linked to previous condom use experience and more specifically, to knowledge about condoms and perception of own proficiency in using them.

"Relevance for the problem". This theme focuses on participants' perception of how adequately eHIS addresses condom use issues, and on perception of its potential to improve the condom use experience.

(Not) relevant for the problem. The content of the intervention was seen as a relevant, comprehensive and credible resource for condom use issues and with potential to improve condom use experience, as participant 6 said "it seems to cover all bases". Participants commented on "equipment that works for an individual" and the "practice to develop skills" metaphors [2, 5, 6, 9] as particularly relevant, as participant 6 explained:

> I think it is helpful because (…) with shoes it's (…) very obvious what size you need, whereas it might be a little bit less so with condoms. It might be less obvious what sort of type suits you best (…) so I think just letting people know that there are sometimes different options is helpful.

Participant 2 pointed out the relevance of the intervention rationale:

> About liking the equipment, I think that just for males in general, that's quite a good angle to get guys [they] don't see it as a piece of equipment, they see it as a hindrance, I think that's just quite a good way to spin it.

The condom use errors and problems section[8] [3, 5, 6, 7, 8, 9] and common condom use errors [1, 6] were seen as particularly relevant for the condom use. As participant 1 commented on the latter:

> It's quite good it tells you about common errors because you might not be aware of the some of them (…) like the air in the tip or all this. Say if you're unsure it gives you guidance rather than make me find it for yourself.

Other parts of eHIS which participants found relevant were explanation why men should use condoms [6], correct condom use steps [5 SSI, 6, 7 SSI], information about finding the

[8] The errors and problems section was moved from optional link in the main menu to the core pages during the study (from session 5).

right condom [6], message not to use oil based lubricants [8], and skills review [5, 6]. The last one explained by participant 5:

> Many men take for granted that [they] know how to use [condom], that it's very straightforward. And then when you give here the opportunity for the person to see "well let me check if I use it correctly" I think that's very relevant.

Showing different types of condoms to raise awareness about available variety and/or to inform about the kit content [1, 2, 4] was judged to be useful, as one participant explained:

> I think seeing it sort of makes it a bit more real because when you're in the shop (…) people like I don't really get a vast amount of stuff (…) but a lot of people I know are like (…) "just get whatever the box" and it sort of doesn't really work. [2]

The PIS was also seen as relevant for the study and as very informative and covering the essential topics, e.g., benefits and risks to be considered before taking part in the study [1, 3, 5, 6, 7]. Statement that the condoms should be used consistently and correctly was labelled as common sense [4].

There were some mixed opinions about the relevance of practising condom use without the partner present. Whereas it was seen to be relevant to gain confidence in condom use skills [6], there were voices that solo practice may not be relevant for having sex in a partnered situation [3, 6] or "seems a silly thing to practice by oneself" [7]. As participant 3 explained: "It seems like you should do it with your partner more just so you can see what feels right, it [masturbating with condoms] doesn't really seem as relevant." Participant 6 also had doubts about this part of eHIS approach:

> The most important time perhaps (…) is when it's [condom] actually being used, so I can see where it is coming from, but at the same time maybe you may think a condom feels fine on your own and then you try it and then because of movement and stuff it feels weird or something.

Optional information for users who already had favourite condoms [4] and references to previous research [6] were judged as not adding much to the content. Also a

question “How turned on were you when you were using this condom” from condom rating form was seen as not linked to condom use experience [6].

Interestingly, participants commented a lot on study measures being relevant for condom use related issues [3, 4, 5, 6, 8, 9]. Errors and problems and condom use experience questionnaires were seen as particularly relevant for men’s experience [3, 5, 6, 9]. However, one participant pointed out that some questions may not be relevant for homosexual men or if the behaviour in question changed over time [5]. Another questioned the relevance of asking about relationship status [6].

Judgment of relevance in the context of experience and/or beliefs. In judging the relevance of the intervention some participants referred to their own condom use experience or to their beliefs about other men’s experience. Participants shared the view that eHIS was relevant to their own [8] or their colleagues’ [5] condom use problems. One participant highlighted that it specifically addressed the concerns regarding condom use he had as a novice user [6]. Participants also judged the relevance of the items in study measures from the perspective of their own condom use experience [6, 9]. They believed that most men had some knowledge that different types of condoms existed, but it would be limited [2, 6]. For example, they might not know to check condoms for damage before use [9]. One participant believed that some condom use errors and problems were common (e.g., putting condoms on the wrong side) [3].

Participants compared the eHIS website to other sexual health services and/or other websites they use. Some pointed out that the NHS website could provide extended information if required [6, 7]. Participant 6 highlighted how eHIS with information it provides could be different from the services he knew: “You can get free condoms but that’s literally just the condom there’s no extra instructions with it (…). I think it's a really good idea.” In the SSI the same participant said comparing the eHIS website to the NHS one:

> (…) what this can offer, that say something like the NHS choices website can't offer, is that this isn't an institution this isn't something big or nationalised. It's friendly, it's approachable and it doesn't make you feel like you're being talked down to. It's almost a little bit like a family member or a friend sort of telling you and sort of giving you that advice which some people may not have so this is like a really good replacement for them.

Credibility. The reasons participants gave for their judgments of the intervention's credibility varied, and sometimes were even conflicting. One of them pointed out that he could see a person behind the message who he was more likely to listen to, as he explained: "You tend to trust these ones more a bit I think just because the less fancy it is you can see someone's done this" [2]. Another linked trust to the professional appearance of the site (described below), yet another's opinion was that the website did not look anything like an institution such as the NHS but still looked quite professional with qualified people in the study team [7]. Information about the UoS affiliation also seemed important. Acknowledgement of not only benefits but also risks related to taking part in the study [7] and transparency in the study procedure [2] also contributed to perception of eHIS's credibility. Only one participant explored optional pages to find out why the users should "trust" this intervention [9].

According to participants, the things that could undermine the credibility were linked to visual appearance (font in videos [3], some images [7 SSI]). As participant 7 explained in the SSI:

> I think the first page to start with things like that [image], it detracts from the fact that it's a credible psychological piece of research (…) it seems a bit more too like hype and jovial which shouldn't really be.

Perception of potential effectiveness. Participants who commented on the issue of the effectiveness of eHIS generally agreed that it could be beneficial for users, specifically by increasing their knowledge about different types of condoms [2], and helping to

increase their willingness to use them [2]. One participant suggested that even the questions included in the baseline measures could trigger reflection on condom use experience, identify any issues with using condoms, "clarify for some people where their problems lay", and support review of their condom use skills [6]. When asked during SSIs whether they thought that the intervention could be useful in improving condom use experience, all but one participant, who said that it could "possibly" help [1], were very positive.

Links to other themes. Seeing eHIS as relevant and useful for condom use related issues seemed essential for participants' engagement. As described in the previous theme, many participants stated they would be willing to use the intervention themselves or recommend it to others. One participant said that the credibility of the academic study was not a good enough factor to encourage him to take part in the study but that it could be reassuring for other participants [7], whereas another linked higher engagement with trust in the intervention [2]. Perception of study measures' relevance seemed to contribute to the willingness to participate in the study [5].

"Barriers and facilitators". Barriers and facilitators theme focuses on the aspects of the intervention which could hinder users' engagement or to encourage them to engage with and to follow eHIS's approach. While the perception of clarity and personal and problem relevance contributed to the participants' experience with the intervention and their willingness to engage with it, it seems that perception of barriers and facilitators to engage with eHIS was central to their general experience with the intervention.

Friendly atmosphere. A friendly atmosphere was the aspect of the experience with eHIS mentioned by over a half of participants [2, 5, 6, 7, 9]. They linked the atmosphere to: "friendly" and "non-confronting" language, being non-intimidating [6], dealing well with sensitive issues [6, 7], being informative and not too lengthy [7], openness about study procedure [2], variation in format and layout [5, 6] and website navigation [6]. Some participants noted that the questions in the questionnaires felt comfortable [2] and as

participant 5 explained “I don’t feel invaded by the questions even though they are sensitive.” Participant 7 highlighted the importance of the right balance between seriousness of the topic and not being too formal.

Participants also appreciated the less conventional approach to depicting condoms. Some declared that they enjoyed the images or that there was nothing they did not like about them [3,6]. There were explicit declarations of feeling comfortable with them [5, 6], some finding them humorous and funny [6, 9] and “almost like art” and contributing to the “feel of the website” [6]. Participant 5 commented that “they make the issue lighter” [5], Also participant 6 said:

> [laughs] just so many pictures of condoms of where they shouldn’t be (…) I think it’s good it’s making me laugh a little bit, I just think it’s quite friendly (…) you can’t really put pictures of a condom in use on your page so to do little humorous pictures like this I think it’s a good way to do it.

However, one of the participants pointed out that too many condom pictures and the association of condoms and fruit made him uncomfortable [5]. The same participant [5] made suggestions to add some photographs of “nature” or couples to make going through the intervention more relaxing.

There were aspects of the intervention pointed out that could negatively impact the atmosphere of the intervention. Participant 5 commented that eHIS was “too serious” in places and could benefit from “a touch of lightness”. Another participant was concerned that some of the phrases used in the skills review might not resonate well with users. He explained, commenting on condom use skills review:

> It says ‘read more if you think you do not need guidance on how to use condoms correctly’ or because it implies that if you did think that you’re a bit stupid (…) it just doesn't come across as very friendly, it’s almost sort of mocking (…) ‘Don’t think you need guidance? I’ll show you why you need guidance.’ [6]

Individual's choice. The perception that eHIS's approach was not forced or prescriptive contributed to the general positive experience with the intervention. As participant 1 explained: "[The intervention] makes suggestions rather than saying you should do this. (…) The user is making the decision rather than being told what you should do." Another liked that the encouragement to try new condoms did leave the final choice of which one to use to the individual [8]. The topic of having choice appeared also in relation to a participant's decision whether or not to access additional information [1, 4]. Participant 4 commented on the Main Menu: "if the kit takes a week to arrive you might as well refresh your memory (…) I'd prefer it to be there than not be there even if I don't use it, it's nice to have the option." Participants also welcomed the possibility to choose the kit collection or delivery [3, 4, 6] as well as choosing the charity to make a donation [7].

Emotional reactions. Participants' emotional reactions were consistent with their comments regarding the intervention's friendly atmosphere. Despite some level of discomfort/embarrassment displayed when they were going through study pages or initial parts of eHIS, after some time most of the participants looked relaxed. They often laughed, expressed being surprised and/or amused. These reactions were most frequently in response to condom images [3, 5, 6], the questions about condom fit and feel [6, 9], or when reading about condom use practice [7, 9]. As described by participant 7: "It just made me laugh at [reading about practicing alone] I know what they mean but would chuckle to myself [laughs]."

There were mixed reactions to specific elements. As discussed above, the images of condoms triggered mostly laughter, but also made one participant uncomfortable. Some participants seemed embarrassed because of the directness of the questions [1] while others appreciated this [4].

Negative emotional reactions were infrequent. For example, participant 5 suggested that asking men about the number of sexual partners might be embarrassing as could lead to conclusion of "promiscuity" [5]. Other negative emotional reactions were linked to

unclear navigation [5] or being annoyed by the login procedure or length of the rating form [7]. Feeling obliged to take part in the study, when not really willing to do so, after receiving free kit was also mentioned [7]. Disagreement with some of the intervention content (discussed below) was also a source of annoyance for one of the participants.

Interest. Interest was one of the facilitators maintaining participants' engagement throughout the intervention. They explicitly declared their interest in various parts of eHIS, for example: FAQs [3, 8, 9] or study team information [3, 7]. However, the sections which participants paid the most attention to were the ones focused on condom use errors and problems [1, 2, 3, 5, 7].

Novel aspects of eHIS highlighted by participants included: different types of condoms [7, 8, 9], non-latex condoms [5], focus on condoms fit and feel, thinking about different aspect of condom use experience [3, 6], BSI and CE marks [6] or the way of depicting condoms (discussed above) [3, 6]. Participants often seemed surprised that they found information that was novel to them [6], as they believed they had good knowledge about using condoms [6, 9]. As participant 9 said "I didn't realise they were this many types of condoms and different sizes."

Only one participant reported lack of interest at the stage of reading the PIS and later on when he was going through eHIS because the issues covered were already well known to him. However, even he was interested in some information in errors and problems section: "I don't wanna get too personal but I would click on two sections here that apply to me and then the others I would ignore." [7]

Perception of the study and the intervention demands. The study and the intervention demands were generally not seen as burdensome. Although the first impression of the PIS was that it was too lengthy [7] with a lot of information [9] but later it was stated that the length was justified [7]. Participants agreed that the PIS was easy to follow and understand [1, 5, 8]. One participant complained about the registration procedure; however, despite earlier reservations, on completion he commented that the

process was quick and simple [7]. Questionnaires were described as "straightforward" [1], "to the point" [8] and easy to follow and complete [1, 6, 7, 8]. Despite some comments about their length or number of questions [3,6] most of the participants did not feel they would be discouraged if they were to complete them [6, 7, 8]. Participant 7 described his experience with the measures, saying:

> I suppose the questionnaire doesn't seem as long as I first thought. (…) it is still a bit tedious but I really think I'd fill this in within less than five minutes (…) I'm already a bit tired of the questionnaire by page nine, I think I would be if I was filling it.

The participants appreciated the option of skipping non-relevant questions to save time [1, 6]. Once a concern was raised that answering some of the questions may be challenging, as participant 5 explained: "even though they are real situations it may be difficult for people to remember all of them."

The commitment to the study was not seen as too demanding [7, 8]. Commenting on this aspect study participant 8 said: "It's quite a long study but it's pretty well explained how it's going to flow through three months to complete that shouldn't be a problem really." However, one participant said he would not commit to the study to get access to the intervention [7].

The participants highlighted that the intervention was simple, easy to use and to follow [1, 4, 6, 7, 8, 9], and "user friendly" [6]. They especially liked the easy ways of obtaining the kit [3, 4, 7, 8]. Participants were also very positive about the amount of information given [3, 5, 6, 7, 9] and the option to read more if they were interested [1]. Phrases such as "short and sweet" [3], "little info bites" [6], not too long [7], "smaller chunks of information on different pages" [9] were used in comments about the amount of the information.

There were some suggestions, seen as minor points, to slightly reduce the content on specific pages [7]. Only one participant said he felt there was too much information

about the intervention procedure to remember [5]. There were mixed opinions regarding the length of the condom rating forms, from judging it to be too long [6, 7] to adequate [8]. Participant 6's reaction can illustrate the first impression when accessing the form: "Blimey that's a lot of things to answer about one condom and there're lots of different options, but if had to do that about a condom I might be a bit like 'Christ that's a lot to answer about.'" Home practice was not seen as too time-demanding [3] but the skills review part could seem too tedious [7].

Incentives. Participants liked the study incentives, especially the donation to charity [2, 4, 6, 7]. Despite liking the idea one participant said it would not be enough for him to commit to the study [7]. There was a suggestion to add the option to enter a charity of the users' own choice and for charities to be related to sexual health [6]. Participants also seemed keen to see the prize draw [4, 6, 7]. Although a surprise gift also generated some positive reactions [4, 5], it was rarely mentioned. As participant 4 said "I think it's good to have a prize draw because it incentivises you to keep going." and also commented on a surprise "I laughed that in each condom kit you will find a small surprise (…) I'd be quite excited." However, participant 7 said that the perception of chances to win the prize may reduce its attractiveness and that it doesn't seem to be worth the effort. Participant 5 would most value the appreciation shown for users' time.

Only one participant indicated that the kit was an incentive in itself and pointed out that the ratings summary could be incentives too [7]. Another said that that possibility of enjoying using condoms as a result of taking part in the intervention could be itself an incentive [1].

Disagreement and concerns. Only participant 6 voiced his disagreement with two parts of the eHIS content. The first was the page which suggested that condoms may be sexy and fun and that using them may be a pleasurable experience. He said: "I really don't see why a condom would be fun like unless you filled it up with water and threw it as a water bomb or something". He also strongly disagreed with the information that men can

"overestimate" their condom use skills: "I can't ever imagine someone feels too confident about putting a condom on (…) like 'oh this is below my intelligence you do it darling'". However, at a different place the same participant was concerned that men might not know what correct condom use behaviour would be.

Some of the participants were concerned whether masturbation would be acceptable as it was seen as "a very controversial issue" [5] and some men might have ethical reservations about it [3]. There were also single concerns regarding a suggestion to add a little of water based lubricant inside a condom and the risk of slippage [3] or that sending condoms through post could damage them [6].

Barriers and facilitators links to other aspects of experience with the intervention. There were numerous aspects of participants' experience that facilitated their engagement with the intervention. As discussed above the strongest link was evident between interest, especially in novel information, and engagement; and conversely, lack of interest and disengagement. It can be illustrated by participant 8's comments about common condom use problems information: "That's quite a range of errors to be honest I have not known about half of these so that would definitely convince me to carry on" [8]. The novel approach focusing on enjoying using condoms was seen as an incentive, motivating men to engage in the intervention [1]. On the other hand information seen as standard did not garner much attention [6, 7].

Friendliness and a "light atmosphere" were linked to willingness to carry on with the intervention, as participant 5 explained "it is too serious but with a touch of lightness so the person gets more engaged." On the other hand emotional discomfort could be a barrier to engagement, as participant 5 declared that he would skip the items in the questionnaires which he was not comfortable with. Lack of relevance could also lead to disengagement [5, 7].

Participants also pointed to the links between perceived low study and intervention demands and willingness of the future users to engage with it. However, also a less

overwhelming amount of information could contribute to better understanding of the content, including study and intervention demands, as one participant explained: “People will be able to understand it more if they don’t get load and load of information straight away” [9]. Too low demands could be also a barrier to engagement because too basic information could be seen “a bit insulting to someone’s intelligence” [6].

“Personal preferences”. This theme describes aspects of participants’ experience with eHIS: its design, level of detail, format, organisation, and wording of the information as well as participants’ new ideas.

Design. Commenting on eHIS’s website design participants focused primarily on its appearance, features, and only marginally on the navigation issues. They judged the design [2, 6] and the interactive features in the context of those available on other websites [7]. One commented that it looked as professional as an “NHS sort of website” or other standard sexual health websites [6], but another said that the images were not something he “could imagine” on such websites [7]. There were also voices that the website looked “dated” [6] or basic [4]. Most of the participants liked the images [2, 3, 4, 6, 7] because they “make page look nicer” [2], made the user laugh [3], and “add to the feel of the website” [6] (as described above in “Friendly atmosphere” and “Emotional reactions” paragraphs). However, poor quality of some of them or lack of their obvious connection to the topic of the intervention were criticised [1, 5, 6, 7]. Other comments regarding eHIS’s website design were mostly positive especially in regard to its layout [1, 4, 5, 6, 7]. The skills review webpage design received most negative comments – it was seen as not well organised, “messy” [1, 2, 3, 4, 5, 7, 8], and “not pleasing on the eye” [7]. The main suggested change was swapping Comic Sans font to another as “[it] just seems not very serious” [3], and “looks really unprofessional” [6]. Suggestions of numerous minor changes were also made.

Website features. Participants frequently commented on the features used on the website. They found safety reminders useful [1] and described the idea of receiving the

condom ratings summary as "pretty cool" [7]. They liked seeing their progress through eHIS [4, 6], and the possibility of returning to the sections already seen [8]. To improve existing elements participants suggested to replace videos with animations [1, 2, 5, 7] or use interactive videos with hyperlinks to specific parts for the skills review [7]. Suggestions for the website use experience improvements were based on the features they liked on other websites, for example progress bars on the questionnaires pages [3] or interactive videos [7].

Navigation. Most of the participants did not seem to have any difficulties going through eHIS and some explicitly stated that it was clear and easy [2, 6]. Some navigation issues were revealed at the entry page [1, 7] and at condom use steps [5, 6, 7, 8]. Buttons to return to already accessed sections were never used. Participants also shared ideas how to improve navigation, for example by adding the intervention menu on each page, again similar to other websites [3].

Organisation. Participants commented positively on the organisation of study pages [6, 7, 8] as well as on eHIS flow [1, 4, 6, 8], and were very positive about having the option to read additional information if they were interested [1, 5, 6, 7]. Only one participant [2] explored the options in the main menu to ensure that he had not missed anything. Many minor amendments to the organisation of the content were suggested [2, 3, 4, 5, 6, 7, 8], with the key being placing the condom use errors and problems information within the core pages [2, 6]. Suggestions to reshuffle the information across webpages were not consistent between participants.

Format. Presenting information in various formats received positive reactions from the participants. [1, 2, 3, 4, 5, 6, 7, 9]. Amongst elements they liked were diagrams [4, 6, 7] and the kit content images [1]. Many participants agreed that the videos on the skills review page could be improved [2, 3, 5, 7].

Detail. Participants highlighted that the level of detail of the information on the study pages [4, 6, 7, 9] and core pages [4] was sufficient. On a few occasions they asked

for more detailed information [3, 5, 6, 7], for example about condoms included in the kit [6, 7]. There were also requests to have fewer details on the study and the intervention pages [1, 3, 4, 6, 7]. For example, asking about different type of intercourse was too specific for two of the participants [1, 3] or information about studies investigating previous versions of the intervention was seen as not necessary [6, 7].

Rephrase. There were only a few minor suggestions to rephrase the content of eHIS. The main suggested change was to make it more concise [3, 4, 6, 7], "short and sharp" [6], and more "straightforward" [6]. Other ones were to avoid the intervention's language being patronising, too "childish" [6] or too academic [7]. Most participants asked to simplify or clarify some of the questionnaires' items or titles [1, 2, 3, 5, 6, 7, 8, 9] to avoid repetition, negative phrases or remove ambiguity (the last mentioned above under the "Clarity" theme).

New ideas. Numerous ideas were shared regarding adding elements to eHIS. Examples of them include interactive buttons with information why specific questions are being asked or hyperlinks, accessed directly from the questionnaires, to provide more information about the specific STIs [5]. Regarding content, adding expert advice [5] or providing links to credible external websites for detailed information [6 SSI, 7] would improve eHIS's credibility. In another example participant 9 said in the SSI that he would like to see the option of sharing personal stories on the website. Humorous illustrations/drawings and drawings showing a partner putting a condom on could be also added to improve the atmosphere of eHIS [5]. More details of new ideas are presented in Appendix B.

Links of "Preferences" to other themes. The participants' previous experience was influencing their preferences regarding eHIS linking them to their Internet use habits and preferences. This was mainly focused around technical and visual aspects of websites that were facilitating or hindering participants' engagement.

Design seemed to play an important role in keeping participants engaged. Visual features such as bolding and change of colour were attracting and guiding participants' attention. Occasionally the images were competing for attention with information [5, 7]. Some participants reported that they would skim read, paying attention mainly to the elements standing out visually and/or avoiding long paragraphs [3, 7].

Design, especially images, played an important role in building a friendly and light-hearted atmosphere of eHIS [3, 9, 5] many times invoking positive emotional reactions and curiosity as described above. According to participant 2 images also helped to make eHIS's message more convincing, whereas a basic layout contributed to building trust between participant and the intervention.

The use of a video format also engaged participants with eHIS's content [2, 3, 4, 5]. However, not all participants were interested [7] and some had reservation about the video aesthetic and usability on the skills review page which might "put some people off" and lead them to skipping this part [8]. Across comments there was agreement that adding more technically advanced features could make the intervention more engaging.

Organisation of and navigation between the content also had an impact on participants' engagement. For example participant 8 suggested putting information about errors and problems at the beginning would motivate participants to continue with the intervention. Interestingly, the errors and problems page did not get much attention when it was placed on the main menu page; however, this changed after it was moved to the core pages section (for all of the participants). Small amount of information on the webpages was welcomed and fostered engagement with the intervention [5]. Providing better links between specific parts of the intervention would lead to increased engagement [5].

"Privacy". This theme focuses on two aspects of participants' experience with the intervention: privacy of engagement with eHIS and confidentiality.

Participants would more likely use eHIS in a private space [5, 7]. They liked the discrete package of the kit [4, 5, 6, 8], which was seen as especially important "if you live

with (…) parents or you live in a shared house" [8]. Participants appreciated that the study participation was confidential [4, 7, 9] and could be anonymous [5, 7]. Although participant 7 noted that no requirement of direct contact with researchers made taking part feel "a bit more distant", he appreciated that this protected his privacy.

General experience with eHIS. When asked in the SSIs all of the participants reported that their general experience with eHIS was positive. The points they emphasised mirrored the TAIs comments. Participant 7 summarised the key points saying:

> I think it flowed very nicely from one part to the other throughout the time. (…) It's not only finding out more about the study but things maybe I didn't know about condoms, just useful things and it went in a very good sequence.

When asked what they liked the most different participants indicated various aspects of their experience already praised in TAIs such as: design [1, 2, 4], images [3, 6], study progress information [4], clear description of the intervention [9], or friendly atmosphere [6]. As participants explained: "I was flowing through slides, I felt like I was flying through them not because I just generally tend to rush these things but because it was never like too much on one page" [7, SSI] and "When telling people how to do it, it was really detailed so (…) no one's gonna be left asking questions and know exactly what to do" [9, SSI].

When asked about the aspects of eHIS participants did not like some answered "nothing" [2, 9], others noted that everything was covered and well explained [1, 2, 4]. The eHIS aspects participants did not like mirrored the points raised in TAIs.

Discussion.

Experience with the prototype versus computerised version. There was noticeable improvement in general experience with eHIS as well as the experience within all specific themes when compared to the experience with its prototype. This suggests that the amendments introduced following the prototype evaluation worked as intended. The experience was also more consistent between participants than in Study 1.

The key themes identified in Study 2 mirrored the ones identified in the analysis of the prototype evaluation. However, there were some, substantial in the case of a couple of themes, changes to their content.

Clarity or rather its lack was no longer one of the dominant aspects of the participants' experience, therefore it was decided that "Understanding" would be a better label for the theme than "Clarity" used previously.

In Study 2 the study webpages of the feasibility study (Chapter 5) were also evaluated for their clarity, relevance and acceptability. This directed participants' attention to the study participation issues. To reflect this aspect of their experience "Engagement" theme was relabelled as "Participation and engagement".

The level of engagement with the intervention was more consistent between participants in Study 2 than in Study 1. Lack of interest seemed to be the main reason linked to the risk of a participant disengaging. Placing the intervention within a study context was mentioned only once as a possible reason to not engage with eHIS.

Comments regarding the intervention relevance for the problem were definitely more positive in Study 2. The perception of eHIS's potential for effectiveness improved as well. Similarly to Study 1, some participants in Study 2 pointed out that going through the intervention during the session already made them think about their own condom use experience or learn something new. This consistent feedback supports the hypothesis that such a brief intervention as eHIS could potentially impact the way men perceive condoms and think about their personal experience.

Unlike in the previous study, the intervention's personal relevance was notably less frequently commented on as described in the "Personal relevance" theme. Participants also seemed to refer less to their personal condom use experience than in the previous study, but their beliefs about condoms and lubricants still had an impact on the judgment of eHIS's content, especially its relevance for the condom use related problems.

Participants in Study 1 tended to relate more to their own condom use experience when they were going through the prototype pages than participants in Study 2, who focused more on the website features instead. This could be explained by more basic stimuli material used in Study 1 triggering more in depth feedback, not distracted by the website features (Krug, 2006).

One of the most apparent changes in feedback received in Study 2, comparing to Study 1, was the perception of the burden of taking part in the intervention. This showed that the changes introduced following evaluation of the prototype such as rephrasing procedure description and its presentation or amending study procedure achieved their goal.

The comments regarding atmosphere were also definitely more positive. There was just one request to tone down eHIS message about positive condom use experience, but it did not seem to affect overall positive experience with the intervention, nor it was linked to the risk of disengagement, as it was observed in Study 1. As no aspects that would lead to definite leaving eHIS were indicated "Breaking points and facilitators" theme was relabelled to "Barriers and facilitators".

Unlike in Study 1, participants in Study 2 did not comment on security issues whereas they commented on privacy issues. This changed could be explained by the satisfactory level of additional information provided. To reflect this change "safety" and "security" were dropped from the "Privacy, safety and security" theme.

Regarding specific elements of eHIS, participants in Study 2 had more positive opinions about condom use problems section and study rationale. There were fewer doubts or objections towards practising condom use without a partner, however this still remained the key questioned point. Although less pronounced, the critique of the design, ease of use of the skills review and clarity of intervention and study procedure presentation were still present. Comments about the new images introduced in the computerised version were much more positive than those about images used in Study 1 materials, with only occasional negative comments.

In general there were fewer suggestions to change to the design. This could be linked to the study materials being more defined which did not require "imagining how it would work". For that reason, it seems plausible that the "real" experience was more positive than the "mock" one.

Further development to improve experience with eHIS. The analysis of the transcripts of TAIs confirmed that improving content clarity, enhancing positive atmosphere and emphasising novelty, as well as developing the elements aiming to support users' engagement contributed to participants' positive experience. However, several areas which could be further developed to improve users' experience (none of them critical for experience with eHIS) were identified.

Minor or no changes. Participants' comments regarding eHIS atmosphere as well as perception of study participation and commitment to the intervention indicated that changes introduced after the prototype evaluation achieved their goal and there is no need to introduce more substantial changes in these aspects. Although there were some comments about lack of interest in the intervention content they all came from one participant. Many participants pointed out the elements that they found particularly interesting and that would motivate them to engage more with the intervention. Again it seems that following feedback from Study 1 emphasising novelty showed to contribute positively to engagement with the intervention, therefore no major further changes seem to be necessary. However, there were some comments highlighting minor issues causing discomfort, raising concerns or simply not meeting participants' preferences which should be reviewed.

Content and procedure clarity. The understanding of the content improved noticeably. Occasional comments pointed towards specific parts of the content (i.e. measures' items, intervention procedure) not being entirely clear. Changes to improve the clarity of procedure presentation were introduced already during the study, which led to more positive feedback. Study measures required most attention to improve participants'

understanding and ensure measurement accuracy (Fenton, Johnson, McManus, & Erens, 2001). To improve clarity the areas indicated need to be reviewed and where possible rephrased and/or simplified, following the same process as in the development of eHIS computerised version (see Chapter 2 and Appendix B). The evidence discussed following Study 1 should be reviewed again and new evidence should be sought for if required. Request for more detailed information should be reviewed and addressed in the context of the GPRs (see Table 1) to keep the intervention brief and focused.

Improving perception of measures relevance. Although most of the measures (including condom rating form) were seen as relevant for the intervention focus, there were a few items which were seen as less relevant for certain groups or not relevant at all. Displaying only relevant measures would have an additional benefit of minimising the perceived effort required to complete them and in turn increase the likelihood of maintaining participation in the study. The option of tailoring measures for specific groups could also be explored.

Intervention approach. The areas that seemed to be most sensitive and occasionally triggered the strongest reactions were practising alone, perception of own condom use skills and positive message that was not in line with personal experience. The rationale behind practising alone did not seem to be convincing to all of the participants. As this is one of eHIS's key elements, the message needs to be conveyed better. Within the project's pragmatic approach (see Chapter 2) the implications of users not following the approach should also be considered. Also, similarly to Study 1, participants presented themselves as skilled and knowledgeable condom users. Options to facilitate assessment of own skills should be explored (Morrison, Moss‐Morris, Michie, & Yardley, 2014).

The same mechanisms as discussed following Study 1 could explain participants not being convinced to the intervention approach. One could be linked to negative judgment of information that contradicts one's beliefs (Edwards & Smith, 1996) together with individual knowledge perception (Strømsø et al., 2011). These aspects of the

intervention should be reviewed again to decide whether further amendments would be justified. If the answer is 'yes' it should be discussed how the message of the intervention could be strengthened. Additionally, a further exploratory study of self-image and personality traits in the context of sexual health knowledge and experience could shed more light on these specific issues.

Increasing the ease of use. Participants did not seem to have any major problems with using eHIS. Following participants' feedback and website design guidance (Krug, 2006), it is advisable to remove elements which do not seem to fit their purpose (e.g. buttons to previous pages) to limit the risk of users' confusion and make navigation through the website easier, which could contribute to potential users staying longer on the intervention website (Brouwer et al., 2008). This in turn could counteract the effects of their Internet use habits such as skim reading, going through content quickly.

Many of participants' suggestions to have more advanced and interactive features in eHIS were linked to their experience with other websites. These suggestions, although valid, need to be considered within the technical limitations of the LifeGuide software (Hare et al., 2009) used to design eHIS. As primarily research software, LifeGuide lacks some of interactive features that Internet users may be familiar with such as revealing additional content when hovering with the cursor over an element of a webpage. However, it may be still possible to improve website structure, design and some interactive features or add interactive elements. This aspect of experience with eHIS may have stronger implication for rolling out the intervention outside research context and using alternative modern software with less usability issues may be more relevant (Arning, Ziefle, & Arning, 2008; Krug, 2006).

New ideas. There were also a few ideas to add new elements to eHIS. All of them should be considered in the context of eHIS GPRs to ensure that the new elements, if introduced, do not change the intervention to the level at which making comparison to its other versions would not be possible (for example adding an option of sharing experience

with other users). Limitations of the software (as discussed above) or the project resources could also be a barrier to implement some of the changes (e.g. choosing condoms to be included in the kit). It should also be considered whether the suggested changes are relevant for the factors assumed to impact the target behaviour and/or addressed key aspects of the experience with the intervention or whether they reflect personal preferences of individual participants which may not all be addressed within the project timeline and resources. In the next step the extent to which they would be expected to improve eHIS's impact and general experience with the intervention should also be considered before making decisions about changes (Bradbury et al., 2014; Clegg & Barker, 1994; Kuhn, 2009).

Implications of the results for the assessment of the intervention feasibility.

Study measures. Completing the feasibility study (Chapter 5) measures can potentially lead to reflection on own condom use and trigger change in behaviour. This in turn can affect the assessment of the preliminary effectiveness of the intervention planned to be completed in the feasibility study. The potential impact of measures completion should be taken into consideration in analysis of the feasibility study results (Godin et al., 2010; Godin et al., 2008). In the future, a large scale study with three groups design in which the impact of the measures completion is controlled for (Yardley, Miller, Schlotz, & Little, 2011) could be considered.

Intervention target groups. Feedback received on perception of the intervention target group was somehow contradicting. On one hand, similarly to Study 1, participants suggested that it would be best suited for younger, less experienced men; on the other all but one declared that they would be interested in taking part in eHIS. This in the context of participants' characteristics in both studies, especially age and self-presentation in terms of skills and knowledge, may suggest that there is a need for this type of intervention also amongst those more experienced. However, they may be some barriers to admitting it openly, such as for example not seeking help regarded as more masculine (Mansfield,

Addis, & Mahalik, 2003). In that situation it would be advisable to keep the recruitment for the feasibility study as open as possible and explore who will be interested in accessing eHIS.

Contribution of the Study 2 results to the aims of the thesis. Study 2 results showed some changes in participants' experience with eHIS in comparison to Study 1; however, its the key aspects such as personal relevance, relevance for the problem and barriers and facilitators were only slightly amended. The intervention's GPRs and LM were reviewed in the context of Study 2 results and it was decided that no further amendments were required to either of them.

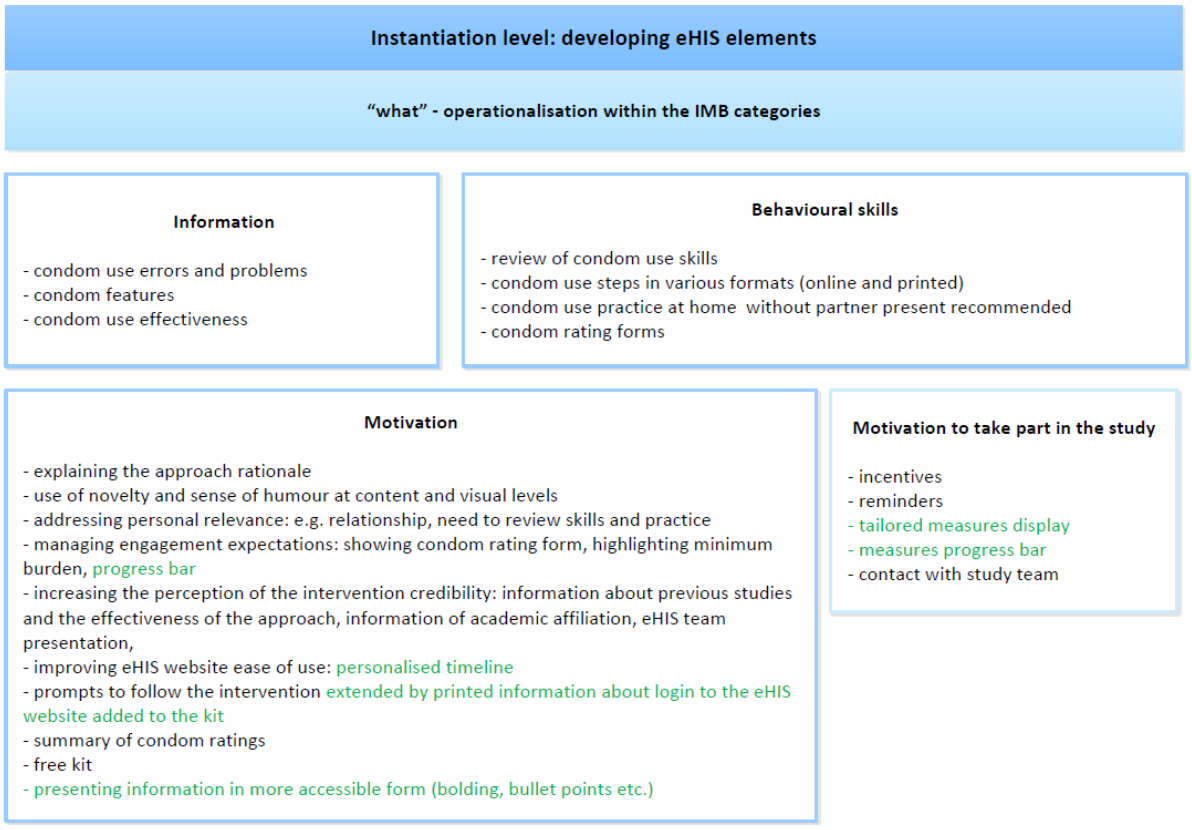
Similarly to Study 1, this study informed the intervention development at the content and design levels. The evaluation confirmed that most of the amendments introduced after the prototype evaluation (Study 1) were adequate as the improvement of participants' experience with the intervention was apparent. However, there were also a few aspects of the intervention which required further amendments e.g., the website design, ease of use of the skills review, general usability of the eHIS website, feasibility study procedure information, and wording and organisation of some of the measures. The participants' feedback on using facilitators such as novelty and humour as well as on simplified and more flexible content was positive. Amendments to the eHIS's operationalisation are presented in Figure 14.

A balanced approach was taken to deciding which amendments should be implemented to differentiate between the essential ones and the ones which related to personal preferences. Examples of amendments to the interventions made following Study 2 results included incorporating FAQ pages into other elements of the website or replacing the diagram with steps of the intervention with a personalised timeline displayed at each visit to the eHIS website. To ensure that the results of the evaluation were reviewed and implemented systematically, the same process as in developing the computerised version

of eHIS was used (see Appendix B). Examples of amended webpages are presented in Appendix A.

Figure 14

Changes at the operationalisation level following Study 2



Discussion of the Role of Qualitative Evaluation

Strengths of studies.

Users' perspectives. The biggest strength of these studies was that they provided insight into participants' experience with the intervention at various stages of its development, which proved to be invaluable in creating the eHIS version to be tested in the feasibility study (Chapter 5). This approach gave users an opportunity to have their input in creating the content, language, design and focus of the intervention (Lohan, Aventin, Oliffe, Han, & Bottorff, 2015; Yardley, Morrison, et al., 2015). Most importantly, it confirmed that the approach used in the intervention can be useful to address condom use problems

and allowed identifying the areas that were acceptable for participants, as well as the ones that required further development. It also highlighted how the content of the intervention can be made more acceptable and personally relevant. Study 2 results also allowed verification of the accuracy of changes made in response to feedback on the eHIS prototype.

Models of experience. The model of participants' experience allowed better understanding of the links between its various aspects. It also helped to link specific aspects of participants' experience to existing evidence and to models guiding online interventions development (Mohr et al., 2014; Ritterband et al., 2009) (see Chapter 2). This aided finding solutions to issues raised by the participants.

Comparison of models between both studies shed the light on the impact of changes introduced after evaluation of the intervention prototype and the impact of the format of the materials. Additionally, the findings may provide a point of reference for future studies indicating which aspects of users' experience should be taken into account in development and/or evaluation of behaviour change interventions.

Understanding the applications of theoretical constructs. The studies confirmed the relevance of the theoretical models chosen to guide eHIS development and accuracy of employing integrative approach to theoretical models (Reid & Aiken, 2011). The operationalisation of all of its constructs was accurate i.e., the participants adequately responded to information, motivational and skills development elements, and all of them were important in participants' overall experience with the intervention. Analysis of the experience allowed better understanding of the links between theoretical constructs and participants' experience. Factors derived from the CUE model (Sanders et al., 2012) that were important for participants' condom use experience such as previous condom use experience and condom beliefs were also identified as having impact on perception of the

intervention approach. The intervention LM was reviewed in the context of both studies' results.

Studies limitations.

Participants characteristics. Participants were mostly well educated, with an age range of 19 to 61 in Study 1 and 18 to 48 in Study 2. The education level makes the group less representative for the intervention's target audience. However, there is also a possibility that these groups may be representative for actual users. For example higher level of education has been related to more frequent Internet use for health information (Hardiker & Grant, 2011). It is also worth noting that men were found to be less willing to engage with online health sites than women (Sillence, Briggs, Harris, & Fishwick, 2007a), therefore, they may be generally a group more difficult to recruit. A high proportion of students in both studies can be also linked to convenience, familiarity with the campus and research itself being facilitators of participation.

The sample in Study 2 was less diverse in terms of age and occupational background. The less diverse sample could have also contributed to the experience of the participants being more consistent than in Study 1. For future studies it might be beneficial to reach a more varied group, especially engaging those with lower socio-economic status, using targeted recruitment and by highlighting the value of everyone's involvement (Freimuth & Mettger, 1990; Magnani, Sabin, Saidel, & Heckathorn, 2005; Thompson & Phillips, 2007). Due to limited resources this was not possible in the studies completed within the current project.

Interviewer's gender. It is possible that some of the participants would provide feedback differently had the interviewer been male. Interviewer's gender could also be the reason for some drop outs after initial contact or opting out from the condom use practice in Study 1. Having an option of choosing interviewer's gender when talking about a sex related topic, may reduce dropout rate (Catania et al., 1996). For that reason, the option of

having the interviews with a male interviewer should, if feasible, be considered in the future studies.

Methods of data collection. The methods employed allowed collection of rich informative data, collected in real-time while participants interacted with the intervention. However, the difficulties related to the TAIs reported in previous research (Cotton & Gresty, 2006) were also observed during the current study. Participants varied in the ease of providing spontaneous feedback, some of them finding it difficult. Using SSIs to complete the data gathered during TAIs was useful as some participants provided more feedback when guided by the questions.

Study procedure and materials. Another limitation relates to some weaknesses of the study procedure. In Study 1 one of the questions in the SSIs about opinions of the home practice guide seemed to be confusing for some participants and required further explanation. The practice during the session included in Study 1 did not seem to fit well with following the intervention's flow. That might be one of the reasons why most of the participants declined the practice option.

It was not possible to present the interactive features in the paper based prototype. Judgment of them relied mostly on participants' imagination of "how it would work" and often required additional clarification. Because of that, feedback on the skills review should be interpreted with caution. On the other hand stimuli materials in Study 2 directed participants' attention more towards the website features, which could potentially lead to lesser focus on the intervention content.

Conclusions

The studies showed the importance of users' perspectives in the intervention development. Participants' experience proved to be rich and extensive, raising awareness of the areas which might be important for future users of the intervention. Exploring users' perspectives provided knowledge about acceptance of eHIS, its approach, format, and

factors that may affect engagement with the intervention and contribute to its effectiveness. Analysis of participants' experience gave invaluable insight into the complexity of the links between its different aspects. Specific suggestions that can be used to make changes to improve future users' experience were equally important. They were often creative and reflected the unique individual perspective. The results of Studies 1 and 2 guided eHIS development from the prototype to the version used in the feasibility and preliminary effectiveness evaluation (Chapter 5).

The implications of these studies' results go beyond the current project. The findings help to assess the relevance of the theoretical models of behaviour determinants (Sanders et al., 2012), behaviour change (Annon, 1976; J. D. Fisher & Fisher, 1992) and development of online behaviour change interventions (Mohr et al., 2014; Ritterband et al., 2009), link their constructs to specific elements of the intervention and can be used in further development of these models. Proving the value of involving participants in developing behaviour change interventions provides supporting evidence for the PBA (Yardley, Morrison, et al., 2015).

The results may also provide context for evaluations of other online interventions, especially in the sexual health area, or contribute to research investigating various aspects of users' experience important for engagement with interventions and their effectiveness. Understanding of factors increasing participants' willingness to engage with the intervention and follow its approach may also be useful for clinical practice, by supporting practitioners in their efforts to enhance correct and pleasurable condom use.

Chapter 5

An Evaluation of Feasibility and Preliminary Effectiveness of eHIS (Study 3)

Chapter Introduction

The final study of the project is presented in this chapter. The method employed to evaluate the feasibility and preliminary effectiveness of eHIS is described. This is followed by presentation of the study results. The key findings include identification of groups of potential eHIS users and their interaction with the intervention, and identification of significant changes in condom use behaviour and related outcomes. New research areas identified during the results analysis are also discussed. The chapter closes with a discussion of the implications of the study's results, the study's strengths and limitations as well as suggestions for future research and further steps in the intervention's development.

Feasibility and Preliminary Effectiveness Evaluation[9]

Feasibility evaluation is an essential step in development of many eHealth interventions (D. J. Bowen et al., 2009; Haerens, Deforche, Vandelanotte, Maes, & De Bourdeaudhuij, 2007; M. J. Moore, Soderquist, & Werch, 2005; Vandelanotte & De Bourdeaudhuij, 2003). Evaluation of engagement, acceptability and an intervention's potential to change targeted behaviour and cognitions (preliminary effectiveness) can provide a "proof of concept" for approach proposed by a specific intervention (Bottorff et al., 2016; A. M. Bowen, Williams, Daniel, & Clayton, 2008; Yardley et al., 2011). To promote an intervention's implementation on a large scale it is necessary to ascertain whether the target group is willing to use it and understand how the intervention is used (Yardley et al., 2013). This can be achieved in a feasibility evaluation (Demment, Graham, & Olson, 2014; Leslie, Marshall, Owen, & Bauman, 2005).

[9] Part of Chapter 5 (pp. 197-211) was published as a journal article (Glowacka, Yardley, Stone, & Graham, 2018). 'Programme' changed to 'intervention' and present tense changed to past tense to maintain consistency across the thesis. Minor amendments made in the chapter.

According to the PBA (Yardley, Morrison, et al., 2015), as discussed in Chapter 2, understanding users' perspectives and their psychosocial context is essential in developing persuasive, feasible and relevant interventions. Highlighted by this approach, users' acceptance of the intervention is essential for it to be feasible. Users' satisfaction, perceived relevance and usefulness of an intervention are important aspects of users' experience therefore impacting its acceptance (M. J. Moore et al., 2005; Yardley, Morrison, et al., 2015).

The results of an exploratory evaluation may justify further intervention development and/or the need for conducting a large scale intervention effectiveness evaluation and provide valuable guidance regarding its optimal design (Cunningham, Humphreys, Kypri, & van Mierlo, 2006; Kwan, Faulkner, & Bray, 2013). Investigating an intervention evaluation approach allows assessment of whether the specific study design and approach employed for the intervention evaluation are appropriate. It also can help to review the choice of the intervention measures (Geense et al., 2016).

Aims and Objectives

This study aimed to evaluate the feasibility and the preliminary effectiveness of eHIS. Firstly, participants' engagement with the intervention and its acceptability (dimensions of feasibility, primary outcomes) as well as the potential of the intervention to change the targeted behaviour (preliminary effectiveness) were evaluated. Condom use related variables assessed in this study were: condom use consistency and frequency of sexual intercourse without a condom being used (primary outcomes), condom use errors and problems, condom use experience, condom use self-efficacy, condom use attitudes and condom fit and feel (secondary outcomes)[10].

The study did not target men based on characteristics such as sexual orientation or condom use history as it has not yet been established for whom eHIS may be most useful.

[10] Secondary outcomes: condom use problems, condom use experience, condom use self-efficacy, condom use attitudes and condom fit and feel, henceforth described as "condom use related outcomes".

Therefore, whether the intervention's feasibility and preliminary effectiveness were linked to participants' demographic characteristics, sexual history or previous condom use variables was 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 was investigated. Estimation of the effect size of observed changes to allow comparison of results between the current study and other studies evaluating FTF versions of the intervention was also an aim of the study.

Research questions. This study was guided by the following research questions:

1) *Was eHIS feasible?*

   1a) How did participants engage with the intervention?

2) *Was the engagement with the intervention linked to the demographic, sexual history or baseline condom use variables of the participants?*

3) *Was eHIS acceptable for participants?*

4) *Was the acceptability of the intervention linked to the demographic, sexual history or baseline condom use variables of the participants?*

5) *Did eHIS have potential to be effective in:*

   5a) increasing consistent condom use?

   5b) reducing the frequency of sexual intercourse without a condom being used?

   5c) improving condom use experience?

   5d) improving condom use self-efficacy?

   5e) reducing the number of condom use related errors and problems?

   5f) changing condom use attitudes to more positive ones?

6) *Was the preliminary effectiveness of the intervention in changing the condom use related outcome variables linked to demographic, sexual history or baseline condom use variables of the participants?*

7) *Was the approach to evaluate eHIS feasible?*

8) *Were enrolment to study, compliance and retention linked to demographic, sexual history or baseline condom use variables of the participants?*

Method

Study design. A pre-test post-test, within-subject study design was chosen as the most appropriate one to answer the research questions. This allowed verification the feasibility of the intervention delivered online and exploration of engagement with the intervention and its acceptability. It was also sufficient to assess the potential of the intervention to change specific condom use-related outcomes.

Recruitment. Participants meeting the inclusion criteria (Table 8) and who provided informed consent were recruited. Any individuals who would need specific intervention adjustments or third person support to access the website were not eligible to take part. This included persons: having a learning disability (Rotondi et al., 2007), and those with severe visual impairment (Krug, 2006). Special adjustment of the website format and content would be needed to accommodate their needs, which was beyond the scope of this project.

Recruitment for the study took place between December 2016 and May 2017. Participants were recruited in the UK only 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 – see Appendix AN). 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, community centres, youth organisations) and in social media (Facebook and Twitter). People from professional and personal networks were also asked to share the advertisements.

Table 8

Study 3 inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
gender: male; aged 18-69; fluent in English (written and spoken); have access to the Internet for the duration of the study; living in the UK	gender: other than male; below the age of 18 or aged 70 or above; not fluent in English (written and spoken); allergic or sensitive to latex, non-latex condoms and/or lubricants; 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

The target sample size to be recruited was estimated to be 140 based on the number of participants required to conduct statistical analysis to evaluate feasibility and preliminary effectiveness of the intervention (power calculation assuming α-level of .05, power of .8 and expected medium effect size (d = .5)) (J. Cohen, 1992), taking into account possible high dropout rate (in the region of 60%), more likely in self-guided intervention (Devineni & Blanchard, 2005; Eysenbach, 2005; Karyotaki et al., 2015; Leslie et al., 2005; Melville, Casey, & Kavanagh, 2010), study resources and numbers of participants recruited to similar studies (Ahmed, Roumani, Szucs, Zhang, & King, 2016; Bailey, Webster, et al., 2015; Emetu et al., 2014; Kendzor et al., 2016; Kwan et al., 2013; Milhausen et al., 2011; M. J. Moore et al., 2005; Santer et al., 2014; Vandelanotte & De Bourdeaudhuij, 2003).

Incentives. As a part of the intervention participants ordered the kit. After completion of each set of study measures (3 in total) participants had the choice to donate 50p to one of three charities (£1.50 total per participant). After completion of the third set of questionnaires (T3) they received a £5 Amazon voucher. Psychology students at the UoS had an option to claim up to 32 research participation credits.

Study procedure. Following the link or QR code from the advertisement participants were directed to the study website where they read the PIS (see Appendix AO). Participants indicated their consent for taking part in the study and for data they provide to be used for research and research dissemination purposes by ticking the box next to the consent statement (Appendix AP). They were reminded that they have a right to withdraw at any time without giving a reason. In the next step they completed eligibility screening (Appendix AQ) and if eligible, they were directed to the study registration page and then to T1 measures (Table 9). If they were ineligible to take part, they were thanked for their interest in the study.

Participants were given access to the core eHIS website immediately and were able to order the kit while on the website. The kit was sent to them within 3 working days from placing the order. They had 4 weeks, counting from the date they completed T1 measures, ("start point" henceforth) to practise condom use at home and complete condom rating forms (Appendix AR). Four weeks from the start point the website was no longer available to participants. They were asked to complete T2 measures (Table 9) and were able to make a charity donation. Ten weeks after the start point they were asked to complete the final T3 measures (Table 9). After this they were able to make a charity donation, were directed to the Debriefing Sheet (Appendix AS) and received a £5 Amazon voucher. The study procedure is presented in Figure 15. Ethical approval from the Psychology Ethics Committee at the UoS was obtained. The study was registered in the Research Registry, Unique Identifying Number researchregistry2325.

During the study participants received one e-mail reminder and one optional text reminder on the day T2 and T3 measures were due to be completed. They also received 2 condom ratings e-mails and optional text reminders per week for the duration of home practice (weeks 2, 3 and 4). The condom rating reminders were automatically cancelled for the particular week if at least one rating was completed; all reminders were automatically

cancelled if at least 4 ratings were completed. Participants had the option to cancel e-mails and/or text messages when they visited the intervention's website.

Data collection. Questionnaires and website usage data were used to collect data. The questionnaires were chosen to mirror as closely as possible the measures used in the FTF KIHIS (Emetu et al., 2014; Milhausen et al., 2011) and HIS-UK (Stone et al., 2017) studies. They were reviewed and modified as informed by the feedback received in the qualitative evaluation of the intervention during its development phase (Chapter 4, Study 2). Additional measures/items were chosen or developed for this study to allow investigation of the aspects of the intervention related to its specific mode of delivery. The data collection schedule is presented in Table 9.

Figure 15

Study 3 procedure

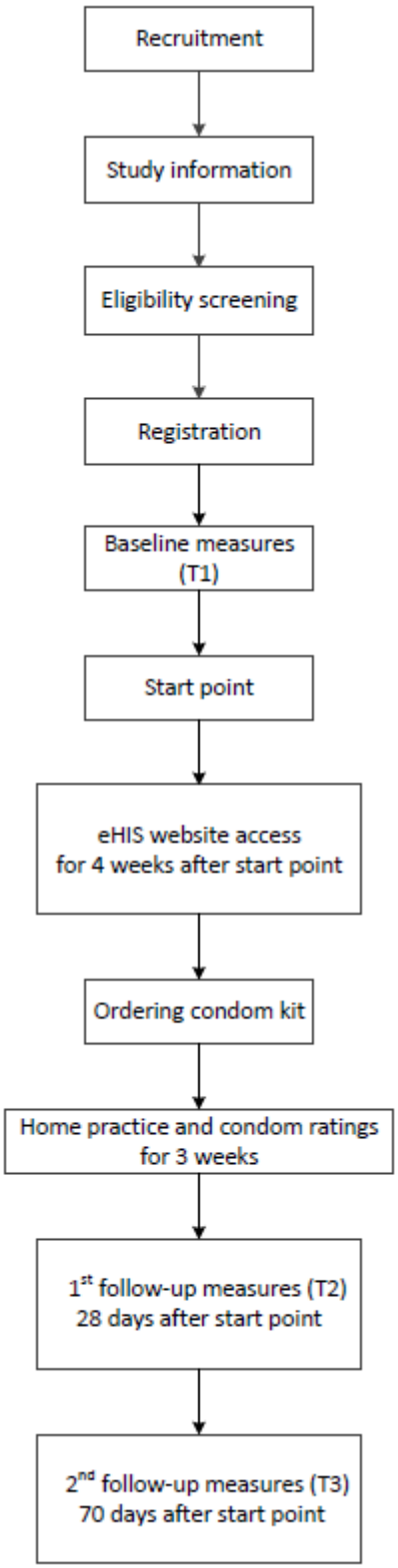


Table 9

Study 3 measures (Glowacka et al., 2018)

T1	T2	T3
Eligibility screening questionnaire Study registration Motivation to take part in the study Recruitment information Background information Sexual history		
STIs and unplanned pregnancy[a] Condom use and sexual activity[b] Effect on Sexual Experience subscale from Condom Barriers Scale[c] Correct Condom Use Self-Efficacy Scale (CCUSS) Condom Use Errors and Problems Survey (M-CUES)[c] Condom Fit and Feel Scale[d] 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 were collected throughout the period when the website was available to the participants.		

Note. [a]at T1 questions were 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 practised using condoms over the last 4 weeks

Eligibility screening questionnaire. The screening questionnaire included questions assessing the inclusion/exclusion criteria (Table 8).

Study registration. Following screening eligible participants were asked to provide an e-mail address that the study reminders were sent to and an optional phone number if they also preferred to receive text messages with study reminders.

Background information. Participants provided 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 (Office for National Statistics, 2016).

Sexual history. Participants were asked about their current sexual activity (they could 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 could choose one of the options: "Women", "Men", "Women and men", "I have never had sex") (Badgett, 2009) and number of sexual partners so far.

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

Condom use and sexual activity. To assess the consistency of condom use[11] and frequency of sexual intercourse without a condom, participants were 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. They were also asked whether they practised using condoms in the last four weeks. Participants provided reasons for using condoms (they could 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 practise", "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 were asked whether they had been taught how to use condoms, and if so, where they had learnt 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)", "practising how to use condoms correctly instructed by somebody else (i.e. during sex

[11] "Consistency of condom use was calculated as the percentage of time that a participant used a condom (…) (number of times a condom was used divided by the number of times he had [sexual intercourse], then multiplied by 100)". (Emetu et al., 2014, p. 120)

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 practised using them without a partner present.

Condom use experience. This questionnaire was only displayed to those who reported that they had used condoms during sexual intercourse over the last 4 weeks. The Effect on Sexual Experience subscale from the Condom Barriers Scale (Doyle et al., 2009; St. Lawrence et al., 1999) is a seven-item scale which measures participants' condom use experience 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, with $\alpha = .74$ (Milhausen et al., 2011) and $\alpha = .81$ (Emetu et al., 2014).

Condom attitudes. Five items chosen from the Multidimensional Condom Attitudes Scale (MCAS) (Helweg-Larsen & Collins, 1994), focusing on pleasure associated with condoms, were used to assess attitudes toward condoms (Emetu et al., 2014). 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 reverse scored). An option of "neither agree nor disagree" for item number (4) was added because of participants' feedback in the qualitative study evaluation the eHIS website (Chapter 4, Study 2). The subscale showed good reliability in a previous study evaluating the KIHIS intervention (Emetu et al., 2014), with $\alpha = .81$.

Condom use self-efficacy. Participants' perception of their condom use ability (e.g., finding condoms that fit properly, keeping condoms from drying out during sex) was measured by seven items adapted from the Correct Condom Use Self-Efficacy Scale (CCUSS) (Crosby, Graham, Milhausen, Sanders, & Yarber, 2011b; Milhausen et al., 2011). 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 (Crosby, Salazar, et al., 2008). This scale was demonstrated to have good internal reliability in previous studies: α = .72 (Milhausen et al., 2011), α = .70 (Crosby, Salazar, et al., 2008).

Condom use errors and problems. The survey was only displayed to those who reported that they had used condoms during sexual intercourse over the last 4 weeks. The 17-item Condom Use Errors/Problems Survey (M-CUES) (Crosby et al., 2011a) assesses condom use errors and problems experienced during the last condom-protected sexual event. Respondents were 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 were calculated, with higher scores indicating more condom use errors and problems. The M-CUES has good face and content validity (Crosby et al., 2011a).

The M-CUES was modified in line with feedback received from participants in Study 2 (Chapter 4) and from materials developed for the HIS-UK feasibility study (Stone et al., 2017). The form of the questionnaire was simplified, as were the scale instruction and item wording. An item asking about checking a condom's expiry date was added to the scale. 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. (Reece, Herbenick, & Dodge, 2011). This 14-item scale was only displayed to those who reported that they had used condoms during sexual intercourse or practised condom use over the last 4 weeks. 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 applies to me) with some items being reverse scored. An overall score is obtained; higher scores indicate more negative experiences with condom fit and feel. Satisfactory scale validity and reliability were demonstrated previously α = 0.60–0.86 (Reece et al., 2007).

Condom rating form. Participants were asked to complete this form after each condom use practice. In the first part of the form they gave information about which condom they used during a practice session and whether they had used it before. They indicated what type of sexual activity the condom was used for, whether they ejaculated while wearing a condom, and whether they stopped testing a condom. In the second part of the rating form participants rated condoms on different aspects of fit and feel. They were also asked about the use of lubricant and their preference for using the particular condom in the future. Participants were expected to complete at least 6 condom rating forms; a maximum of 15 ratings could be completed across the time when participants had access to the intervention's website. The condom rating form was adapted from materials used in other studies evaluating the FTF version of the intervention (Emetu et al., 2014; Milhausen et al., 2011; Stone et al., 2017) and modified in line with feedback received in the qualitative evaluation of the intervention's computerised version (Chapter 4, Study 2).

eHIS Evaluation Survey. This survey assessed the acceptability of the intervention's content and format. The survey was developed for this study to explore participants' opinions about the intervention and its website. A literature search of previous studies using questionnaires to evaluate eHealth interventions, treatment preferences, and measures used to evaluate websites' content and usability (Chiew & Salim, 2003; Elling, Lentz, de Jong, & van den Bergh, 2012; Haerens et al., 2007; P. Kim, Eng, Deering, & Maxfield, 1999; Miranda et al., 2013; Sidani, Epstein, Bootzin, Moritz, & Miranda, 2009; Spittaels, De Bourdeaudhuij, & Vandelanotte, 2007; Stoyanov et al., 2015; Tsai & Chai, 2005; Vandelanotte & De Bourdeaudhuij, 2003), as well as the themes identified in the qualitative phase of the eHIS website development (Chapter 4), were used to define key categories and guided items development.

The 24-item survey (Appendix AT) assesses agreement or disagreement (from strongly disagree to strongly agree) with statements related to relevance of the intervention 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 intervention 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 intervention's content and design in open text entry questions, as well as to 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. In three questions participants were 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"), as well as 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 were used to assess the intervention completeness and credibility (dimensions of acceptability).

Engagement. Website usage data were used as a measure of participants' engagement with the intervention (Arden-Close et al., 2015; Bailey, Webster, et al., 2015; Kwan et al., 2013; Leslie et al., 2005). eHIS logs were used to analyse participants' activities e.g., number of visits and specific pages seen by participants.

Whether participants ordered the kit and the number of completed condom rating forms were used as measures of engagement with the intervention alongside participants' self-reports on the specific items in the eHIS evaluation survey.

The feasibility of the study evaluation approach was 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 were asked how they heard about the

study, what their reasons to take part were (a multiple choice question) and whether they had taken part in any study in the intervention's development stage. Measures' acceptance was assessed on the basis of proportion of participants completing specific scales and providing answers to their specific items. Attrition was assessed on the basis of the completion rate of baseline and follow-up questionnaires.

Data Analysis

Feasibility of the intervention and the evaluation approach were assessed through the analysis of engagement with the intervention, its acceptability, recruitment and retention rates. Before the analysis was performed the full data was cleaned. The answers about sexual activity, number of partners, and ever having sexual intercourse were checked for consistency (between "not active", "no intercourse" and "no partners" answers). At the analysis stage it appeared to be difficult to draw conclusions about the type of the relationship participants were in. Although the question was designed for only one answer to be chosen, after further consideration it was decided that the answers were not necessarily exclusive and could lead to inaccurate representation of the participants' relationship status. It was also found that the answers to questions about STIs diagnosis and pregnancy in the lifetime and in the last year could overlap, therefore only lifetime ones were included in the analysis. Some outcome variables were calculated by combining the data (for example, condom use consistency, see p. 206) or by calculating variables on the basis of the eHIS website usage logs (for example visits to optional pages, see p. 210).

The scales and indexes scores were calculated and missing values were computed on the basis of the participant's scale mean if no more than one item of data was missing (Hawthorne, Hawthorne, & Elliott, 2005; Shrive, Stuart, Quan, & Ghali, 2006). Cronbach's alphas were calculated for all standardised scales and in Fit and Feel Scale (Reece et al., 2011) one item was removed to improve the scale reliability score. All scales showed good reliability (see Table 10).

Table 10

Study 3 Cronbach's α for standardised scales

Scale	Cronbach's α
Effect on Sexual Experience subscale from Condom Barriers Scale	0.81
Correct Condom Use Self-Efficacy Scale (CCUSS)	0.77
Condom Fit and Feel Scale[a]	0.82
Multidimensional Condom Attitudes Scale (MCAS) (selected 5 items)	0.85

Note. [a]item 4 excluded

The assumption of normal distribution for continuous variables was assessed using the analysis of skewness, kurtosis, Kolmogorov-Smirnoff test, Shapiro-Wilk test, visual inspection of histograms, q-q plots and mean and median comparison (Field, 2009) to decide whether parametric tests could be used for their analysis. When data were non-normally distributed non-parametric data was transformed by removing outliers or computing square root transformations where possible. When this was ineffective an exploratory analysis was performed to decide whether transforming data into categorical variables was a viable option.

After a series of exploratory analyses based on a planned analysis a detailed analysis schedule was developed (Appendix AU). Descriptive statistics (T1) were used to describe the characteristics of the sample in the following categories: demographic, sexual activity, sexual health and unplanned pregnancy, condom use experience, recent sexual behaviour, recent condom use, condom use errors and problems, and condom use related cognitions. Descriptive statistics were also used to present participants' engagement with eHIS, their study participation, and to summarise the evaluation survey results. The variables that showed the same value across all of the participants were included in the descriptive analysis only (for example, no one reported having ever been diagnosed with HIV).

Categorical data were assessed for the frequencies within categories and exploratory analysis was performed to assess whether the numbers in specific categories were sufficient to perform further statistical analysis. Where the numbers were not sufficient the option of merging the categories for further analysis was explored and if this was not possible, the variables were only included in the descriptive analysis.

The preliminary effectiveness of the intervention was assessed through evaluation of the change on primary and secondary condom use related outcomes using paired t-tests for T1-T2 and T1-T3 comparison and repeated measures ANOVAs for T1-T2-T3 comparison for parametric data, and Friedman's ANOVA and Wilcoxon signed-ranks test for non-parametric data.

Within-group comparisons were undertaken to assess whether there were differences between specific subgroups defined in the context of recruitment, measures completion, engagement with the intervention and a range of relevant participants' characteristics where sufficient data was available. The potential associations between outcome variables and participants' characteristics were explored using appropriate tests: t-tests for correlation between binomial and parametric variables, chi square tests for categorical variables, Mann-Whitney tests for investigation of correlation between non-parametric continuous and binomial variables, Kruskal-Wallis tests for association between non-parametric and multinomial variables, and Kendall's tau-b for correlation between continuous non-parametric variables.

Assumptions for the tests were checked before making decisions on the results' significance. Results close to significance were reviewed for the direction of association or change. The results of the preliminary effectiveness were used to calculate the effect size of changes in condom use related outcomes. SPSS software v.24.0 (IBM Corp., 2012) and Microsoft Excel 2010 were used for data analysis.

Results

Participants. There were 139 accounts registered. Three were duplicate accounts and were dropped from the analysis, resulting in 136 completed baseline measures. Full participant characteristics are presented in Table 11.

Demographic characteristics. Two thirds of participants were in the 18-25 age group. They were predominantly White British (74.3%, *n* = 101). Participants were recruited from across the UK (see Figure 16), with the majority from the Southampton and London areas.

Participants were well educated with most having completed A-levels (36.8%, *n* = 50) or a degree (22.1%, *n* = 30). Almost half were employed and a third was in education. Over two thirds of participants declared that they were in a relationship (69.1%, n = 94). All but two declared that they were competent computer users. Six participants had taken part in the studies at the development stages of the intervention (Chapter 4).

Sexual activity. At baseline over half of the sample reported having one current sexual partner. The same proportion (13.3%, *n* = 18) chose the options of "frequent different sexual partners" and "not sexually active". The average number of lifetime sexual partners was *M* = 2.61, *SD* = 59.61, range 0-500 (*n* = 110) and almost two-thirds of the men were heterosexual. Among those who reported to have sexual intercourse in the last 4 weeks (*n* = 104), they had on average 10.66 intercourse events (*SD* = 9.57, range 1-46). Details of participants' sexual activity are presented in Table 12.

Figure 16

Geographical locations of the participants (in green) described by postcode area

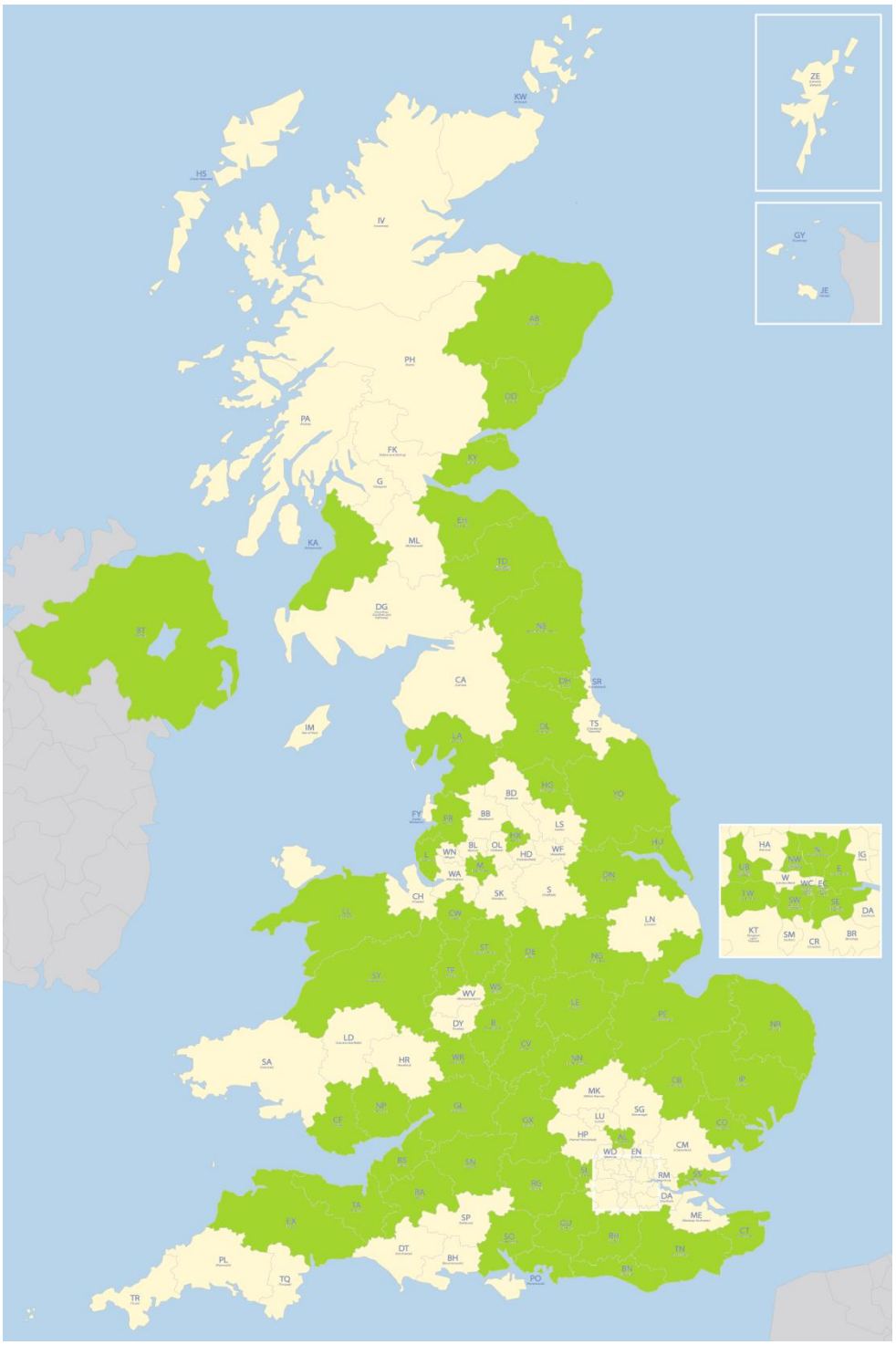


Image by Maximilian Dörrbecker/Wikipedia. Licence: cc-by-sa-3.0.
(Modified for the purpose of presenting data.)

Table 11

Sample characteristics – demographic (T1)

		n	%
Age (136)	18-25	90	66.2%
	26-35	26	19.1%
	36-45	19	14%
	46-55	1	0.7%
Ethnic background (136)	White British	101	74.3%
	White other	17	12.5%
	Indian, Any other Mixed/Multiple background	6	4.4%
	Chinese	5	3.7%
	White Black Caribbean, White and Black African, Any other Black background, Arab, Any other ethnic group	5	3.7%
	White and Asian	2	1.5%
Education (136)	GCSE	27	19.9%
	A-levels	50	36.8%
	Degree	30	22.1%
	Postgraduate Degree	20	14.7%
	Other	9	6.6%
Employment (136)[a]	Not employed	17	12.5%
	Employed/self-employed	66	48.5%
	Student/in education	47	34.6%
	Apprenticeship	6	4.4%
	Other	4	2.9%
Currently in a relationship (136)	Yes	94	69.1%
	No	42	30.9%
Relationship type (96)	Living together	27	28.1%
	Living apart	41	42.7%
	Married/civil relationship	14	14.6%
	Steady partner	12	12.5%
	Other	2	2.1%
Computer competent (135)	Yes	133	98.5%
	No	2	1.5%
Took part in the previous studies at the development stage of the programme? (134)	Yes	6	4.5%
	No	128	95.5 %

Note. [a]Some participants chose more than one category.

Table 12

Sample characteristics – sexual activity (T1)

		n	%
Current sexual activity (135)	One partner only	80	59.3%
	Frequent different	18	13.3%
	Infrequent different	7	5.2%
	Occasional	12	8.9%
	Not sexually active at the moment	18	13.3%
Sexual orientation (134)	Women	87	64.9%
	Men	21	15.7%
	Women and men	15	11.2%
	never had sex	11	8.2%
Number of partners so far (110)[a]	none	6	5.5%
	one	12	10.9%
	Some (2 -12)	58	52.7%
	Many (13-500)	34	30.9%

Note. [a]'some' and 'many' categories divided on the basis of average number of men's partners as in NATSAL 2013 (Mercer et al., 2013). Range was 0-500, *M* = 2.61 (*SD* = 59.61).

Sexual health and unplanned pregnancy. At baseline 11.1% (15 out of 135) reported that they have ever been diagnosed with STI, and 19.3% (*n* = 26) of participants had experience of unplanned pregnancy. None of the participants at baseline reported being ever diagnosed with HIV (*n* = 132).[12]

Condom use experience at baseline. Two-thirds of participants declared that they were taught how to use condoms. The most common method was a leaflet in a condom box reported by 45.5% (*n* = 60) followed by practice reported by 42.4% (*n* = 56). Majority of the participants used condoms with a partner (88.1%, *n* = 119). Slightly above 70% of participants (*n* = 94) have already practised using condoms without a partner. For full details see Table 13.

[12] None of the participants reported STI or HIV diagnosis or unplanned pregnancy at T2 or T3.

Table 13

Condom use experience (T1)

		n	%
Have you ever been taught how to use condoms? (132)	No	45	34.1%
	Yes	87	65.9%
Did you learn how to use condoms from … (132)	Leaflet in condom box	60	45.5%
	Leaflet given	14	10.6%
	Demo video	32	24.2%
	Demo live	27	20.5%
	Practice	56	42.4%
	Movie	20	15.2%
	Magazine	1	0.8%
	Not learnt	12	9.1%
Have you ever used condoms with a partner? (135)	No	16	11.9%
	Yes	119	88.1%
Have you ever practised using a condom (on yourself) without a partner? (134)	No	40	29.9%
	Yes	94	70.1%

Table 14 presents sexual activity and condom use in the last 4 weeks. Amongst those who declared to have sexual intercourse in that period (n = 104) different patterns of using condoms were reported from never using condoms (29.13%, n = 30) to using them always (22.33%, n = 23). The frequency of sexual intercourse without condoms at T1 was M = 5.62 (SD = 7.39, range 0 - 40, n = 103), and they were used mainly to prevent unplanned pregnancy (39.7%, n = 48). Only 11.7% (n = 15) of participants practised using condoms without a partner in the last 4 weeks.

Table 14

Sexual activity and condom use in the last 4 weeks (T1, T2, T3)

Outcomes			T1		T2		T3
		n		*n*		*n*	
Number of partners in the last 4 weeks		124	*M* = 1.23, *SD* = 1.04, range 0-6	35	*M* = 0.97, *SD* = 1.01, range 0-5	30	*M* = 1.13, *SD* = 1.38, range 0-7
Condoms use consistency in last 4 weeks [a]		103	*M* = 46.94, *SD* = 39.92, range 0-100	26	*M* = 57.84, *SD* = 39.78, range 0-100	21	*M* = 58.79, *SD* = 43.68, range 0-100
	Never	30	29.13%	6	23.08%	5	23.8%
	Infrequent – less likely (0.01 – 50 %)	29	28.16%	5	19.23%	4	19.05%
	Infrequent – more likely (50.01 – 99.9%)	21	20.39 %	7	26.92%	4	19.05%
	Always (100%)	23	22.33%	8	30.77%	8	38.1%
Frequency of sex without condoms in the last 4 weeks[b]		103	*M* = 5.62, *SD* = 7.39, range 0-40	26	*M* = 4.12, *SD* = 5.3, range 0-20	21	*M* = 3.76, *SD* = 6.5, range 0-28
	None (0)	23	22.3%	8	30.8%	8	38.1%
	Some[c] (1-4)	46	44.7 %	10	38.8%	7	33.3%
	Many (5 or more)	34	33%	8	30.8%	6	28.6%
Did you practise using condoms on your own in the past 4 weeks?		128	No 88.3% (113) Yes 11.7% (15)	35	No 20% (7) Yes 80% (28)	30	No 70% (21) Yes 30% (9)
In the past 4 weeks, why did you use condoms? (121 at T1, 36 at T2, 30 at T3)	Avoid STIs	28	23.1%	10	27.8%	30	26.7%
	Avoid HIV	20	16.5%	9	25%	6	20%
	Please partner	9	7.4%	3	8.3%	4	13.3%

	Sex more pleasurable	8	6.6%	2	5.6%	1	3.3%
	Sex last longer	12	9.9%	4	11.1%	1	3.3%
	Pregnancy	48	39.7%	10	27.8%	9	30%
	Practice	5	4.1%	18	50%	4	13.3%
	other	6	5%	6	16.7%	1	3.3%
	Not used	42	34.7%	3	8.3%	12	40%
Types of condoms used in the last 4 weeks	Latex	63	51.6%	29	80.6%	19	63.3%
(122 at T1, 36 at T2, 30 at T3)	Non-latex	12	9.8%	16	44.4%	8	26.7%
	Don't know	23	18.9%	4	11.1%	2	6.7%

[a]Those who did not give answers and those who answered they did not have sex were excluded from consistency of using condoms calculations. Groups divided at 50% as in HIS-UK (Stone et al., 2017). [b]Those who did not give answers and those who answered they did not have sex were excluded from frequency of sex without condom calculation.
[c]Groups defined on the basis of median score (5) at T1.

Feasibility of the study.

Recruitment. Social media recruitment was the most effective, indicated by over two-thirds as the place where they have seen the study advert, with Facebook being the most frequently chosen (65.4%, *n* = 89) in comparison to Twitter (5.9%, *n* = 8) (for details see Table 15). Those educated to GCSE level were less likely to respond to advertisements other than social media; 11.1% in comparison to 39.6% for those educated to A-level or 36% of educated to a degree level (χ^2 (2) = 7.050, *p* = .029, *n* = 125). On the other hand those from Black Asian and Minority Ethnic (BAME), were more likely to respond to adverts other than social media; 58.8 % in comparison to 24.2 % White British and White other 38.9% (χ^2 (2) = 8.844, *p* = .012, *n* = 134). Similar association was found for students responding more likely to adverts from sources other than social media (48.9%) in comparison to non-students (20.7%), χ^2 (1) = 11.465, *p* = .001, *n* = 134. Leaflets and business cards were the least frequently reported to be the source of information about the study. The workplace was the least likely place to see study advertisements.

Motivation for participation. Fun and receiving condoms were the main reasons given for participating in the study (63.2%, *n* = 86 and 62.5%, *n* = 85, respectively), followed closely by curiosity (59.6%, *n* = 81). Less than half of participants were motivated to take part in the study to enjoy using condoms more (44.9%, *n* = 61), or learn how to use condoms (41.9%, *n* = 57). 37.5% of participants (*n* = 51) wanted to improve their condom use experience. Donation to charity and receiving a voucher were indicated by almost a third of participants each (29.4%, *n* = 40) as one of the motivations to take part in the study. Searching for help with condom use problems was the least frequently chosen option (19.1%, *n* = 26).

Table 15

Recruitment approach

		n	%
Type of advert they responded to (134)	Poster	10	7.5%
	Leaflet	1	0.7 %
	Business card	2	1.5%
	Social media post	42	31.3%
	Social media ad	51	38.1%
	Email	12	9%
	Word of mouth	10	7.5%
	other (most through UoS, Part One Orders)	6	4.5%
Where adverts were seen? (134)	University	20	14.7%
	Facebook	89	65.4%
	Twitter	8	5.9%
	Other social media, Workplace	2	1.5%
	Mailing list	8	5.9%
	other (friends, word of mouth, partner, housemate, WhatsApp message post, UoS)	5	3.7%

Some types of motivation to take part in the study were found to be significantly associated with participants' characteristics. For example participants aged 18-25 were significantly more likely to choose fun as motivation to take part in the study than older participants (χ^2 (1) = 5.238, p = .022, n = 136). Improving condom use skills was found to be significantly more likely motivation for those who were not sexually active (χ^2 (2) = 7.045, p = .030, n = 135), have never used condom with a partner (χ^2 (1) = 7.407, p = .006, n = 135), have lower self-efficacy (t(133) = 3.124, p = .002, 95% CI [1.01, 4.49], n = 135) or higher fit and feel scores (t(112) = -2.801, p = .006, 95% CI [-5.44, 6-.93], n = 114) at baseline. Higher number of errors (U = 614.00, z = -2.198, p = .028, r = .21, n = 109), higher fit and feel score (t(112) = -3.065, p = .003, 95% CI [-7.02, -1.51], n = 114) and lower self-efficacy score (t(133) = 3.978, p = .000, 95% CI [2.15, 6.41], n = 135) were all significantly associated with seeking help with condom use problems indicated as

motivation to take part in the study. The full list of significant associations between participants' characteristics and type of motivation are presented in Appendix AV.

Incentives. On majority of occasions (95%, *n* = 192) participants chose a charity to make donation after completing study measures. The most popular charity was Movember Foundation with 132 donations, followed by Brook (36 donations) and NoLimits (24 donations). Eleven participants picked the option to receive study credits if they were Psychology students at the UoS at the registration stage.

Retention. Thirty-six participants (26.47%) completed T2 measures and 30 (22.06%) completed T3 measures. In comparison with participants who completed baseline, those educated to GCSE level were significantly less likely to complete follow-up measures (14.8%) than those educated to degree (32%) or A-levels (46%), χ^2 (2) = 7.741, *p* = .021, n = 127. Those participants who were motivated to take part in the study by voucher were twice as likely to complete follow-up measures (50%), than those who did not indicate this motivation (25%), χ^2 (1) = 8.063, *p* = .005, *n* = 136. Those who responded to study advertisements other than social media were significantly more likely to complete follow-up measures (46.3%) than those recruited through social media (26.9%), χ^2 (1) = 4.886, *p* = .027, *n* = 134. Post hoc analysis showed that participants who were more engaged with the intervention were significantly more likely to complete follow-up measures (see Table 16).

Table 16

Significant associations between engagement and completing follow-ups

Engagement variable	*n*	*U*	*z*	*p*	*r*
Number of completed ratings	71	282.5	-3.898	.000	-.46
All visits to eHIS (not registration)	136	475.5	-7.592	.000	-.65
Number of return visits to eHIS	136	403.5	-8.012	.000	-.69

Note. Mann-Whitney test

Measures completion. Although, other than screening questions, none of the measures were compulsory, most of the questions had at least 97% responses rate. The question with lower response rate was the question about the number of sexual partners in a lifetime answered by 89.4% of participants who declared that they had sex before (*n* = 123). However, the questions about recent sexual activity were answered in almost 100% (single responses missing) by those who completed T2 and T3 measures.

eHIS feasibility - participants' engagement with the intervention.

Intervention visits. There were 326 visits to the eHIS website during the study. Most of them were to see core pages only (103 visits) and rating pages only (100 visits). There were also 68 visits in which participants saw at least one rating and one optional page accessed from "Main menu" at return visit. Details of number of eHIS visits are presented in Table 17.

Table 17

Visits to the eHIS website

	Number of visits	Number of participants
All visits	326	136
Visits to the core pages only	106	105
Visits to core and at least one optional page in the core part	32	31
Return visits after reaching final intervention page during previous session, including (see rows below):	185	77
Visits in which only condom ratings page was seen	100	55
Visits in which only optional page from Main Menu was seen	11	8
Visits in which at least one optional page and at least one rating page were seen	68	45
Visits in which only Main Menu was seen but not other pages visited	6	6

Participants who chose voucher as motivation to take part in the study were also significantly more likely to visit eHIS more frequently, $U = 1475.00$, $z = -2.240$, $p = .025$, $r = -.19$, $n = 136$. The general trend was that having less or no sexual and/or condom use experience was significantly associated with more frequent visits to the eHIS website. Also

those who had lower level of educational attainment (educated to GCSE level) ($H(2) = 6.951$, $p = .031$, $r = .22$, $n = 127$) or were not in employment or education ($U = 701.00$, $z = -2.153$, $p = .031$, $r = -.18$, $n = 136$), visited the website less frequently. Significant associations between participants' characteristics and frequency of eHIS visits are presented in Table 18.

Table 18

Participants' characteristics significantly associated with number of all visits to the website

	n	*H*/*U*/ τ	*z*	*p*	*r*	More/less frequent visits
Not being sexually active [a]	135	$H(2) = 6.078$		.042	.19	more
Never having sex before [b]	134	$U = 407.50$	-2.298	.021	-.20	more
Not using condoms before [b]	135	$U = 574.00$	-2.709	.006	-.23	more
Educated to GCSE level [a]	127	$H(2) = 6.951$		.031	.22	less
Unemployed and not students [b]	136	$U = 701.00$	-2.153	.031	-.18	less
Taught how to use condoms before [b]	132	$U = 1487.50$	-2.378	.017	-.21	less
Experience of unplanned pregnancy [b]	135	$U = 1018.00$	-2.348	.019	.20	less
More lifetime partners [c]	110	$\tau = -.177$		.016	.27	less
Higher condom fit and feel score [c]	114	$\tau = -.149$		.040	.23	less

Note. [a]Kruskal-Wallis test. [b] Mann-Whitney test. [c]Kendall's tau.

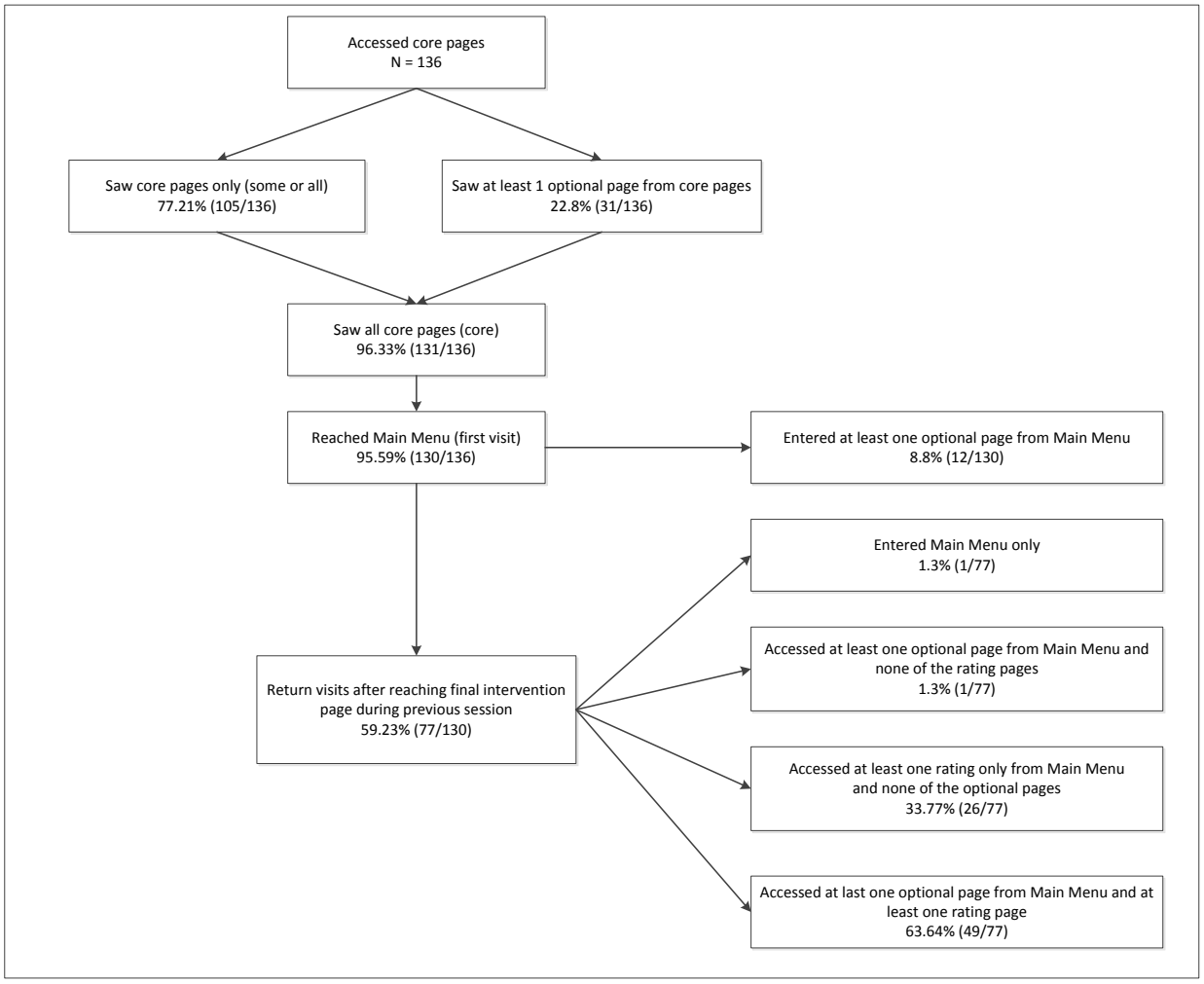
All participants who completed the baseline accessed the first page of the intervention and 96.3% ($n = 131$) saw all of the core pages. The participants' flow throughout the intervention is presented in Figure 17. Participants did not access optional pages very often; however, some of the pages gained more interest than others. The optional pages most frequently accessed from core pages were information about condom ratings and fit and feel problems (visited 11 times by 11 participants each). Other frequently visited optional pages were: condom use steps (9 visits by 9 participants), practice during masturbation (8 visits by 8 participants), relationship (6 visits by 6 participants) and problems with arousal whilst using condoms (6 visits by 6 participants).

Accessing optional pages from “Main menu” in the first visit participants were mostly interested in information about what to do if anything goes wrong (5 visits by 5 participants), practice instructions and the study information menu, both seen 4 times by 4 participants each. Over a third of participants visited only condom rating page(s) at subsequent visits. The rating summary page was visited 57 times by 41 participants. During return visits participants most frequently visited menu page for condom use problems (visited 10 times by 9 participants), and the menu for study information (visited 11 times by 10 participants). Other pages seen frequently during return visits included: practice instructions (8 visits by 7 participants) and reasons for practice (7 visits by 6 participants).

Participants who were significantly more likely to see at least one optional page at any stage of the intervention were: not sexually active (χ^2 (2) = 7.743, p = .021, n = 135), never used condoms before (χ^2 (1) = 9.532, p = .002, n = 135), had significantly fewer partners in their lifetime (U = 994, z = -2.981, p = .003, r = -.28, n = 110), had some sexual intercourse without condoms (χ^2 (2) = 6.562, p = .038, n = 103). Participants who were significantly less likely to see at least one optional page were educated to the GCSE level (χ^2 (2) = 7.158, p = .028, n = 127) or had experience of unplanned pregnancy (χ^2 (1) = 6.355, p = .012, n = 135).

Figure 17

Flow chart of participants' visits to the eHIS website



Intervention compliance - practising condom use. Of 136 participants recruited, 130 ordered the kit. Out of all who ordered the kit, 71 (54.61%) completed at least one condom rating. There were 286 ratings completed in total (M = 4.03, SD = 2.18, range 1 – 11). All the condoms were tried similar number of times (45 – 50). Out of 285 practices lubricant was used in 50.89% (145). There was only one case when condom other than the ones included in the kit was used. The numbers of completed condom ratings are presented in Table 19.

Table 19

All completed condom rating forms (n = 136)

Number of all ratings completed	Number of participants	%
1	71	54.61%
2	58	44.61%
3	53	40.77 %
4	40	30.77%
5	28	21.54%
6	25	19.23%
7	5	3.85%
8	3	2.3%
11	1	0.74%

There was no notable change in the number of participants completing the ratings after reaching the rating summary point (3rd rating). 28% (*n* = 20) of all participants who completed the ratings completed maximum 6 of them. This was followed by 18.31% (*n* = 13) and 16.9% (*n* = 12) who completed three and four ratings respectively. Table 20 presents summary of maximum number of ratings completed.

Table 20

Maximum number of completed condom rating forms (n = 71)

Maximum number of ratings completed	Number of participants	%
1	13	18.31%
2	5	7.04%
3	13	18.31%
4	12	16.90%
5	3	4.23%
6	20	28%
7	2	2.82%
8	2	2.82%
11	1	1.41%

Characteristics of participants significantly associated with completing at least one rating included: never having sex before (χ^2 (1) = 4.202, p = .040, n = 134), never using condoms before (χ^2 (1) = 5.979, p = .014, n = 135) or having significantly fewer lifetime partners (*Mdn* = 4) than those who did not complete any ratings (*Mdn* = 8.50), U = 1060.50, z = -2.685, p = .007, r = -.26, n = 110. Participants who were neither employed nor students were more likely not to complete any condom rating (χ^2 (1) = 6.403, p = .011, n = 136). Those who chose voucher as motivation to take part in the study were more likely to complete at least one rating (χ^2 (1) = 5.312, p = .021, n = 136).

Participants most frequently practised alone (53.52%, n = 38), followed by a mix of solo practice and practice with partner (25.35%, n = 18) and practice with partner only (21.13 %, n = 15). Participants who were significantly more likely to practise alone were: students (χ^2 (1) = 8.574, p = .003, n = 71), not in a relationship (χ^2 (1) = 9.585, p = .002, n = 71), or who had never used condoms before (χ^2 (1) = 13.820, p = .000, n = 71). They also reported significantly fewer condom problems at baseline (*Mdn* = 2) than those who practiced at least once with a partner (*Mdn* = 3), U = 158.00, z = -2.859, p = .004, r = -.40, n = 50, as well as fewer sexual intercourses without condoms being used at baseline (*Mdn* = 2) than those who did practice at least once with a partner (*Mdn* = 4), U = 194.00, z = -1.967, p = .049, r = .28, n = 49. Using condoms to avoid infection (χ^2 (1) = 4.419, p = .036, n = 61) or to avoid pregnancy (χ^2 (1) = 8.495, p = .004, n = 61) was also significantly associated with involving partners in practice.

Contact with participants. Out of 136 participants who completed the baseline, 49 (36.03%) provided their phone number at registration additionally to e-mails. There were no significant differences between those who provided the number and those who did not on any of the demographic characteristics. During the study seven participants contacted the study e-mail address. Their queries regarded login issues, kit delivery, study credits, vouchers and technical issues. There was one cancellation of the reminders using the automatic website option.

eHIS feasibility - intervention's acceptability.

eHIS content. The T2 evaluation survey was completed by 36 participants. Opinions about eHIS content and format were for the most part favourable; 82.86% (*n* =29) out of 35 participants said that eHIS was useful for issues linked to condom use as well as personally useful. The same proportion of participants enjoyed using the intervention and as many would recommend it to other men.

Twenty-five participants (69.44%) shared their opinions about the most useful parts of the intervention and 50% (*n* = 18) about the "most liked" parts of eHIS. Nine participants (25%) commented on the least useful parts of eHIS and six (16.67%) on the ones they did not like. The useful and liked part of the intervention most frequently mentioned was the possibility of trying various types of condoms, especially the ones participants would never buy or had not heard about. Three participants (8.33%) explicitly mentioned finding condoms that fitted well or were more comfortable than the ones used before. Information on how to use condoms correctly, followed by information about different types of condoms was also seen as useful and/or liked by 11 (30.65%) and 3 (8.33%) participants respectively. Nineteen (52.78%) participants regarded getting free condoms and/or trying different types of condom useful and/or liked. Correcting misconceptions on condom use was also mentioned as useful. Vouchers and free lubricants were mentioned amongst the liked eHIS aspects by one participant each. Flexibility of engagement with the intervention "timings and ways to complete" and "the wanking for science bit" were the liked aspects of the intervention highlighted by two participants. One participant pointed out that masturbation in condoms was "awkward" and "unnatural". However, he also commented "no harm in doing weird stuff to get a varied taste of life".

Some participants explicitly stated that there was nothing in eHIS they found not useful or not liked. Amongst the things seen as the least useful were: too narrow a range of condoms and lubricants, inconvenience of using lubricant sachets, and learning about condom sizes and correct condom use. Two (5.56%) participants found some of the

condoms in the kit to be too small for them or already known. There was a comment about confusion regarding practice, another one about "too short period of time" [for practice] and two about vagueness of the survey questions or condom rating forms.

Twenty-nine (80.56%) participants agreed that they received all information they needed and 34 (94.44%) declared that they trusted the information they received. 31 (86.11%) said that they followed the information when it was relevant for them. Ten participants (27.78%) reported that they searched elsewhere for information about condom use related issues during the intervention period. They accessed the NHS website (13.89%, *n* = 5), other health information websites (11.11%, *n* = 4), social media (8.33%, *n* = 3), sexual health clinic (5.56%, *n* = 2), GP surgery (2.78%, *n* = 1) and search engine (2.78%, *n* = 1). They looked for information about different types of condoms (25%, *n* = 9), advice on dealing with condom use problems (13.89%, *n* =5), information about different types of lubricants (11.11%, *n* = 4) and condom use steps (8.33%, *n* = 3). The amount of information was judged to be "just right" by 80.56% (*n* = 29) of participants.

The overwhelming majority (91.67%, *n* = 33)found the intervention clear and easy to follow and (75%, *n* = 27) agreed that taking part in the intervention fit with their daily life, except one participant stating inconvenience of practice in a shared flat. The majority of the participants would not like to have any personal contact in addition to using the intervention (72.22%, *n* = 26).

eHIS format. Most of the participants agreed that it was clear what was included in eHIS as well as the content flow and navigation. In the open questions some participants explicitly stated there was nothing particular they liked or did not like in website design or usability. Most participants liked that it was easy to use and navigate. However, there were two voices pointing out that some information was hard to find and that the login process was confusing. A few comments brought up the issue of the website not displaying well on mobile phones.

Although there were more positive opinions about the look of the eHIS website than negative, this aspect of the intervention was the most criticised. Clear and simple layout was praised by some, while it looked outdated, not aesthetic and unfriendly to others. There was one comment on the website images: "I liked all of the humorous condom juxtaposition photos. Made it quite entertaining." One participant asked for "more innuendo jokes" and another suggested including images of the condoms on the rating form.

Changes in condom use behaviour and condom use related outcomes.

Preliminary effectiveness in increasing condom use frequency and consistency.

When results between T1, T2 and T3 were analysed (see Table 21)[13],[14] there were significant changes in condom use consistency (χ^2= 11.692, *df* = 2, *p* = .001, *n* = 13) and frequency of sexual intercourse without condoms being used (χ^2= 10.146, *df* = 2, *p* = .004, *n* = 13). However, when Wilcoxon signed rank tests were used in the following step, significant change was only found for condom use consistency between T1 and T2 (T = 20, r = -42, p = .001)[15] and none for frequency of sexual intercourse without a condom being used (see Appendices AX – AY).

Preliminary effectiveness in changing secondary condom use related outcomes.

There was significant increase in condom use self-efficacy (χ^2 = 9.100, *df* = 2, *p* = .010, *n* = 22), and significant decrease in condom use errors (χ^2 = 11.128, *df* = 2, *p* = .003, *n* = 12) and condom use problems (χ^2 = 7.400, *df* = 2, *p* = .021, *n* = 12) between T1-T2-T3 (see Table 21). Following Wilcoxon signed-ranks tests were significant for self-efficacy and fewer condom use errors between T1 and T2 and self-efficacy and fewer condom use problems between T1 and T3 (see Appendices AX – AY). Participants also reported significantly improved condom use experience as measured by the Effect on Sexual Experience subscale from the Condom Barriers Scale (Doyle et al., 2009; St. Lawrence et

[13] All reported significant changes T1-T2-T3 calculated with Friedman's ANOVA.
[14] Table with the scale scores at T1-T3 presented in Appendix AW
[15] Bonferroni correction applied.

al., 1999) between T1 and T2, $t(22) = -2.450$, $p = .023$, $n = 23$, 95% CI [-.41, -.03] and T1 and T3, $t(19) = -2.815$, $p = .011$, $n = 20$, 95% CI [-.37, -.05].

There were no significant changes in condom use attitudes and condom fit-and-feel between any measurement points. However, the direction of change was consistent with changes in other condom use related outcome variables, with slightly more positive attitudes towards condoms and better condom fit and feel (see Figures 18 - 20). There were no significant changes on any of the primary or secondary condom behaviour or related outcomes between T2 and T3 measures (Appendix AZ).

Table 21

T1-T2-T3 change in condom use behaviour and condom use related outcomes

	n[a]	T1		T2		T3		T1 – T2 – T3		
		Mdn	*IQR*	*Mdn*	*IQR*	*Mdn*	*IQR*	χ^2	*df*	*p*
Condom use consistency[b]	13	33.33	50.83	60.00	85.00	75.00	96.67	11.692	2	.001*
Frequency of sex without condoms[b]	13	4.00	8.00	2.00	4.00	1.00	8.00	10.146	2	.004*
Condom use self-efficacy[b]	22	26.50	7.50	29.00	5.00	28.00	6.00	9.100	2	.010*
Condom use errors[b]	12	3.00	2.00	2.00	2.00	2.00	2.00	11.128	2	.003*
Condom use problems[b]	12	3.00	3.00	1.50	3.00	1.00	2.00	7.400	2	.021*
		M	*SD*	*M*	*SD*	*M*	*SD*	*F*	*df*	*P*
Condom use experience[c,d]	13	4.18	0.53	4.39	0.47	4.36	0.54	2.745	1.393,16.718	.107
Condom use attitude[c,e]	22	19.00	6.35	20.10	6.82	19.85	6.26	1.137	2,42	.330
Condom use fit and feel[c,f]	14	24.29	5.40	23.50	3.96	22.71	3.63	1.239	2,26	.306

Note. [a]Number of cases (pairwise). [b]Friedman's ANOVA. [c]Repeated measures ANOVA. [d]Greenhouse-Geisser correction (sphericity significant), square root transformation for the analysis, missing values added by completing the values with mean for participant's scale. [e]Missing values added by completing the values with mean for participant's scale. [f]Outliers removed, missing values added by completing the values with mean for participant's scale.
*p < .05 (exact)

Figure 18

T1-T2-T3 change in Condom Use Experience score (non-significant)

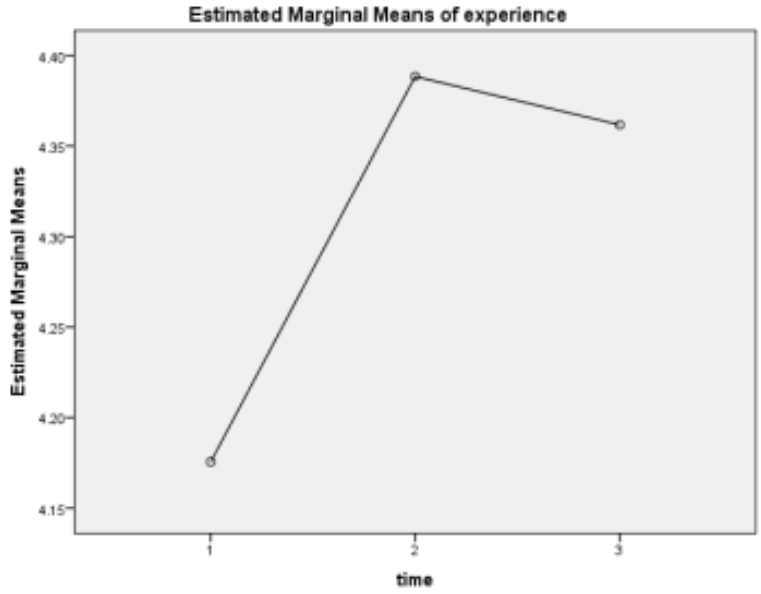


Figure 19

T1-T2-T3 change in Condom Attitudes score (non-significant)

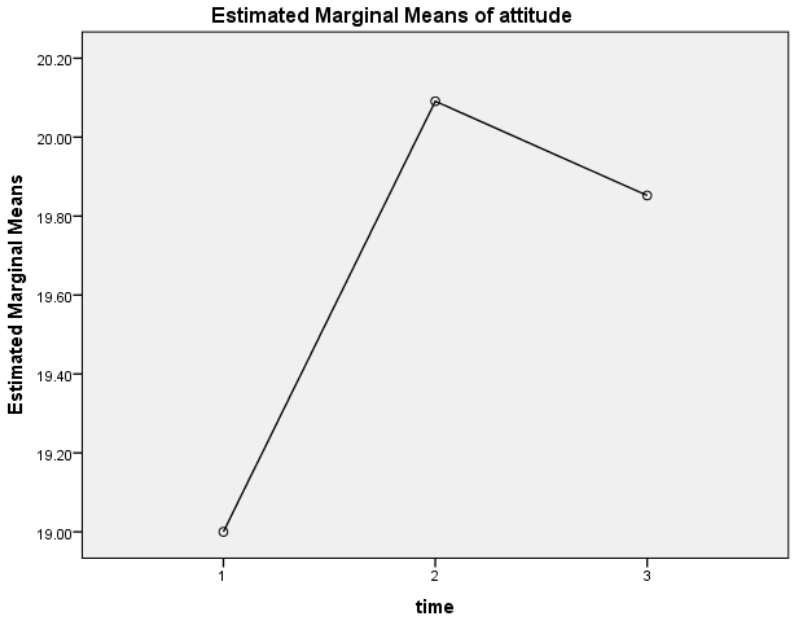
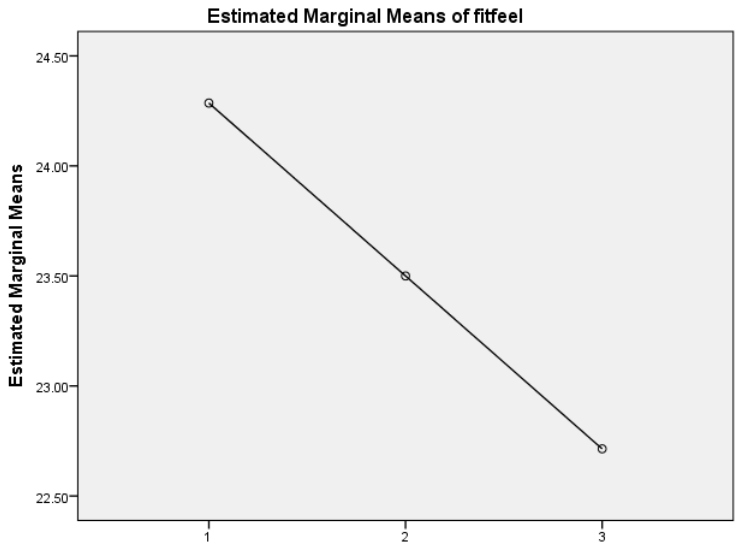


Figure 20

T1-T2-T3 change in Condoms Fit and Feel score (non-significant)



Discussion

The analysis of the study results allowed investigation of the intervention usage, compliance with its approach, assessment of eHIS's acceptability, its potential to change condom use behaviour and condom use related outcomes, as well as investigation of whether the approach to evaluate the intervention was adequate. Exploration of a range of participants' characteristics helped to assess who was interested in eHIS and identify the characteristics associated with engagement with the intervention and with the study.

Participants' characteristics, motivation and engagement. The intervention attracted men varying across most of the investigated characteristics. The groups represented less frequently were those who had never learnt how to use condoms and who had never used condoms before with a partner. This means that majority of participants had some prior knowledge and experience of using condoms and that the content and format of the intervention were likely to be judged in the context of these.

Considering the methods through which participants declared to learn about condoms and that at baseline almost a fifth of them did not know what type of condoms they used in the last 4 weeks, it can be assumed that eHIS approach was novel for them.

This was confirmed by the comments in the evaluation survey where trying different types of condoms and focusing on fit and feel seemed to be a new experience for many participants. This could be linked to the third most frequently indicated motivation to take part in the study – curiosity. As novelty is one of the key features of eHIS it should be highlighted in future studies.

Two-thirds of participants were in the youngest age group (18 - 25) frequently targeted in condom promotion interventions (Gott, Hinchliff, et al., 2004). However, a third of participants were men aged 26 - 45. This shows that there is an interest in interventions aiming to improve condom use in the population that may be overlooked in this aspect (see Chapters 1 and 3). This is a particularly interesting finding considering that, with the convenience sample recruited, there were more channels through which younger participants could join the study. This may suggest that even more men from the older age group could potentially be interested in eHIS. The results of the study showed that men in this group may have different motivations to access the intervention than younger men, being less interested in the "having fun" aspect. Better understanding of older men's condom use needs and addressing other types of motivation at the recruitment stage may help to increase older men's interest in eHIS.

The engagement with the intervention was comparable to the study investigating the FTF version of the intervention (Stone et al., 2017). Almost all participants who completed the baseline saw all core pages of the intervention and ordered the kit, and over 50% of them completed at least one condom rating. The results indicated the areas that gained most attention and should be highlighted in future iterations of the intervention, these were: information about correct condom use, condom use steps, condom use practice in the context of relationship and condom use problems.

Participants of all education levels were represented at baseline with slightly more of those educated to A-level or degree level than in the general population (Valle & Ranchin, 2014). Participants with lower educational attainment (educated to GCSE level),

despite initial interest in eHIS, were less engaged with the intervention and/or also less likely to complete the study follow-up measures. Lower engagement was also found amongst those who were not employed or in education. Links between lower educational attainment, lower socioeconomic status and lower engagement has been previously observed in online behaviour change interventions (Eysenbach, 2005; Geraghty, Torres, Leykin, Pérez-Stable, & Muñoz, 2013). There should be further investigation of what action can be taken to improve intervention and study engagement within these groups or alternatively whether alternative formats (FTF, telephone supported) would be more appropriate. Better understanding of motivation to engage with the intervention and/or study of men with lower educational attainment and exploring methods to support their engagement throughout is needed.

Participants' engagement between different groups of users varied, indicating that some might have found the intervention more relevant for their condom use than others. Although a majority of participants reported being in a relationship and sexually active at baseline, not being sexually active, never having sex before and/or never using condoms with a partner was associated with higher engagement with the intervention and with the study. This may suggest that eHIS could be treated primarily as an educational tool by those with no or less sexual experience. This interpretation is supported by the analysis of the motivation to take part in the study, where those less experienced were more likely to be motivated by wanting to learn how to use condoms and/or by improving their condom use skills. Another explanation may be that those more experienced condom users or those with higher number of partners did not find the specific information they were looking for and left the intervention. This result is consistent with the results of Study 1 where more positive opinions about the intervention were voiced by participants interested in the educational aspect of eHIS. Also in Study 2 it was suggested that the intervention may be relevant for less experienced men. The usefulness of eHIS as an educational tool could be explored in a younger population than the one addressed in the current study.

The fact that seeking help with condom use problems was the least frequently chosen motivation to take part may suggest that eHIS could be seen as not relevant and/or useful to address condom use problems already at the recruitment stage. One hypothesis could be that those experiencing condom use issues were less interested in eHIS. Better understanding of support needs of those with low condom use self-efficacy and condom use errors and problems (in the current study found to be associated with motivation to seek help) is needed.

An alternative explanation may be that more participants with other types of motivation could have been recruited before the recruitment limit was reached. This issue could be addressed by purposefully recruiting participants with specific motivation, type of condom use experience etc.

Another hypothesis that can be formulated on the basis of the Study 3 results is that those who had an experience of unplanned pregnancy may have specific condom use needs. They were less likely to be motivated to take part in the study by fun, curiosity or wanting to learn how to use condoms than those who did not report such experience. Those with the experience of unplanned pregnancy were also less engaged with the intervention than those without it. It is possible that their condom use issues and needs related to them may be different than those who did not have this experience. To the author's knowledge, similar to older men and those with less sexual experience, this is another group whose condom use issues have not been investigated comprehensively. In-depth exploration of condom use needs in these groups should precede further iterations of the intervention if the intervention was to address these groups.

Regarding incentives it was found that not employed participants were less likely to be interested in vouchers, which may be linked to their online shopping behaviour or the amount not sufficient to be used for a meaningful purchase. Alternative methods of compensating participants for taking part in the study such as monetary rewards (Stone et

al., 2017), gadgets, or higher amount donated to chosen charity should be considered to make it more inclusive.

Participants' relationship status seemed to be linked to the approach to practising condom use as those who had partners were likely to involve them into at least some of the practice. This raises the question whether practising alone is a viable option for participants in a relationship. This issue was already raised in the qualitative evaluation (Chapter 4). The attitude towards practising condom use without a partner could be explored further, especially amongst men in a relationship. It might also be worth to investigate whether practising with a partner could be equally effective as practising alone if focused on sensation and complemented with condom ratings. This is especially important as those who involved partners in practice reported more condom use problems at baseline.

eHIS acceptability. The evaluation survey results shed the light on the acceptability of the intervention. The overwhelmingly positive response could be linked to those less satisfied with the intervention dropping out earlier and not completing the evaluation. However, the feedback was similar to the ones received in other studies that evaluated the FTF versions of the intervention (Emetu et al., 2014; Milhausen et al., 2011; Stone et al., 2017). It would be advisable in the future evaluations of eHIS to also reach those who did not engage with the intervention and/or did not complete follow-up measures with the post-intervention interviews to understand their experience with the intervention (Gross, Julion, & Fogg, 2001; Nicholas et al., 2010).

The content was seen as complete for most of the participants. However, some searched for additional information in other sources. As potentially confounding the results of the effectiveness of the intervention, searching for additional information should be included in future studies evaluating eHIS. Following specific suggestions, for example increasing selection of condoms and lubricants, could improve experience of users of future iterations of the intervention. The format of the online intervention was accepted by the participants. They were not in favour of any additional support which may suggest that

the intervention may be particularly useful for those who would not access services involving direct contact. However, e-mail support seemed to be acceptable and useful in resolving minor technical/administrative issues.

The website design was the most criticised aspect of eHIS. Many of the issues were linked to the limitations of the LifeGuide software (as discussed in Chapter 4). Using more advanced software and professional graphic design could make the website look more modern and be compatible with mobile devices. Alternatively eHIS could be developed as a mobile application.

eHIS' potential effectiveness in changing condom use behaviour and condom use related outcomes. The findings showed that eHIS has the potential to change both condom use behaviours and condom use related outcomes. All significant changes observed between baseline and follow-ups were in the intended directions (increased condom use consistency, self-efficacy and experience and decreased frequency of sexual intercourse without condoms, and fewer condom use errors and problems). The same was observed for non-significant changes in the secondary condom use related outcomes. The results are a good prognosis for the intervention's effectiveness.

Compared to studies evaluating FTF versions of the intervention (Emetu et al., 2014; Milhausen et al., 2011; Stone et al., 2017) there were, in general, more significant changes observed on the outcome variables, and all of the changes were, as in the other studies, in the intended direction. Some differences were found between specific assessment points. Condom use experience was found significantly improved in the current study but no significant changes were reported in the study of Emetu et al. (2014). On the other hand Emetu et al. (2014) reported significant change in condom use attitudes not observed in the current study. In the current study significant decrease in both condom use errors and problems numbers were observed in repeated measures ANOVA, whereas in the HIS-UK study (Stone et al., 2017) only the change in comparison on a combined score between T1 and T2 was found to be significant The significant change observed in

decrease of frequency of sexual intercourse without a condom being used across three assessment points was not observed when comparisons were made between any two points in the current study, but it was found to be significant in Emetu et al. (2014) between T1 and T3. It should be noted that, similarly as in previous studies, the potential effectiveness of the intervention could be inflated due to complete cases analysis (Emetu et al., 2014; Milhausen et al., 2011; Stone et al., 2017).

The effect sizes of the significant changes for condom use experience and condom use self-efficacy were mostly within the medium range (with one in large) ($.34 < r < .54$), which was comparable to the effect sizes reported by Milhausen et al. (2011) ($.35 < r < .46$) and lower for self-efficacy as reported by Emetu et al. (2014) (r. = .69). For consistency of condom use the effect size in the current study (r = -.42) was similar to the one reported in Emetu et al. (2014) (r = .44). Also close effect sizes were observed for condom use errors and problems between the current study (r = -.41, r = -.50) and HIS-UK (r = .61) (Stone et al., 2017). This demonstrates that the similar medium effect size may be expected regardless of the format of the intervention delivery and across different populations.

The similarities in the results between the studies can stem from following the same approach. On the other hand different formats of delivery, differences in the characteristics of the recruited samples, possibility of including a partner in practice or even fewer/different condoms in the kit in the current study could contribute to the differences found. Impact of these elements on various outcomes should be investigated in further studies. The differences in the results between the current and other studies investigating KIHIS could be also explained by possible subtle variations of emphasis on different aspects of the intervention between different studies. This however, would be difficult to explore, as there are no known materials existing to assess the fidelity of delivery of FTF studies. Consistency of delivery and/or responding to the needs of those who would not attend a FTF session could be responsible for wider range of significant changes on

condom use behaviour and related outcomes in the current study. All possible explanations of differences between studies could be investigated in future studies.

Feasibility of the intervention's evaluation approach.

Recruitment. Recruitment approach use in the current study was found effective in recruiting participants from across the UK and with varied characteristics. However, as discussed above recruitment of convenience sample could lead to over or under representation of men sharing some of the characteristics. In the future studies approach systematically targeting specific groups, in specific settings, using different methods, could be used to ensure balance between participants' characteristics (Casler, Bickel, & Hackett, 2013; Frandsen, Walters, & Ferguson, 2013). This should allow more definitive evaluation of links between the intervention engagement, acceptability and preliminary effectiveness and participants' characteristics.

However, participants recruited through social media were less likely to complete the whole study. This could be linked to over-recruitment attributed to relative ease to sign in through this channel in the first place. This could be also explained to some degree by participants' characteristic (i.e. lower educational attainment), as those with lower education level were also less likely to engage and were more likely to be recruited through social media. In future studies evaluating eHIS a balance between wider reach of recruitment given by social media and the choice of methods and resources to maintain participation will need to be reached.

Some of these characteristics were found to be linked to the higher risk of attrition (as discussed below). This could explain the difference in engagement between participants recruited using different methods. However, research investigating links between different recruitment methods and the level of participants' commitment to the study participation could provide guidance regarding choice of the recruitment approach.

BAME participants, unemployed and students were more likely to respond to non-social media adverts. This may indicate that various types of study advertisement (e-mail,

posters) reached different populations and that a range of methods needs to be used in future studies to ensure sample diversity. However, leaflets and business cards might be not worth the investment as they brought the lowest number of participants.

The most frequent motivations to take part, namely fun, condoms and curiosity, should be highlighted in future studies' advertisements to increase recruitment. However, as discussed above different participants' groups varied in terms of motivation to take part in the study, tailoring the information in advertisements and participation information could increase the diversity of a sample. There are also suggestions that framing research participation as benefiting others and socially desirable may increase the likelihood of participation motivated by altruism (Williams, Entwistle, Haddow, & Wells, 2008). However, as condom use is a private behaviour which participants may not want to share with others, the altruistic motivation to take part in research linked to perceived social norms may be limited (Feigin, Owens, & Goodyear-Smith, 2018).

Retention. The dropout between T1 and T2 completion was higher than in other studies investigating FTF versions of the intervention (Emetu et al., 2014; Milhausen et al., 2011; Stone et al., 2017). The high attrition rate could be linked to accumulation of factors which were found to contribute to higher dropout in self-guided depression interventions: male participants, young age, and lower educational attainment (Karyotaki et al., 2015), especially with eHIS being a self-guided intervention (D. Richards & Richardson, 2012). In a previous study male participants were found to be less adherent to online psychological interventions (Beatty & Binnion, 2016). eHIS's preventive focus could also be linked to higher attrition, especially if participants did not observe immediate positive impact on their wellbeing (Eysenbach, 2005). An alternative explanation of the dropout rate may be that participants received the information they sought for at early contact with the intervention and did not feel the need or the obligation to continue their engagement (Mohr, Burns, Schueller, Clarke, & Klinkman, 2013). Additionally the current intervention did not require much effort or personal contact to sign up to but lacked human contact

and/or support to maintain engagement and complete study measures, which was found to be a factor reducing attrition in previous studies investigating online interventions (Beatty & Binnion, 2016; Geraghty et al., 2013). The dropout rate could also be linked to number and value of incentives discussed above. Finally the rate of completing follow-ups could be linked to disengaging with the intervention in the first place.

Minimising participation burden was one of the principles guiding the design of the current study; however, higher number of reminders to complete follow-up measures could improve the retention rate as it would counterbalance forgetfulness or leaving the task to be completed at later time (Donkin & Glozier, 2012). Alternatively, reducing over-recruitment (as discussed above) could result in higher retention rates.

As curiosity was found to be one of the key facilitators of engagement (also observed in Study 1 and Study 2), maintaining it throughout the ratings completion stage could increase the retention in the intervention. Another suggestion to increase measures completion may be adding a message appealing to the sense of duty, satisfaction from task completion or wider community or society benefit that could be especially important in unguided interventions (Donkin & Glozier, 2012). On the other hand this may reduce external validity as in non-research context this type of motivation would not be relevant (Eysenbach, 2005). Including follow-up phone calls could improve study retention (Geraghty et al., 2013) but on the other hand this could increase risk of losing participants for whom not having direct contact was one of eHIS's advantages.

Taking a different perspective, the high dropout rate in an online intervention can also be seen as one of their characteristic (Eysenbach, 2005). As such it may not necessarily need to be challenged but considered at the stage of designing future trials. In this case the focus could be more on depth of understanding who and in what circumstances engage more with the intervention and whether the characteristic of engagement (such as frequency, length, interest in specific parts) translates into higher effectiveness of eHIS.

Incentives. A donation to a national level charity with a more general health focus was preferred by most of the participants. This may suggest that adding more similar options or an option to nominate charity for a donation could increase the motivating role of this incentive. Choosing the voucher as motivation for participation was an incentive positively associated with T3 completion and engagement with the intervention. Introducing vouchers or other incentives for completing ratings and/or T2 measures might as well improve study retention rate. This may be particularly effective considering that other studies investigating FTF versions of the intervention which achieved higher retention rate, offered higher monetary compensation (Emetu et al., 2014; Milhausen et al., 2011; Stone et al., 2017) or additional free condoms (Stone et al., 2017). Furthermore, the value of incentives was found to be positively linked to retention in other Internet based studies (Alexander et al., 2008; Göritz, 2006) and randomised trials (Brueton et al., 2014).

Measures. All standardised scales used in the study showed good reliability and can be recommended to be used in future studies. The eHIS evaluation survey provided a good overview of the acceptability of the intervention's content and format. The question about the number of lifetime partners may not be acceptable for all participants, as was highlighted in the qualitative evaluation during eHIS development (Chapter 4). Additional explanations for why these questions are asked could help to increase response rates.

Data analysis. The data analysis approach taken in this study was to ensure the best fit between data and the analysis method. Due to the nature of data a mix of parametric and non-parametric methods needed to be used. This, together with the number of participants in some of the categories, limited the possibility of conducting more advanced statistical analysis. Despite these limitations there was sufficient data to explore which participant characteristics contributed to their interest in the intervention and their engagement with it.

Study strengths. The current study explored feasibility of eHIS and the approach to its evaluation. The study provided an insight into who might be interested in the intervention, who and how would engage with it, and whether the intervention has the

potential to change condom use behaviour and condom use related outcomes in the intended direction. It also helped to reveal new avenues for the intervention development (e.g., as an educational tool) complementary to the original aim of supporting those with negative condom use experience.

Recruiting volunteers is often seen as a weakness of a study caused by self-selection bias (Fortmann & Killen, 1994; Muller et al., 2004; Saunders, Fisher, Hewitt, & Clayton, 1985; N. Trivedi & Sabini, 1998), especially when sample representativeness of specific population is sought for (Coolican, 2004; Emetu et al., 2014; Milhausen et al., 2011; Sarkin, Marshall, Larson, Calfas, & Sallis, 1998; Tripepi, Jager, Dekker, & Zoccali, 2010). In the current study, however, it was important to explore who was interested in the intervention and this goal was achieved. Wide scope of recruitment allowed reaching a diverse sample of men, including those not usually addressed in condom use promotion interventions. However, the results should be interpreted with caution due to limitations discussed in the "Recruitment" section above. For that reason they should be used for hypothesis generation rather than to provide answers, especially regarding associations between variables.

This approach allowed identification of potential new target groups (older men, those less experienced in using condoms) as well as groups for whom eHIS may need to be adjusted to support their engagement (those with experience of pregnancy, with lower educational attainment or unemployed). However, this finding should be treated as a preliminary indication of potential target groups with awareness that some specific groups for example ethnic minorities (Jutlla & Raghavan, 2017; Rooney et al., 2011) or groups such as sexual minorities (Lucassen, Fleming, & Merry, 2017) may be harder to reach and/or engage in research.

Results of the review of the approach to the intervention evaluation provide guidance for a large scale RCT to evaluate the intervention's efficacy (Abbott, 2014). The

findings help to identify issues that could support or hinder the success of a bigger trial and guide formulation of recommendations for future evaluation studies.

Study limitations. The dropout between baseline and follow-ups was expected to be high; however, the actual attrition was higher than expected. A combination of factors could contribute to that as discussed above. All of these factors should be explored in the context of specific target groups and specific settings and addressed appropriately.

The pre-test post-test design chosen for this study was appropriate for its aims, allowing the assessment of the feasibility of the intervention and key points of feasibility of evaluation approach. It was also the most practical approach considering the study's practical constraints (project timeline and resources). However, the lack of a control group limited the extent of conclusions of eHIS potential for effective impact on changing condom use behaviour and related cognitions, for example it was not possible to separate the effect of completing the questionnaires from the impact of the intervention (Godin et al., 2010). This may be particularly important in the context of results of the eHIS qualitative evaluation where participants pointed out that going through questionnaires triggered the reflection on own condom use (see Chapter 4). Introducing two control groups (one controlling for the intervention and the other for possible questionnaire completion effects) would be recommended to investigate the impact of measures completion on the changes in the study outcome (Yardley et al., 2011).

Relying on self-reports for condom-related behaviour and condom use-related outcomes carries the risk of the results not accurately representing actual behaviour or cognition due to recollection, and self-presentation biases (Catania, 1999; Graham et al., 2005; Lust & Bartholow, 2009; Schroder et al., 2003). Including assessment of biological indicators of behaviour change (such as rates of new STIs) could provide more objective measure of the intervention effectiveness. However, considering the prevalence of STIs in general population (Public Health England, 2017a) this could be only measured in a well-resourced large scale study.

The relatively short follow-up did not allow the evaluation of the long term effectiveness of eHIS. However, the chosen follow-up period mirrored the one set in HIS-UK study (Stone et al., 2017) and allowed to compare the results within the same timeframe. Longer follow-up would be adequate for a large scale evaluation study to assess whether the behaviour change would be sustained and to assess possible biological indicators of change.

Due to the answers in the evaluation survey being homogenous it was not possible to answer the question whether any of the participants' demographic characteristics, sexual history or baseline condom use experience were associated with acceptability of the intervention. It could be hypothesised that those who dropped out earlier were less satisfied with eHIS. This should be explored in further studies by interviewing also those who dropped out (Gross et al., 2001; Nicholas et al., 2010).

Low numbers in some of the variables/variables categories together with higher than expected attrition rate did not allow some of the analyses to be performed (considered if the subsamples' sizes were sufficient) or the analyses were performed on more generalised level. They could also lead to some of the analyses being underpowered which carry the risk of both type I and type II errors (Christley, 2010; Coolican, 2004). However, achieved results may still be useful to support recruitment and retention strategies and to generate hypotheses to be explored in future studies.

Contribution of the Study 3 results to the aims of the thesis. Completion of Study 3 allowed meeting the final aim of the thesis which was the evaluation of the fully developed online intervention. Exploration of demographic and condom use related characteristics of participants interested in the intervention highlighted the potential target groups which may benefit from the eHIS approach. Participants' feedback on eHIS indicated that its approach and format were acceptable. The preliminary effectiveness results suggested that eHIS has a potential to be an effective tool in reducing frequency of

intercourse without condoms being used and condom use errors and problems, increasing condom use consistency, and improving condom use experience and self-efficacy. After further amendments, mainly at the website design level eHIS could move to the next stage of its development – a large scale evaluation. The study demonstrated that the intervention and the approach to its evaluation were feasible. Study 3 results also confirmed that the approach taken to develop eHIS was accurate to produce a feasible, acceptable and potentially effective intervention.

Conclusions

The results analysis suggests that the goals of exploring the feasibility of eHIS, its potential to be effective in impacting condom use behaviour and related outcomes and assessing feasibility of its evaluation were met. Exploring associations of participants' characteristics with specific outcomes was partially fulfilled.

The results of the study have numerous scientific implications. Firstly they provide support for the models and theories underpinning the intervention. Further they allow better understanding of potential target audiences of the intervention with various motivations to engage with eHIS and different patterns of following its approach. The study results also indicated the areas that require further investigation to provide both background and intervention specific knowledge to advance eHIS development, to maximise its impact and increase its chances to be effective in changing condom use behaviours and related outcomes in specific groups.

The study results showed that eHIS content and online format were acceptable and could provide an alternative to FTF interventions, especially for those who may not be willing to discuss condom use in a direct contact. The accessible format made it easy for participants to engage with eHIS at their own convenience.

The preliminary effectiveness results demonstrate the potential of the intervention to impact condom use behaviour and related outcomes. However, they should be explored

further in a large scale RCT to allow conclusions about eHIS's effectiveness. A large scale study should help to clarify the reasons behind the observed differences. Comparing FTF and online modes of delivery should deliver definite results regarding the impact of mode of delivery on the intervention's effectiveness. The assessment of the feasibility of eHIS evaluation approach provided guidance for designing a large scale RCT (Cunningham et al., 2006; Kwan et al., 2013).

From a clinical point of view the study delivers an overview of a novel tool that could complement existing sexual health education and condom promotion. The results provide insight into men's needs in relation to condom use and their willingness to engage with an intervention to improve their condom use experience. It also highlights specific topics that may be especially interesting for them.

Chapter 6

General Discussion

Chapter Introduction

This chapter includes a discussion of whether the aims and objectives of the thesis were met followed by an overview of the project completion. The impact of the results of the studies completed within the project to inform specific stages of the intervention development (the systematic review, qualitative evaluations of the prototype and the computerised version of eHIS) is also presented. Next, the lessons learnt from the eHIS development are discussed followed by a discussion of the project's strengths and limitations. The chapter closes with a discussion of the implications of the project's results for scientific research, clinical and educational practice, and addressing health inequalities.

Thesis Aims and Objectives

The main aim of the project – development and evaluation of eHIS – was completed, and the process was reported in the thesis. The studies completed within the project informed the intervention development (Chapters 3 and 4). Majority of the specific research questions was answered. When comprehensive answers were not possible, gaps in the evidence were identified and areas requiring further research were indicated. The intervention's feasibility and potential for effectiveness were evaluated and its potential to change some of the condom use behaviours and condom use related outcomes was demonstrated (Chapter 5).

The eHIS development process was carefully planned, with consideration for the role of all of the steps needed to develop a full version of the intervention from theoretical level conceptualisation, through operationalisation to assessing its feasibility. Potential users' perspectives were brought to the process by inviting men to participate in the qualitative evaluations of the intervention at its development stage. In this complex

development process various theoretical models and evidence from behaviour change and DIs development areas were applied. Alongside the intervention development results achieved at the particular steps of the process informed its future stages. Although the process is described in a linear manner in the thesis, it was dynamic and often circular, requiring revisiting steps completed earlier and referring to them in completing the following ones. The GPRs and the LM constituted the core of the eHIS development process and were used as reference points in decisions about changes to the intervention. They were particularly useful in monitoring the development progress alongside subsequent iterations of the intervention. The final versions of the intervention's GPRs and LM are presented in Table 22 and Figure 21. The operationalisation of the intervention is presented in Figure 22.

To inform the choice of methods supporting review of condom use skills a systematic review of the TCUS development techniques was completed (Chapter 3). The results advised the development of the skills focused elements of eHIS. To maximise the chance of the users engaging with the intervention and accepting its content and format, their perspectives were included in the development process as advised by the PBA (Yardley, Morrison, et al., 2015). This was accomplished by completing two qualitative studies in which eHIS prototype and then its computerised version were evaluated (Chapter 4). As a result models of participants' experience with the intervention were formulated to guide further eHIS development. The changes introduced as a result of the feedback improved participants' experience with the intervention (Chapters 4 and 5).

Table 22

eHIS guiding principles

Intervention design objectives	Key features
To persuade men that they can improve their condom use experience	To present men with a new perspective on condom use: pleasure- and sensation- oriented as opposed to performance-oriented To provide men with a condoms and lubricants kit to explore at home To ask men to complete a condom rating form directing their attention on pleasure and sensation aspects of condom use To inform about the causes of condom use problems and how to address them
To encourage men to practise condom use without the partner to help them to improve their condom use experience	To provide a rationale for practising using condoms alone
To support men in correct condom use skills development	To encourage men to review their condom use skills[a] To provide information about condom use steps
To maintain men's engagement with the intervention	To include summative feedback on condom ratings[b] To ensure content clarity and ease of use[a] To make design attractive and inducing curiosity[b] To support users' perception of choice[a] Reminders
To minimise the intrusiveness of the intervention	To ensure that the intervention is brief, home based, self-guided, not requiring in person contact[a] To ensure that the intervention is not seen as too demanding or interfering with daily life[b]
To ensure users that the information provided in the intervention is perceived as credible[b]	To provide information about previous research and academic affiliation[b]

Note. Adapted from Yardley, Morrison, et al. (2015). [a]Added at the stage of developing eHIS prototype to adjust the feature to online format. [b]Added after qualitative evaluation of the intervention prototype.

Lastly the feasibility and preliminary effectiveness evaluation study was completed (Chapter 5) to explore characteristics of men interested in the intervention and links of these characteristics to engagement with eHIS. The study results demonstrated eHIS's potential to increase condom use consistency and decrease number of sexual intercourses without a condom being used, improve condom use experience and condom use self-efficacy and reduce condom use errors and problems. They also demonstrated that the

impact of the intervention on these outcomes when it was delivered online was of similar magnitude as when it was delivered FTF. At the end of the process the approach to the intervention evaluation was also reviewed and suggestions for its improvements were made in relation to recruitment strategy, target group and study measures. Further research which could benefit future iterations of eHIS was also suggested.

Figure 21

eHIS logic model

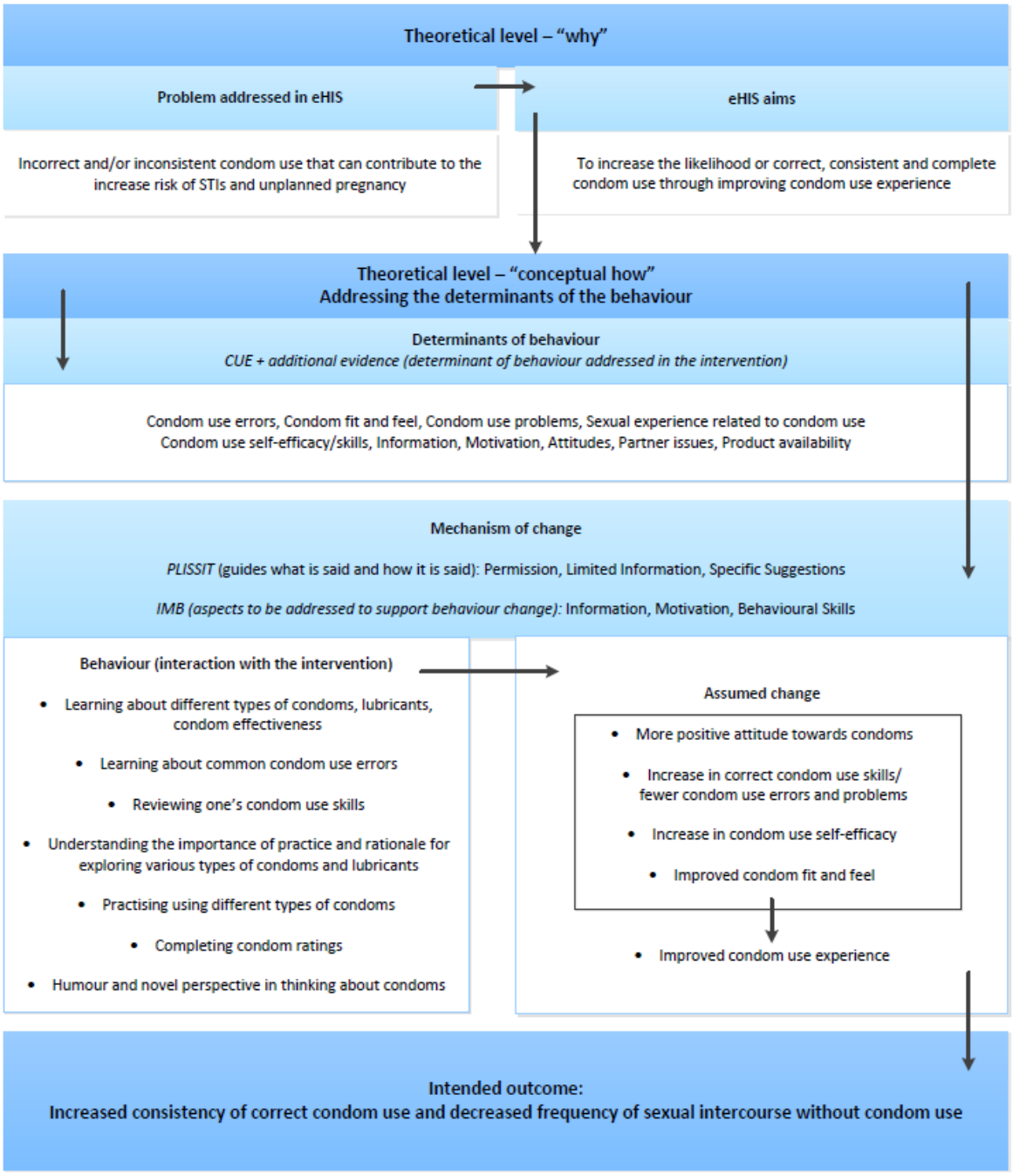
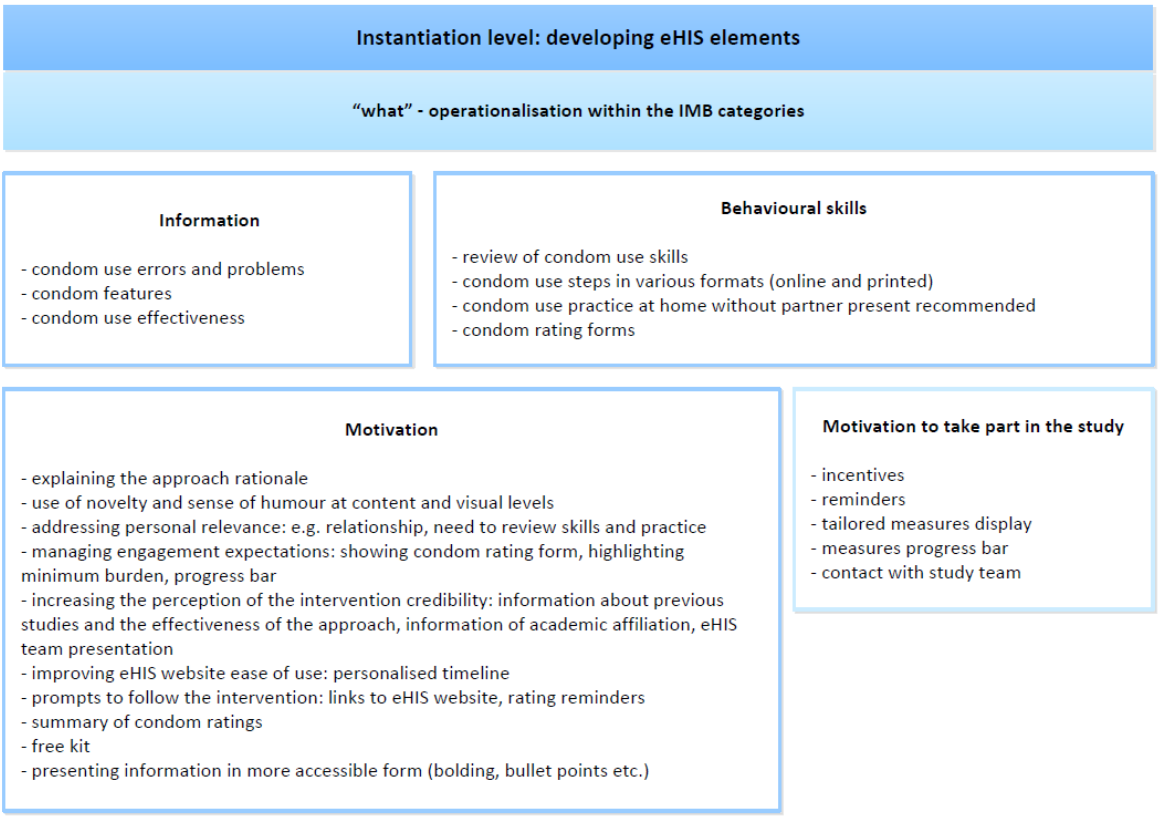


Figure 22

eHIS operationalisation



eHIS in the Context of Other Interventions

In many aspects eHIS remains as unique at the completion of the project as it was when it was first planned. In the context of the recent DIs promoting sexual health and condom use, eHIS can be classified as one of the briefer, most focused interventions (Carvalho, Alvarez, Pereira, & Schwarzer, 2016; Danielson et al., 2016; DeSmet, Shegog, Van Ryckeghem, Crombez, & De Bourdeaudhuij, 2015; Levy, Gidron, Deschepper, Olley, & Ponnet, 2019; Marcell, Gibbs, & Lehmann, 2016; Newby et al., 2019; Starosta, Cranston, & Earleywine, 2016; Wadham, Green, Debattista, Somerset, & Sav, 2019; Whiting, Pharr, Buttner, & Lough, 2019). It addresses one specific behaviour – condom use, its entire content can be accessed in one session, and the assumption is that no refresher sessions are required to maintain behaviour change. By promoting approach to support condom use

focused on sensation and pleasure, eHIS can be placed amongst steadily growing numbers of interventions addressing these issues (M. B. Anderson, Okwumabua, & Thurston, 2017; Anstee et al., 2019; Crosby, Mena, & Smith, 2018; Milhausen et al., 2016; Newby et al., 2019; O'Neal & Berteau, 2015; Webster, Michie, Estcourt, Gerressu, & Bailey, 2016; Yarber et al., 2018; Ybarra, Liu, Prescott, Phillips, & Mustanski, 2018).

eHIS Development – Lessons Learnt

The eHIS development described in this thesis provides a comprehensive overview of the process that can be useful to other researchers developing behaviour change interventions, both promoting condom use as well as more generally promoting preventive health behaviours.

Interventions development and adaptation frameworks. Although PBA (Yardley, Morrison, et al., 2015) was chosen to guide eHIS development, the clearly described steps of the eHIS development fit within the key stages of behaviour change interventions development or adaptation of other established frameworks (as discussed in Chapter 2). The eHIS development also fits within general interventions development stages of more recent frameworks: six Steps for Quality Intervention Development (6SQuID) (Wight, Wimbush, Jepson, & Doi, 2016), holistic framework (Y. Wang, Reiterer, Fadhil, & Lange, 2019) and IDEAS framework (Mummah et al., 2016). The prototyping and evaluating minimum viable product stages and an iterative development approach described in the IDEAS framework (Mummah et al., 2016) were particularly important during the eHIS development. Although the conceptual review stage could fit well within the adaptation frameworks, all steps from formulation of the GPRs and the LM, through qualitative evaluation up to feasibility study were the same as in a newly developed intervention. In this context the choice of the PBA (Yardley, Morrison, et al., 2015) to lead eHIS development is justified.

The results of the project provide support for the value of the PBA (Yardley, Morrison, et al., 2015) in developing an online behaviour change intervention. Giving importance to the participants' perspectives in eHIS development proved to be invaluable. It allowed understanding of eHIS's aspects that were important for participants' experience, maximising the impact of the facilitators on positive experience and engagement, and minimising the impact of the aspects leading to negative experience and disengagement. This in turn led to development of the intervention which was found to be acceptable.

Models integration. The eHIS development demonstrated that integrating different models to guide interventions development can be beneficial as they inform different aspects of the process. While the PBA (Yardley, Morrison, et al., 2015) offered a general conceptual guidance and supported the whole project design, the models of DIs development (Mohr et al., 2014; Ritterband et al., 2009) informed specific aspects of the development and the evaluation of eHIS. Integrating various models helped to ensure that key issues of the development process were considered from different perspectives and addressed accordingly. Each of the three theoretical models underpinning the intervention itself provided different perspectives on improving condom use experience and increasing consistent and correct condom use. All of the models used in the project assisted in better understanding and implementing the results of the completed studies. For example, referring to the eight main areas of the website component of the BIT model (Mohr et al., 2014) helped to interpret the results of the qualitative evaluations.

Adaptation between modes of delivery. The eHIS project completion provides an insight into a process of adaptation of an intervention between different modes of delivery, which is not frequently reported (Escoffery et al., 2018). At the stage of translating elements of eHIS into an online environment, the lack of specific guidance was apparent. One example being the adaptation of the use skills review completed in the KIHIS' FTF session (Milhausen et al., 2011). In the context of lack of clear evidence supporting any specific method, as demonstrated in the systematic review, a more creative approach based

on evidence from other areas of psychology was employed. This example brings attention to the complexity of the adaptation between modes of delivery process, which should be addressed in more details by relevant guidance rather than being included under general "materials development" category (Escoffery et al., 2018; Escoffery et al., 2019). This could be addressed by extending existing taxonomies such as BCTT (Michie et al., 2013) by creating sets of equivalent methods to deliver specific techniques through different modes of delivery (Y. Wang et al., 2019).

Adaptation between contexts. In the current study not only mode of delivery of eHIS but also its context changed. Engaging potential users from the early stages of its development, as recommended by PBA (Yardley, Morrison, et al., 2015), was crucial in ensuring that the intervention was relevant and acceptable for men in the UK. Decision to extend the target group of the intervention, informed by the review of the country's specific context, allowed identification of new groups, other than traditionally defined as "at risk", who could potentially benefit from eHIS (Rohleder & Flowers, 2018; Simoni, Kutner, & Horvath, 2015). Extending the intervention reach to these groups could contribute to decreasing inequalities in access to the health services discussed below.

The intervention's fidelity. Maintaining the fidelity of eHIS was another issue that was important during its development. As learnt from this project, it cannot be simply assumed that a new version of an intervention is equivalent or "similar enough" without introducing checking procedures. Reviewing the intervention at the conceptual level, explicitly stating its GPRs and formulating its LM were instrumental in ensuring the conceptual consistency between different versions of the intervention (Card, Solomon, & Cunningham, 2011; S. J. Lee et al., 2008; E. Smith & Caldwell, 2007). The need for only minor changes to the intervention's GPRs and LM following the results of the studies completed within the project also confirmed conceptual fidelity of the new version of the intervention. Additionally, consultation with the authors of the KIHIS intervention (Milhausen et al., 2011) added another level of scrutiny, especially important at the

operationalisation and intervention production stages. The consistence of the results between other versions of the intervention (Emetu et al., 2014; Milhausen et al., 2011; Stone et al., 2017) and the current project also confirmed eHIS's fidelity. However, an additional level of research, systematically exploring fidelity of different versions of the intervention, could shed more light on more nuanced aspects related to delivering them through different modes and in different contexts. This could include independent coding of the behaviour change techniques used in different versions of the intervention or experimental testing of their specific elements.

Participants' feedback. The results of studies 1 and 2 demonstrated that different types of stimuli brought up slightly different focus. Although this issue is addressed in the digital products development field (Krug, 2006), its further exploration in the DIs area could lead to setting more specific guidance. Based on the experience of developing eHIS, obtaining different types of feedback and their specific purpose/focus at various stages of an intervention development could help to plan future behaviour change interventions development. This may be particularly important for planning consecutive evaluation studies.

Decision making. Involving experts throughout the project proved to be particularly useful at the stages where evidence was contradicting or missing or when the choice had to be made between options equally supported by the evidence. Their tacit knowledge added another dimension to the analysis of the evidence (Oyebode, Patrick, Walker, Campbell, & Powell, 2016). The MoSCoW analysis (Bradbury et al., 2014; Clegg & Barker, 1994; Kuhn, 2009) fit well within the pragmatic approach, and allowed to complete the project within its resources.

Further eHIS development. Following the results of Study 3 which provided information about the feasibility and preliminary effectiveness of eHIS for men in general population in the UK, the intervention reached the stage of development at which it can be, after amendments guided by the feasibility study results, tested in RCTs. At the current

stage eHIS meets the requirements formulated by Murray et al. (2016) to qualify for a more extensive evaluation: it is stable, can be implemented with fidelity and the results of preliminary effectiveness of eHIS suggest that it has the potential to be clinically meaningful. However future studies should consider study design more relevant for large scale investigation and which would address impact of measures completion on behaviour change, limitations and benefits of various recruitment approaches, re-define the intervention audience and review some of the measures.

Other options of further development of eHIS could include adapting it to be delivered through mobile technology as an app, developing it into a gaming format or using virtual reality to support skills development (Muessig et al., 2015; Zhao, Freeman, & Li, 2016). Use of just-in-time adaptable technologies responding to users' changing needs or promotion of eHIS approach through interventions delivered via social media could be also explored (Arigo et al., 2019; Muessig et al., 2015; Nahum-Shani et al., 2018; Simoni et al., 2015). Developing eHIS in a variety of modes of delivery could make it easier to adapt to complement existing services.

Strengths of the Project

Methodological approach. Following the mixed method approach allowed the results of the studies completed within the project provided knowledge relevant for eHIS development. The choice of the research questions and methods to answer them was relevant to gain knowledge important to inform the development process, with both qualitative and quantitative approaches being equally important. The quantitative approach in the systematic review allowed creation of the reliable evidence base to guide transferring skills elements of the FTF intervention into an online format. Qualitative evaluations (Studies 1 and 2) were invaluable in revealing aspects of its content and design that could lead to lower engagement with the intervention and as a result hinder its effectiveness. Think-aloud interviews helped to explore in-depth various aspects of the

participants' experience with the intervention, which was not only useful directly in the development process but also in informing the development of the evaluation survey used in the feasibility study. The use of standardised methods (Study 3) allowed the evaluation of the intervention's potential for effectiveness and comparison of eHIS's results with other versions of the intervention.

The pragmatic approach followed in this project proved to be an adequate to support its completion throughout of all of its stages. The flexibility of the pragmatic approach was useful in responding to participants' feedback and guiding the choice of specific research questions and methods within the project scope and timeline. As suggested by the framework for mixed method research process (Onwuegbuzie & Leech, 2006), the results of the current project, through providing better understanding of the intervention development, can be used to reformulate the research questions for future studies investigating various aspects of eHIS.

The PBA (Yardley, Morrison, et al., 2015) combining participants' views in the centre with theory, evidence and expert knowledge provided a comprehensive basis for eHIS development. This was particularly important in ensuring that the intervention was not only evidence and theory based, but also acceptable to its users. If the latter condition is met the chances of the intervention being followed and in consequence being effective in changing actual behaviour increase (Yardley, Morrison, et al., 2015).

Identifying new directions of eHIS development. The results of the studies completed within the project supported the initial decision to extend the intervention target group. The results of the systematic review were in line with earlier conclusions made on the basis of the literature review that there is a gap in interventions addressing older men. Furthermore, men from older age groups volunteered to participate in both qualitative evaluations of eHIS and approximately a third of participants in Study 3 were 26 or older. Addressing needs of the groups that are not identified as the most at risk at population level (Public Health England, 2017b) may not be a priority at public health level; however, one

cannot deny its importance at clinical and individual level. A low cost, easily accessible online intervention may be a sensible way of filling the identified gap.

The feasibility study allowed identification of new target groups as well as an alternative focus of the intervention. These findings may guide new directions of eHIS development. However, further investigation would be needed to establish whether and what type of modifications would be required to make eHIS more relevant to the needs of these specific groups (older men, those with less sexual experience or with previous experience of unplanned pregnancy) or to be developed into a primarily educational resource.

Development process. Transparency of the development process facilitated understanding of the role of its specific elements. Formulating the LM of the intervention's working mechanisms by incorporating various eHIS theoretical underpinnings and evidence at the conceptual level and linking them to the specific intervention components at the operationalisation level was crucial in maintaining the transparency of the process. This in turn allows replicating and/or amending the process in further iterations of the intervention.

This may be particularly important when comparing the results of various versions of the intervention. Differences at any of the levels can be considered when different findings are obtained. The model also ensures grounding the intervention in the wider body of evidence and theory, increasing its chances to be effective in changing the behaviours and cognitions it addresses (Yardley, Morrison, et al., 2015).

Multidisciplinarity. The intervention was developed primarily on the basis of condom use behaviour and behaviour change research. However, it also incorporated theory and evidence from the human-computer interaction area. Combining knowledge from both disciplines helped to address condom use related issues in a format that was acceptable and easy to use (Krug, 2006; Mohr et al., 2014; Ritterband et al., 2009).

Limitations of the Project

Extent of the project. Although the intervention development process steps were completed as planned, throughout the project completion an extent of gaps in the evidence relevant for the project became apparent. Exploration or additional areas or more in-depth investigation could have been included in the process to make it more comprehensive. However, as this project was constrained by its resources and timeline, it was not possible to comprehensively investigate all of the relevant areas. The pragmatic approach (see Chapter 2) guided the choice of the investigations most relevant to achieve the project aims. This resulted in a fully developed and evaluated intervention, but did not allow in-depth understanding of its more nuanced mechanisms or wider contextual issues relevant for the intervention implementation. The examples of possible research that could enhance the project are described below.

The first example could be an experimental study investigating in a controlled way the effectiveness of various methods of reviewing and developing condom use skills. The skills review in eHIS was based on theory and evidence from research completed in a different context as no evidence regarding mechanisms of recall and recognition in the specific condom use context was found. Exploring which format of the skills review would be most effective and preferred by users could improve their satisfaction with the intervention. Moving further, a detailed experimental investigation of the effectiveness of specific eHIS components and their interactions would add another layer of evidence to support the content of the intervention. However, this would constitute a separate large-scale long term project.

A study exploring the views of sexual healthcare professionals and sex education specialists could provide additional perspectives on the barriers and facilitators of engaging the users with the intervention in various settings and specific cultural contexts. Analysis of the intervention implementation framework could direct further changes that could help to implement the intervention in real-life settings (May, Johnson, & Finch, 2016).

A combination of quantitative evaluation in the feasibility study with in-depth qualitative interviews could provide more detailed understanding of users' experience with the intervention in the real life setting, extending or amending the models formulated in the results of qualitative evaluations in eHIS development process (Gross et al., 2001; Morton et al., 2018; Nicholas et al., 2010; Yardley, Morrison, et al., 2015). In its place the evaluation survey with open text questions was designed to gather relevant information within the project timeline. This approach limited the richness of the data. However, the data collected was sufficient to assess the acceptability of the intervention amongst those who completed T2 follow-up.

Recruitment. Recruitment of the convenience samples was also determined by the project timeline. In the feasibility study it was in line with its aim to explore who would be interested in the intervention (Chapter 5). However, recruiting volunteers in the qualitative evaluation studies completed in the eHIS development stage resulted in samples with a higher proportion of well-educated men and/or students, and with men from lower socioeconomic backgrounds or not linked to academia less represented. This in turn could lead to eHIS development being biased towards those with higher educational attainment (see Chapter 4).

Specific studies limitations. The limitations of specific studies discussed in the thesis chapters add to the limitations of the project as a whole. One example is the choice of the pre-test post-test design in Study 3. In future studies exploring the effectiveness of the intervention using RCT would be more appropriate. Another limitation was the method of recruitment used in Studies 1, 2 and 3. Wider recruitment approach could potentially affect data collection and shed more light on the variation of richness of data in TAIs in Studies 1 and 2. However, it is important to note that the choice of specific methodology was directed by following the pragmatic rule of choosing the options to be seen as the most optimal within the project resources and timeline constraints.

Resources limitations. Time and resources constraints had large impact on the eHIS development process. As a result, some of the changes suggested to improve the intervention but not categorised as high priority were not implemented. The design and content of the kits was limited by the available financial resources. Other limitations were linked to the LifeGuide software used to design the eHIS website, which did not support many technical features that users may be used to on contemporary commercial websites. As the importance of the quality of design, fitting with modern technologies and the kit content were highlighted in the feedback received from participants in Studies 1 – 3, the lack of resources could negatively impact the participants' experience and engagement with the intervention, and in consequence the preliminary results of its effectiveness.

The Project Contributions

Contribution to condom use theory. The findings of the studies completed within the project contribute to the development of theory and produce new evidence, unique in the area of the online self-guided preventive behaviour change interventions. The feedback received in the qualitative evaluations as well as the direction of changes observed in the feasibility study on condom use behaviour and condom use related outcomes generally support the assumptions of the LM regarding the outcomes involved in the process leading to changes in condom use experience and consistency of condom use. All three empirical studies completed within the project add further evidence supporting models included in the LM, especially the CUE model (Sanders et al., 2012).

Contribution to evidence. The results of the studies completed within the project may be applied to condom promotion and behaviour change intervention development, especially useful, but not limited to, development of digital health promotion interventions. Firstly, the preliminary effectiveness results indicate that a brief, focused, online intervention has potential to positively impact condom use experience and behaviour, and through these results it can strengthen the evidence of impact of DIs in this area (Daher et

al., 2017). On a more detailed level, the insight into specific motivations that users may have to engage with this type of intervention may be particularly useful, especially when considered at wider categories level (e.g. incentives, motivation, extending knowledge and skills etc.). Through developing understanding of the impact of different stimuli material on received feedback this project could help in making decisions regarding the most appropriate approach to elicit specific type of feedback sought in future studies. Some of the facilitators of engagement with the intervention employed in the eHIS development, namely use of curiosity, fun, and recall rather than recognition, have been since recommended to be used in designing effective behaviour change interventions (Mummah et al., 2016; van Genugten, Dusseldorp, Webb, & van Empelen, 2016). In the process of the systematic review completion, gaps in existing BCTT (Michie et al., 2013) were identified and definitions of new behaviour change techniques were formulated. This could contribute to extending the existing frameworks and better understanding of nuanced differences between different behaviour change techniques.

Inspiring further research. The results obtained within this project may also contribute to formulation of new research questions regarding specific issues of condom use experience, intervention feasibility or study design. One could be an exploration of specific condom use experience and support needs in men with little or no condom use experience. Another could be an experimental investigation of different TCUS development techniques discussed in Chapter 3.

Going one step back, experimental research could shed more light on the active ingredients of eHIS and their interaction (Peters, de Bruin, & Crutzen, 2015) and help to define the "minimum threshold" of the intervention required to achieve behaviour change (Ainsworth et al., 2017, p. 423). This could inform future iterations of eHIS suitable for different groups of users (Beyer et al., 2018; Bidargaddi, Pituch, Maaieh, Short, & Strecher, 2018; T. Fleming et al., 2019; Godinho et al., 2016; Muench & Baumel, 2017).

The role of facilitators of engagement: novelty and humour in health promotion and ways in which they could be introduced should be further explored, especially in sexual health context. Only a handful of recent research on these issues, exploring them from various perspectives in no systematised way, has been identified (Byron, Albury, & Evers, 2013; S. Cooper & Dickinson, 2013; Gold, Lim, Hellard, Hocking, & Keogh, 2010; R. B. T. Lim, Tham, Cheung, Adaikan, & Wong, 2019; Pariera, 2017; Stevens, 2018; Swigart et al., 2019; Winskell, Obyerodhyambo, & Stephenson, 2011).

Further research on various formats and/or mode of delivery (as discussed above) would also allow exploration of who they appeal the most to. If eHIS was to be introduced into other settings (such as educational or clinical ones) or addressing personal circumstances (for example relationship situation), it would be recommended to carry out qualitative explorations of condom use experience and support expectations within the specific target audience first. Areas requiring further research are discussed in details in Chapters 3-5.

Contribution to practice. The results of the studies completed within the project can also inform educational and clinical practice. They highlight issues men may experience before they start using condoms and when they use condoms, contributing to increasing their awareness. The results may help educators and health care professionals to gain more insight in what type of information men may seek in relation to their condom use. Following the study results practitioners may also consider approaching condom use issues in a novel way proposed by eHIS – focused on pleasure and sensation. Depending on the needs of users, eHIS could be delivered as a stand-alone intervention or be integrated with existing systems (Labrique, Vasudevan, Weiss, & Wilson, 2018; Serrano-Santoyo & Rojas-Mendizabal, 2017).

Contribution to wider health care issues. Finally, but not less importantly, the project has potential to address health issues at a wider societal level by contributing to improving access to health services. There was interest in the intervention across the whole

country with a large group of participants coming from urban areas, where many health services are placed. One explanation of this may be that the brief, home-based approach of eHIS may appeal to men who otherwise would not see their condom use issues as serious or important enough to seek help through existing health care services. The fact that participants praised eHIS's convenience and showed no willingness for FTF contact may suggest that its online format was appealing to those who would not reach the existing services due to inconvenience and/or embarrassment (Ennis et al., 2012).

The intervention potential can be limited by lack of access to good quality Internet (Philip et al., 2017; Riddlesden & Singleton, 2014). On more complex level it can also be limited by the digital divide, with those over the age of 65, with lower educational attainment, having a disability or not being employed, or those with lower health literacy levels being most likely to be excluded from access to digital health services (Helsper & Reisdorf, 2017; Mackert, Mabry-Flynn, Champlin, Donovan, & Pounders, 2016). All of these groups deserve special consideration especially as access to digital health tools is seen an essential for securing human rights to healthcare (Susło, Paplicki, Dopierała, & Drobnik, 2018). It may be particularly important as men from various groups, including some of the vulnerable ones, were interested in the intervention.

Through appealing to groups with specific service needs as well as making it easily accessible to those from vulnerable groups, eHIS can contribute to better health equity in the society (Azzopardi-Muscat & Sørensen, 2019). For this to happen, eHIS should be integrated with existing services to complement them, rather than replace them or be implemented outside them (Labrique et al., 2018; Serrano-Santoyo & Rojas-Mendizabal, 2017). This can be achieved through purposeful segmentation, developing DIs for specific groups of users, for example for those digitally literate, who are most likely to engage with them (Evans, Thomas, Favatas, Smyser, & Briggs, 2019; Yee et al., 2018), while providing FTF support such as in the HIS UK intervention (Stone et al., 2017), for those who would benefit more from it. Additionally, the monetary cost (access to the Internet) and personal

resources (knowledge, time etc.) required to engage with eHIS are relatively low. This may make the intervention more appealing to men from lower socio-economic status groups, who still experience great health inequity in the UK (Carson & Laverty, 2019).

Conclusions

Within the project a full process of adaptation, development and evaluation was completed. This was a complex multi-stage and multi-layered process which required integration of various theoretical and methodological approaches. The pragmatic approach leading the intervention development was invaluable in supporting decisions regarding the choice of theory, methods and implementation of participants' feedback. The lessons learnt from the process may contribute to the development of guidance on adaptation of interventions between modes of delivery and in a wider context adds to the body of evidence on DIs development. Having a transparently formulated theoretical background makes eHIS an intervention that can be easily used in further research. Due to its online format eHIS can be easily amended to target specific sociodemographic groups or to be tested in a different contexts.

eHIS was demonstrated to be a feasible intervention with results indicating that it can also be effective in improving numerous aspects of condom use. The results of the studies completed within the project contribute to the body of evidence of developing preventive health behaviour change online interventions and support theoretical models employed in the current project. Further eHIS evaluation in a large scale RCT should provide information about its efficacy. If it was confirmed to be effective, the intervention could complement existing services in the UK, especially for those not willing to discuss condom use related issues in an FTF setting. Further eHIS development could be considered to explore its usefulness in various settings and with diverse audiences. Implementing the intervention nationwide has potential to contribute to reducing health inequalities.

List of Appendices

Appendices

Appendix A

Examples of eHIS Webpages and Amendments to Them throughout the Development

Examples of core pages

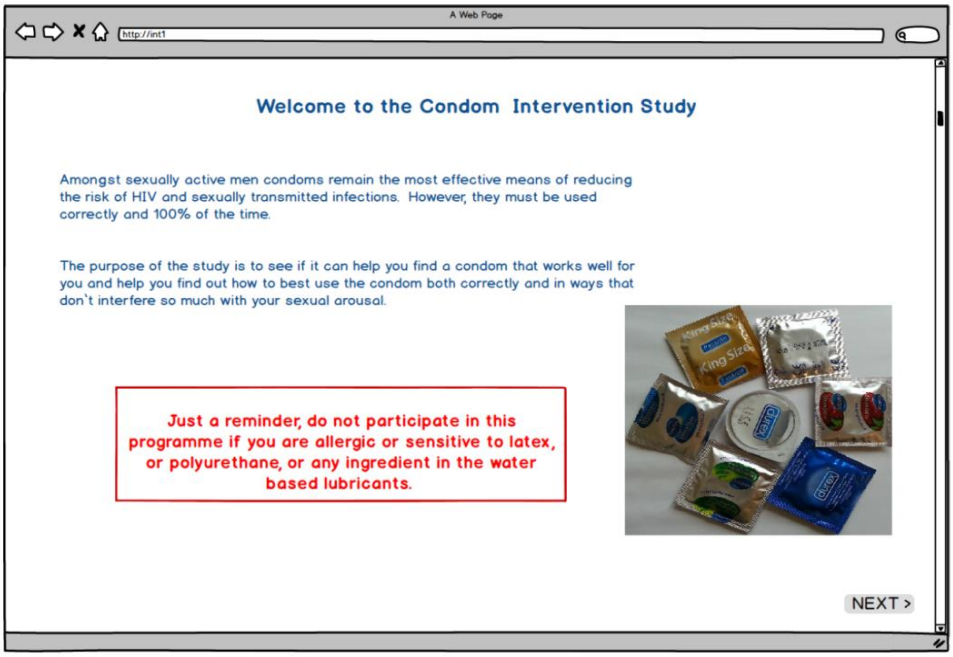


Figure A1. Study 1

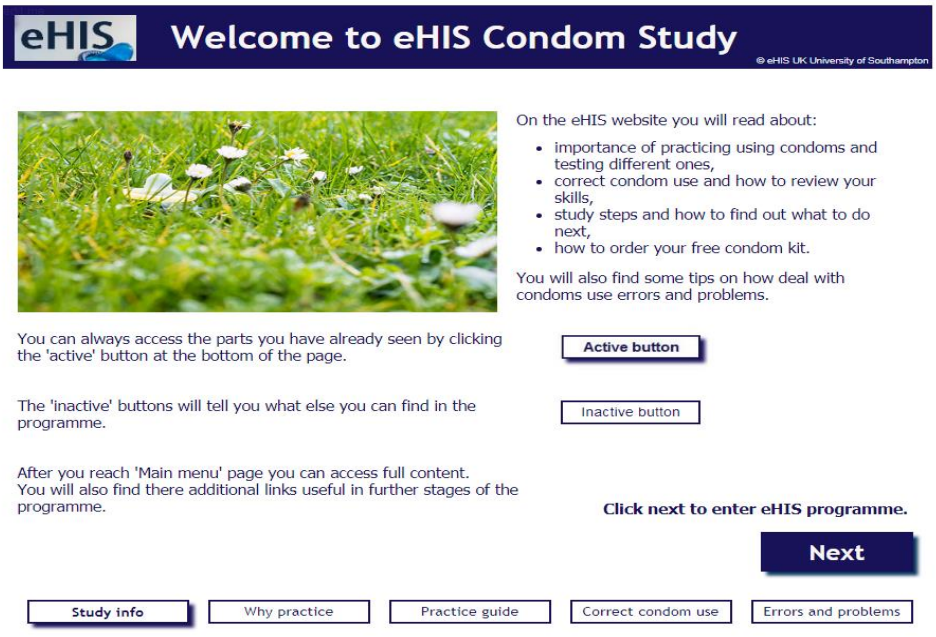


Figure A2. Study 2

Appendix A

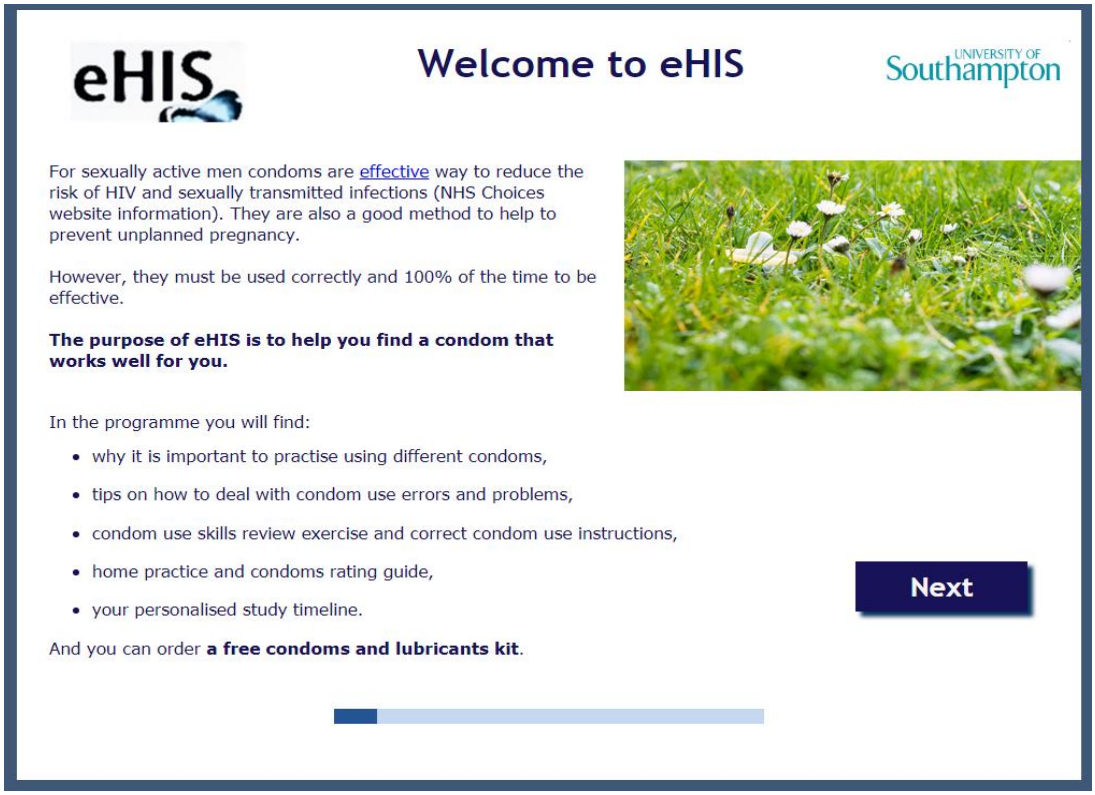


Figure A3. Study 3

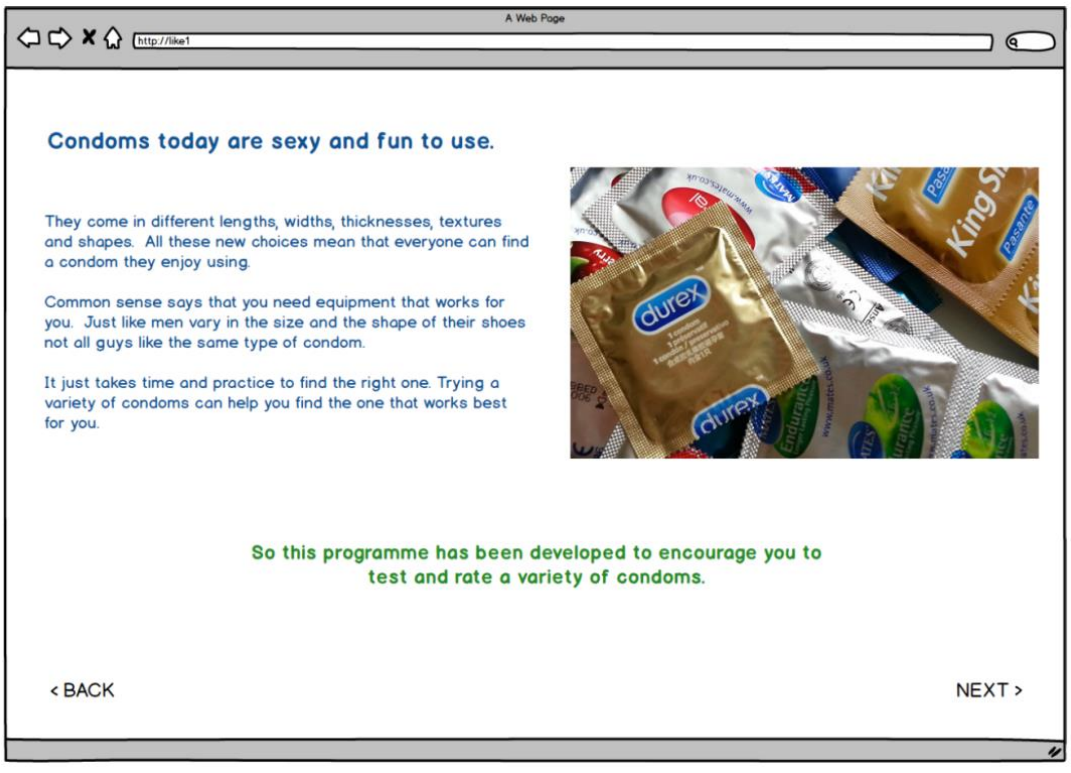


Figure A4. Study 1

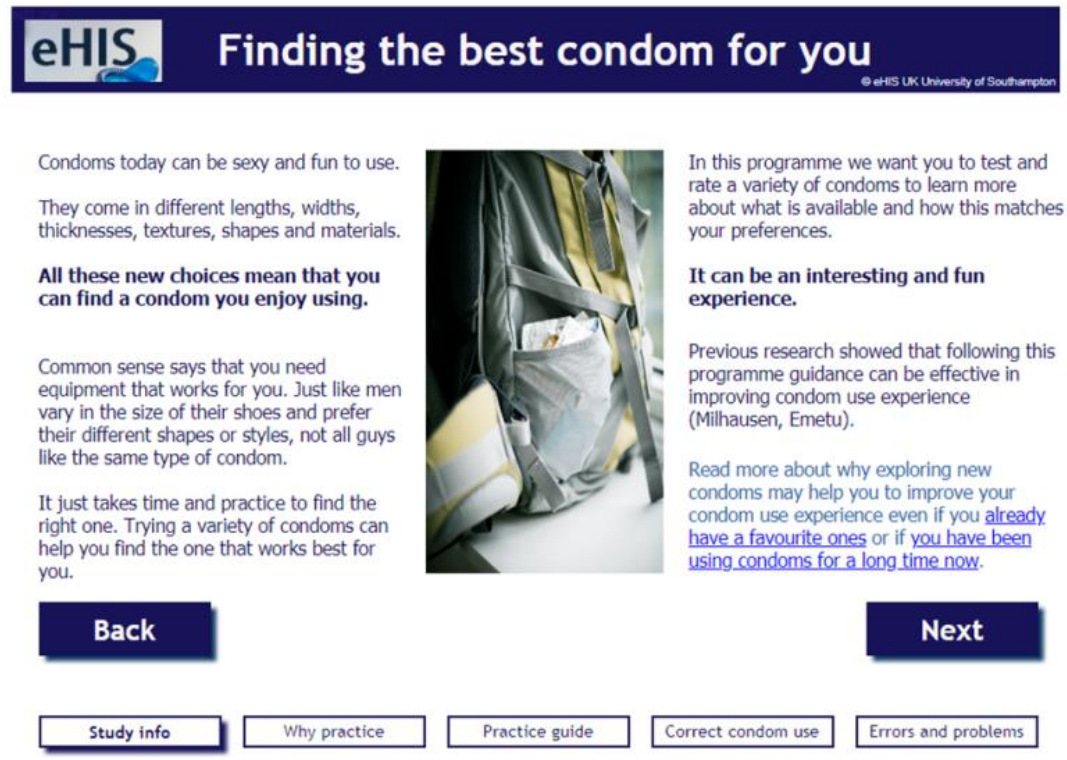


Figure A5. Study 2

Figure A6. Study 3

Appendix A

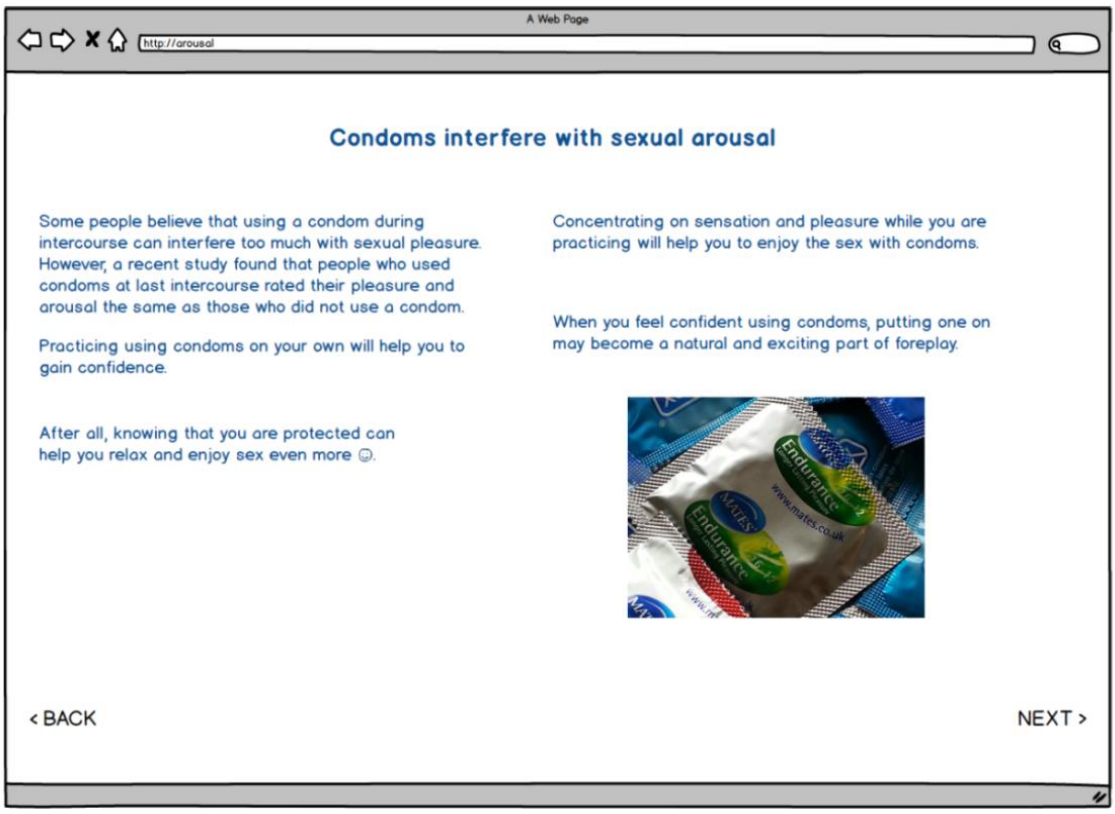


Figure A7. Study 1

Figure A8. Study 2

Figure A9. Study 3

Figure A10. Study 2 (version a)[16]

[16] Example of a page added in the computerised version and moved from additional to core pages in the final version of the intervention

Appendix A

Figure A11. Study 2 (version b)

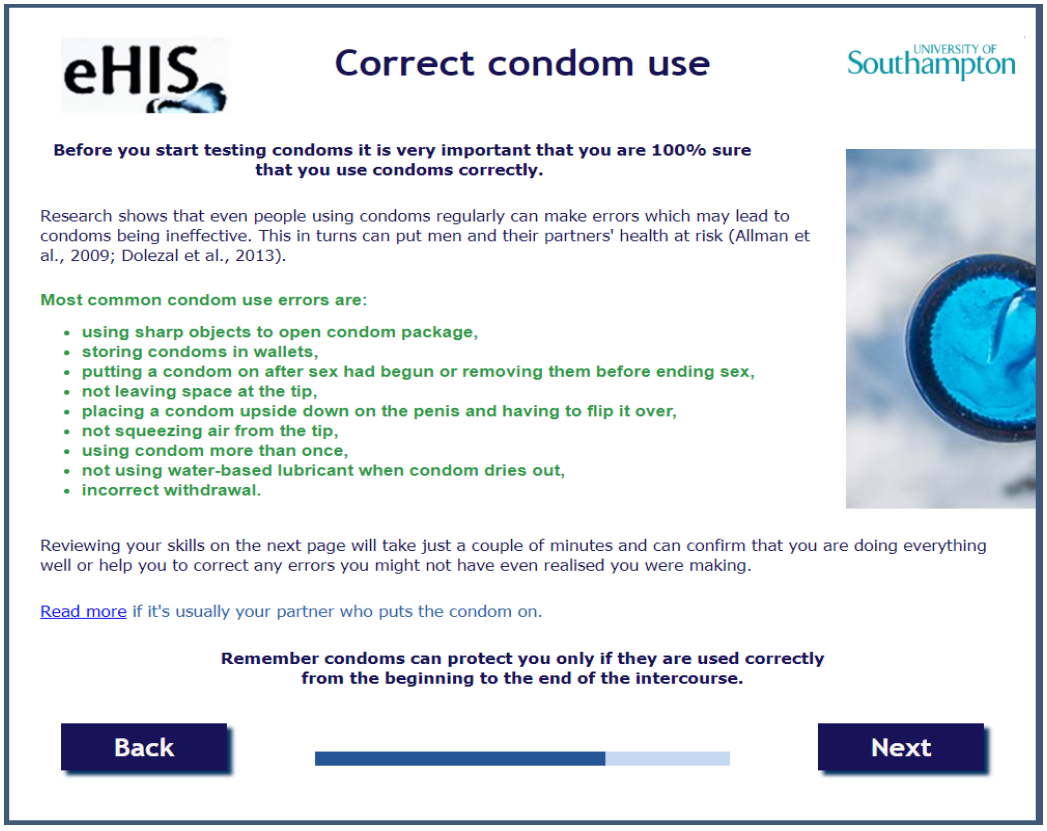


Figure A12. Study 3

Figure A13. Study 1

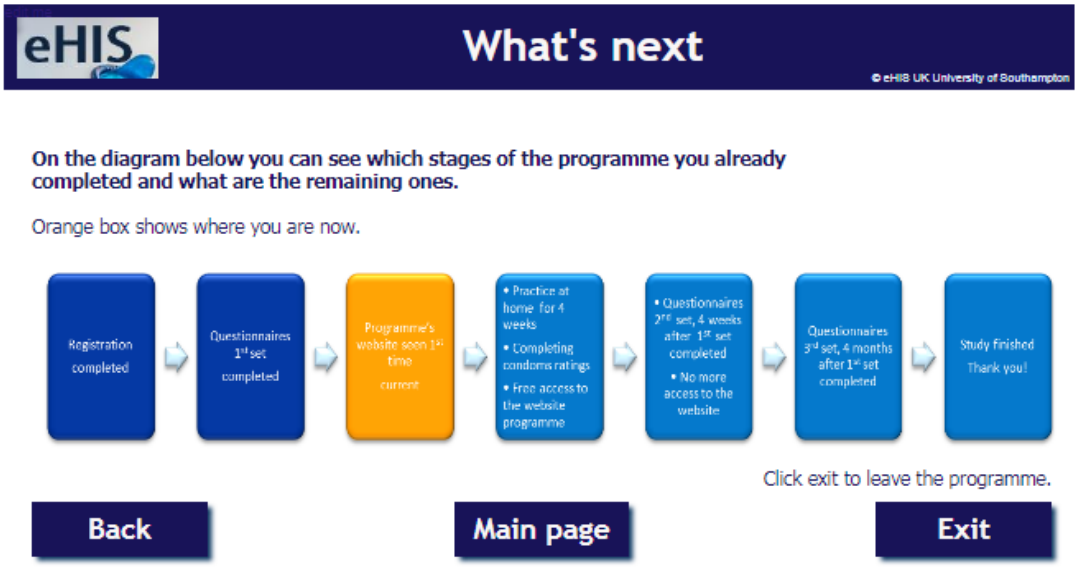


Figure A14. Study 2[17]

[17] Page incorporated into main menu in Study 3, see Figure A15.

Appendix A

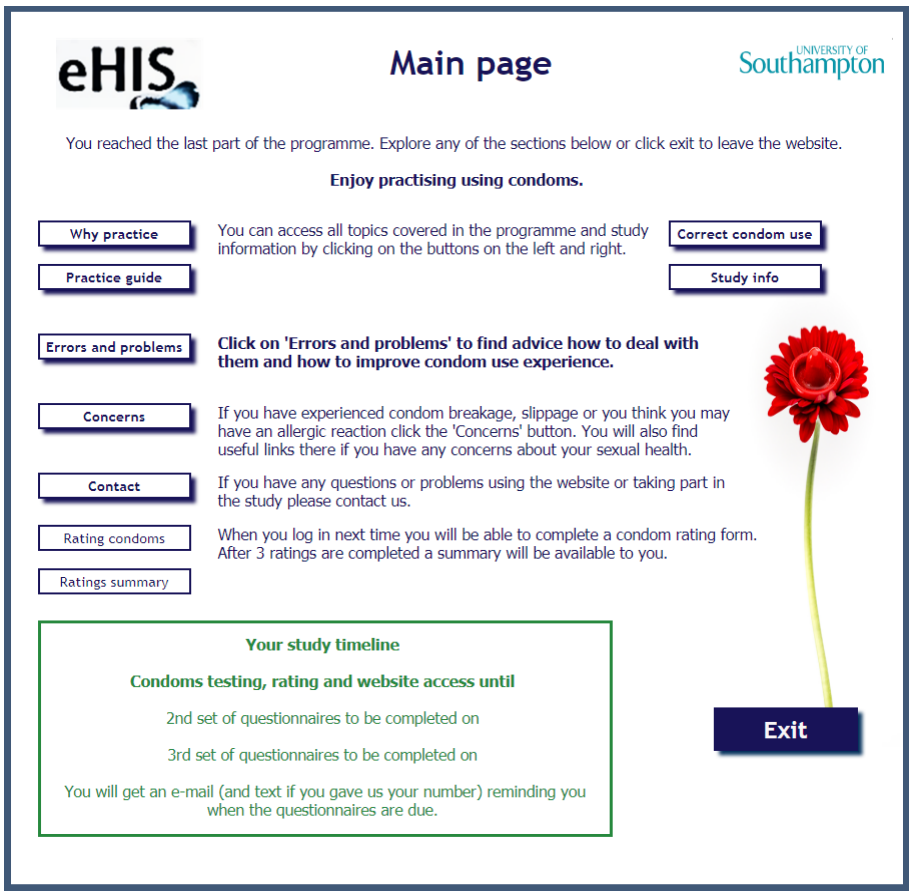


Figure A15. Study 3

Examples of optional pages added in computerised version

Figure A16. Study 2 and 3 (general layout change in Study 3)

Figure A17. Study 2 and 3 (general layout change in Study 3)

Appendix B

Log of Decision Making Process and Amendments Following the Qualitative Evaluation of the eHIS Prototype (Study 1) and the Qualitative Evaluation of the eHIS Computerised Version (Study 2) – Examples [18,19]

Prototype			Computerised version[20] [21]		
Feedback, (priority[22])	**Review context[23]**	**Decision/change introduced**	**Feedback, (priority)**	**Review context**	**Decision/change introduced**
Theme: Clarity			**Theme: Understanding**		
Elements that were mentioned as unclear: skills review, home practice, study procedure, condom box content. Too difficult, academic language. (M, S)[24] [also 'Personal preferences']	Simple text presented on one page, with points visually separated, and uncluttered design liked by participants in the study and similar to the preferences of male users for online information (Arcand & Nantel, 2012). Simplified language makes the information more accessible for users with different literacy levels (Abraham & Kools, 2011; Birru et al., 2004; El-Ibiary & Youmans, 2007; Plimpton & Root, 1994). Use of images improved understanding of health message for	Rephrased in line with feedback and made concise with parts of the content which were well understood. Content was reviewed for academic jargon and rephrased. Visual features such as bolding, bullet points, and shorter paragraphs were introduced to help process the information. The intervention flow diagram depicting upcoming steps of	Study procedure not entirely clear. (M) [also Barriers and facilitators]	Specific points of procedure reviewed in the context of evidence (see the second column) and possible amendments discussed with CG.	Specific points rephrased, use of visual presentation of information was increased (bolding, bullet points). Individualised study and intervention timeline added to reduce confusion. 'What's next' page removed as not visited often and would require too much resource to develop it into an interactive feature updating with the study and the intervention progress.

[18] Simplified table containing only parts focused on negative experience/aspects requiring change. Does not include errors corrections, minor design and grammar changes and positive comments marked 'maintain and/or use more across the intervention'.
[19] All changes discussed in detail with Professor Cynthia Graham (CG), project supervisor, specific aspects discussed with Professor Lucy Yardley (LY), project supervisor.
[20] Most of the comments in the evaluation of computerised version were single/occasional comments suggesting the change and were reviewed in the context of the whole sample experience.
[21] Most of the stronger negative comments in Study 2 came from the same participant.
[22] MoSCoW analysis: M – Must have, S – Should have, C – Could have, W – Won't have (Bradbury et al., 2014; Clegg & Barker, 1994; Kuhn, 2009)
[23] Guiding principles (GPR), logic model (LM), evidence, expert opinion and experience with the prototype.
[24] Specific changes in design were reviewed in the context of the project timeline and resources and prioritised accordingly. For concise presentation they were placed together as one category in the Appendix. Same applies below when multiple categories assigned.

	those with lower literacy levels. (Meppelink & Bol, 2015) Explicitly structuring information can improve understanding of medical information by lay persons (Langewitz et al., 2015).	the intervention and the study was introduced. Study procedure was simplified. Better quality image was used to present the condom rating form.			Printed information about login to the intervention website to complete ratings added to the kit. Login/registration procedure explanation reviewed.
			Specific items or response options in the study measures were vague/not always clear. (M)	Items in specific study measures and possible amendments were discussed with CG and HIS-UK team. Clarity of items essential for data validity (Urbina, 2014). Feedback explicitly suggesting simplifying some of the questionnaire to avoid ambiguity, negative phrases, repetition.	Study measures items were amended where possible, in line with feedback and where relevant in line with HIS-UK study (Stone et al., 2017).
			Links descriptions not reflecting the content of optional pages. (M)		Links text rephrased where relevant.
			Occasional comments regarding clarity of content of the kit and home practice. (M)		Kit description rephrased and home practice message clarified and strengthened.
Theme: Personal relevance				**Theme: Personal relevance**	
eHIS more relevant for younger, less	Methods of enhancing motivational message discussed with supervisors and	Optional pages raising awareness of common	eHIS more relevant for younger, unexperienced	Discussed with CG in the context of GPR and LM.	Page raising awareness of common condom use errors

skilled, less experienced, less confident men. (S) Those confident in their own skills don't see eHIS as personally relevant and/or are not motivated to review their skills. (S) Having favourite condoms already was linked to not seeing eHIS as personally relevant. (S) Relationship status determining the relevance of the intervention. (C) Partner putting condom on – not personally relevant. (C) Language 'heterosexually centred'. (M)	during CAHP25 seminar: "Challenges of development of the on-line version of the Home Intervention Strategy programme to enhance male condom use." on 14th October 2015 – explicit addressing of the reasons not to engage within optional content to avoid overloading core content suggested. Raising awareness of common condom use errors may help to accurately assess their own skills (Langer et al., 1994). Encouraging skills review prompted reflection on own skills in Study 2. Targeting and tailoring used in behaviour change intervention considered to make the message more focused and personal (Catania, 1999; Chesney et al., 2003; Couper et al., 2010; Kiene & Barta, 2006; Kreuter & Wray, 2003; T. Lehto & Oinas-Kukkonen, 2011; Neuhauser & Kreps, 2010; Noar et al., 2007; Smit, Linn, & van Weert, 2015; Strecher et al., 2008) Self-assessment with tailored feedback more acceptable to participants; lack of feedback was no more effective than information alone. (Morrison, Moss - Morris, et al., 2014) Tailoring – not always effective in increasing engagement (McClure et al., 2013) Tailoring not recommended by the online behaviour change expert (LY) as	condom errors, explaining why taking part in eHIS may be relevant for experienced users and those in relationship were added to enhance motivational message. New optional pages available through links. Introduction to skills review was rephrased to increase its persuasiveness. Language made inclusive, neutral for sexual orientation.	men, in a school setting or at a university – basic educational intervention. (W)	Agreement that the comments were occasional and intervention being basic was in line with GPR.	rephrased and moved to core pages.

[25] CAHP – Centre for Application of Health Psychology, Psychology Department, University of Southampton (currently CCCAHP – Centre for Community and Clinical Applications of Health Psychology)

	requiring substantial resources and not having large impact on the outcome of the intervention. Use of optional content addressing specific issues recommended as effective and additionally encouraging users' autonomy (Deci & Ryan, 1985) (in line with the PBA leading the project (Yardley, Morrison, et al., 2015)). Optional content can be introduced if does not go beyond the scope of the intervention - in line with eHIS GPR of briefness and participants' feedback to avoid large volume of information.				
Masturbation is not for me. (M) [Linked to 'Personal preference' theme: involving partner in practice.]	Masturbation may not be acceptable due to cultural or personal norms (Aldridge, 1983; Das, 2007; Flank, 2013; Gerressu et al., 2008; K. S. Hall & Graham, 2014; Madanikia et al., 2013). Normalising and emphasising benefits of masturbation for developing confidence in condom use (Annon, 1976; C. Lee, Brown, & Blood, 2000) may help accept the approach. One of the key points of KIHIS is practice without a partner present (Milhausen et al., 2011). Project pragmatic approach (Chapter 1) assumes adjusting solutions to the real life context.	To normalise the idea of masturbation additional content focused on its benefits and challenging beliefs on masturbation inadequacy was introduced. To follow the pragmatic approach of the project a possibility of practice with a partner was added while highlighting that practice alone was a preferred option.			
eHIS more relevant for stereotypical risk groups. (W)	Suggestion against GPR of eHIS aiming to improve condom use experience of men in general population regardless of their background.	Not followed.			
			Suggested adding 'n/a' or 'other' options to the	Discussed with CG – agreement that making	Information to skip not relevant questionnaires added.

			questionnaires and/or rating form. (S) Some of the measures/measures' items not personally relevant. (C)	changes suggested in feedback would be in line with GPR and can improve participants' experience while completing measures/rating form. Agreement that tailoring questionnaires display on the basis of earlier answers could improve measures completion experience. Feedback explicitly suggesting making the items more relevant for individual situations.	'N/a'/'other' options added to the questionnaires; 'Oral intercourse' added to condom rating form, Interactive display of the questionnaires.
Theme: Relevance for the problem				**Theme: Relevance for the problem**	
Condom use is self-explanatory and guidance is not needed. (S)	High confidence with own skills and content seen as obvious could cause perception of this part of the intervention as not needed. Other participants appreciate having it in eHIS. (Seal & Agostinelli, 1996) This part is an integral part of core content.	To improve perception of eHIS relevance for improving condom use experience the possibility of misjudging skills was raised, and optional information about common condom use errors was added to increase motivation to reflect on own condom use and review own skills.	Occasional comment that some information seen as not adding much to the content (references to previous studies, page for those who already have favourite condoms). (W)	Discussed with CG. Agreement that optional content not relevant for some may be relevant for others. Differences in need for information to be expected.	Not followed.
Checking condom manufacturers' sites not relevant for condom use problems. (S)	After review in the context of Study 1 results (especially participants' expectations) the information on manufacturers' sites about condom features was judged to be inconsistent or was missing.	Links to external sides removed to avoid confusion.			
"This condom is too thick." item was judged to be not	Discussed with CG – agreement to reformat and slightly amend the form and seek further feedback.	Graphical organisation of rating form changed to improve clarity. Drop list	"How turned on were you when you were using this condom" in	Discussed with CG. Agreement that this item might not be clear and not	Specific item removed in the final version of the rating form.

relevant for condom use experience. (S) Adding to condom rating form: items about using condoms for oral sex. (W)		added to choose a condom that was rated. Not followed at this stage.	the rating form not relevant for condom use experience. (S)	necessary. Condom rating form (items and length) reviewed in line with participants' suggestions and amended after discussion with (CG) and in the context of the changes made to the original condom rating form in HIS-UK study (Stone et al., 2017).	Items in the condom rating form reviewed and amended to improve clarity, relevance (e.g. using condoms for oral sex) and to reduce perception of the intervention demands.
Condom use practice not relevant for condom use experience. (S) Practicing without a partner not relevant for real life situation. (S)	Users need to be motivated to perform behaviour - IMB (J. D. Fisher & Fisher, 1992)	Motivational message (the intervention rationale) reviewed and rephrased where relevant (LG). Optional pages addressing specific circumstances added (see above).	Occasional comment that practicing without a partner still seen as not relevant for the real life situation. (W)	Discussed with CG in the context of GPR and LM. After content was reviewed and perception of eHIS relevance for the problems improved - agreement that no further changes were to be introduced.	Not followed.
Content not covering various sexual intercourse scenarios. (W)	Outside the scope of the intervention.	Not followed.	Some measures' items may not be relevant for homosexual men,	Discussed with CG – decided that the items may be relevant.	Not followed.
Lack of belief in the intervention effectiveness and/or home practice effectiveness. (M)	Feedback discussed with CG and reviewed in the context of GPR and LM.	Intervention content reviewed and rephrased where relevant to emphasise trying and exploring how the approach works for an individual.			
Searching for information on external websites while using eHIS. (C)	Discussed with CG. Agreed that it would be beneficial to ask about additional information searching in the feasibility study to understand the need for information.	Questions added to the feasibility study measures (Study 3) to explore additional information seeking and the sources used.	Frequent comparing eHIS to other websites. (C)		Questions for searching other sources of information revised.

Choice of kit content not satisfactory for all participants. (C)	Kit content discussed with CG, some lubricants and condoms suggested.	Reviewed and amended in line with participants' and colleagues' suggestions and availability.			
Theme: Breaking points and facilitators			**Theme: Barriers and facilitators**		
Study and intervention demands: procedures difficult to follow, timeline confusing, skills review too difficult, condom rating form too long, repetitive [last point also Personal Preferences]. (S)	Many of these points were linked to lack of clarity of the content and structure of the intervention. Use of facilitators of engagement identified in the study was discussed with the project supervisor (CG). An intervention designed to manage cold symptoms (Yardley et al., 2010) - the quantity of information presented had to be limited and access to more detailed information flexible to meet users' preferences for information provision and to be suited to their literacy level.	Content revised and rephrased to improve clarity (see above). Study procedure was simplified in line with participants' feedback (instant access to the website after completing study measures). Varied need for information provision was addressed by splitting information between core and optional pages and adding FAQ section. It also helped to reduce the volume of information presented on core pages. Condom rating form formatted (see above).	Condom rating form may be too long. (S) Some items in the questionnaires could be difficult to answer accurately – memory (occasional comment) (S)	Discussed with CG in the context of participants feedback and HIS-UK qualitative study (Stone et al., 2017).	Condom rating form shortened and redesigned. Timescale for specific items in study measures redefined.
Study and intervention demands: taking part intensive, too frequent practice, required commitment too extensive. (S)	Discussed with CG in context of GPR and/or LM. Agreement that the intervention aimed to be brief should be perceived as such. Improving content clarity (see above) and amending the procedure to reduce participation burden should improve this aspect of experience with the intervention. Health belief model – perceived barriers/cost are important factor in behaviour change (Ogden, 2007)	To reduce intensity of the intervention the time for home practice was extended by one week. Expectation regarding intensity of practice explicitly addressed to avoid misunderstandings. Option to opt out from reminders added (in the final computerised			

		version).			
Receiving daily e-mails in the evening inconvenient. (C)	Discussed with CG in context of GPR and/or LM. Agreement that the convenience is important and feedback should be followed to reduce it. Health belief model (as above) (Ogden, 2007)	E-mail reminders number reduced and timings set to follow registration time.			
Perception of large volume of information to process, long time required going through the intervention. (S)	Reorganising structure of the intervention could reduce the perception of the study's cognitive demands (Brünken et al., 2002; Mayer & Moreno, 2003; Moreno, 2006; van Merriënboer & Sweller, 2010).	Content simplified, restructured and reformatted (see above).	Participants information Sheet (PIS) somehow lengthy (W).	Discussed with CG – agreement that all information was necessary.	Not followed.
Disagreement with the evidence, too positive tone of the intervention regarding condom use experience, some participants feeling that their personal experience was invalidated. (M)	Message discordant with one's beliefs could be rejected (Edwards & Smith, 1996). Individual differences in knowledge perception can affect how the message contradicting personal believes is perceived (Strømsø et al., 2011). Addressing individual differences in knowledge perception outside the scope of the intervention.	Some of eHIS arguments were toned down to reduce the dissonance between the intervention message and users' future personal experience. Other points not followed.	Occasional disagreement with positive tone and suggestions that men may overestimate their skills. (C)	Discussed with CG. After content review agreement that because of only single comments they could have been linked to personal preferences rather than eHIS message style.	Some of the arguments further toned down.
Negative emotional reactions to: disagreement, repetition of some statements, similarity of items in the ratings form, information obvious or lacking relevance for	Information negating strong beliefs may be negated (Edwards & Smith, 1996). Individual attitudes towards knowledge acquisition may determine perception of information (Gold et al., 2010; Huang, 2003; Kraft et al., 2009; Shneiderman, 2004; Strømsø et al., 2011)	Addressed by changes to tone, clarity, emphasising motivational message (see above) and adding optional content addressing specific issues. The use of facilitators of users' engagement and	Masturbation as a controversial issue (occasional comment). (W) Too many condom images, uncomfortable association of condom and fruit (single	Discussed with CG. Agreement that current content was satisfactory. Discussed with CG – agreement to avoid elements causing discomfort if possible and in line with GP and	Not followed. The front page image has been changed to more neutral.

experienced problems. (M)	For evidence/discussion regarding clarity and relevance see above.	positive atmosphere (Chapter 4) such as less formal language, sense of humour, novel images was extended to make the intervention more friendly and engaging, and to break possible embarrassment.	comments, liked by others). (C) Question about the number of partners see as not appropriate. (single comment) (W) Feeling obliged to take part in the study after receiving kit – uncomfortable. (single comment) (W)	intervention aims. The question seen as essential to assess the characteristics of those interested in the intervention. Information that participants can withdraw at any time without giving the reason already included.	Not followed. Not followed.
Some parts of content seen as boring. (S)	Amusing content supported the information acquisition in text message sexual health promotion interventions (Gold et al., 2010). Novelty and interest linked to engagement with behaviour change interventions (Ferney & Marshall, 2006; Harle et al., 2008; Hurling, Fairley, & Dias, 2006; Mackenzie et al., 2007). See above (Morrison, Moss - Morris, et al., 2014).	Emphasis on novelty (e.g. images, approach) to invoke interest and curiosity. Ratings summary was introduced to make the intervention more interactive.			
Occasional comment regarding risk of embarrassment. (S)	Discussed with CG in context of GPR and/or LM. Agreement that highlighting privacy and increasing atmosphere should lead to reduced risk of embarrassment.	Increased positive atmosphere of the intervention (see above). Privacy and confidentiality of taking part emphasised.	Some embarrassment about directness of the questionnaires items. (W)	Should not be relevant in online study. Questions already not compulsory.	Not followed
Perception of eHIS credibility could be improved. The UoS affiliation should be emphasised.	Author's affiliation and expertise can improve perception of credibility (Fogg, 2002). Websites' features such as name, design,	Presentation of the intervention's academic affiliation, providing information about eHIS team, adding optional	Design and features not looking professional or not serious enough (images) could undermine perception	Website design reviewed considering available resources, technical limitations of software and website design guidance	Website design aesthetics and usability improved where possible.

(S)	navigation, etc. were found to be related to perception of credibility in studies investigating perception of online health information (Rains & Karmikel, 2009; Sillence et al., 2007c; Ye, 2011). Clear and simple language and information presentation were linked to judgement of health websites' credibility (Sillence et al., 2004). Providing clear references to supporting evidence should strengthen trust in the approach (Fogg, 2002).	content directly addressing trust and ensuring that the eHIS website looked and worked up to professional standards were employed to improve perception of eHIS credibility. Language was simplified (see above) and reference to the evidence provided where relevant.	of credibility. (C)	(Krug, 2006).	
Possible negative reactions if a 'right' condom was not found by future users. (W)	Discussed with CG in context of GPR and/or LM. Reviewing eHIS approach showed that it was clear that the focus is on developing attitude to explore rather than finding 'the one' fitting condom in the kit.	Not followed.			
			Occasional comments - Too serious, could have touch of lightness versus to jovial. (W)	eHIS reviewed for balance. Most of participants were satisfied.	Not followed.
			Occasional concerns	Discussed with CG, agreed that well addressed.	Relevant points reviewed.
			Skipping well known parts. (C)	Discussed with CG in the context of GPR and LM and reviewed in the context of results of Study 1 and literature regarding novelty and interest (see column 2).	Parts that participants were particularly interested in moved from optional to core pages. Wording, design and novelty elements reviewed and slightly amended to maintain users' attention.

Appendix B

Theme: Personal preferences[26],[27]			Theme: Personal preferences		
Design not attractive, some images seen as inappropriate. For example requests for redesigning entry and registration pages, changing layout of some pages, adding more colour, more appealing pictures. (S, C, W)	(Danaher et al., 2005; Pengnate & Antonenko, 2013; Sillence et al., 2007c). Rules for designing appealing websites reviewed as in Krug (2006).	Changes to the website navigation, structure and design were introduced in line with participants' feedback to improve the usability and attractiveness of the website. Images replaced with custom ordered images, design made more attractive.	Dated and basic design Some poor quality images, change font (S) Skills review webpage design should be improved. (S) More interactive features would be welcomed (such as showing progress through questionnaires). Some images seen as inappropriate (see barriers and facilitators theme) (C) Navigation buttons not used. (C) [also covered under Understanding] Lack of connection between images and content. (C) Add menu on each page. (W) Highlight key points. (C)	eHIS reviewed in line with literature (see column 2) considering the limitations of the LifeGuide software. All negative comments much less frequent in Study 2 compared to Study 1.	Font changed as suggested by participants. The webpage aesthetics was improved in line with the comments and within the technical possibilities of software. Key points highlighted (use of colour, bullet points and bolding). Navigation buttons removed. Skills review page design improved. Progress bars added to measures and core content pages.
Information may be perceived as forced. (S)	Addressing individual differences in knowledge perception outside the scope of the intervention.	Content divided into core and optional and personal circumstances addressed	Parts introduction and some wording in the skills review use may	Content discussed with CG and reviewed.	Rephrased where relevant.

[26] Only comments regarding 'dislikes' included, analysed in the context of parts 'liked' by the participants.
[27] Only added if points are not already covered above.

		in the additional optional content (see above).	sound patronising. (single comment). (S)		
	Dividing content into core and optional as well as strengthening the motivational message should improve perception of the content. (see above)		Too basic information in skills review may be seen as patronising. (single comment) (W)	Discussed with CG – all information judged to be essential. Feedback explicitly suggesting rephrasing content to avoid patronising (see below) or being too academic.	Not followed.
			FAQ page redundant (C)	Discussed that this page contained important information that was not seen by many participants.	Important info moved to menu page and split where relevant.
Asked for new information to be added: correct condom disposal, rate of STIs from incorrect condom use, more complex explanation of the mechanisms underlying problems they experienced, e.g., psychological processes linked to specific errors etc. fear appeal message (highlighting consequences of STIs etc.). (C, W)	Most of the requests for more information were outside the scope of the brief focused intervention (GPR). Fear-based message potentially effective method of communicating heath related topics (Witte, 1992; Witte & Allen, 2000) and it may be expected (Tanton et al., 2015). However, adding more fear appeal to motivate users to use condoms was against eHIS GPR to focus on building positive condom use experience.	Not followed. Added information how to dispose of condoms properly. 'Common condom user errors' optional page (see above) added to raise awareness and trigger reflection on own condom use.	Adding an interactive button explaining the purpose of the questions suggested (S). Hyperlinks to external information assisting measures accessed directly from the questionnaires pages suggested. (W)	Outside of technical possibilities of software used to design eHIS. Outside of the scope of the intervention.	Introduction to measures reviewed and rephrased where relevant. Not followed.
Asked for more detailed information on: programme's rationale, references to its sources, study procedure, condom use steps, information about kit content.	Including comprehensive, detailed information was against GPR to focus on a specific behaviour rather than comprehensively cover all related topics. Too detailed information could take the focus from personal experience to following detailed instructions (as	Specific suggestions reviewed and more details and/or optional content added (see above) when judged to emphasise the key message rather than adding a new content.	Asked for fewer details about study and on intervention pages. (W) Asked for more detailed info in core parts, for example about condom in the kit. (W)	Contradicted previous study feedback. Too detailed information, not in line with GPR and LM.	Not followed. Not followed.

Asked to add condoms packages images, more detailed condom use problems section. Message too vague not explicit enough. (S, C)	discussed with CG). Cognitive interference, anxiety, focus on performance can negatively affect sexual functioning (Barlow, 1986; McCabe, 2005; Sanders et al., 2014) Limited information recommended in dealing with sexual functioning problems (Annon, 1976). Addressing unrealistic expectations is an essential point in treatment of erectile dysfunction (Althof, 2002; McCabe, 2001; B. W. McCarthy & Fucito, 2005) Improving the clarity of the approach presentation, highlighting its key points and supporting evidence and enhancing the positive message about the benefits of home practice could help to address the solution expectations (C. Lee et al., 2000).	Content and procedure reviewed and rephrased/simplified/amended to improve clarity where relevant (see above). Providing detailed description of condoms in the kit or images of packaging not followed. Due to changes to condoms packaging and lack of ability to update them once the intervention was live package images were not added.	Errors and problems section to be moved to core pages. (S)	(See above)	Moved to core during study.
Too much emphasis on health and safety not enough on comfort and fun. Too strong focus on shortcomings of condoms. (S)	Focus on positive message is one of GPR of eHIS. Note: single opinions, may be linked more to personal focus/preferences rather than the actual content focus.	Content reviewed to ensure that the positive message was conveyed. Used customised images to make the atmosphere of the intervention more positive (see above).	Request for justification of the length of practice.	Discussed with CG. Not essential for the content. Could add distraction.	Not followed.
More emphasis on important points, for example fit of a condom. (S)	Inconsistent feedback across participants.	Bolding, bullet points and colour (see above) used to highlight the key points of the content.			.
Reorganise content to place more important or more useful info first: more information moved to entry page, introduce	Inconsistent feedback across participants.	Changes to the structure of the content and splitting in into core and optional parts (see above). Additional content added			

study procedure earlier, home practice earlier. Avoid repetition of the content but repeat info that need to be remembered. (S)		on the entry page.			
Make the navigation easier. (S)	Structure and navigation to be as easy as possible (Krug, 2006).	Buttons to navigate between sections of the intervention added.			
Change format: replace text with images and/or add more images to illustrate the text. Make design more attractive. (S)	Pictures and text facilitated recall of health information for users with lower and higher levels of health literacy respectively (Krug, 2006; Meppelink & Bol, 2015).	Changes made (see above)			
Introduce more interactive features. (C)	LifeGuide technical possibilities are limited.	Ratings summary added (see above)			
New ideas: eHIS team page, a FAQs section, information about what to do in emergency situations, option of opting out from receiving reminders, condom choice in the kit (C)	Suggestions were discussed with CG and agreed to be in line with GPR therefore included in the intervention.	Team page added (see above). FAQ section including info about emergency situation added. Content of the kit changed to make it similar to the one used in HIS-UK study.	New idea – links to other credible sources of information relevant to condom use	Comprehensive information outside of the scope of the intervention. For participants reassurance relevant information placed in the optional content.	Links to NHS choices and local GUM clinic search websites on concerns page.
New ideas : alternative sexual activities e.g. not just penetrative sex, including printed intervention	Suggestions were discussed with CG and inspired some changes to the intervention.	Changes introduced in the context of feedback: condom ratings summary and contact form added.	New ideas: reading others stories, humorous illustration/drawings, choosing condom to be included in the kit,	Suggestions could not be followed within timeline and resources of current project but could be considered in future versions of the intervention.	Not followed

information in the kit, feedback on the ratings they completed, adding contact details on every page. (C)			animations, interactive features. (W)		
Suggestions of incentives to engage users with the intervention and motivate them to complete the study (a pack of their favourite condoms). (C)	The possible incentives discussed with CG with consideration for available resources.	Incentives within the study resources added (prize draw, surprise in the kit, and donation to a chosen charity – three choices).	Adding an option to indicate any charity for donation other than the given option suggested. Charities to be related to sexual health. (W)	Choice of charities guided by aim to include possible wide range of preferences. Charity of choice could be more relevant in a large scale study. Note: Available resources lower than initially planned. Expert advice (LY) to change the prize draw to a guaranteed one (but lower value) "Thank you" voucher linked to measures completion.	Not followed. Incentives changed to fit within the resources and follow expert advice.
Friendly reminders. (C)	Discussed with CG.	Used the same as in Stone et al. (2017) study.			
New ideas: condom myths, highlighting the importance of developing partner's correct condom use skills, introducing diary to make notes about experience, include the partner's experience in the condom ratings, rating lubricants, information about new types of condoms e.g., spray on condoms and female condoms, inclusion of online forums or links to social media,	Suggestions judged to be outside of the scope of the intervention or not in line with the intervention GPR. Additionally social media type features would pose moderation and confidentiality issues (O. McCarthy et al., 2012) Reminders text was the same as the one used in HIS-UK study (Stone et al., 2017).	Not followed.	New ideas: other men or medical doctor supporting the intervention message, adding nature images, sharing experience with other users. (W)	Suggestions judged to be outside of the scope of the intervention or not in line with the intervention GPR. See references (O. McCarthy et al., 2012) in the second column.	Not followed.

making reminders interesting and inspiring. (W)			
Adding ratings of the importance of specific items in the condom ratings form. (W)	Beyond the scope of the project.	Not followed	
	Theme: Privacy, Safety, security		**Theme: Privacy**
Future users should be reassured more about privacy and confidentiality. (S)	(see references to in possible embarrassment)	Privacy and confidentiality of taking part was emphasised.	

Appendix C

The List of Databases with the Search Terms Sets Created for Each One

Database	Search terms	Limits
PsycINFO (through EBSCO)	(TI (Condom OR Condoms OR “Male Contraceptive device*”)) OR (KW (Condom OR Condoms OR “Male Contraceptive device*”)) OR (AB (Condom OR Condoms OR “Male Contraceptive device*”)) OR (DE Condoms) AND (TI (Intervention* OR Project* OR Program* OR Promot* OR Prevent* OR Teach* OR Training OR Practice* OR education* OR evaluat* OR skill*)) OR (KW (Intervention* OR Project* OR Program* OR Promot* OR Prevent* OR Teach* OR Training OR Practice* OR education* OR evaluat* or skill*)) OR (DE ("Intervention" OR "Program Development" OR "Program Evaluation" OR "Prevention" OR "AIDS Prevention" OR "Education" OR “Teaching” OR "Sex Education")) OR (DE (“Behavior Change” OR “Behavior Modification” OR “Psychosexual Behavior” OR “Safe Sex” OR “Sexual Risk Taking”)) OR (AB (reduc* OR chang* OR modif* OR increas* OR decreas* OR improv*)) OR (KW (reduc* OR chang* OR modif* OR increas* OR decreas* OR improv*)) NOT (TI (Review* OR Meta-anal*))	English Adulthood (18 years & older) Adolescence (13-17 years) Peer reviewed
MEDLINE (through EBSCO)	TI (Condom OR condoms OR “Male Contraceptive device*”) OR AB (Condom OR condoms OR “Male Contraceptive device*”) OR MH (Condoms OR “Contraceptive Devices, Male”) AND (TI (Intervention* OR Project* OR Program* OR Promot* OR Prevent* OR Teach* OR Training OR Practice* OR education* OR evaluat* OR skill*)) OR (AB (Intervention* OR Project* OR Program* OR Promot* OR Prevent* OR Teach* OR Training OR Practice* OR education* OR evaluat* OR skill*)) OR (MH "Intervention studies") OR (MH "Program Development") OR (MH "Program Evaluation") OR (MH “Health Promotion”) OR (MH "Education") OR (MH “Sexual Behavior”) OR (MH ("Behavioral Research" OR "Behavioral Medicine" OR “Health Behavior”)) OR (MH “Safe Sex”) OR (MH “Unsafe Sex”) OR (MH ”Risk-Taking”) OR (MH “Risk Reduction behavior”) OR (MH “Preventive Medicine”) OR (MH “Preventive Health Services”) OR (MH “Behavior Control”) OR (AB (reduc* OR chang* OR modif* OR increas* OR decreas* OR improv*)) NOT (TI (Review* OR Meta-anal*))	English 19+ years Adolescent: 13-18 years Journal articles

Appendix C

Database	Search terms	Limits
EMBASE (through Ovid)	(condom or condoms or "male contraceptive device$").ti,ab. or condom/ AND (intervention$ or project$ or program$ or promot$ or prevent$ or teach$ or training or practice$ or education$ or evaluat$ or skill$).ti,ab. or intervention study/ or health program/ or program development/ or health education/ or health promotion/ or prevention/ or sexual education/ or safe sex/ or unsafe sex/ or risk reduction/ or high risk behavior/ or sexual behavior/ or behavior change/ or behavior modification/ or behavioral research/ or health behavior/ or (reduc$ or chang$ or modif$ or increas$ or decreas$ or improv$).ab. NOT (review$ or meta-anal$).ti.	English language Adult <18 to 64> Adolescent (13 to 17) Journal Exclude MEDLINE records
CINAHL Plus with Full Text (through EBSCO)	TI (Condom OR condoms OR “Male Contraceptive device*”) OR AB (Condom OR condoms OR “Male Contraceptive device*”) OR MH Condoms AND TI (Intervention* OR Project* OR Program* OR Promot* OR Prevent* OR Teach* OR Training OR Practice* OR education* OR evaluat* OR skill*) OR AB (Intervention* OR Project* OR Program* OR Promot* OR Prevent* OR Teach* OR Training OR Practice* OR education* OR evaluat* OR skill*) OR MH ("Intervention trials" OR "Program Development" OR "Program Evaluation" OR “Program Implementation” OR “Preventive healthcare” OR “Health Promotion” OR "Education" OR “Safe sex” OR “Unsafe sex” OR “Risk Taking Behavior”) OR MH ("Behavioral Changes" OR "Behavioral Research" OR "Behavior Modification" OR “Health behavior”) OR (AB (reduc* OR chang* OR modif* OR increas* OR decreas* OR improv*)) NOT (TI (Review* OR Meta-anal*))	English All adult Adolescent: 13-18 years Peer reviewed Exclude MEDLINE records
CENTRAL Cochrane	"condom" OR "condoms" OR "male contraceptive device" (ALL Text) AND "Intervention*" or "Project*" or "Program*" or "Promot*" or "Prevent*" or "Teach*" or "Training" or "Practice*" or "evaluat*" or “skill*” :ti,ab,kw	trials

Appendix D

Data Extraction Form

Adapted from Centre for Reviews and Dissemination's guidance for undertaking reviews in health care (Centre for Reviews and Dissemination, 2009, pp. 30-31)

Date of data extraction:	Researcher performing data extraction:	Comments
General information		
Study ID number:		
Author		
Article title		
Citation		
Type of publication (e.g. journal article, conference abstract)		
Country of origin		
Source of funding		
Study characteristic		
Aim/objectives of the study		
Study design		
Study inclusion/exclusion criteria		
Recruitment procedures used (e.g. details of randomisation, blinding)		
Unit of allocation (e.g. participant, GP practice, etc.)		
Participant characteristic		
Age		
Gender		
Ethnicity		
Additional characteristic (e.g. HIV/ STIs status)		
Number of participants allocated to the intervention and control group(s)		
Intervention and setting		
Technical condom use skills development techniques 1) Instruction – complete use 2) instruction – correct use 3) demonstration 4) skills rehearsal 5) feedback 6) self-monitoring 7) monitoring of behaviour by others 8) observation of others performing behaviour 9) home- practice 10) behavioural experiment	*Example: skills rehearsal and feedback*	

Mode of delivery: A) face-to-face B) printed materials for group use C) printed materials for individual use D) illustrated materials E) technology mediated (e.g. video, audio, computerised, web-based, smartphone application)				
Format of delivery a) individual b) dyad c) group				
Other condom related components	*Example:* communication training			
Context topics	*Example: basic HIV information*			
Number of sessions				
Duration in minutes				
Intervention facilitator (e.g. nurse, researcher etc.)				
Setting (e.g. school, clinic etc.)				
Theoretical basis				
Control group intervention characteristic				
Outcome data/results				
Unit of assessment/analysis				
Statistical Techniques used				
Outcomes/measures: Frequency and consistency of condom use Correct condom use complete condom use Condom use problems Condom use experience Condom use self-efficacy New STIs rate	Yes/No	Measure		
Results/effect size of the study analysis for the above outcomes Dichotomous: (number of events, number of participants) odds ratio, risk ratio, confidence intervals and p-value Continuous: mean difference, confidence intervals, p-value	Outcome	Results	Effect size	
Length of follow-up				
Number of follow-up measurements				
Number of participants enrolled				
Number of participants included in the analysis				
Number of withdrawals				

Appendix D

Number of exclusions		
Number of lost to follow-up		
Type of analysis used in the study (e.g. intention to treat, per protocol)		
Adverse events		
Additional information		

Appendix E

Definitions of Methods of TCUS Development

Technique	Definition	BCTT[a] definition
Instruction – complete use	Providing information that condoms should be used consistently and correctly without any further instructions. Providing information that it is possible/ advisable for individual to find the most suitable condom type and/or size (but no instruction, demonstration or practice). Providing information about various types of available condoms and lubricants.	4.1 Instruction of how to perform a behaviour Advise or agree on how to perform the behaviour (includes 'Skills training')
Instruction – correct use	Giving description of steps required for complete and correct condom application and removal. Providing information how to find the most suitable type and/or size of condom.	4.1 Instruction of how to perform a behaviour Advise or agree on how to perform the behaviour (includes 'Skills training')
Demonstration	Showing how to use condoms correctly using, for example, a model of penis, fingers, and/or other objects.	6.1 Demonstration of the behaviour Provide an observable sample of the performance of the behaviour, directly in person or indirectly e.g. via film, pictures, for the person to aspire to or imitate (includes 'Modelling')
Skills rehearsal	Allowing participants to practice correct condom use skills on model of penis, fingers, and/or other objects.	8.1 Behavioural practice/rehearsal Prompt practice or rehearsal of the performance of the behaviour one or more times in a context or at a time when the performance may not be necessary, in order to increase habit and skill
Feedback	Inform the person how well they perform on correct condom use skills practice, provide correction if necessary.	2.2 Feedback on behaviour Monitor and provide informative evaluative feedback on performance of the behaviour (e.g form, frequency, duration, intensity)
Self-monitoring	Observing own performance and/or experience whilst applying and removing condoms (self or model) during session or individual skills rehearsal	2.3 Self-monitoring of behaviour *Establish a method for the person to monitor and record their behaviour(s) as part of a behaviour change strategy (not part of data collection)* Modified: Observing own performance to improve skills/correct it, does not require recording the behaviour
Monitoring of behaviour by others	Others (researchers and/or other participants) are observing participant's condom correct condom application and removal(during practice in small groups or in individual session if feedback is not given)	2.1 Monitoring of behaviour of others without feedback *Observe or record behaviour with the person's knowledge as part of behaviour change strategy, no feedback given.* Modified: observe behaviour (skills rehearsal) with the person's knowledge as part of behaviour change strategy (can be used together with feedback if feedback was given by facilitator, but other participants observed skills rehearsal without giving feedback)
Observation of others performing behaviour	Observation of others practicing correct condom application and removal	New: Observing others behaviour (skills rehearsal) with their knowledge as part of behaviour change strategy without giving them feedback

Appendix E

Technique	Definition	BCTT[a] definition
Home practice	Allowing and/or encouraging participants to practise condom use at home, not during sexual intercourse	8.1 Behavioural practice/rehearsal Prompt practice or rehearsal of the performance of the behaviour one or more times in a context or at a time when the performance may not be necessary, in order to increase habit and skill
Behavioural experiment	Allowing and/or encouraging participants to practice use of different types and/or sizes of condoms and/or lubricants.	4.4 Behavioural experiments Advise on how to identify and test hypotheses about behaviour, its causes and consequences, by collecting and interpreting data

[a]Michie, S., & Prestwich, A. (2010). Are interventions theory-based? Development of a theory coding scheme. Health Psychology, 29(1), 1-8. Michie, S., Abraham, C., Eccles, M. P., Francis, J. J., Hardeman, W., & Johnston, M. (2011). Strengthening evaluation and implementation by specifying components of behaviour change interventions: a study protocol. Implementation Science: IS, 6, 10-10.

Appendix F

Condom-related Content (Other than TCUS Development Techniques)

Category	Included topics
knowledge	information about the condom features (how they look like, what are made of etc.), presentation and/or comparison of different types of condoms, purpose of using condoms, condom use rates, condom knowledge quiz
misconceptions	correction and/or discussion about condom use related misconceptions
benefits	presentation and/or discussion of condom use advantages, benefits
protection	information about condom protection against HIV/STIs
contraception	condom as contraception
condoms and spermicides	information about use of condom together with spermicide (only if a spermicide was not presented as an option to be used without condom)
experience/perception	condom fit-and-feel, sensual experience, evaluation of different types of condoms, condoms rating, condoms likes and dislikes, condom perception
self-efficacy	self-efficacy, confidence in being able to use condoms
emotions	condoms enjoyment, emotional responses to using condoms
erotisation	condom erotisation
barriers	barriers related to condom use
solutions	importance of practice and experience, solutions overcoming barriers
preparatory skills	purchasing, obtaining carrying condoms
negotiation/communication	condom negotiation skills, communication about condoms, refusing sex without condoms
beliefs, norms, attitudes	beliefs, norms, attitudes related to condom use using condoms to protect family
relationship	responsibility in relationship, partner protection, partner's respect
general condom promotion	general condom promotion (slogans, posters), community supporting actions
familiarisation	encouraging to examine condom closely, unwrap it, touch it etc.
discussion/Q&A	discussion, Q&A about condoms
free condoms	providing condoms (one type, various types) providing condom coupons
low price condoms	providing low price condoms
free lubricants	providing lubricants (one type, selection)
prizes	providing prizes for participants for taking part in the intervention (not for assessment completion)

Appendix G

Context Topics

Category	Included topics
basic STIs/HIV information	basic HIV/STIs information , HIV transmission, HIV/STIs protection/prevention
risk awareness - information	HIV/AID/STIs/ pregnancy rates, pregnancy motivation
risk awareness – vulnerability	personal stories

Appendix H

Quality Assessment Tool for Quantitative Studies (EPHPP, 2010; Thomas et al., 2004)

QUALITY ASSESSMENT TOOL FOR QUANTITATIVE STUDIES

COMPONENT RATINGS

A) SELECTION BIAS

(Q1) Are the individuals selected to participate in the study likely to be representative of the target population?

1 Very likely
2 Somewhat likely
3 Not likely
4 Can't tell

(Q2) What percentage of selected individuals agreed to participate?

1 80 - 100% agreement
2 60 – 79% agreement
3 less than 60% agreement
4 Not applicable
5 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

B) STUDY DESIGN

Indicate the study design

1 Randomized controlled trial
2 Controlled clinical trial
3 Cohort analytic (two group pre + post)
4 Case-control
5 Cohort (one group pre + post (before and after))
6 Interrupted time series
7 Other specify _____
8 Can't tell

Was the study described as randomized? If NO, go to Component C.

No Yes

If Yes, was the method of randomization described? (See dictionary)

No Yes

If Yes, was the method appropriate? (See dictionary)

No Yes

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

1

Appendix H

C) CONFOUNDERS

(Q1) Were there important differences between groups prior to the intervention?

1 Yes
2 No
3 Can't tell

The following are examples of confounders:

1 Race
2 Sex
3 Marital status/family
4 Age
5 SES (income or class)
6 Education
7 Health status
8 Pre-intervention score on outcome measure

(Q2) If yes, indicate the percentage of relevant confounders that were controlled (either in the design (e.g. stratification, matching) or analysis)?

1 80 – 100% (most)
2 60 – 79% (some)
3 Less than 60% (few or none)
4 Can't Tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

D) BLINDING

(Q1) Was (were) the outcome assessor(s) aware of the intervention or exposure status of participants?

1 Yes
2 No
3 Can't tell

(Q2) Were the study participants aware of the research question?

1 Yes
2 No
3 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

E) DATA COLLECTION METHODS

(Q1) Were data collection tools shown to be valid?

1 Yes
2 No
3 Can't tell

(Q2) Were data collection tools shown to be reliable?

1 Yes
2 No
3 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

2

F) WITHDRAWALS AND DROP-OUTS

(Q1) Were withdrawals and drop-outs reported in terms of numbers and/or reasons per group?

1 Yes
2 No
3 Can't tell
4 Not Applicable (i.e. one time surveys or interviews)

(Q2) Indicate the percentage of participants completing the study. (If the percentage differs by groups, record the lowest).

1 80 -100%
2 60 - 79%
3 less than 60%
4 Can't tell
5 Not Applicable (i.e. Retrospective case-control)

RATE THIS SECTION	STRONG	MODERATE	WEAK	
See dictionary	1	2	3	Not Applicable

G) INTERVENTION INTEGRITY

(Q1) What percentage of participants received the allocated intervention or exposure of interest?

1 80 -100%
2 60 - 79%
3 less than 60%
4 Can't tell

(Q2) Was the consistency of the intervention measured?

1 Yes
2 No
3 Can't tell

(Q3) Is it likely that subjects received an unintended intervention (contamination or co-intervention) that may influence the results?

4 Yes
5 No
6 Can't tell

H) ANALYSES

(Q1) Indicate the unit of allocation (circle one)

community organization/institution practice/office individual

(Q2) Indicate the unit of analysis (circle one)

community organization/institution practice/office individual

(Q3) Are the statistical methods appropriate for the study design?

1 Yes
2 No
3 Can't tell

(Q4) Is the analysis performed by intervention allocation status (i.e. intention to treat) rather than the actual intervention received?

1 Yes
2 No
3 Can't tell

Appendix H

GLOBAL RATING

COMPONENT RATINGS

Please transcribe the information from the gray boxes on pages 1-4 onto this page. See dictionary on how to rate this section.

A	**SELECTION BIAS**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
B	**STUDY DESIGN**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
C	**CONFOUNDERS**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
D	**BLINDING**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
E	**DATA COLLECTION METHOD**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
F	**WITHDRAWALS AND DROPOUTS**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	Not Applicable

GLOBAL RATING FOR THIS PAPER (circle one):

1	STRONG	(no WEAK ratings)
2	MODERATE	(one WEAK rating)
3	WEAK	(two or more WEAK ratings)

With both reviewers discussing the ratings:

Is there a discrepancy between the two reviewers with respect to the component (A-F) ratings?

No Yes

If yes, indicate the reason for the discrepancy

1	Oversight
2	Differences in interpretation of criteria
3	Differences in interpretation of study

Final decision of both reviewers (circle one):

1	**STRONG**
2	**MODERATE**
3	**WEAK**

Appendix I

Quality Assessment Tool for Quantitative Studies Dictionary (EPHPP, 2009; Thomas et al., 2004)

Quality Assessment Tool for Quantitative Studies Dictionary

The purpose of this dictionary is to describe items in the tool thereby assisting raters to score study quality. Due to under-reporting or lack of clarity in the primary study, raters will need to make judgements about the extent that bias may be present. When making judgements about each component, raters should form their opinion based upon information contained in the study rather than making inferences about what the authors intended.

A) SELECTION BIAS

(Q1) Participants are more likely to be representative of the target population if they are randomly selected from a comprehensive list of individuals in the target population (score very likely). They may not be representative if they are referred from a source (e.g. clinic) in a systematic manner (score somewhat likely) or self-referred (score not likely).

(Q2) Refers to the % of subjects in the control and intervention groups that agreed to participate in the study before they were assigned to intervention or control groups.

B) STUDY DESIGN

In this section, raters assess the likelihood of bias due to the allocation process in an experimental study. For observational studies, raters assess the extent that assessments of exposure and outcome are likely to be independent. Generally, the type of design is a good indicator of the extent of bias. In stronger designs, an equivalent control group is present and the allocation process is such that the investigators are unable to predict the sequence.

Randomized Controlled Trial (RCT)

An experimental design where investigators randomly allocate eligible people to an intervention or control group. A rater should describe a study as an RCT if the randomization sequence allows each study participant to have the same chance of receiving each intervention and the investigators could not predict which intervention was next. If the investigators do not describe the allocation process and only use the words 'random' or 'randomly', the study is described as a controlled clinical trial.

See below for more details.

Was the study described as randomized?

Score YES, if the authors used words such as random allocation, randomly assigned, and random assignment.

Score NO, if no mention of randomization is made.

Was the method of randomization described?

Score YES, if the authors describe any method used to generate a random allocation sequence.

Score NO, if the authors do not describe the allocation method or describe methods of allocation such as alternation, case record numbers, dates of birth, day of the week, and any allocation procedure that is entirely transparent before assignment, such as an open list of random numbers of assignments.
If NO is scored, then the study is a controlled clinical trial.

Was the method appropriate?

Score YES, if the randomization sequence allowed each study participant to have the same chance of receiving each intervention and the investigators could not predict which intervention was next. Examples of appropriate approaches include assignment of subjects by a central office unaware of subject characteristics, or sequentially numbered, sealed, opaque envelopes.

Score NO, if the randomization sequence is open to the individuals responsible for recruiting and allocating participants or providing the intervention, since those individuals can influence the allocation process, either knowingly or unknowingly.

If NO is scored, then the study is a controlled clinical trial.

Controlled Clinical Trial (CCT)
An experimental study design where the method of allocating study subjects to intervention or control groups is open to individuals responsible for recruiting subjects or providing the intervention. The method of allocation is transparent before assignment, e.g. an open list of random numbers or allocation by date of birth, etc.

Cohort analytic (two group pre and post)
An observational study design where groups are assembled according to whether or not exposure to the intervention has occurred. Exposure to the intervention is not under the control of the investigators. Study groups might be non-equivalent or not comparable on some feature that affects outcome.

Case control study
A retrospective study design where the investigators gather 'cases' of people who already have the outcome of interest and 'controls' who do not. Both groups are then questioned or their records examined about whether they received the intervention exposure of interest.

Cohort (one group pre + post (before and after)
The same group is pretested, given an intervention, and tested immediately after the intervention. The intervention group, by means of the pretest, act as their own control group.

Interrupted time series
A time series consists of multiple observations over time. Observations can be on the same units (e.g. individuals over time) or on different but similar units (e.g. student achievement scores for particular grade and school). Interrupted time series analysis requires knowing the specific point in the series when an intervention occurred.

C) CONFOUNDERS

By definition, a confounder is a variable that is associated with the intervention or exposure and causally related to the outcome of interest. Even in a robust study design, groups may not be balanced with respect to important variables prior to the intervention. The authors should indicate if confounders were controlled in the design (by stratification or matching) or in the analysis. If the allocation to intervention and control groups is randomized, the authors must report that the groups were balanced at baseline with respect to confounders (either in the text or a table).

D) BLINDING

(Q1) Assessors should be described as blinded to which participants were in the control and intervention groups. The purpose of blinding the outcome assessors (who might also be the care providers) is to protect against detection bias.

(Q2) Study participants should not be aware of (i.e. blinded to) the research question. The purpose of blinding the participants is to protect against reporting bias.

E) DATA COLLECTION METHODS

Tools for primary outcome measures must be described as reliable and valid. If 'face' validity or 'content' validity has been demonstrated, this is acceptable. Some sources from which data may be collected are described below:

Self reported data includes data that is collected from participants in the study (e.g. completing a questionnaire, survey, answering questions during an interview, etc.).

Assessment/Screening includes objective data that is retrieved by the researchers. (e.g. observations by investigators).

Medical Records/Vital Statistics refers to the types of formal records used for the extraction of the data.

Reliability and validity can be reported in the study or in a separate study. For example, some standard assessment tools have known reliability and validity.

F) WITHDRAWALS AND DROP-OUTS

Score **YES** if the authors describe BOTH the numbers and reasons for withdrawals and drop-outs.

Score **NO** if either the numbers or reasons for withdrawals and drop-outs are not reported.

The percentage of participants completing the study refers to the % of subjects remaining in the study at the final data collection period in all groups (i.e. control and intervention groups).

G) INTERVENTION INTEGRITY

The number of participants receiving the intended intervention should be noted (consider both frequency and intensity). For example, the authors may have reported that at least 80 percent of the participants received the complete intervention. The authors should describe a method of measuring if the intervention was provided to all participants the same way. As well, the authors should indicate if subjects received an unintended intervention that may have influenced the outcomes. For example, co-intervention occurs when the study group receives an additional intervention (other than that intended). In this case, it is possible that the effect of the intervention may be over-estimated. Contamination refers to situations where the control group accidentally receives the study intervention. This could result in an under-estimation of the impact of the intervention.

H) ANALYSIS APPROPRIATE TO QUESTION

Was the quantitative analysis appropriate to the research question being asked?

An intention-to-treat analysis is one in which all the participants in a trial are analyzed according to the intervention to which they were allocated, whether they received it or not. Intention-to-treat analyses are favoured in assessments of effectiveness as they mirror the noncompliance and treatment changes that are likely to occur when the intervention is used in practice, and because of the risk of attrition bias when participants are excluded from the analysis.

Appendix I

Component Ratings of Study:

For each of the six components A – F, use the following descriptions as a roadmap.

A) SELECTION BIAS

Strong: The selected individuals are very likely to be representative of the target population (Q1 is 1) **and** there is greater than 80% participation (Q2 is 1).

Moderate: The selected individuals are at least somewhat likely to be representative of the target population (Q1 is 1 or 2); **and** there is 60 - 79% participation (Q2 is 2). 'Moderate' may also be assigned if Q1 is 1 or 2 and Q2 is 5 (can't tell).

Weak: The selected individuals are not likely to be representative of the target population (Q1 is 3); **or** there is less than 60% participation (Q2 is 3) **or** selection is not described (Q1 is 4); and the level of participation is not described (Q2 is 5).

B) DESIGN

Strong: will be assigned to those articles that described RCTs and CCTs.

Moderate: will be assigned to those that described a cohort analytic study, a case control study, a cohort design, or an interrupted time series.

Weak: will be assigned to those that used any other method or did not state the method used.

C) CONFOUNDERS

Strong: will be assigned to those articles that controlled for at least 80% of relevant confounders (Q1 is 2); **or** (Q2 is 1).

Moderate: will be given to those studies that controlled for 60 – 79% of relevant confounders (Q1 is 1) **and** (Q2 is 2).

Weak: will be assigned when less than 60% of relevant confounders were controlled (Q1 is 1) **and** (Q2 is 3) **or** control of confounders was not described (Q1 is 3) **and** (Q2 is 4).

D) BLINDING

Strong: The outcome assessor is not aware of the intervention status of participants (Q1 is 2); **and t**he study participants are not aware of the research question (Q2 is 2).

Moderate: The outcome assessor is not aware of the intervention status of participants (Q1 is 2); **or** the study participants are not aware of the research question (Q2 is 2); **or b**linding is not described (Q1 is 3 and Q2 is 3).

Weak: The outcome assessor is aware of the intervention status of participants (Q1 is 1); **and** the study participants are aware of the research question (Q2 is 1).

E) DATA COLLECTION METHODS

Strong: The data collection tools have been shown to be valid (Q1 is 1); **and** the data collection tools have been shown to be reliable (Q2 is 1).

Moderate: The data collection tools have been shown to be valid (Q1 is 1); **and** the data collection tools have not been shown to be reliable (Q2 is 2) **or** reliability is not described (Q2 is 3).

Weak: The data collection tools have not been shown to be valid (Q1 is 2) **or** both reliability and validity are not described (Q1 is 3 and Q2 is 3).

F) WITHDRAWALS AND DROP-OUTS - a rating of:

Strong: will be assigned when the follow-up rate is 80% or greater (Q2 is 1).

Moderate: will be assigned when the follow-up rate is 60 – 79% (Q2 is 2) **OR** Q2 is 5 (N/A).

Weak: will be assigned when a follow-up rate is less than 60% (Q2 is 3) or if the withdrawals and drop-outs were not described (Q2 is 4).

Appendix J

Descriptions of Studies Included in the Review

Study	Setting and location	Study design[a]	Follow-up length (number of assessments)	Outcomes[b]/ Measure(s)	Quality assessment[c]
Beltrami et al. (1998)	US, prison	controlled study control: no intervention	89 days - mean time between first two visits (1)	new STIs rate/ STIs symptoms, LET results (males only) frequency/consistency of condom use/ condom use at last sex	strong
D. Cohen et al. (1991)[d]	US, clinic	controlled study control: no intervention	1 year (1)	new STIs rate/ medical records review	moderate
D. Cohen, Dent, et al. (1992)	US, clinic waiting area	controlled study control: no intervention	6-9 months - average 230 days (1)	new STIs rate/ medical records review	strong
D. Cohen, MacKinnon, et al. (1992)	US, clinic, waiting area	controlled study control: no intervention	7-9 months (1)	new STIs rate/ medical records review	moderate
Crosby et al. (2009)	US, clinic	randomised controlled trial control: standard care, nurse delivered condom education	6 months - medical records review (1) 3 months – questionnaire and skills assessment (2)	new STIs rate/ medical records review frequency and/or consistency of condom use/ condom use at last act of sexual intercourse (female partner), frequency of unprotected penetrative sexual intercourse in the past 3 months (female partner), condom use skills/ checklist	strong
Elkins et al. (1998)	Thailand, community	pre-test, post-test within subjects	immediately after intervention (1)	condom use self-efficacy/ structured interview adapted from the Condom Use Self-Efficacy Scale for College Students (CUSES)[e]	weak

Appendix J

Study	Setting and location	Study design[a]	Follow-up length (number of assessments)	Outcomes[b]/ Measure(s)	Quality assessment[c]
Emetu et al. (2014)	US, university	pre-test, post-test within subjects	6 weeks (2)	frequency and/or consistency of condom use/ per cent of IPAI events for which condom was used, frequency of unprotected IPAI in the past 30 days condom use experience/ Condom Use Experience subscale from Condom barriers Scale[f], Negative Condom attitudes[g] condom use self-efficacy/ Correct Condom Use Self Efficacy Scale (CCUSES)[h]	weak
Hayden (1993)	US, College	pre-test, post-test within subjects	2 weeks[i] (1)	condom use self-efficacy/ Condom Use Self-Efficacy Scale (CUSES)[e]	weak
Hill and Abraham (2008)	UK, school	randomised clinical trial control: no intervention	4 weeks (1)	frequency and/or consistency of condom use/ frequency of condom use with a new and steady partner in the last 4 weeks condom use self-efficacy use/ 4-item measure[j]	strong
Kajubi et al. (2005)	Uganda, community	controlled trial control: increased condom accessibility without skill workshop	6 months (1)	frequency and/or consistency of condom use/ consistent condom use (all and casual partners), inconsistent condom use (all partners), unprotected sex partners (all and casual)	strong
Lindemann et al. (2012)	US, university	controlled trial control: yoga ball exercises	Immediately (1)	condom use skills/ Measure of Observed Condom Use Skills (MOCUS)[k]	moderate
Lindemann and Harbke (2013)	US university	controlled trial control: yoga ball exercises	Immediately after intervention (1)	condom use skills/ Measure of Observed Condom Use Skills (MOCUS)[k]	moderate

Study	Setting and location	Study design[a]	Follow-up length (number of assessments)	Outcomes[b]/ Measure(s)	Quality assessment[c]
Milhausen et al. (2011)	Canada, clinic	pre-test post-test within subjects	4 months (3)	condom use frequency and/or consistency/ condom use frequency for the last 5 PVI events condom use experience/ Condom Use Experience subscale of Condom Barriers Scale[f] condom use self-efficacy/ condom use ability 9-item subscale adapted from the Condom Use Self-Efficacy Scale (CUSES)[e], 8-item measure of self-efficacy to apply condoms correctly[l] condom use errors and problems/ Condom Use Errors/Problems Survey (CUES)[m]	weak
Norton et al. (2012)	US, University	controlled trial control: no intervention	8 weeks (2)	condom use frequency and/or consistency/ percentage of condom use during sexual intercourse, frequency of condom use, condom use at last sex (vaginal intercourse), total number of unprotected vaginal sexual events	weak
O-Prasertsawat and Koktatong (2002)	Thailand, college	controlled study between conditions	2 weeks (1)	condom use skills/ skills evaluation form with a checklist	weak
Orr et al. (1996)	US, Clinic (family planning or STD)	controlled study control: standard education	5-7 month (2)	condom use frequency and/or consistency/ reported condom use for vaginal intercourse in the preceding 6 months STIs reinfection - C.trachomatis reinfection/ culture specimens obtained during gynaecologic examination	moderate
E. A. Smith and Dickson (1993)	Canada, university	controlled study control: no intervention	2 months (2)	condom use frequency and/or consistency/ condom use index[n]	strong
Weisse, Turbiasz, and Whitney (1995)	US university	controlled study control: no intervention	3 month (2)	condom use frequency/ condom use at 3 months	moderate

Appendix J

Note. LET – leukocyte esterase test; IPAI – insertive penile-anal intercourse; PVI – penile-vaginal intercourse.

[a]Due to terminology inconsistent across studies, unified terms were used for clarity. Definitions of terms used are described in method section. [b]Only outcomes in the scope of the review are listed. [c]Assessed using Quality Assessment tool for Quantitative Studies (Thomas et al., 2004; http://www.ephpp.ca). [d]All clinic patients were included whether or not they listened to the intervention. [e]Brafford, L. J., & Beck, K. H. (1991). Development and validation of a condom self-efficacy scale for college students. Journal Of American College Health, 39(5), 219-225. [f]Doyle, S. R., Calsyn, D. A., & Ball, S. A. (2009). Factor structure of the Condoms Barriers Scale with a sample of men at high risk for HIV. Assessment, 16(1), 3-15; St Lawrence, J. S., Chapdelaine, A. P., Devieux, J. G., O'Bannon, R. E., 3rd, Brasfield, T. L., & Eldridge, G. D. (1999). Measuring perceived barriers to condom use: psychometric evaluation of the Condom Barriers Scale. Assessment, 6(4), 391-404. [g]Helweg-Larsen, M., & Collins, B. E. (1994). The UCLA Multidimensional Condom Attitudes Scale: Documenting the complex determinants of condom use in college students. Health Psychology, 13(3), 224-237. [h]Crosby, R. A., Graham, C. A., Milhausen, R. R., Sanders, S. A., & Yarber, W. L. (2010). Correct Condom Use Self-Efficacy Scale. In T. D. Fisher, C. M. Davis, W. L. Yarber & S. L. Davis (Eds.), Handbook of Sexuality-Related Measures (Third Edition). New York: Routledge. [i]Follow-up two weeks after baseline measurement, but immediately after intervention. [j]4-item measure, created for the study. [k]Lindemann, D. F., & Brigham, T. A. (2003). A Guttman scale for assessing condom use skills among college students. AIDS and Behavior, 7(1), 23-27. [l]Crosby, R. A., Salazar, L. F., Yarber, W. L., Sanders, S. A., Graham, C. A., Head, S., & Arno, J. N. (2008). A theory-based approach to understanding condom errors and problems reported by men attending an STI clinic. AIDS and Behavior, 12(3), 412-418; Charnigo, R., Crosby, R. A., & Troutman, A. (2010). Psychosocial constructs associated with condom use among high-risk African American men newly diagnosed with a sexually transmitted disease. Annals of Behavioral Medicine, 39(3), 303-310. [m]Crosby, R. A., Graham, C. A., Milhausen, R. R., Sanders, S. A., & Yarber, W. L. (2010). Condom Use Errors/Problems Survey. In T. D. Fisher, C. M. Davis, W. L. Yarber & S. L. Davis (Eds.), Handbook of Sexuality-Related Measures (Third Edition). New York: Routledge. [n]"Frequency of condom use over the previous two months divided by the frequency of intercourse occasions, multiplied by 100" (E. A. Smith & Dickson, 1993, p. 5).

Appendix K

Systematic Review Sample Characteristics

Study	Sample size/ group size	Age	Gender	Ethnicity[a] Percentage of sample	Chosen sample characteristics[b]
Beltrami et al. (1998)[c]	***N* = 644** intervention *n* = 329 control *n* = 315	*M* = 29 range 13 - 72	male 85%	African-American 76% White 23% other 1%	**intervention** condom use at last sex: yes 31%, no 69% sexual behaviour: number of different sex partner in the last month 0-1 69%, 2+ 31% STIs: previous yes 38% (123), no 62% (203); current symptoms of STIs yes 5% (17), no 95% (308); LET (males) positive 16% (39) negative 84% (209) relationship: unmarried 91% (299) married 9% (29) **control** condom use at last sex: yes 36%, no 64% sexual behaviour: number of different sex partner in the last month 0-1 75%, 2+25% STIs: previous STIs yes 34% (108) , no 66% (206); current symptoms of STIs yes 4% (12), no 96% (303); LET (males) positive 15% (37) negative 85% (206) relationship: unmarried 84% (265) married 16% (50)
D. Cohen et al. (1991)[d]	***N* = 192** intervention *n* = 97 control *n* = 95	*Mdn* = 25 range 15 - 61 approx. 50% <25	female 41% male 59%	Black 76%, Hispanic 15% other 9%	STD clinic patients sexual behaviour: 30% two or more sexual partners at the time of study enrolment STIs (prior history): 42% gonorrhoea, 13% syphilis, clinic visits: 14% had been to this clinic before, 56% came to the clinic because experiencing symptoms, 29% follow-up visit, 15% alleged contacts to known STD patients; relationship status: married: 8.2% study, 12.6% control single: 91.8% study, 87.3% control

Appendix K

Study	Sample size/ group size	Age	Gender	Ethnicity[a] Percentage of sample	Chosen sample characteristics[b]
D. Cohen, Dent, et al. (1992)[d]	***N* = 903** condom skills *n* = 208 social influence *n* = 192 distribution *n* = 225 control *n* = 278	female *Mdn* = 26.6 male *Mdn* = 27.9	female 38.1% male 61.2%	Black, 71.5% Hispanic 20.6% White, 4.5% Asian 3% not known 3.5%	STD clinic patients relationship status: 11% married, 64.8 % single, 8.4% separated or divorced

Study	Sample size/ group size	Age	Gender	Ethnicity[a] Percentage of sample	Chosen sample characteristics[b]
D. Cohen, MacKinnon, et al. (1992)[d]	***N* = 426** intervention *n* = 220 control *n* = 206	intervention female *M* = 29.1 male *M* = 26.6 control female *M* = 27.6 male *M* = 30.4	intervention female 35.9% male 64.1% control female 22.3% male 77.7%	intervention Black 89.9% (female) Black 93.6% (male) control Black 76.1% (female) Black 96.9% (male)	STD clinic patients **Intervention:** **female** condom use**:** condom user 11.4% sexual orientation: homosexual or bisexual 2.5 % sexual behaviour: multiple sex partners in past month 8.9% STIs (prior history): gonorrhoea 32.9%, syphilis 16.5%, PID 5.1%, NGU 1.3%, other STD 24%, any prior STD 59.5% relationship status: married 6.3% **male** condom use**:** condom user 37.6% sexual orientation: homosexual or bisexual 2.8% sexual behaviour: multiple sex partners in past month 31.2% STIs (prior history): gonorrhoea 66%, syphilis 14.9%, NGU 6.4%, other STI 3.6%, any prior STI 70.9% relationship status: married 6.4% **Control** **female** condom use**:** condom user 15.2% sexual orientation: homosexual or bisexual 4.4 % sexual behaviour: multiple sex partners in past month 13% STIs (prior history): gonorrhoea 32.6%, syphilis 15.2%, PID 2.2%, NGU 0.0%, other STI 21.7%, any prior STI 52.2% relationship status: married 15.2% **male** condom use**:** condom user 34.4% sexual orientation: homosexual or bisexual 3.1% sexual behaviour: multiple sex partners in past month 33.1% STIs (prior history): gonorrhoea 69.4%, syphilis 15%, NGU 8.8%, other STI 3.8%, any prior STI 74.4% relationship status: married 6.9%

Appendix K

Study	Sample size/ group size	Age	Gender	Ethnicity[a] Percentage of sample	Chosen sample characteristics[b]
Crosby et al. (2009)[c]	***N* = 266** intervention *n* = 141 control *n* = 125	**intervention** *M* = 23.1 *SD* = 3.4 **control** *M* = 23.4 *SD* = 3.1	male	African-American	STD clinic patients **intervention** condom use: demonstrated condom use skills *M* = 3.83 *SD* = 2.24, used condoms last time sexual intercourse occurred 52.5%, unprotected acts of sexual intercourse, past 3 months *M* = 16, *SD* = 47.3 sexual behaviour: female sexual partners in the last 3 months 2.91 SD = 2.73 STIs: multiple STIs diagnosed at baseline 29.3%, Chlamydia 39%, Gonorrhoea 61.7% relationship: current relationship monogamous 48.6%, current relationship not monogamous 42.1 % **control** condom use**:** demonstrated condom use skills *M* = 2.6 *SD* = 1.67, used condoms last time sexual intercourse occurred 42.4% , unprotected acts of sexual intercourse, past 3 months *M* = 14.3, *SD* = 21 sexual behaviour: female sexual partners in the last 3 months M = 3.08, SD = 2.43 STIs: multiple STIs diagnosed at baseline 22.1%, Chlamydia 40.3%, Gonorrhoea 61.3% relationship: current relationship monogamous 60 (48%), current relationship not monogamous 54 (43.2%)
Elkins et al. (1998)[d]	***N* = 164**	female *M* = 23 range 13-40 male *M* = 21 range 15-36	female 53% male 47%	not reported	Northeast Thai villages, living in rural areas, many seasonal workers at work break at home condom use: 92% seen condoms, 25% ever used condoms, of those 11% used within past 2 months
Emetu et al. (2014)[d]	***N* = 30**	range 18 – 24: 90% range 25 – 29: 10%	male	White 50% Asian 17% Black 17% Hispanic 13% other 10 % multi-racial 7 %	participants recruited at a university, a gay-friendly bar and a student housing condom use: IPAI events for which condom was used 59.6 % sexual orientation: bisexual 13%, gay 87% relationship status: single/never married 90% , living with partner 10%
Hayden (1993)[c]	***N* = 84**	*M* = 19 range 17 – 32	female 73% male 27%	White 83%	students sexual orientation: 91% heterosexual sexual behaviour: 85 % sexually active relationship: 60% in their current relationship for an average 12.8 months

Study	Sample size/ group size	Age	Gender	Ethnicity[a] Percentage of sample	Chosen sample characteristics[b]
Hill and Abraham (2008)[d]	***N* = 404** intervention *n* = 238 control *n* = 166	range 16-18	intervention male 44% female 56% control male 50% female 50%	British	6th form college students **intervention** **condom use:** condom use with new partner *M* = 2.25, *SD* = 1.6, condom use with steady partner *M* = 3.68, *SD* = 1.2 (5 - always 1 – never) sexual behaviour: 45% reported sexual intercourse between intervention and follow-up **control** **condom use:** condom use with new partner *M* = 2.78, *SD* = 1.7, condom use with steady partner *M* = 3.63, *SD* = 1.5 (5 - always 1 – never) sexual behaviour: 45% reported sexual intercourse between intervention and follow-up
Kajubi et al. (2005)[d]	***N* = 378** intervention *n* = 213 control *n* = 165	**intervention** range 18 – 19: 26.8% 20 – 24: 42.2% 25 – 30: 31% **control** range 18 – 19: 22.4% 20 – 24: 54.6% 25 – 30: 23%	male	not reported	poor urban community members **intervention** condom use**:** consistent condom use (all partners in the last 6 months) 40.9%, consistent condom use with casual partners pre 35.7%, Inconsistent condom use (all partners) 31% sexual behaviour: overall average number of partners in the past 6 months 2.13, overall average number of casual partners in the past 6 months 1 relationship status: never married 74.6%, married/cohabiting 52 (24.4%), Separated/divorced 2 (0.93%) **control:** condom use**:** consistent condom use (all partners in the last 6 months), 46.7% consistent condom use with casual partners 43%, inconsistent condom use (all partners) 24.9% sexual behaviour: overall average number of partners in the past 6 months 2.20, overall average number of casual partners in the past 6 months 1.07 relationship status: never married 135 (81.8%), married/cohabiting 14.5%, separated/divorced 3.6%

Appendix K

Study	Sample size/ group size	Age	Gender	Ethnicity[a] Percentage of sample	Chosen sample characteristics[b]
Lindemann et al. (2012)[c]	***N* = 205** intervention *n* =102 control *n* = 103	*M* = 19.36 *SD* = 2.36 range 18 - 42	female 55% male 45%	White 81%	undergraduate students sexual behaviour: 91% ever having sexual intercourse condom use: 89% ever using a condom **intervention** condom use: used condoms (ever) 89.7%, experienced condom failure (ever) 43.6%, responsible for condom application 54.1%; Mean (SD) Condom Self-efficacy Score[e] (baseline): condom mechanics 3.86 (0.96), personal disapproval 4.62 (0.55), assertive 4.53 (0.62), intoxicants 4.07 (0.92), intended to use condoms in the future 90.2% sexual behaviour: sexually active (ever) 90.6 % **control** condom use: used condoms (ever) 88.2%, experienced condom failure (ever) 62.2%, responsible for condom application 47.5%; Mean (SD) Condom Self-efficacy Score[e] (baseline), condom mechanics 3.77 (1.02), personal disapproval 4.69 (0.64), assertive 4.5 (0.72), intoxicants 4.14 (0.96) intended to use condoms in the future 94.6, sexual behaviour: sexually active (ever) 91.3%
Lindemann and Harbke (2013)[c]	***N* = 193** intervention *n* = 106 control *n* = 87	*M* = 19.82 *SD* = 2.52 range 18 - 36	female 45% male 55%	intervention: White 69.8% African-American 20.8% Latina/Latino 2.8% Asian 2.8% Other or multiple 3.8% control: White 66.7% African-American 25.3% Latina/Latino 4.6% Asian 1.1% other or multiple 2.3%	undergraduate students: sexual behaviour: 95% ever having sexual intercourse condom use: 96% ever using a condom **intervention:** condom use: used condoms (ever) 95.9%, experienced condom failure (ever) 54.8%, responsible for condom application 55.6%; Mean (SD) Condom Self-efficacy Score[e] (baseline):, condom mechanics 4.17 (0.97), personal disapproval 4.69 (0.64), assertive 4.61 (0.64), intoxicants 4.34 (0.83), intended to use condoms in the future 96.9% sexual behaviour: sexually active (ever) 93.4 % **control:** condom use: used condoms (ever) 96.4%, experienced condom failure (ever) 67.9%, responsible for condom application 53.2%; Mean (SD) Condom Self-efficacy Score[e] (baseline): condom mechanics 4.19 (1.02), Personal disapproval 4.53 (0.93), assertive 4.52 (0.81), intoxicants 4.20 (0.98), intended to use condoms in the future 89.2 sexual behaviour: sexually active (ever) 97.7%

Study	Sample size/ group size	Age	Gender	Ethnicity[a] Percentage of sample	Chosen sample characteristics[b]
Milhausen et al. (2011)[c]	***N* = 32**	*M* = 19.62 *SD* = 1.31 range 18-21	male	White 91%	students/ planned parenthood clinic patients condom use: condom-use frequency for the last 5 PVI events baseline: none used a condom on more than 3 of the last 5 out of the last 5 intercourse events sexual orientation: self-identified heterosexuals relationship status: 62.5% seriously dating one person, 12.5 % casually dating one person, 6.3% casually dating more than 1 person, 15.6% - not dating anyone, 3.1% living with their partner
Norton et al. (2012)[d]	***N* = 198** intervention *n* = 116 control *n* = 82	*M* = 18.63 *SD* = 0.98	female 69.7% male 30.3%	White 85.4% non-white 14.6%	undergraduate students Sexual behaviour: engaged in sexual intercourse at least once in the last 3 months
O-Prasertsawat and Koktatong (2002)[c]	***N* = 78** hands-on *n* = 39 look-on *n* = 39	range 17 – 20 74% > 18	male	not reported	3rd year primary vocational students at Ratchaburi Technical College, Ratchaburi Province, Thailand
Orr et al. (1996)[d]	***N* = 112 follow-up** intervention *n* = 54 control *n* = 58	*M* = 17.9 *SD* = 1.7 range 14 – 19	female	Black 55%	urban family planning and sexually transmitted disease clinic patients with *C. trachomatis* genitourinary tract infection condom use: approx. 49% never used a condom, 22% used a condom at their last sexual encounter, 38% never used condoms for STIs protection, and 39% never used condoms for contraception, 74% of engaging in anal intercourse group did not use a condom, 6 of the 34 women who practiced fellatio used condoms sexual behaviour: *M* = 4.9 (range, 1 to 32) life-time sexual partners, 2.2 (range 1- 12) sexual partners in the past year, 24% had engaged in anal intercourse STIs: 21% gonoccocal infection

Appendix K

Study	Sample size/ group size	Age	Gender	Ethnicity[a] Percentage of sample	Chosen sample characteristics[b]
E. A. Smith and Dickson (1993)[d]	***N* = 166** intervention *n* = 69 control *n* = 97	intervention *M* = 18.8 control *M* = 18.82	female	not reported	first year university students, residents of large dormitory **intervention** sexual behaviour: mean multiple act criterion *M* = 0.57 experienced sexual intercourse ever 43.65% relationship status: not dating 46.38%, dating several 10.14%, dating one 14.4% , steady relationship 27.54%, engaged 1.45% *29 sexually active now:* condom use: ever used condoms 52.38%, condom use in last month 49.75% Sexual behaviour: age at first sexual intercourse *M* = 17.62 numbers of sexual partners ever *M* = 1.83, numbers of sexual partners in last year *M* = 1, **control** sexual behaviour: mean multiple act criterion *M* = 0.59 experienced sexual intercourse ever 46.87% relationship status: not dating 33.33%, dating several 11.46%, dating one18.75% , steady relationship 36.46%, engaged 0% *46 sexually active now* condom use: ever used condoms 70%, condom use in last month 61.29% Sexual behaviour: age at first sexual intercourse *M* = 17.11 numbers of sexual partners ever *M* = 2.3, numbers of sexual partners in last year *M* = 1.36
Weisse et al. (1995)[c]	***N* = 69**	*M* = 19.4 range 17-23	male	not reported	undergraduate students sexual orientation: heterosexual condom use: 88% used condoms before, 60% using condoms as primary method of contraception, 12.2% using condoms during intercourse every time sexual behaviour: 82% had at least one experience of sexual intercourse, average age of first intercourse *M* = 16.7 (range 12 – 22)

Note. LET – leukocyte esterase test; PID – pelvic inflammatory disease; NGU – nongonococcal urethritis; IPAI – insertive penile-anal intercourse. [a]Terms used consistent with ones used by the authors [b]Only chosen characteristics are presented, where available general characteristic of group presented, separate for groups only if general are not available. [c]Sample characteristic at baseline, sample size provided at enrolment. [d]Sample characteristic at follow-up (analytical sample), sample size provided for analytical sample. [e]Brafford, L. J., & Beck, K. H. (1991). Development and validation of a condom self-efficacy scale for college students. Journal Of American College Health, 39(5), 219-225.

Appendix L

Descriptions of Interventions

Study	Intervention components	BCTT	Mode of delivery[a]	Other condom related topics	Context topics	No of sessions	Duration (min)	Individual dyad group (size)	Theoretical background	Facilitator
Beltrami et al. (1998)	**demonstration**	6.1	FTF	knowledge discussion/Q&A free condoms	n/a	1	10	group	----	trained female study personnel
D. Cohen et al. (1991)	**demonstration**	6.1	FTF	knowledge spermicides experience/perception discussion/Q&A	n/a	1	10 - 15	group	----	female health educator
D. Cohen, Dent, et al. (1992)	"Condom Skills" condition **instruction – correct use** **demonstration** **skills rehearsal**	4.1 6.1 8.1	FTF	knowledge protection condoms and spermicides experience/perception familiarisation discussion/Q&A	risk awareness - information	1	15 - 20	group	----	health educator
D. Cohen, Dent, et al. (1992)	"Social influence" condition **demonstration**	6.1	FTF	protection experience erotisation beliefs, norms, attitudes relationship negotiation/communication discussion/Q&A	risk awareness - information	1	15 - 20	group	----	health educator
D. Cohen, Dent, et al. (1992)	"Distribution" condition **demonstration**	6.1	FTF	protection free condoms	risk awareness - information	1	15 - 20	group	----	health educator

Appendix L

Study	Intervention components	BCTT	Mode of delivery[a]	Other condom related topics	Context topics	No of sessions	Duration (min)	Individual dyad group (size)	Theoretical background	Facilitator
D. Cohen, MacKinnon, et al. (1992)	**instruction – correct use**	4.1	PR, IL	protection experience/perception beliefs/norms/attitudes negotiation/communication discussion/Q&A free condoms	basic STIs information	1	----	group (10-25)	----	health educator
Crosby et al. (2009)	**instruction – complete use** [b] **instruction – correct use** **demonstration** **skills rehearsal** **feedback** **self-monitoring**	4.1 4.1 6.1 8.1 2.2 (2.3)[d]	FTF	knowledge protection experience/perception negotiation/communication discussion/Q&A free condoms (various types) free lubricants	risk awareness - information	1	45-50	individual	lay health adviser model, IMB	lay health adviser, nurse[c]
Elkins et al. (1998)	**instruction – correct use** **demonstration** **skills rehearsal** **self-monitoring** **feedback** **monitoring of behaviour by others** **observation others performing behaviour**	4.1 6.1 8.1 (2.3)[d] 2.2 ----	FTF	familiarisation general condom promotion low price condoms reward social reward	basic HIV information	1 session active, a few passive	----	group	social learning theory	village leaders, village health volunteer and shop keepers
Emetu et al. (2014)	**instruction – complete use** **instruction – correct use** **demonstration** **home practice** **behavioural experiment** **self-monitoring**	4.1 4.1 6.1 8.1 4.4 (2.3)[d]	FTF, PR, OS	experience/perception free condoms (various types) free lubricants (various types)	n/a	1	2 weeks	individual	PLISSIT sex therapy model	research assistant

Study	Intervention components	BCTT	Mode of delivery[a]	Other condom related topics	Context topics	No of sessions	Duration (min)	Individual dyad group (size)	Theoretical background	Facilitator
Hayden (1993)	**demonstration** **skills rehearsal** **monitoring of behaviour by others** **observation of others performing behaviour**	6.1 8.1 (2.1)[d] ----	FTF	preparatory skills discussion/Q&A reward[e]	n/a	1	10 race, plus playing with condoms and discussion	group	social learning theory	researcher
Hill and Abraham (2008)	**instruction – correct use**	4.1	PR, IL	knowledge benefits protection contraception experience/perception preparatory skills beliefs/norms/attitudes self-efficacy relationship negotiation/communication reward	risk awareness - pregnancy motivation	1	20	individual	TPB	n/a
Kajubi et al. (2005)	**demonstration** **skills rehearsal** **feedback** **monitoring of behaviour by others** **observation of others performing behaviour**	6.1 8.1 2.2 ----	FTF	barriers solutions negotiation/communication preparatory skills free condoms	basic HIV information risk awareness – information	1	180	group	----	nurses
Lindemann et al. (2012)	**instruction – correct use**	4.1	PR, IL	n/a	n/a	1	----	individual	----	n/a
Lindemann and Harbke (2013)	**instruction – correct use**	4.1	PR, IL	n/a	n/a	1	----	individual	----	n/a

Appendix L

Study	Intervention components	BCTT	Mode of delivery[a]	Other condom related topics	Context topics	No of sessions	Duration (min)	Individual dyad group (size)	Theoretical background	Facilitator
Milhausen et al. (2011)	**instruction – complete use** **instruction – correct use** **demonstration** **skills rehearsal** **feedback** **self-monitoring** **monitoring of behaviour by others** **home practice** **behavioural experiment**	4.1 4.1 6.1 8.1 (2.3)[d] (2.1)[d] 8.1 4.4	FTF, PR, OS	knowledge experience erotisation solutions relationship discussion/Q&A free condoms (various types) free lubricants (various types)	n/a	1	----	individual	PLISSIT sex therapy model	health educator
Norton et al. (2012)	**demonstration**	6.1	video	misconceptions contraception[f] preparatory skills beliefs, norms, attitudes negotiation/communication	risk awareness - information, risk awareness - personal stories	1	60	individual	IMB	n/a
O-Prasertsawat and Koktatong (2002)	"Hands-on" condition **skills rehearsal** **monitoring of behaviour by others** **observation of others performing behaviour**	8.1	FTF	n/a	n/a	1	----	group (39)	----	----
O-Prasertsawat and Koktatong (2002)	"Look-on" condition **demonstration**	6.1	FTF	n/a	n/a	1	----	group (39)	----	----
Orr et al. (1996)	**demonstration,** **skills rehearsal** **monitoring of behaviour by others**	6.1 8.1 (2.1)[d]	FTF	negotiation/ communication	basic STI information	1	10-20	individual	HBM	research assistant

Study	Intervention components	BCTT	Mode of delivery[a]	Other condom related topics	Context topics	No of sessions	Duration (min)	Individual dyad group (size)	Theoretical background	Facilitator
E. A. Smith and Dickson (1993)	**instruction – correct use** **demonstration** **skills rehearsal** **monitoring of behaviour by others** **observation of others performing behaviour**	4.1 6.1 8.1 (2.1)[d] ----	FTF PO IL	misconceptions experience/perception negotiation/communication reward	basic STIs/HIV information, risk awareness – information	1	30	group (approx. 48)	TRA TPB	two female program providers approx. 5 years older than the participants
Weisse et al. (1995)	**skills rehearsal** **monitoring of behaviour by others** **observation of others performing behaviour**	8.1 (2.1)[d] ----	FTF	benefits protection emotions preparatory skills discussion/Q&A	basic STIs/HIV information	1	----	group	----	----

Note. BCTT – Behaviour Change Techniques Taxonomy (Michie et al., 2013); FTF – face-to-face; PO – poster, board etc. (for group, not individual use); PR – printed, individual (leaflet, pamphlet); IL – illustrated; IMB – Information-Motivation-Behavioural Skills model; PLISSIT - Permission, Limited Information, Specific Suggestions, and Intensive Therapy; TPB – Theory of Planned Behaviour; HBM – Health Belief Model; TRA – Theory of Reasoned Action

[a]Mode of delivery of TCUS development techniques. [b]Provided as part of standard care for both groups intervention and control. [c]Lay health advisor in the intervention group only, nurse all participants. [d]BCTT modified, see Appendix E. [e]Prizes referred to in the description but not explicitly stated that in this study were given, or what was given. [f]Only in pregnancy protection condition.

Appendix M

Techniques, Modes of Delivery, and Effectiveness

Study	condition	TCUS development techniques	Outcomes						
			Mode of delivery	Frequency and/or consistency of condom use	Condom use errors and problems	Condom use experience	Condom use skills	Condom use self-efficacy	New STIs
D. Cohen, MacKinnon, et al. (1992)		Instruction – correct use	PR, IL	----	----	----	----	----	Significant reduction in new infection rate (OR =.45) (d =.44)
Hill and Abraham (2008)		Instruction – correct use	PR, IL	NSC	----	----	----	Significant increase of self-efficacy score (d = 0.28)	----
Lindemann et al. (2012)		Instruction – correct use	PR, IL	----	----	----	NSC[a]	----	----
Lindemann and Harbke (2013)		Instruction – correct use	PR, IL	----	----	----	NSC[a]	----	----
Beltrami et al. (1998)		Demonstration	FTF	NSC	----	----	----	----	NSC
D. Cohen et al. (1991)		Demonstration	FTF	----	----	----	----	----	Significant new infection OR reduction (OR = .51) (d =.37)
D. Cohen, Dent, et al. (1992)	Social influence	Demonstration	FTF	----	----	----	----	----	NSC[b]

			Outcomes						
D. Cohen, Dent, et al. (1992)	Distribution	Demonstration	FTF	----	----	----	----	----	NSC
O-Prasertsawat and Koktatong (2002)	Look-on	Demonstration	FTF	----	----	----	Significant improvement in skills score (d = .97)	----	----
Norton et al. (2012)		Demonstration	video	NSC	----	----	----	----	----
D. Cohen, Dent, et al. (1992)	Condom skills	Instruction – correct use	FTF	----	----	----	----	----	NSC
		Demonstration	FTF						
Orr et al. (1996)		Demonstration,	FTF	inconclusive	----	----	----	----	NSC
		Skills rehearsal	FTF						
		Monitoring of behaviour by others	FTF						
O-Prasertsawat and Koktatong (2002)	Hands-on	Skills rehearsal	FTF	----	----	----	Significant improvement in skills scores (d = 4.20)	----	----
		Monitoring of behaviour by others	FTF						
		Observation of others performing behaviour	FTF						
Weisse et al. (1995)		Skills rehearsal	FTF	NSC	----	----	----	----	----
		Monitoring of behaviour by others	FTF						
		Observation of others performing behaviour	FTF						

		Outcomes						
Emetu et al. (2014)	Instruction – complete use	FTF	Significant increase in consistency, Significant decrease of unprotected sex (d =.98)	----	NSC[a]	----	Significant increase of self-efficacy score (d = 1.93)	----
	Instruction – correct use	FTF, PR						
	Demonstration	FTF						
	Home practice	OS						
	Behavioural experiment	OS						
	Self-monitoring	OS						
Hayden (1993)	Demonstration	FTF	----	----	----	----	NSC	----
	Skills rehearsal (condom race)	FTF						
	Monitoring behaviour by others	FTF						
	Observation of others performing behaviour	FTF						
Kajubi et al. (2005)	Demonstration	FTF	NSC	----	----	----	----	----
	Skills rehearsal	FTF						
	Feedback	FTF						
	Monitoring of behaviour by others	FTF						
	Observation of others performing behaviour	FTF						
E. A. Smith and Dickson (1993)	Instruction – correct use	FTF, PR, IL	NSC	----	----	----	----	----
	Demonstration	FTF						
	Skills rehearsal	FTF						

		Outcomes						
	Monitoring of behaviour by others	FTF						
	Observation of others performing behaviour	FTF						
Crosby et al. (2009)	Instruction – complete use[c]	FTF	Inconclusive	----	----	Significantly higher score in the condom application skills assessment (d = 2.52)	----	Significantly less likely to acquire a subsequent STD (OR = .32)
	Instruction – correct use	FTF						
	Demonstration	FTF						
	Skills rehearsal	FTF						
	Feedback	FTF						
	self-monitoring	FTF						
Elkins et al. (1998)	Instruction – correct use	FTF	----	----	----	----	Significant increase of self-efficacy score[d]	----
	Demonstration (steps)	FTF						
	Skills rehearsal	FTF						
	Self-monitoring	FTF						
	Feedback	FTF						
	Observation others performing behaviour	FTF						
	Monitoring of behaviour by others	FTF						
Milhausen et al. (2011)	Instruction – complete use	FTF	----	Significant decrease in breakage, fit-and-feel problems, experience of	Significant improvement in condom use experience (d = .44)	----	Significant increase of self-efficacy score (d = .41)[e] (d = .56)[f]	----
	Instruction – correct use	FTF, PR						
	Demonstration	FTF						

		Outcomes
Skills rehearsal	FTF	erection problems, significant increase in adding water based lubricants
Feedback	FTF	
Monitoring behaviours by others	FTF	
Self-monitoring	OS	
Home practice	OS	
Behavioural experiment	OS	

Note. PR – printed; IL – illustrated; NSC – not significant change; FTF – face to face; OS – outside the session; OR – odds ratio. [a]Only specific items. [b]Potentially harmful for female participants, STIs rate increased. [c]Provided as part of standard care for both groups intervention and control. [d]Assessed on the basis of proportion of items where significant change occurred (8 out of 11). [e]9-item subscale adapted from the Condom Use Self-Efficacy Scale (CUSES). [f]8-item measure of self-efficacy to apply condoms correctly.

Appendix N

Study 1 Advertisements

Poster Advertisement

QR code

UNIVERSITY OF Southampton

E·S·R·C ECONOMIC & SOCIAL RESEARCH COUNCIL

I am developing an online version of a

Condom Intervention Study

And want to make sure that the intervention will be effective and acceptable for users

I would like to meet you and hear what you think about the prototype of the website.

£15 for completing the session

I am looking for participants who:

- ✓ are male, age 18 or over, fluent in English
- ✓ already use condoms, OR don't use them regularly OR have stopped using them*, OR you are considering using condoms in the future

If you are interested in finding out more about the study and how you can contribute to the development of the intervention follow the link below.

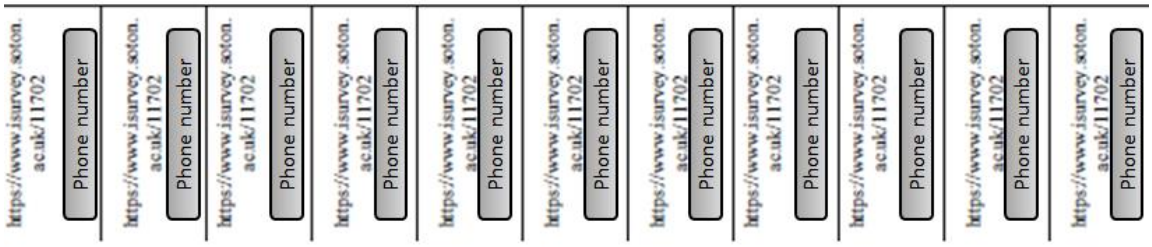
https://www.isurvey.soton.ac.uk/11702

For more information you can also call me on Phone number or e-mail mag1g10@soton.ac.uk

If you are a student in the School of Psychology, University of Southampton you can alternatively earn 5 CREDITS for participation in the study

*For reasons other than allergy or sensitivity to latex, non-latex condoms and/or lubricants.

School of Psychology, Research Ethics Committee approval number TBC



Appendix N

eFolio Advertisement (Psychology– University of Southampton)

Title: Condom Intervention Study

I would like to hear **what you think** about the prototype of a Condom Intervention Study website I develop. I am looking for male participants, age 18-69, fluent in English who: already use condoms, OR don't use them regularly OR have stopped using them*, OR are considering using condoms in the future.
(*For reasons other than allergy or sensitivity to latex, non-latex condoms and/or lubricants.)
The session will take between 50 and 90 minutes and you can earn 5 credits or £15 for completing the session.
For more information, you can also call me on (phone number)
or e-mail mag1g10@soton.ac.uk

E-mail Advertisement

e-mail subject: Request for participation – Condom Intervention Study

I am a PhD Health Psychology student at the University of Southampton.
I am developing an online version of a Condom Intervention Study.
I want to make sure that the intervention will be effective and acceptable for users.
I would like to meet you and hear **what you think** about the prototype of the website.
You will receive £15 for completing the session.

I am looking for participants who:

- are male, age 18 or over, fluent in English
- live in the south of England
- already use condoms, OR don't use them regularly OR have stopped using them *, OR are considering using condoms in the future

*For reasons other than allergy or sensitivity to latex, non-latex condoms and/or lubricants.
If you are interested in finding out more about the study and how you can contribute to the development of the intervention follow the link below.
(iSurvey link)
For more information, you can also call me on (phone number) or e-mail mag1g10@soton.ac.uk
This study has been approved by the School of Psychology Ethics Committee at the University of Southampton, approval number xxx
The PhD is funded through Economic and Social Research Council studentship.

Facebook Advertisement

I am a PhD Health Psychology student at the University of Southampton.
I am developing an-online version of a Condom Intervention Study.
I want to make sure that the intervention will be effective and acceptable for users.
I would like to meet you and hear **what you think** about the prototype of the website.
You will receive £15 for completing the session.

I am looking for participants who:

- are male, age 18 or over, fluent in English
- live in the south of England
- already use condoms, OR don't use them regularly OR have stopped using them*, OR are considering using condoms in the future

*For reasons other than allergy or sensitivity to latex, non-latex condoms and/or lubricants.

If you are interested in finding out more about the study and how you can contribute to the development of the intervention follow the link below.
(iSurvey link)

For more information you can also call me on (phone number) or e-mail mag1g10@soton.ac.uk
This study has been approved by the School of Psychology Ethics Committee at the University of Southampton, approval number xxx
The PhD is funded through Economic and Social Research Council studentship.

Twitter Advertisement

Interested in participating in evaluation of a prototype of an on-line condom intervention study? £15 for participation (iSurvey link)

Appendix O

Study 1 Information Sheet Online/Printed Version (Adapted from the University of Southampton Ethics Templates)

UNIVERSITY OF Southampton

Participant Information Sheet (Version 2, 29/07/2014)

Study Title: ***Condom Intervention Study***
Researcher: Marta Glowacka,
Dr Cynthia Graham, Prof Lucy Yardley (supervisors)
ERGO Study ID number:

Please read this information carefully before deciding to take part in this research. If you are happy to participate you will be asked to sign a consent statement.

What is the research about?

This study is a part of my PhD project (MPhil/PhD in Health Psychology Research and Professional Practice funded through the Economic and Social Research Council studentship), aiming to design and evaluate an on-line programme to enhance condom use. The aim of this evaluation of the website prototype is to find out what men think about the website at the early stage of its development. This will inform further work on the development of the web-based programme.

Why have I been chosen?

I am looking for male participants who already use condoms, have tried to use them but for some reasons (other than medical i.e. allergy) don't use them regularly, have stopped using them, or for those who are considering using condoms in the future. You need to be in good health, to be able to take part in a 50 – 90 minutes session.
Unfortunately, people with visual, or hearing impairments, or with learning disability are not eligible to take part in this study

What will happen to me if I take part?

After you complete the screening questionnaire and if you are eligible to take part in the study, a face-to face session will be arranged. You will see a paper-based prototype of the webpages and you will be asked to tell what you think about them. You will be also asked to complete one practical exercise involving putting a condom on a wooden model (This is an optional exercise and you do not need to complete it to take part in the study). Following this you will be asked a few more questions related to the website and the condoms and lubricants samples kit. The study requires you to take part in only one session, and this should last between 50 and 90 minutes. The session will be audio-recorded.

Are there any benefits in my taking part?

By taking part in this study you will have a chance to contribute to the development of an on-line version of a novel programme to enhance male condom use. You will also learn about the website development process. Your input is invaluable to create an online programme that will be effective and acceptable for users.

You will receive £15 or 5 credits for completing the think-aloud session.

Are there any risks involved?

Some people may feel uncomfortable or embarrassed answering questions about sexual behaviour and condoms. You do not need to give answers to any questions that may make you feel uncomfortable. Also, you do not need to practice putting a condom on a wooden model if you do not feel comfortable doing this. Taking part in the study may raise your awareness regarding sexual health and some aspects of your sexual behaviour that could put you at risk of contracting sexually transmitted infections or of pregnancy for a partner. At the end of the study you will receive information on services providing advice and support on issues related to sexual health. Unfortunately, if you have an allergy to latex or polyurethane condoms or to any type of lubricants you cannot take part in the study. Also, currently it is not possible to include people with visual or hearing impairments or with learning disability in the study.

Will my participation be confidential?

All study procedures will comply with the Data Protection Act/University policy. The sessions will be conducted in private rooms (at the University of Southampton or other locations chosen by you) to ensure your comfort and confidentiality.

You will be asked in a consent statement to give permission to use some verbatim quotations from the session to illustrate the data analysis. The quotations would be accompanied by information about your age but not your name or any other identifying information. You may still take part in the study if you do not agree to this.

All data (electronic and hard copy) will be securely stored in line with procedures approved by the School of Psychology Ethics Committee at the University of Southampton. Personal information will not be released to or viewed by anyone other than researchers involved in this project.

Data you provide will be used only for research, and the results will be presented in a chapter of a PhD thesis. They may also be submitted for publication in a scientific journal or presentation at a scientific conference, or be disseminated to general public as a part of educational activities. No identifiable data (such as your name or date of birth) will be used in any of the listed publications or activities.

What happens if I change my mind?

You can change your mind and withdraw from the study at any time, without giving a reason for your decision.

What happens if something goes wrong?

If you have any concerns in relation to the study or if you feel that you have been placed at risk, you may contact

Chair of the Ethics Committee Psychology, University of Southampton, Southampton, SO17 1BJ, email fshs-rso@soton.ac.uk or

Dr Martina Prude, Head of Research Governance at the University of Southampton 02380 595058, rgoinfo@soton.ac.uk

Where can I get more information?

If you would like to find out more about the study, or have some questions that you did not find the answer to please contact Marta Glowacka at mag1g10@soton.ac.uk or on (phone number).

Appendix P

Study 1 Online Screening Consent Statement (Adapted from the University of Southampton Ethics Templates)

UNIVERSITY OF Southampton

On-line Screening Consent Statement (Version 2, 29/07/2014)

Study title: *Condom Intervention Study*

Researcher name: Marta Glowacka, PhD student, Trainee Health Psychologist

Dr Cynthia Graham, Prof. Lucy Yardley (project supervisors)

Study reference:

Ethics reference:

Thank you for your interest in our study. My name is Marta Glowacka and I am PhD student at the University of Southampton.

I need to obtain your consent to ask questions to establish your eligibility to take part in the study.

Please tick yes if you agree with the statements:

I have read and understood the information sheet (Version 2, 29/07/2014) and have had the opportunity to ask questions about the study.	*yes*	*no*	
I agree to take part in this research project and agree for my data to be used for the purpose of this study.	*yes*	*no*	
I understand my participation is voluntary and I may withdraw at any time without my legal rights being affected.	*yes*	*no*	
For students: If you are a student at the University of Southampton and you choose not to participate there will be no consequences to your grade or to your treatment as a student in the psychology department.	*yes*	*no*	*not applicable*

Data Protection

I understand that information collected about me during my participation in this study will be stored on a password protected computer and that this information will only be used for the purpose of this study. All files containing any personal data will be anonymised (Data will be coded for the analysis, and only researchers named above would have access to all data).

By clicking submit you give informed consent to complete screening questionnaire and for your data to be used for the purposes of research.

If you have questions about your rights as a participant in this research, or if you feel that you have been placed at risk, you may contact the Chair of the Ethics Committee, Psychology, University of Southampton, Southampton, SO17 1BJ,

email fshs-rso@soton.ac.uk or Dr Martina Prude, Head of Research Governance at the University of Southampton 02380 595058, rgoinfo@soton.ac.uk

Appendix Q

Study 1 Screening Questionnaire (Can Be Completed Online or through Telephone)

Please answer the following question about yourself. Questions marked with * are compulsory. Completion of this questionnaire will take you no longer than 5 minutes.

What is your gender?* male female other

What is your age?

Do you have allergy to latex, polyurethane or any ingredient of lubricants?* yes no

Do you have any of the following:* yes no

- visual impairment?
- hearing impairment?
- learning disability?

Tell us something more about yourself

What is the highest level of education you completed?

What is your current occupation?

Do you think you are a competent computer user?* yes no I don't know

The final questions are about your condom use experience

1. Do you use condoms? yes no
   (if your answer is 'no' go to question number 6)
2. Do you use condom each time you have sexual intercourse (vaginal or anal). yes no
3. Do you use condoms correctly? yes no I don't know
4. Do you feel confident using condoms? yes no Not always
5. Have you ever experienced any condom use problems? yes no
6. If you answered yes in question 5, please specify what condom use problems you have experienced.
7. If you do not use condoms at the moment, do you plan to use them in the future? yes no don't know

Please leave your e-mail or phone number and I will contact you (you will be contacted) within the next 3 working days to confirm your eligibility to take part in the study and arrange the session.*

If you are not eligible to take part in the study, I will contact you to explain the reasons,

Appendix R

Study 1 Participants Information Sheet – Verbal, to Be Used during Phone Calls (Adapted from the University of Southampton Ethics Templates)

UNIVERSITY OF Southampton

Participant Information Sheet – verbal (Version 2, 29/07/2014)

Condom Intervention Study

This study is a part of my PhD project (MPhil/PhD in Health Psychology Research and Professional Practice funded through the Economic and Social Research Council studentship), my supervisors are Dr Cynthia Graham and Prof Lucy Yardley.

I design and evaluate an on-line programme to enhance condom use. The aim of this evaluation of the website prototype is to find out what men think about the website at the early stage of its development. This will inform further work on the development of the web-based programme.

I am looking for male participants who already use condoms, have tried to use them but for some reasons (other than allergy) don't use them regularly, have stopped using them, or for those who are considering using condoms in the future. You need to be in good health to be able to take part in 50 - 90 minutes session.

Unfortunately people with visual or hearing impairment or with learning disability are not eligible to take part in this study.

After you complete the screening questionnaire and if you are eligible to take part in the study, a face-to face session will be arranged. You will see a paper-based prototype of the webpages and you will be asked to tell what you think about them. You will be also asked to complete one practical exercise involving putting a condom on a wooden model. (This is an optional exercise and you do not need to complete it to take part in the study.)

Following this you will be asked a few more questions related to the website and the condoms and lubricants samples kit. The study requires you to take part in only one session, and this should last between 50 and 90 minutes. The session will be audio-recorded.

By taking part in this study you will have a chance to contribute to the development of an on-line version of a novel programme to enhance male condom use. You will also learn about the website development process. Your input is invaluable to create an on-line

programme that will be effective and acceptable for users. You will receive £15 or 5 credits for completing the think-aloud session.

Some people may feel uncomfortable or embarrassed answering questions about sexual behaviour and condoms. You do not need to give answers to any questions that may make you feel uncomfortable. Also, you do not need to practice putting a condom on a wooden model if you do not feel comfortable doing this. Taking part in the study may raise your awareness regarding sexual health and some of your sexual behaviour that could put you at risk of contracting sexually transmitted infections or of pregnancy for a partner. At the end of the study you will receive information on services providing advice and support in issues related to sexual health. Unfortunately, if you have allergy to latex or polyurethane condoms or to any type of lubricants you cannot take part in the study. Also, currently it is not possible to run sessions for people with visual or hearing impairment or with learning disability.

All study procedures comply with the Data Protection Act/University policy. The sessions will be conducted in private rooms (at the University of Southampton or other locations chosen by you) to ensure your comfort and confidentiality.

You will be asked in a consent statement to give permission to use some verbatim quotations from the session to illustrate the data analysis. The quotations would be accompanied by information about your age but not your name or any other identifying information. You may still take part in the study if you do not agree to this.

All data (electronic and hard copy) will be securely stored in line with procedure approved by the School of Psychology Ethics Committee at the University of Southampton. Personal information will not be released to or viewed by anyone other than researchers involved in this project.

Data you provide will be used only for research, and results will be presented in a chapter of a PhD thesis. They may also be submitted for publication in a scientific journal or presentation at a scientific conference, or be disseminated to general public as a part of educational activities. No identifiable data (such as your name or date of birth) will be used in any of the listed publications or activities.

You can change your mind and withdraw from the study at any time, without giving a reason for your decision.

I can give you all security details in the printed version when we meet for the session.

ERGO Study ID number:

Appendix S

Study 1 Verbal Screening Consent Script - for Telephone Screening (Adapted from the University of Southampton Ethics Templates)

Verbal Screening Consent Script for Research Participants (Version 2, 29/07/2014)

Study title: *Condom Intervention Study*

Thank you for your interest in our study. My name is *Marta Glowacka* and I am PhD student at the University of Southampton.

<table>
<tr><td colspan="2">Did you have a chance to read the Participants Information Sheet available on-line?</td></tr>
<tr><td>[no – go to the script No 1]</td><td>[yes – go to script No 2]</td></tr>
<tr><td colspan="2">Script No 1</td></tr>
<tr><td colspan="2">[no] Would you prefer to read the information on-line or would you like me to give you the study information now?</td></tr>
<tr><td>[on-line]
The participant information sheet, consent statement and screening questionnaire are available at [iSurvey link]</td><td>[on the phone]
[The verbal information sheet [version 2, 29/07/2014] will be read to the participant]</td></tr>
<tr><td></td><td>Before we go any further I need to obtain your consent to ask questions to establish your eligibility to take part in the study. Your continued participation in this research will be taken as evidence of your giving informed consent answer screening questions and for your data to be used for the purposes of research, and that you understand that published results of this research project will maintain your confidentially.
Your participation is voluntary and you may withdraw your participation at any time.
[For students: If you are a student at the University of Southampton and you choose not to participate there will be no consequences to your grade or to your treatment as a student in the psychology department].
If you have any questions please ask them now.
If you have questions about your rights as a participant in this research, or if you feel that you have been placed at risk, you may contact the Chair of the Ethics Committee, Psychology, University of Southampton, Southampton, SO17 1BJ, email fshs-rso@soton.ac.uk or Dr Martina Prude, Head</td></tr>
</table>

	of Research Governance at the University of Southampton 02380 595058, rgoinfo@soton.ac.uk	
	Can I now ask you a few questions to confirm you are eligible take part in our study?	
	[yes – verbal consent assumed]	[no – consent not given]
Script 2		
[yes] Did you accept the consent statement on the website?		
[Yes] Verbal consent not required	[no] Before we go any further I need to obtain your consent to ask questions to establish your eligibility to take part in the study. Your continued participation in this research will be taken as evidence of your giving informed consent answer screening questions and for your data to be used for the purposes of research, and that you understand that published results of this research project will maintain your confidentially. Your participation is voluntary and you may withdraw your participation at any time. *[For students:* If you are a student at the University of Southampton and you choose not to participate there will be no consequences to your grade or to your treatment as a student in the psychology department*].* If you have questions about your rights as a participant in this research, or if you feel that you have been placed at risk, you may contact the Chair of the Ethics Committee, Psychology, University of Southampton, Southampton, SO17 1BJ, email fshs-rso@soton.ac.uk or Dr Martina Prude, Head of Research Governance at the University of Southampton 02380 595058, rgoinfo@soton.ac.uk	
	Can I now ask you a few questions to confirm you are eligible to take part in our study?	
	[yes – verbal consent assumed]	[no – consent not given]

Appendix T

Study 1 Consent Form (Adapted from the University of Southampton Ethics Templates)

UNIVERSITY OF Southampton

CONSENT STATEMENT (*Version 2, 29/07/2014*)

Study title: *Condom Intervention study*

Researcher name: Marta Glowacka, PhD student, Trainee Health Psychologist

Dr Cynthia Graham, Prof. Lucy Yardley (project supervisors)

Study reference:

Ethics reference:

Please initial the boxes if you agree with the statements:

I have read and understood the information sheet (Version 2, 29/07/2014) and have had the opportunity to ask questions about the study.	☐
I agree to take part in this research project and agree for my data to be used for the purpose of this study	☐
I give my permission for the session to be audio-recorded and then transcribed for the purpose of this study.	☐
I understand my participation is voluntary and I may withdraw at any time without my legal rights being affected	☐
I give my permission for anonymous quotes recorded during the session to be used, accompanied by information about my age range (e.g. 20-25) in reports written up about the study (optional).	☐
For students: If you are a student at the University of Southampton and you choose not to participate there will be no consequences to your grade or to your treatment as a student in the psychology department	☐

Data Protection *I understand that information collected about me during my participation in this study will be stored on a password protected computer and that this information will only be used for the purpose of this study. All files containing any personal data will be anonymised (Data will be coded for the analysis, and only researchers named above would have access to all data).*

Name of participant (print name).....

Signature of participant.....

Date.....

If you have questions about your rights as a participant in this research, or if you feel that you have been placed at risk, you may contact the Chair of the Ethics Committee, Psychology, University of Southampton, Southampton, SO17 1BJ,email fshs-rso@soton.ac.uk or Dr Martina Prude, Head of Research Governance at the University of Southampton 02380 595058, rgoinfo@soton.ac.uk

Appendix U

Study 1 and 2 Think-aloud Interview Script Adapted from Usability Test Script (Krug, 2010)[28]

Hi, _____. My name is _____, and I'm going to be walking you through this session today.

Before we begin, I have some information for you, and I'm going to read it to make sure that I cover everything.

You probably already have a good idea of why I sked you here, but let me go over it again briefly. I am asking people to go through the paper prototype of my website that I am working on as if you were using the real one so I can see whether it works as intended. The session should take about an hour. And at the end I will ask you some more questions.

The first thing I want to make clear right away is that we're testing the *prototype,* not you. You can't do anything wrong here. In fact, this is probably the one place today where you don't have to worry about making mistakes.

As you go through the pages, I'm going to ask you as much as possible to try to think out loud: to say what you're looking at, what would you do on the real website, and what you're thinking.

Also, please don't worry that you're going to hurt my feelings. I'm doing this to make the website as good as it can be, so I need to hear your honest reactions.

If you have any questions as we go along, just ask them. I may not be able to answer them right away, since I'm interested in how people do when they don't have someone sitting next to them to help. But if you still have any

[28] Not to be reprinted from this thesis.

questions when we're done I'll try to answer them then. And if you need to take a break at any point, just let me know.

If it's ok with you, I will now start the tape recording.

- ❑ **START the RECORDER**

Do you have any questions so far?

OK, great. We can start looking at the pages now.

- ❑ **Show the first page**

First, I'm going to ask you to look at this page and tell me what you make of it: what strikes you about it, whose site you think it is, what you can do here, and what it's for. Just look around and do a little narrative.

- ❑ **Allow this to continue for three or four minutes, at most.**

Thanks. Now I'm going to show you the rest of the pages and I will ask you to go through them as you would go through the real website and try to think out loud as you go along.

- ❑ **Hand the participant the pages in the same order they would appear on the real website. If there is an option of different choices have them ready to hand the page chosen by the participant.**
- ❑ **During the session, if there are two long pauses use the communication tokens.**

Thanks, that was very helpful.

- ❑ **Answer the questions the person had during the session if possible.**

Do you have any questions for me, now that we're done?

- ❑ **Answer the questions the person had during the session if possible**

  Continue with the semi-structured interview.

Appendix V

Study 1 and 2 Communication Tokens - Think-aloud Interview (Krug, 2010)[29]

"Things a therapist would say"

While the participant is doing the tasks, to maintain your neutrality you're going to be saying the same few things over and over, which turn out to be the same kind of non-directive things a therapist typically says to a patient. Here's a handy chart of "permissible" phrases.

When this happens:	Say this:
You're not absolutely sure you know what the participant is thinking.	"What are you thinking?" "What are you looking at?" "What are you doing now?"
Something happens that seems to surprise them. For instance, they click on a link and say "Oh" or "Hmmm" when the new page appears.	"Is that what you expected to happen?"
The participant is trying to get you to give him a clue. ("Should I use the _____?")	"What would you do if you were at home?" (Wait for answer.) "Then why don't you go ahead and try that?" "What would you do if I wasn't here?" "I'd like you to do whatever you'd normally do."
The participant makes a comment, and you're not sure what triggered it.	"Was there something in particular that made you think that?"
The participant suggests concern that he's not giving you what you need.	"No, this is very helpful." "This is exactly what we need."
The participant asks you to explain how something works or is supposed to work (e.g., "Do these support requests get answered overnight?").	"What do you think?" "How do you think it would work?" "I can't answer that right now, because we need to know what you would do when you don't have somebody around to answer questions for you. But if you still want to know when we're done, I'll be glad to answer it then."
The participant seems to have wandered away from the task.	"What are you trying to do now?"

[29] Not to be reprinted from this thesis.

There are also three other kinds of things you can say:

- **Acknowledgment tokens.** You can say things like “uh huh,” “OK,” and “mm hmm” as often as you think necessary. These signal that you’re taking in what the participant is saying and you’d like them to continue along the same lines. Note that they’re meant to indicate that you understand what the participant is saying, not that you necessarily agree with it. It’s “OK.” Not “OK!!!”
- **Paraphrasing.** Sometimes it helps to give a little summary of what the participant just said (“So you’re saying that the boxes on the bottom are hard to read?”) to make sure that you’ve heard and understood correctly.
- **Clarifying for observers.** If the user makes a vague reference to something on the screen, you may want to do a little bit of narration to make it easier for the observers to follow the action. For instance, when the user says “I love this,” you can say, “The list over here on the right?” (Since you’re sitting next to the participant, you sometimes have a better sense of what they’re looking at.)

Appendix W

Study 1 Semi-structured Interview

Thank you for all you said during the think-aloud session. Now I would like to ask you a few questions about your experience with the website prototype. This will take no longer than 10-15 minutes.

1. What was your overall experience of using the prototype?
2. While you were going through the webpages, was there anything specific you liked the most?
3. Was there anything you did not like at all, something that you think should be removed?
4. Would you like to add something to the website, was there anything missing?
5. What do you think about home practice guide?
6. What do you think about practice and condom evaluation reminders?
7. Here is the sample kit that participants in our study will receive. What do you think about it?
8. Would you use this programme yourself?

That was the last question, thank you very much for your help and time.

Do you have any questions?

Appendix X

Study 1 Debriefing Sheet (Adapted from the University of Southampton Ethics Templates)

UNIVERSITY OF Southampton

Condom Intervention Study

Debriefing Statement (Version no 1, 11/04/2014)

The aim of this research was to explore users' experiences and reactions to the programme website prototype and its specific elements such as content, functions, structure, and layout. Specifically, how clear was the information, how useful was the website, and whether the format of the intervention would be accepted by users. It was also important to observe whether elements such as a study information sheet or questionnaires have impact on the experience with the website.

Your data will help our understanding of *users'* experience using the intervention especially in terms of reactions to content, functions and layout. These will guide the development of the e-KIHIS intervention to optimise its effectiveness in increasing frequency, consistency and correctness of condom use. This will also inform further research and work on the most efficient way of translating face-to-face intervention into on-line environment.

Once again, the results of this study will not include your name or any other identifying characteristics.

If taking part in this study raised any concerns regarding your personal circumstances you can

- find more information on NHS choices website http://www.nhs.uk/Livewell/Sexualhealthtopics/Pages/Sexual-health-hub.aspx
- find your local GUM clinic http://www.nhs.uk/chq/Pages/972.aspx?CategoryID=68
- or contact your GP for further advice.

If you have any questions or concerns, please feel free to contact Dr Cynthia Graham, my supervisor who is qualified Clinical Psychologist C.A.Graham@soton.ac.uk.

You can also contact me at mag1g10@soton.ac.uk or (phone number).

Thank you for your participation in this research.

Signature _____ Date _____

Name Marta Glowacka

If you have questions about your rights as a participant in this research, or if you feel that you have been placed at risk, you may contact the Chair of the Ethics Committee, Psychology, University of Southampton, Southampton, SO17 1BJ, email fshs-

rso@soton.ac.uk or Dr Martina Prude, Head of Research Governance at the University of Southampton 02380 595058, rgoinfo@soton.ac.uk

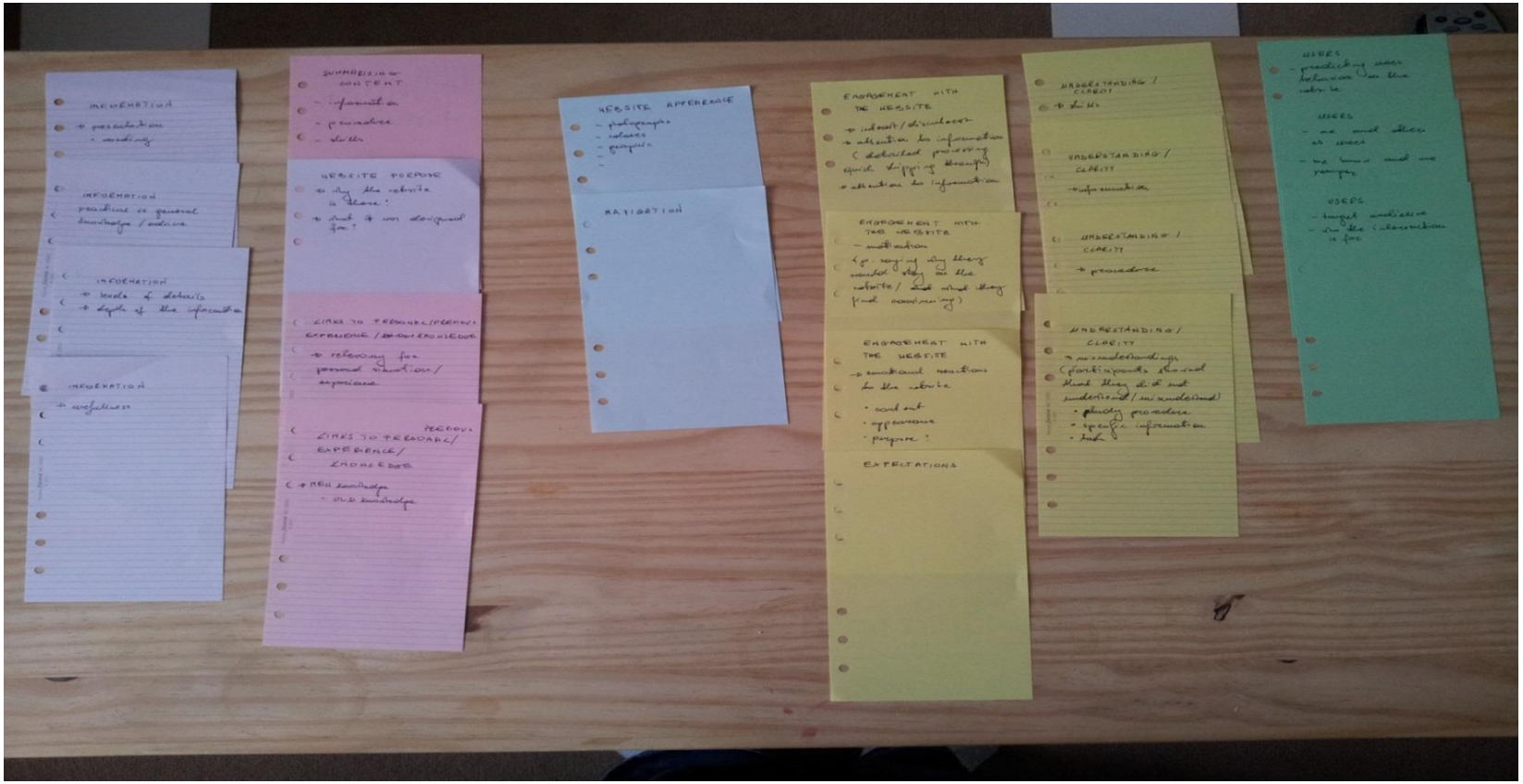
If you are interested in the topic, below you can find the references to other studies reporting KIHIS programme development.

Emetu, Roberta E., Marshall, Alexandra, Sanders, Stephanie A., Yarber, William L., Milhausen, Robin R., Crosby, Richard A., & Graham, Cynthia A. (2014). A Novel, Self-guided, Home-Based Intervention to Improve Condom Use Among Young Men Who Have Sex With Men. *Journal of American College Health, 62*(2), 118-124. doi: 10.1080/07448481.2013.856914

Milhausen, Robin R., Wood, Jessica, Sanders, Stephanie A., Crosby, Richard A., Yarber, William L., & Graham, Cynthia A. (2011). A novel, self-guided, home-based intervention to promote condom use among young men: A pilot study. *Journal of Men's Health, 8*(4), 274-281. doi: 10.1016/j.jomh.2011.06.003

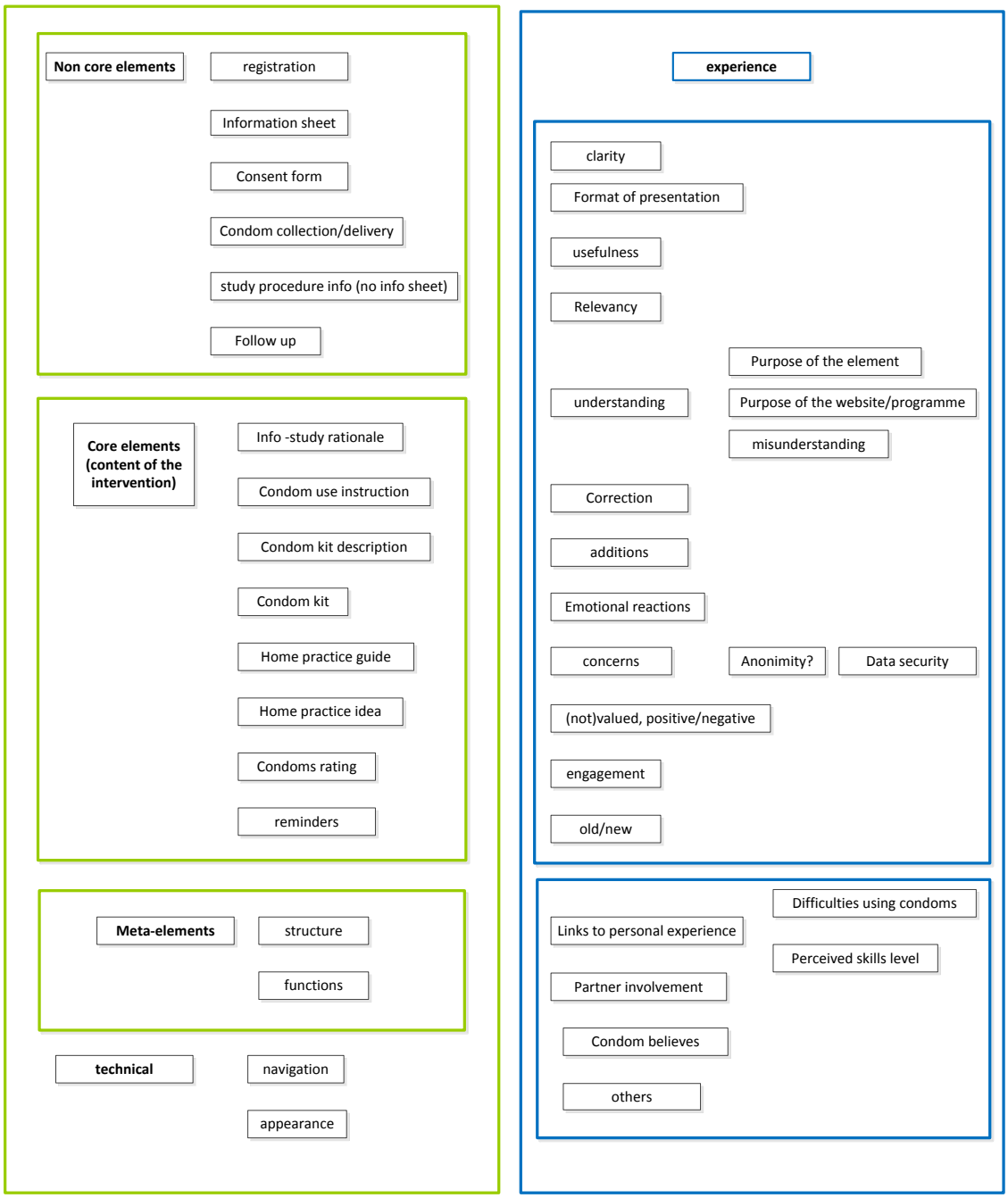
Appendix Y

Study 1 Data Analysis - Codes Candidates



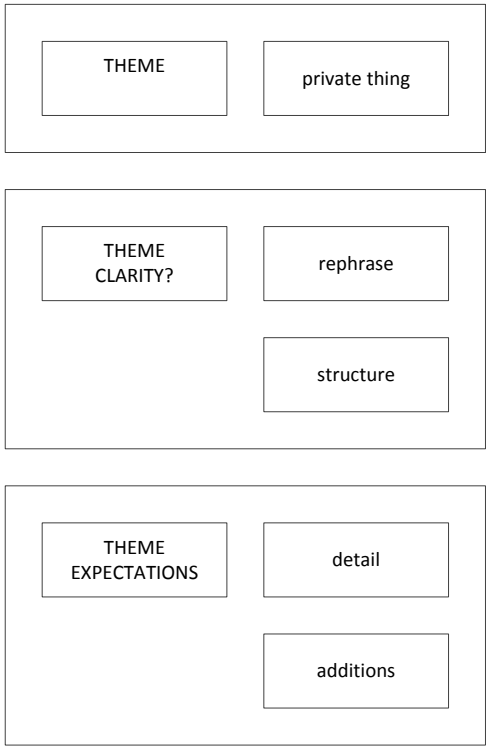
Appendix Z

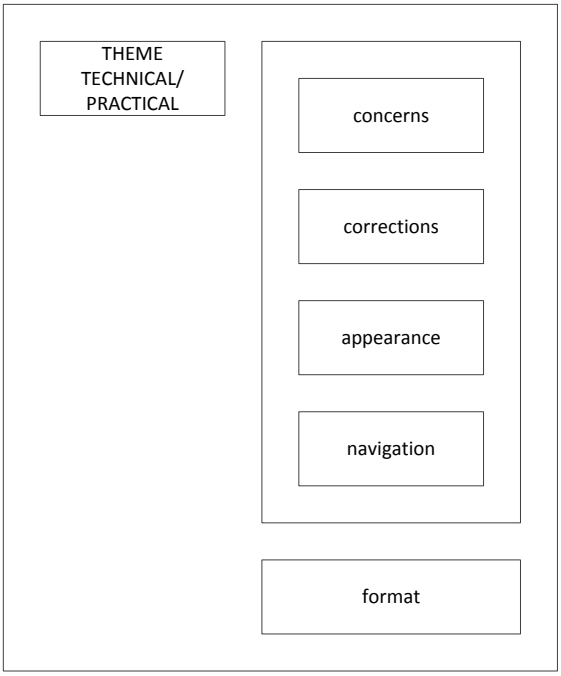
Study 1 Data Analysis - Initial Coding Structure



Appendix AA

Study 1 Data Analysis - Initial Themes


THEME
private thing
THEME
CLARITY?
rephrase
structure
THEME
EXPECTATIONS
detail
additions


THEME
TECHNICAL/
PRACTICAL
concerns
corrections
appearance
navigation
format

Appendix AB

Study 1 Data Analysis – Themes and Codes Development

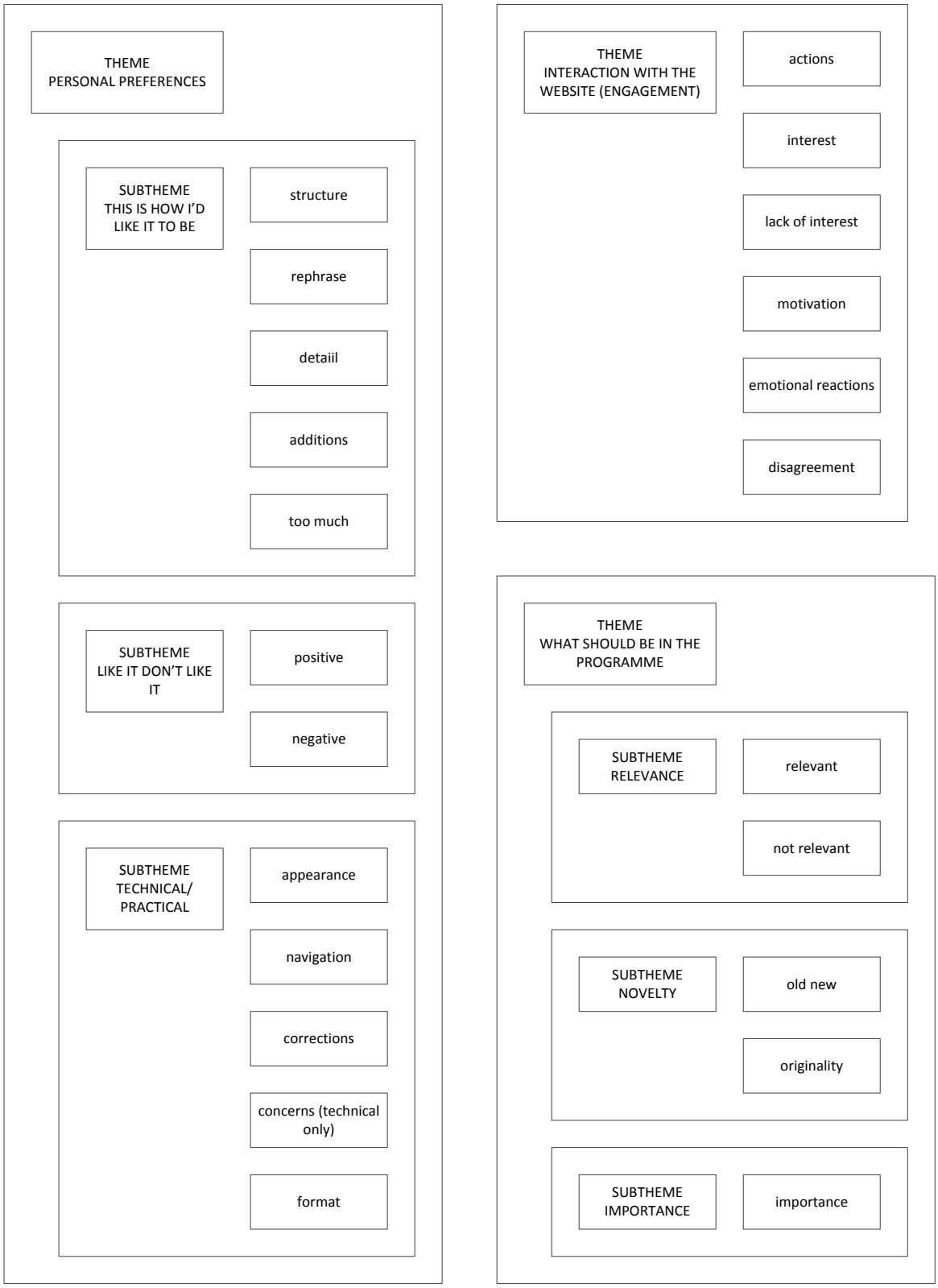


Figure AB1.

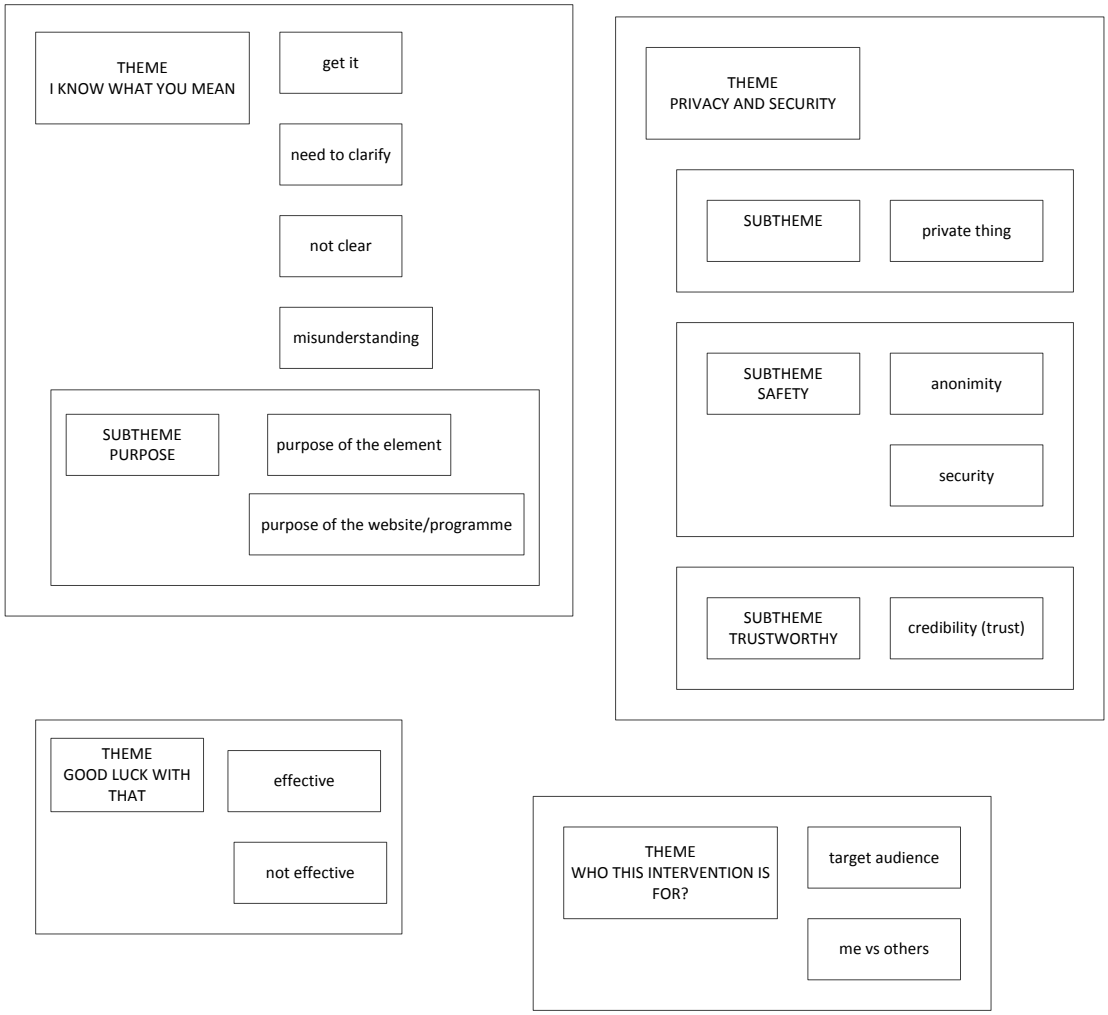


Figure AB1 (continued).

Appendix AB

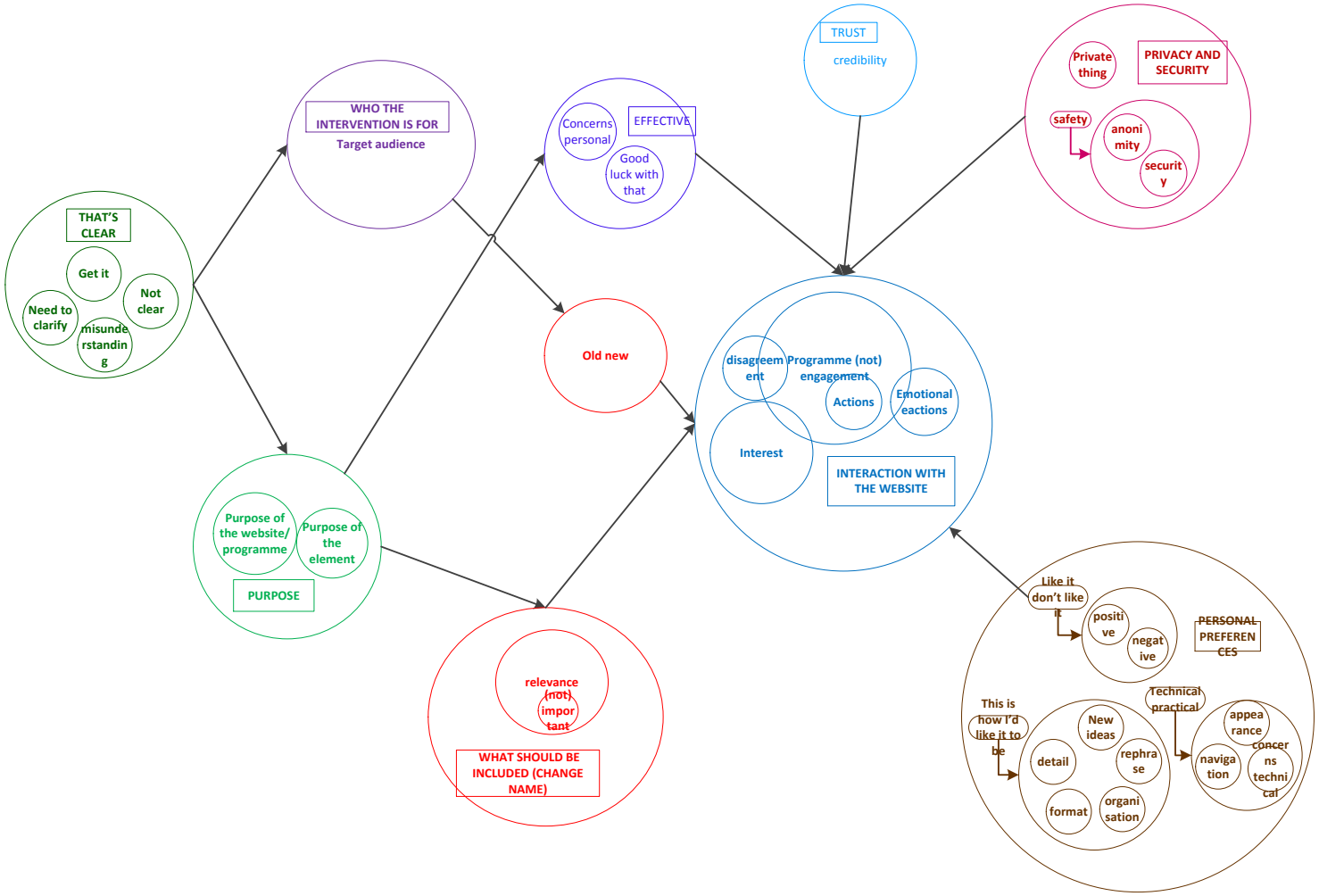


Figure AB2.

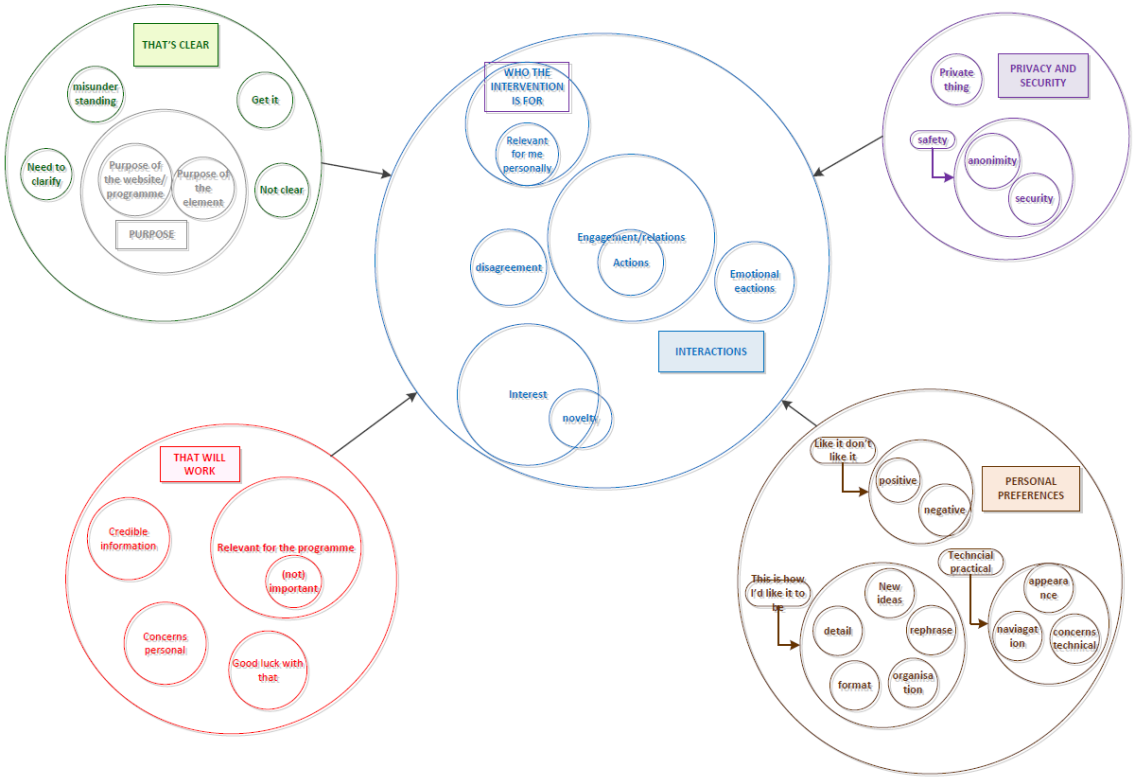

THAT'S CLEAR
misunder standing
Get it
Need to clarify
Purpose of the website/ programme
Purpose of the element
Not clear
PURPOSE
WHO THE INTERVENTION IS FOR
Relevant for me personally
Engagement/relations
Actions
disagreement
Emotional eactions
INTERACTIONS
Interest
novelty
Private thing
PRIVACY AND SECURITY
safety
anonimity
security
THAT WILL WORK
Credible information
Relevant for the programme
(not) important
Concerns personal
Good luck with that
Like it don't like it
positive
negative
PERSONAL PREFERENCES
This is how I'd like it to be
New ideas
detail
rephrase
format
organisa tion
Technical practical
appeara nce
naviagat ion
concerns technical

Figure AB3.

Appendix AB

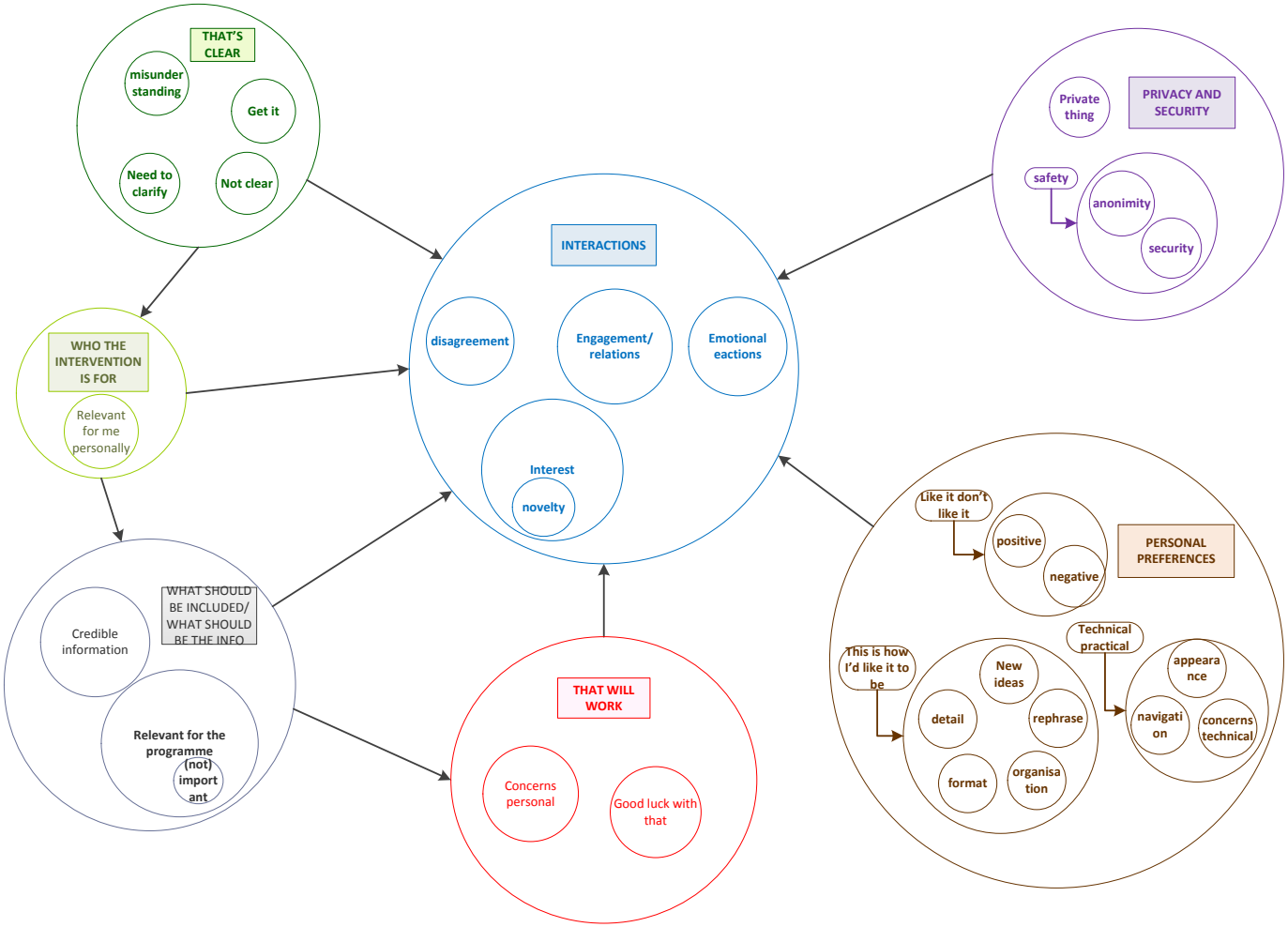


Figure AB4.

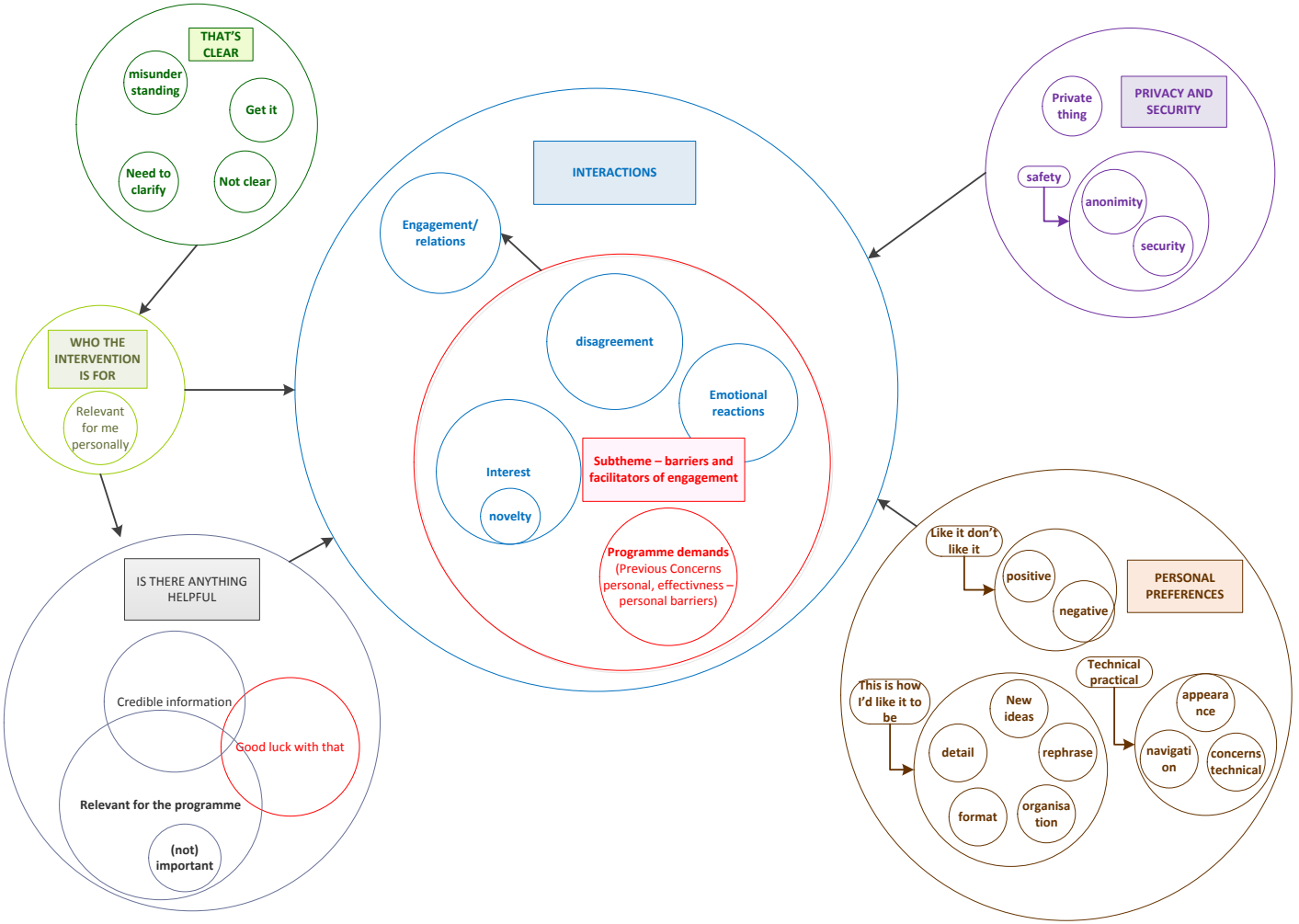

THAT'S CLEAR
misunder standing
Get it
Need to clarify
Not clear
WHO THE INTERVENTION IS FOR
Relevant for me personally
IS THERE ANYTHING HELPFUL
Credible information
Good luck with that
Relevant for the programme
(not) important
INTERACTIONS
Engagement/ relations
disagreement
Emotional reactions
Interest
novelty
Subtheme – barriers and facilitators of engagement
Programme demands (Previous Concerns personal, effectivness – personal barriers)
Private thing
PRIVACY AND SECURITY
safety
anonimity
security
Like it don't like it
positive
negative
PERSONAL PREFERENCES
This is how I'd like it to be
New ideas
detail
rephrase
format
organisa tion
Technical practical
appeara nce
navigati on
concerns technical

Figure AB5.

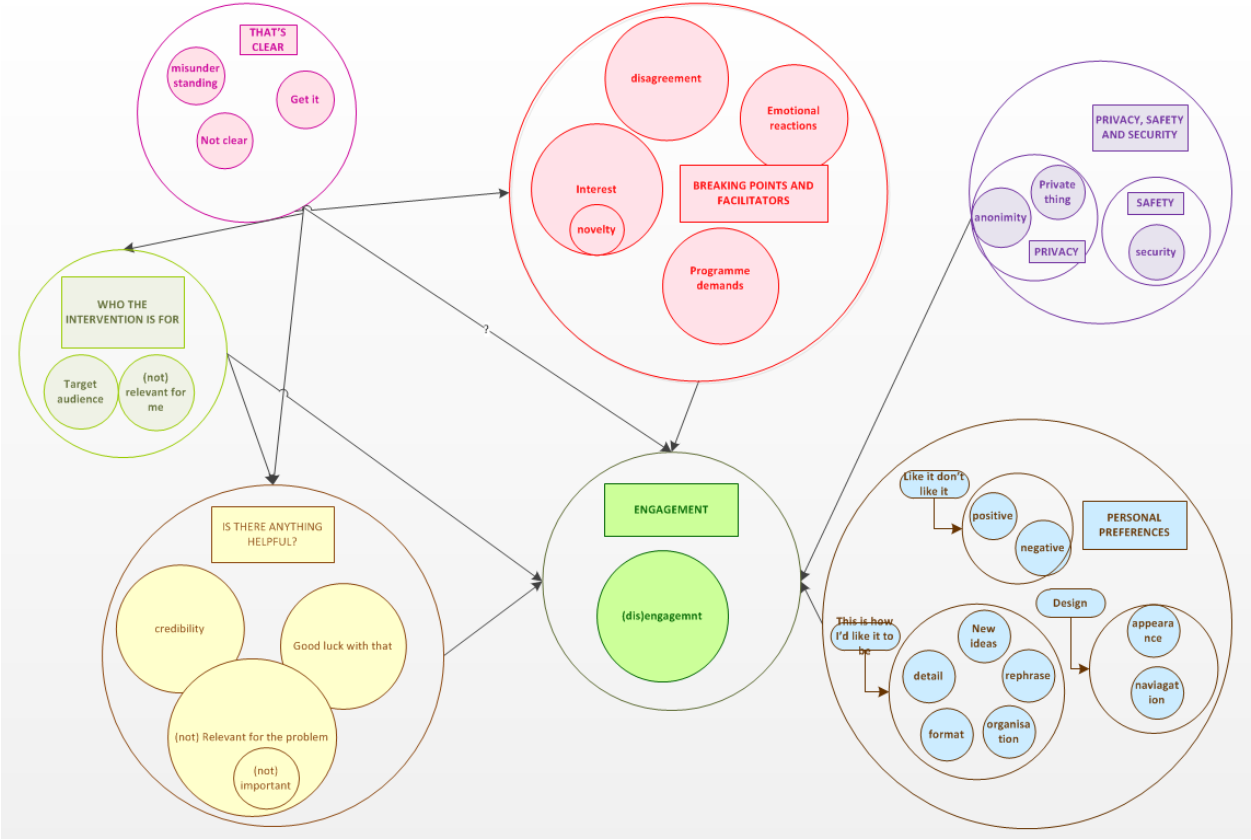

THAT'S CLEAR
misunder standing
Get it
Not clear
disagreement
Emotional reactions
Interest
novelty
BREAKING POINTS AND FACILITATORS
Programme demands
PRIVACY, SAFETY AND SECURITY
Private thing
anonimity
PRIVACY
SAFETY
security
WHO THE INTERVENTION IS FOR
Target audience
(not) relevant for me
IS THERE ANYTHING HELPFUL?
credibility
Good luck with that
(not) Relevant for the problem
(not) important
ENGAGEMENT
(dis)engagemnt
Like it don't like it
positive
negative
PERSONAL PREFERENCES
This is how I'd like it to be
New ideas
detail
rephrase
format
organisa tion
Design
appearance
naviagation

Figure AB6.

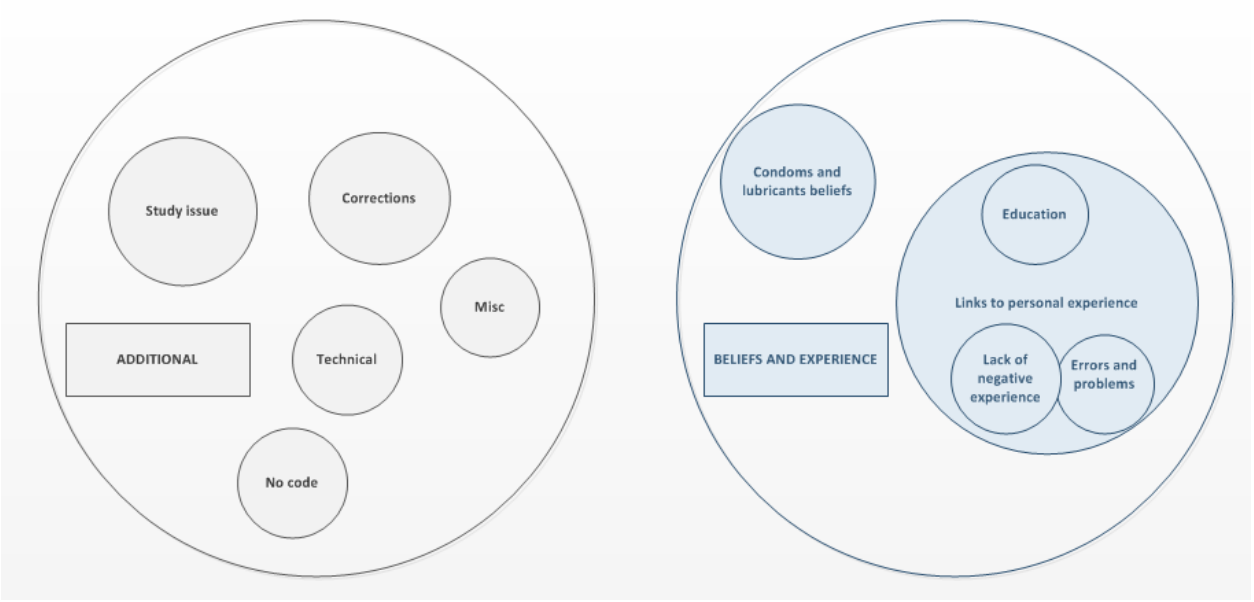


Figure AB6 (continued).

Appendix AB

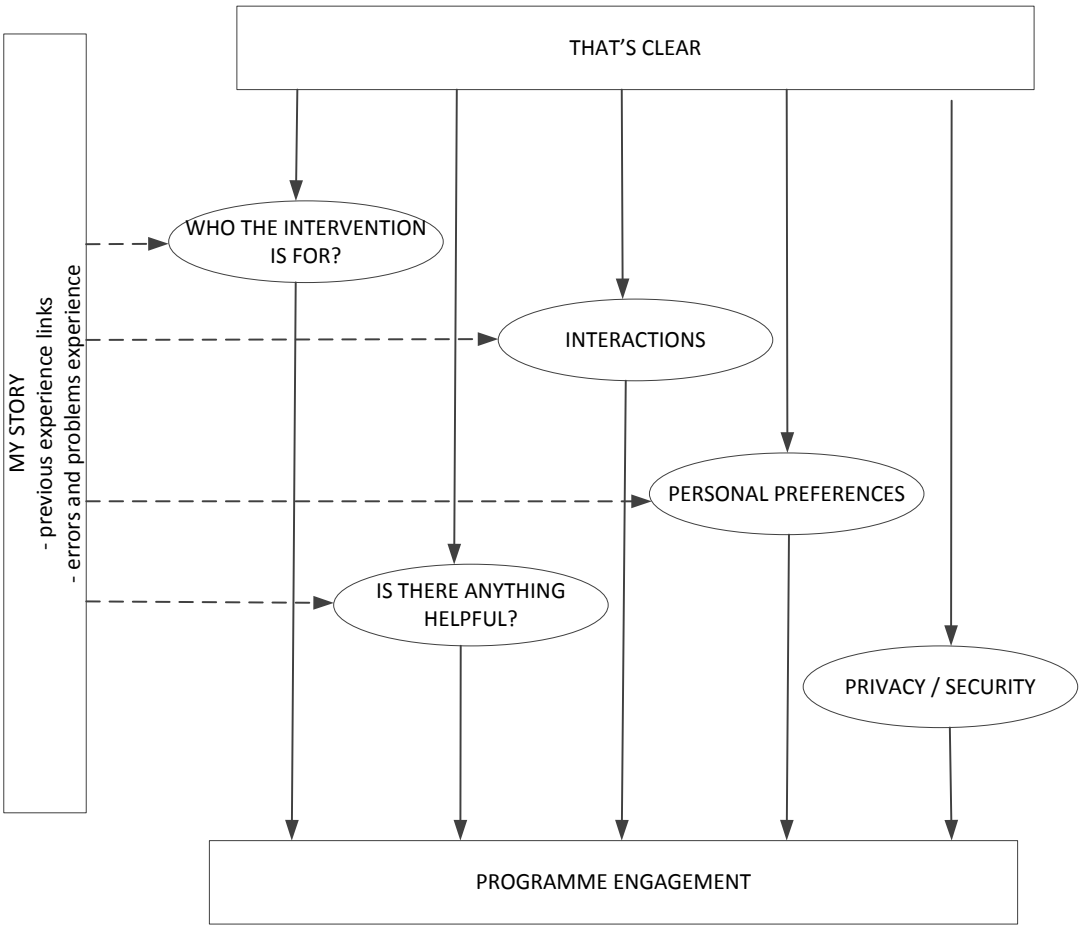


Figure AB7.

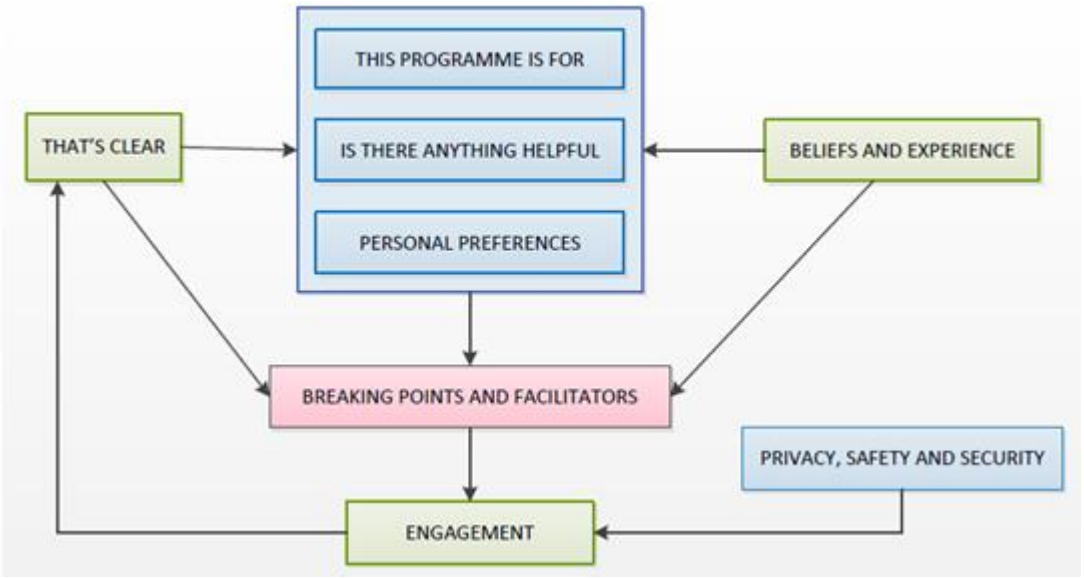


Figure AB8.

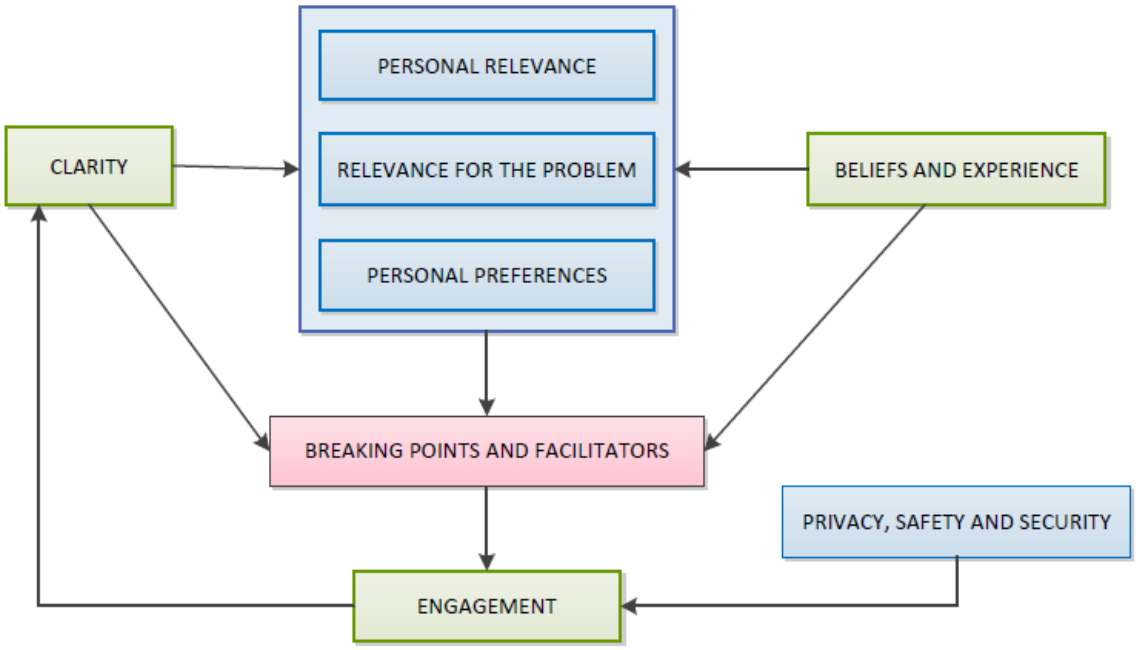

PERSONAL RELEVANCE
CLARITY
RELEVANCE FOR THE PROBLEM
BELIEFS AND EXPERIENCE
PERSONAL PREFERENCES
BREAKING POINTS AND FACILITATORS
PRIVACY, SAFETY AND SECURITY
ENGAGEMENT

Figure AB9.

Appendix AC

Study 1 Coding Manual

Intertwining Theme: Clarity	
Code	**Description**
Get it	a participant demonstrates that he understood well the aim, procedure, information or the purpose of the programme or its specific elements (e.g., by summarising the content correctly using own words)
Not clear	a participant is not sure or states that he does not know the meaning or purpose of a specific element, programme procedure, or the purpose of the programme, does not know what and/or why he is supposed to do something, asks for confirmation that he understood well, or it's obvious that participant is not entirely sure that he understood well; for example "I don't know," "don't understand" etc. don't code: - if participant initially demonstrates lack of understanding or clarity but can demonstrate understanding before moving to the next webpage/gaining additional information, - phrase "I can see this" without additional context allowing making interpretation can be interpreted as *get it* or *(not) relevant for the problem*; **code** *no code*
Misunderstanding	a participant misunderstood the aim, procedure, information or the purpose of the programme or its specific elements

Theme: Personal relevance	
Code	**Description**
(not) Relevant for me	references to the programme and/or its specific elements and/or content being (not) relevant for personal circumstances, a participant explicitly states that the programme or some of its elements are (not) relevant for him personally, or says that it provided answers to his questions or solution for problem(s) he experiences/experienced,
Target audience	references to the target audience of the programme; also when a participants states that the programme is not relevant for him, but may be relevant for others don't code if a participants comments on what others would do when using the programme; **code** *(dis) engagement*

Theme: Relevance for the problem		
Code	**Subcode**	**Description**
(not) Relevant for the problem		references to the programme and/or its specific elements and/or content being (not) relevant for the problem, may include phrases such as "see the point," "does make sense," "answered my questions," "eased my concerns," "it's comprehensive," etc. don't code: - "showed me new perspective," "never thought about it;" **code** *novelty* - "good," 'fine', "I can see this" etc. without additional context allowing making interpretation , can be interpreted as *get it, (not) relevant for the problem* or *positive*; **code** *no code* - "important" or "should be emphasised;" **code** *(not) important*,
	(not) Important for the problem	references to the programme and/or its elements being (not)important for the problem, comments that some elements, parts of the content should be emphasised or ignored don't code comments that the authors of the programme saw some information as important; **code** *get it*, *not clear* or *misunderstanding*
Credibility		references to the website as a credible (trusted) or not credible (untrusted) source of guidance and information, comments regarding programme; authors affiliations, credibility of sources of information etc.
Good luck with that		references to the programme's (or specific elements of the programme) potential (lack of) effectiveness or possible negative effect don't code - comments about concerns regarding technical issues; **code** *technical* - comments regarding factors related to the programme which may hinder the engagement with the programme and/or its effectiveness; **code** *programme demands*

Theme: Privacy, safety and security		
Subtheme	**Code**	**Description**
Privacy	**Private thing**	references to the content of the website, condom kit etc. needed to be seen in private, something that would not be shared with others
	Anonymity	references to the anonymity of the programme users
Safety	**Security**	references to data security, storage, access etc.

Appendix AC

Theme: Breaking points and facilitators		
Code	**Subcode**	**Description**
Disagreement		explicitly expressed disagreement with the programme content or aims
Programme demands		comments regarding factors related to the programme which may hinder the engagement with the programme and/or its effectiveness, for example “too big demand,” “task too difficult”
Emotional reactions		emotional reactions to the content (observed or declared), jokes about the programme or its elements don’t code: expression of curiosity; **code** *interest*
Interest		expressing interest, curiosity, or lack of interest, boredom don’t code - phrase "nothing to say” without additional context allowing making interpretation, can be interpreted as treating information as obvious, lack of interest, lack of engagement etc.; **code** *no code* - gazing at or skipping parts of information/pages/elements; **code** *(dis) engagement*
	Novelty	references to the information and/or instruction(s) being well known or new for a participant, comments about programme’s similarity/difference to other websites/programmes, references to programme or its element(s) providing a new perspective, for example “I have never thought about it”

Intertwining Theme: Engagement	
Code	**Description**
(dis) Engagement	references to reasons/motivation to take part in the programme, and/or to follow programme’s procedure and/or advice, comments about reconsidering own practice in response to the information presented in programme, comments about willingness to stay on the website or to leave it, comments about paying attention to the content or skipping it/gazing through (including information added from observation), remembering information, instruction, advice included in the programme etc.. participants’ actions or predicted actions of others showing interaction with the prototype such as "I would scroll," "I’ll skip," “I'll read carefully” coming back to some of the parts don’t code - linking personal experience with the content of the website; **code** *(not) relevant for me* or one of the sub-codes of *links to personal experience* when appropriate - simple actions that may be just description of behaviour and no additional meaning can be assumed, for example “I click next” - “haven’t thought about it” without explicit comments regarding rethinking own behaviour; code novelty

Theme: Personal preferences		
Subtheme	**Code**	**Description**
Like it, don't like it	**Positive**	positive comments about the programme or it's elements such as "I like it" don't code - phrase "that's very good," "good," "good idea," "useful" etc. may be interpreted as positive or relevant, **code** *no code* - "does make sense," "comprehensive;" **code** *(not) relevant for the problem*
	Negative	negative comments about the programme or its elements "I don't like," "it's horrible"
This is how I'd like it to be	**New ideas**	participants' suggestions to add some new elements to the programme (website, kit), only completely new ideas don't code suggestions to add more details; **code** *detail*
	Detail	references to how detail should be the information, requests to provide detailed/more in depth information, instruction, also comments regarding the content being detailed enough, or too many unnecessary details don't code - "emphasize more;" **code** *(not)important* and *rephrase* - too much information/detail to process; **code** *programme demands*
	Format	comments about format of information presentation (text, video, graphic etc.), suggestions to change format of elements don't code different style, type of picture; **code** *appearance*
	Rephrase	suggestions to rephrase parts of the content, references to the content not being to the point, straightforward, requests to make the content clearer, easier to understand, swapping plain text with bullet points etc.
	Organisation	comments regarding the order of presenting information or repeating the same content at different pages; comments regarding availability of programme content at its different stages, for example suggestion that the website should be available before condoms kit is received don't code - suggestion to divide content between more pages, or consolidate on one; **code** *appearance*; - comments about links between pages; **code** *navigation*
Design	**Appearance**	references to the prototype layout, graphics, colours, buttons, appearance etc. (any visual features)
	Navigation	references to the website navigation, orientation on website, comments regarding easiness/difficulties finding specific content, links, side menu etc.

Appendix AC

Intertwining theme: Beliefs and experience		
Code	**Subcode**	**Description**
Condoms and lubricants beliefs		participants beliefs about condoms and lubricants
Links to personal experience	**Errors and problems**	references to condom use errors and problems experienced by a participant don't code errors demonstrated during condom use practice at the session
	Education	references to previous sex education, sources of information related to correct condom use and/or coping with condom use related problems
	Lack of negative experience	references to previous positive condom use experience

Additional codes not included in the analysis	
Code	**Description**
Study issue	comments regarding issues related to the study, for example about difficulty to imagining how the exercise would on a printed website prototype
Corrections	comments about errors and mistakes found on the website (typos, grammar mistakes, misprinted parts)
Technical	references to predicted technical problems with use of the programme (software, spam filters etc.)
Miscellaneous	comments not assigned to other codes about issues loosely related to the focus of the study
No code	parts of the transcripts unclear or not enough information to assign a code

Appendix AD

Study 2 Advertisements

Poster Advertisement

Appendix AD

eFolio Advertisement (Psychology– University of Southampton)

Title: Condom Promotion Study

I would like to hear **what you think** about the new website encouraging men to use condoms and enjoy it.
I am looking for participants who: are male, age 18 – 69, fluent in English, already use condoms, OR are considering using condoms in the future, OR experience condom use related difficulties or problems OR have stopped using condoms*
(*For reasons other than allergy or sensitivity to latex or non-latex condoms and/or lubricants.)
The session will take approximately 90 minutes and you can earn 20 credits or £10 for completing the session.
To find out more about the study and how you can contribute to the development of the programme follow the link below.
(iSurvey link)
For more information you can also call on (phone number)
or e-mail **mag1g10@soton.ac.uk**
School of Psychology, Research Ethics Committee approval number xxx

E-mail Advertisement

e-mail subject: Condom Promotion Study – Participants Needed

I am a PhD Health Psychology student at the University of Southampton.
I would like to hear **what you think** about the new website encouraging men to use condoms and enjoy it.
You will receive £10 for completing the session, (approximately 90 minutes).
If you are a student in the School of Psychology, University of Southampton you can alternatively earn 20 credits.
I am looking for participants who:
* are male, age 18 – 69,
* fluent in English
* live in the South of England
* already use condoms, OR are considering using condoms in the future, OR experience condom use related difficulties or problems OR have stopped using condoms*
(*For reasons other than allergy or sensitivity to latex or non-latex condoms and/or lubricants.)
To find out more about the study and how you can contribute to the development of the programme follow the link below.
(iSurvey link)
For more information you can also call on (phone number) or e-mail
mag1g10@soton.ac.uk

This study has been approved by the School of Psychology Ethics Committee at the University of Southampton, approval number xxx

The PhD is funded through Economic and Social Research Council studentship.

Facebook Advertisement

Condom Promotion Study

I am a PhD Health Psychology student at the University of Southampton.

I would like to hear **what you think** about the new website encouraging men to use condoms and enjoy it/them

You will receive £10 for completing the session, (approximately 90 minutes).

If you are a student in the School of Psychology, University of Southampton you can alternatively earn 20 credits.

I am looking for participants who:

- are male, age 18 or over, fluent in English
- live in the South of England
- already use condoms, OR are considering using condoms in the future, OR experience condom use related difficulties or problems OR have stopped using condoms*

*For reasons other than allergy or sensitivity to latex or non-latex condoms and/or lubricants.

To find out more about the study and how you can contribute to the development of the programme follow the link below.

(iSurvey link)

For more information you can also call on (phone number) or e-mail

mag1g10@soton.ac.uk

This study has been approved by the School of Psychology Ethics Committee at the University of Southampton, approval number xxx

The PhD is funded through Economic and Social Research Council studentship.

Twitter Advertisement

Share your opinion about a new website promoting condom use (UK study)! £10 for participation (iSurvey link)

Appendix AE

Study 2 Information Sheet Online/Printed Version (Adapted from the University of Southampton Ethics Templates)

UNIVERSITY OF Southampton

Participant Information Sheet (Version 1, 23/10/2015)

Study Title: ***Condom Promotion Study***

Researcher: Marta Glowacka,

Prof Cynthia Graham, Prof Lucy Yardley (supervisors)

ERGO Study ID number: TBC

Please read this information carefully before deciding to take part in this research. If you are happy to participate you will be asked to give consent for screening and sign a consent statement before the research session.

What is the research about?

The research aim is to design and evaluate an-on-line programme to enhance condom use. The purpose of this study is to find out what men think about the programme's website so it can be engaging and enjoyable for men using it in the future.

This study is a part of my PhD project (MPhil/PhD in Health Psychology Research and Professional Practice funded through the Economic and Social Research Council studentship).

Why have I been chosen?

I am looking for male participants, age 18 – 69 who already use condoms or are considering using them in the future or experience condom related difficulties or problems or have tried to use them but for some reasons (other than medical i.e. allergy) have stopped using them.

You need to be in good health and be comfortable using computers, to be able to take part in an approximately 90 minutes session.

Currently it is not possible to include people with visual or hearing impairments or with learning disability in the study.

What will happen to me if I take part?

After you complete the screening questionnaire and if you are eligible to take part in the study, a face-to face session will be arranged. You will see the programme's website on a computer screen and you will be asked to tell what you think about it while going through webpages. Data from questionnaires completed on the programme's website during the session will not be scored. The website is accompanied by a sample condoms and lubricants kit that you can look at as well. After you finish you will be asked a few questions about the website and the sample kit. You are asked to attend only one session and this should last approximately 90 minutes. The session will be audio recorded and the notes will be taken during the session.

Are there any benefits in my taking part?

Your contribution to the development of an on-line version of a novel programme to enhance male condom use which will be effective for future users is invaluable**.** You will also learn about the website development process.

You will receive £10 or 20 credits (2 for screening and 18 for completing the research session). The travel cost to and from the University of Southampton will also be reimbursed.

Are there any risks involved?

Some people may feel uncomfortable or embarrassed answering questions about sexual behaviour and condoms. You do not need to give answers to any questions that may make you feel uncomfortable. Taking part in the study may raise your awareness regarding sexual health and some aspects of your sexual behaviour that could put you at risk of contracting sexually transmitted infections or of pregnancy for a partner. At the end of the study you will receive information on services providing advice and support on issues related to sexual health.

You may feel tired during the session. You may ask for as many break as you need any time during the session.

<u>Unfortunately, if you have an allergy to any type of condoms (latex or non-latex) or to any type of lubricants you cannot take part in the study.</u>

Will my participation be confidential?

Your participation in the study is confidential. All study procedures will comply with the Data Protection Act/University policy. The sessions will be conducted in private rooms (at the University of Southampton or other locations chosen by you) to ensure your comfort and confidentiality.

You will be asked in a consent statement to give permission to use some verbatim quotations from the session to illustrate the data analysis. The quotations may be accompanied by information about your age but not your name or any other identifying information. You may still take part in the study if you do not agree to this.

All data (electronic and hard copy) will be securely stored in line with procedures approved by the School of Psychology Ethics Committee at the University of Southampton. Personal information will not be released to or viewed by anyone other than researchers involved in this project.

Data you provide in the screening questionnaire and during the research session will be used only for research, and the results will be presented in a chapter of a PhD thesis. They may also be submitted for publication in a scientific journal or presentation at a scientific conference, or be disseminated to general public as a part of educational activities. No identifiable data (such as your name or date of birth) will be used in any of the listed publications or activities.

What happens if I change my mind?

You can change your mind and withdraw from the study at any time, without giving a reason for your decision. If you are a student at the University of Southampton and you choose not to participate there will be no consequences to your grade or to your treatment as a student in the psychology department.

What happens if something goes wrong?

If you have any concerns in relation to the study or if you feel that you have been placed at risk, you may contact the Chair of the Ethics Committee, Psychology, University of Southampton, Southampton, SO17 1BJ. Phone: +44 (0)23 8059 3856, email fshs-rso@soton.ac.uk

Where can I get more information?

If you would like to find out more about the study, or have some questions that you did not find the answer to please contact Marta Glowacka at mag1g10@soton.ac.uk or on [phone number]

Appendix AF

Study 2 Screening Questionnaire (Can Be Completed Online or through Telephone)

Please answer the following question about yourself. Questions marked with * are compulsory. Completion of this questionnaire will take you no longer than 5 minutes.

Please answer the questions which are necessary to decide whether you are eligible to take part in the study.

What is your gender?* male female other

What is your age?*

Do you have allergy to any type of condoms (latex or non-latex) or any ingredient of lubricants?* yes no

Do you have any of the following:*

- visual impairment? * yes no

- hearing impairment?* yes no

- learning disability?* yes no

Tell us something more about yourself

What is your ethnic background?

Are you currently in a relationship? yes no

If you answered yes, how would you describe your relationship?

What is the highest level of education you completed?

What is your current occupation?

Do you think you are a competent computer user?* yes no I don't know

The final questions are about your condom use experience

Do you use condoms? yes no

(if your answer is 'no' go to question number 6)

Do you use condom each time you have sexual intercourse (vaginal or anal).	yes		no	
Do you use condoms correctly?	yes	no	I don't know	
Do you feel confident using condoms?	yes	no	unsure	
Have you ever experienced any condom use problems?	yes		no	
If you answered yes in question 5, please specify what condom use problems you have experienced.				
If you do not use condoms at the moment, do you plan to use them in the future?	yes	no	don't know	not applicable

Please leave your e-mail or phone number and a researcher will contact you within the next 3 working days to confirm your eligibility to take part in the study and arrange the session.

If you are not eligible to take part in the study a researcher will contact you to explain the reasons.

Appendix AG

Study 2 Participants Information Sheet – Verbal, to Be Used during Phone Calls (Adapted from the University of Southampton Ethics Templates)

UNIVERSITY OF Southampton

Participant Information Sheet – verbal (Version 1, 23/10/2015)

Condom Intervention Study

This study is a part of my PhD project (MPhil/PhD in Health Psychology Research and Professional Practice funded through the Economic and Social Research Council studentship), my supervisors are Prof Cynthia Graham and Prof Lucy Yardley.

The research aim is to design and evaluate an-on-line programme to enhance condom use. The purpose of this study is to find out what men think about the programme's website so it can be engaging and enjoyable for men using it in the future.

I am looking for male participants, age 18 – 69 who already use condoms or are considering using them in the future or experience condom related difficulties or problems or have tried to use them but for some reasons (other than medical i.e. allergy) have stopped using them.

You need to be in good health and be comfortable using computers, to be able to take part in an approximately 90 minutes session.

Currently it is not possible to include people with visual or hearing impairments or with learning disability in the study.

After you complete the screening questionnaire and if you are eligible to take part in the study, a face-to face session will be arranged. You will see the programme's website on a computer screen and you will be asked to tell what you think about it while going through webpages. Data from questionnaires completed on the programme's website during the session will not be scored. The website is accompanied by a sample condoms and lubricants kit that you can look at as well. After you finish you will be asked a few questions about the website and the sample kit. You are asked to attend only one session and this should last approximately 90 minutes. The session will be audio recorded and the notes will be taken during the session.

Your contribution to the development of an on-line version of a novel programme to enhance male condom use which will be effective for future users is invaluable. You will also learn about the website development process.

You will receive £10 or 20 credits (2 credits for screening and 18 for completing the research session). The travel cost to and from the University of Southampton will also be reimbursed.

Some people may feel uncomfortable or embarrassed answering questions about sexual behaviour and condoms. You do not need to give answers to any questions that may make you feel uncomfortable. Taking part in the study may raise your awareness regarding sexual health and some aspects of your sexual behaviour that could put you at risk of contracting sexually transmitted infections or of pregnancy for a partner. At the end of the study you will receive information on services providing advice and support on issues related to sexual health.

You may feel tired during the session. You may ask for as many break as you need any time during the session.

Unfortunately, if you have an allergy to any type of condoms (latex or non-latex) or to any type of lubricants you cannot take part in the study.

All study procedures will comply with the Data Protection Act/University policy. The sessions will be conducted in private rooms (at the University of Southampton or other locations chosen by you) to ensure your comfort and confidentiality.

You will be asked in a consent statement to give permission to use some verbatim quotations from the session to illustrate the data analysis. The quotations may be accompanied by information about your age but not your name or any other identifying information. You may still take part in the study if you do not agree to this.

All data (electronic and hard copy) will be securely stored in line with procedures approved by the School of Psychology Ethics Committee at the University of Southampton. Personal information will not be released to or viewed by anyone other than researchers involved in this project.

Data you provide in the screening questionnaire and during the research session will be used only for research, and the results will be presented in a chapter of a PhD thesis. They may also be submitted for publication in a scientific journal or presentation at a scientific conference, or be disseminated to general public as a part of educational activities. No identifiable data (such as your name or date of birth) will be used in any of the listed publications or activities.

You can change your mind and withdraw from the study at any time, without giving a reason for your decision. If you are a student at the University of Southampton and you choose not to participate there will be no consequences to your grade or to your

treatment as a student in the psychology department.

If you have any concerns in relation to the study or if you feel that you have been placed at risk, you may contact the Chair of the Ethics Committee, Psychology, University of Southampton, Southampton, SO17 1BJ. Phone: +44 (0)23 8059 3856, email fshs-rso@soton.ac.uk

ERGO Study ID number: TBC

Appendix AH

Study 2 Verbal Screening Consent Script - for Telephone Screening (Adapted from the University of Southampton Ethics Templates)

Verbal Screening Consent Script for Research Participants (Version 1, 23/10/2015)

Study title: *Condom Intervention Study*

Thank you for your interest in our study. My name is *Marta Glowacka* and I am PhD student at the University of Southampton.

Did you have a chance to read the Participants Information Sheet available on-line?

[no – go to the script No 1] [yes – go to script No 2]

Script No 1

[no] Would you prefer to read the information on-line or would you like me to give you the study information now?

[on-line]	[on the phone]
The participant information sheet, consent statement and screening questionnaire are available at [iSurvey link]	[The verbal information sheet [version 1, 23/10/2015 will be read to the participant] Before we go any further I need to obtain your consent to ask questions to establish your eligibility to take part in the study. Your continued participation in this research will be taken as evidence of your giving informed consent. Can I now ask you a few questions to confirm you are eligible take part in our study? [yes – verbal consent assumed] [no – consent not given]

Script 2

[yes]

Did you accept the consent statement on the website?

[Yes]	[No]
Verbal consent not required	Before we go any further I need to obtain your consent to ask questions to establish your eligibility to take part in the study. Your continued participation in this research will be taken as evidence of your giving informed consent. Can I now ask you a few questions to confirm you are eligible to take part in our study? [yes – verbal consent assumed] [no – consent not given]

Appendix AI

Study 2 Consent Form (Adapted from the University of Southampton Ethics Templates)

UNIVERSITY OF Southampton

CONSENT STATEMENT (*Version 1, 23/10/2015*)

Study title: *Condom Promotion Study*

Researcher name: Marta Glowacka, PhD student, Trainee Health Psychologist

Professor Cynthia Graham, Professor Lucy Yardley (project supervisors)

Ethics reference: TBC

Please initial the boxes if you agree with the statements:

I have read and understood the information sheet (Version 1, 23/10/2015) and have had the opportunity to ask questions about the study.	☐
I agree to take part in this research project and agree for my data to be used for the purpose of this study	☐
I give my permission for the session to be audio recorded and the notes to be taken during the session.	☐
I understand my participation is voluntary and I may withdraw at any time without my legal rights being affected	☐
I give my permission for anonymous quotes recorded during the session to be used, accompanied by information about my age range (e.g. 20-25) in reports written up about the study (optional).	☐

For students: If you are a student at the University of Southampton and you choose not to participate there will be no consequences to your grade or to your treatment as a student in the psychology department

Data Protection

I understand that information collected about me during my participation in this study will be stored on a password protected computer and that this information will only be used for the purpose of this study. All files containing any personal data will be anonymised (Data will be coded for the analysis, and only researchers named above would have access to all data).

Name of participant (print name)……

Signature of participant……..

Date……

If you have questions about your rights as a participant in this research, or if you feel that you have been placed at risk, you may contact the Chair of the Ethics Committee, Psychology, University of Southampton, Southampton, SO17 1BJ. Phone: +44 (0)23 8059 3856, email fshs-rso@soton.ac.uk

Appendix AJ

Study 2 Debriefing Sheet (Adapted from the University of Southampton Ethics Templates)

UNIVERSITY OF Southampton

Condom Intervention Study

Debriefing Statement (Version no 1, 12/08/2015)

The aim of this research was to explore users' experiences and reactions to the programme website and its specific elements such as content, functions, structure, and layout. Specifically, how clear was the information, how useful was the website, and whether the format of the intervention would be accepted by users. It was also important to observe whether elements such as a study information sheet or questionnaires have impact on the experience with the website (data from questionnaires completed on the programme's website during today's session will not be scored).

Your data will help our understanding of *users'* experience using the intervention especially in terms of reactions to content, functions and layout. These will guide the development of the Condom Promotion intervention to optimise its effectiveness in increasing frequency, consistency and correctness of condom use. This will also inform further research and work on the most efficient way of translating face-to-face intervention into on-line environment.

Once again, the results of this study will not include your name or any other identifying characteristics.

If taking part in this study raised any concerns regarding your personal circumstances you can

- find more information on NHS choices website http://www.nhs.uk/Livewell/Sexualhealthtopics/Pages/Sexual-health-hub.aspx
- find your local GUM clinic http://www.nhs.uk/chq/Pages/972.aspx?CategoryID=68
- or contact your GP for further advice.

If you have any questions or concerns, please feel free to contact Professor Cynthia Graham, my supervisor who is qualified Clinical Psychologist C.A.Graham@soton.ac.uk.

You can also contact me at mag1g10@soton.ac.uk or [phone number).

Thank you for your participation in this research.

Signature _____ Date _____

Name Marta Glowacka

If you have questions about your rights as a participant in this research, or if you feel that you have been placed at risk, you may contact the Chair of the Ethics Committee, Psychology, University of Southampton, Southampton, SO17 1BJ. Phone: +44 (0)23 8059 3856, email fshs-rso@soton.ac.uk

If you are interested in the topic, below you can find the references to other studies reporting programme development.

Emetu, Roberta E., Marshall, Alexandra, Sanders, Stephanie A., Yarber, William L., Milhausen, Robin R., Crosby, Richard A., & Graham, Cynthia A. (2014). A Novel, Self-guided, Home-Based Intervention to Improve Condom Use Among Young Men Who Have Sex With Men. *Journal of American College Health, 62*(2), 118-124. doi: 10.1080/07448481.2013.856914

Milhausen, Robin R., Wood, Jessica, Sanders, Stephanie A., Crosby, Richard A., Yarber, William L., & Graham, Cynthia A. (2011). A novel, self-guided, home-based intervention to promote condom use among young men: A pilot study. *Journal of Men's Health, 8*(4), 274-281. doi: 10.1016/j.jomh.2011.06.003

Appendix AK

Study 2 Semi-structured Interview

Thank you for all you said during the think-aloud session. Now I would like to ask you a few questions about your experience with the website prototype. This will take no longer than 10-15 minutes.

1. What was your overall experience of using the programme's website?
2. While you were going through the webpages, was there anything specific you liked the most?
3. Was there anything you did not like at all, something that you think should be changed?
4. Would you like to add something to the website, was there anything missing?
5. Here is the sample kit that participants in our study will receive. What do you think about it?
6. Do you think this programme could help to improve condom use experience?
7. Would you use this programme yourself?
8. Would you be interested in taking part in the next study which will be testing the effectiveness of the programme? If yes, can I contact you when I will advertise the next study?

That was the last question, thank you very much for your help and time.

Do you have any questions?

Appendix AL

Study 2 Data Analysis – Themes and Codes Development

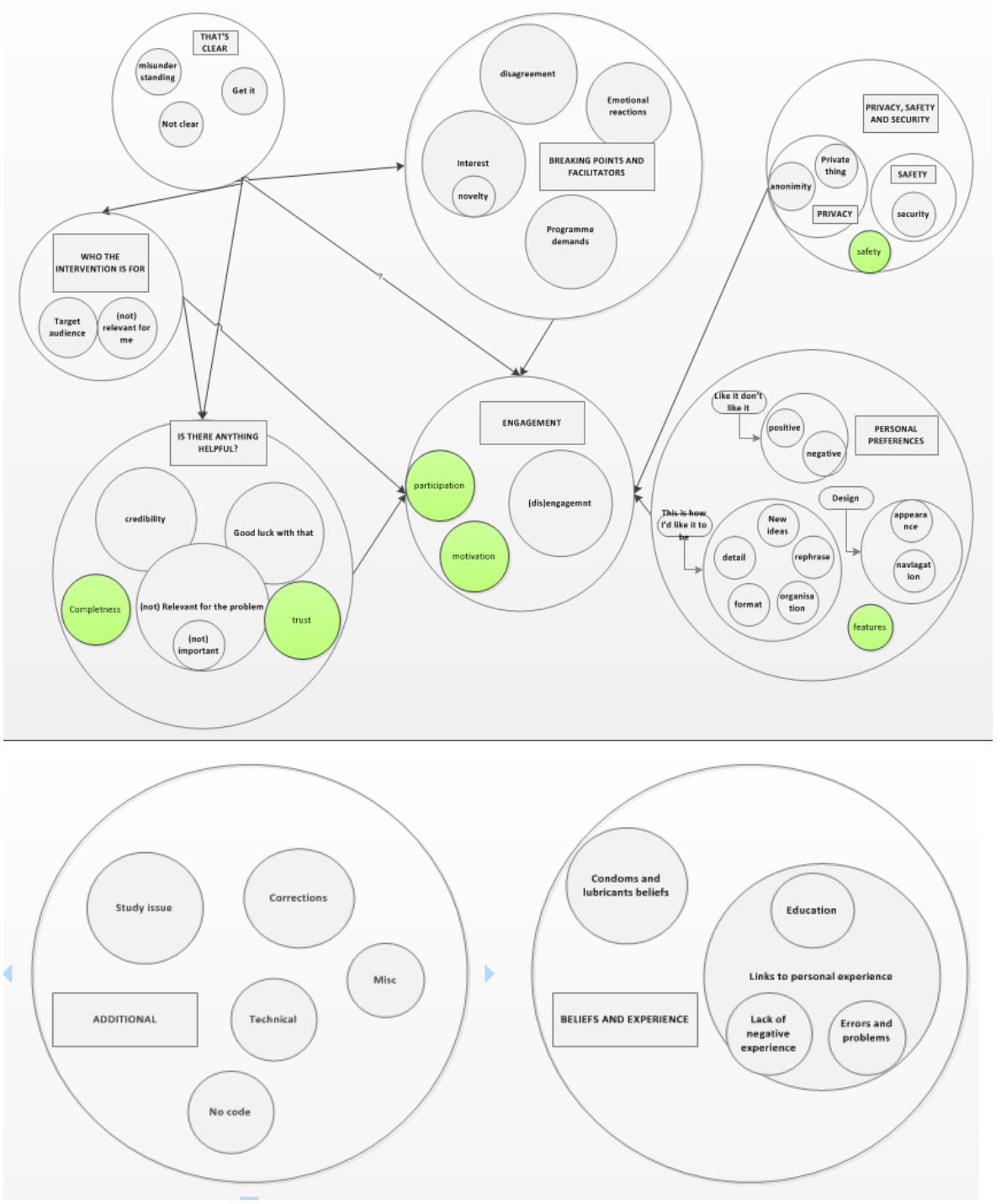


Figure AL1.

Appendix AL

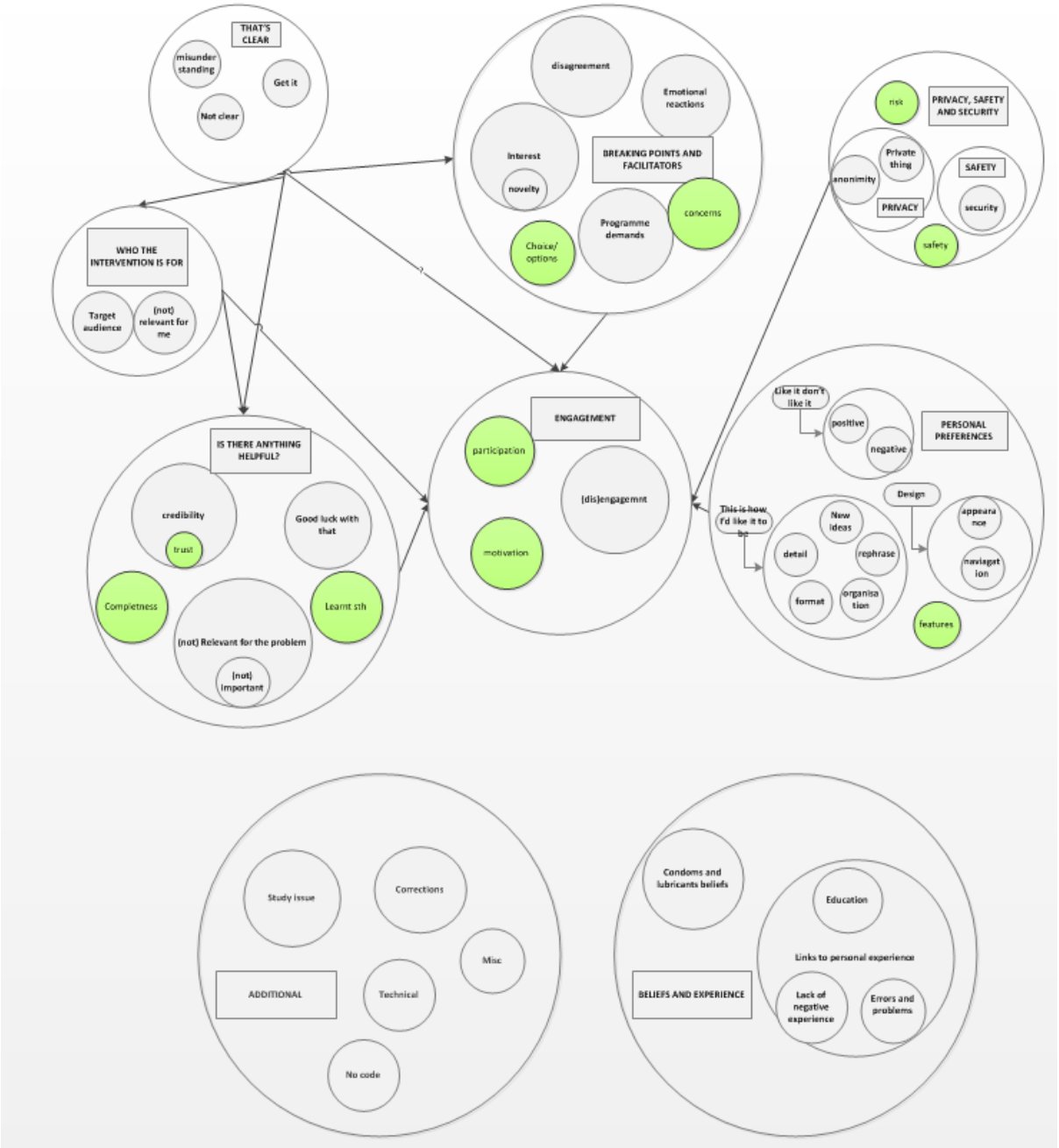


Figure AL2.

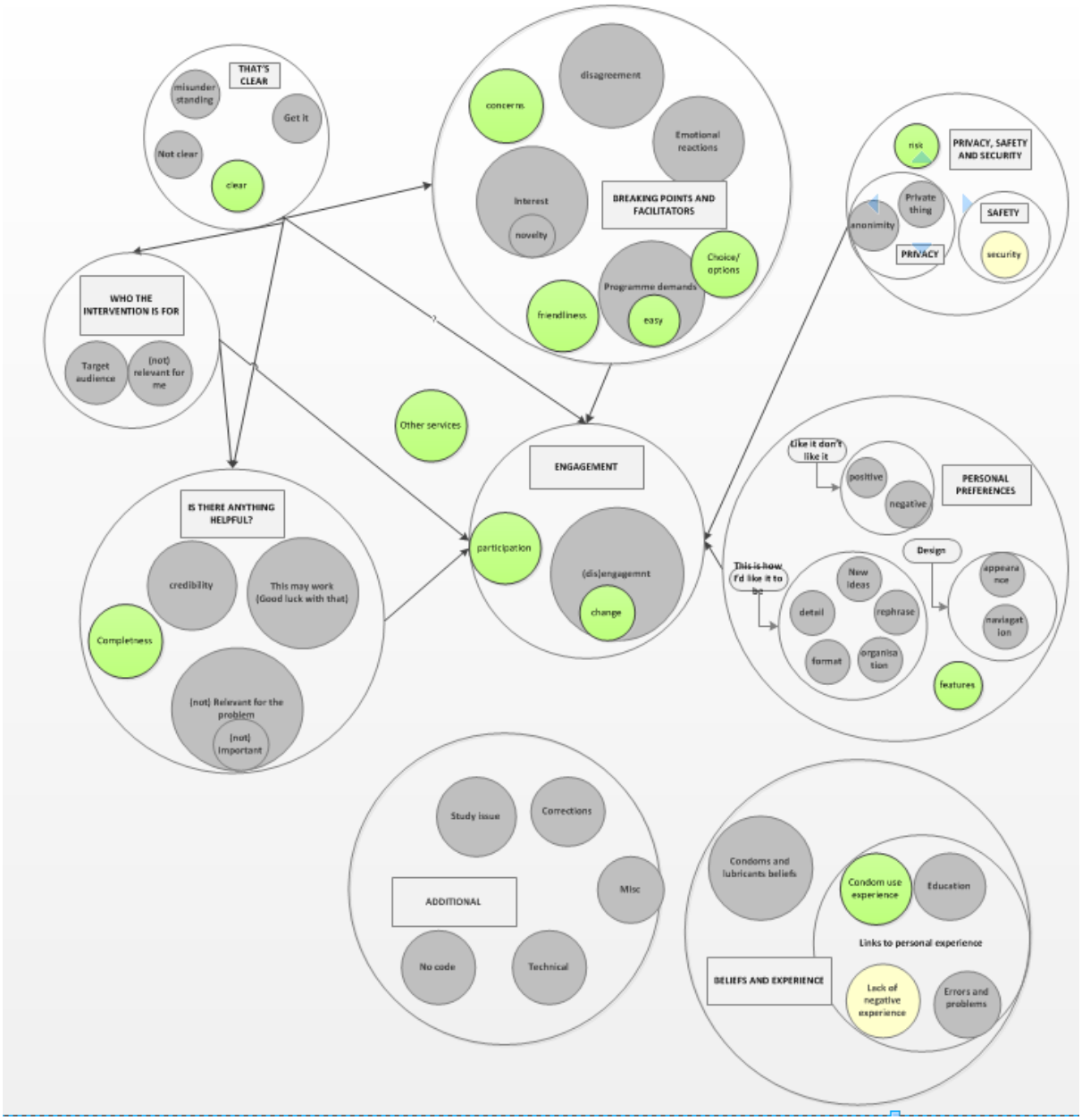

THAT'S CLEAR
misunder standing
Get it
Not clear
clear
WHO THE INTERVENTION IS FOR
Target audience
(not) relevant for me
IS THERE ANYTHING HELPFUL?
credibility
This may work (Good luck with that)
Completness
(not) Relevant for the problem
(not) Important
Other services
ENGAGEMENT
participation
(dis)engagemnt
change
BREAKING POINTS AND FACILITATORS
disagreement
concerns
Emotional reactions
Interest
novelty
Programme demands
Choice/ options
friendliness
easy
PRIVACY, SAFETY AND SECURITY
risk
Private thing
anonimity
PRIVACY
SAFETY
security
PERSONAL PREFERENCES
Like it don't like it
positive
negative
This is how I'd like it to be
Design
New ideas
detail
rephrase
format
organisa tion
appearan ce
navigat ion
features
ADDITIONAL
Study issue
Corrections
Misc
No code
Technical
BELIEFS AND EXPERIENCE
Condoms and lubricants beliefs
Condom use experience
Education
Links to personal experience
Lack of negative experience
Errors and problems

Figure AL3.

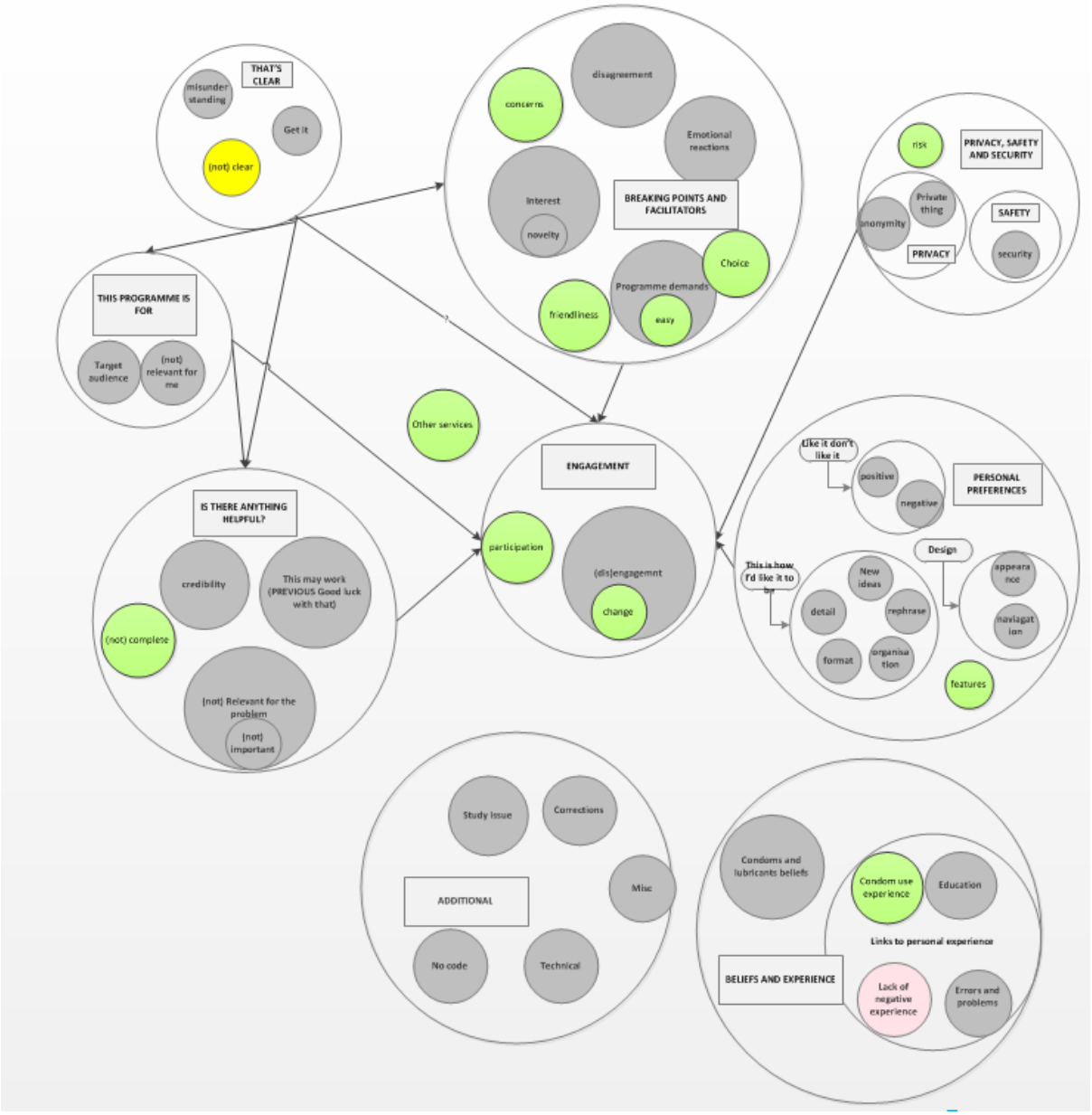

THAT'S CLEAR
misunder standing
Get it
(not) clear
disagreement
concerns
Emotional reactions
Interest
novelty
BREAKING POINTS AND FACILITATORS
Choice
Programme demands
easy
friendliness
risk
PRIVACY, SAFETY AND SECURITY
Private thing
anonymity
PRIVACY
SAFETY
security
THIS PROGRAMME IS FOR
Target audience
(not) relevant for me
Other services
ENGAGEMENT
participation
(dis)engagemnt
change
Like it don't like it
positive
negative
PERSONAL PREFERENCES
This is how I'd like it to be
New ideas
detail
rephrase
format
organise tion
Design
appearance
navigation
features
IS THERE ANYTHING HELPFUL?
credibility
This may work (PREVIOUS Good luck with that)
(not) complete
(not) Relevant for the problem
(not) important
Study issue
Corrections
ADDITIONAL
Misc
No code
Technical
Condoms and lubricants beliefs
Condom use experience
Education
Links to personal experience
BELIEFS AND EXPERIENCE
Lack of negative experience
Errors and problems

Figure AL4.

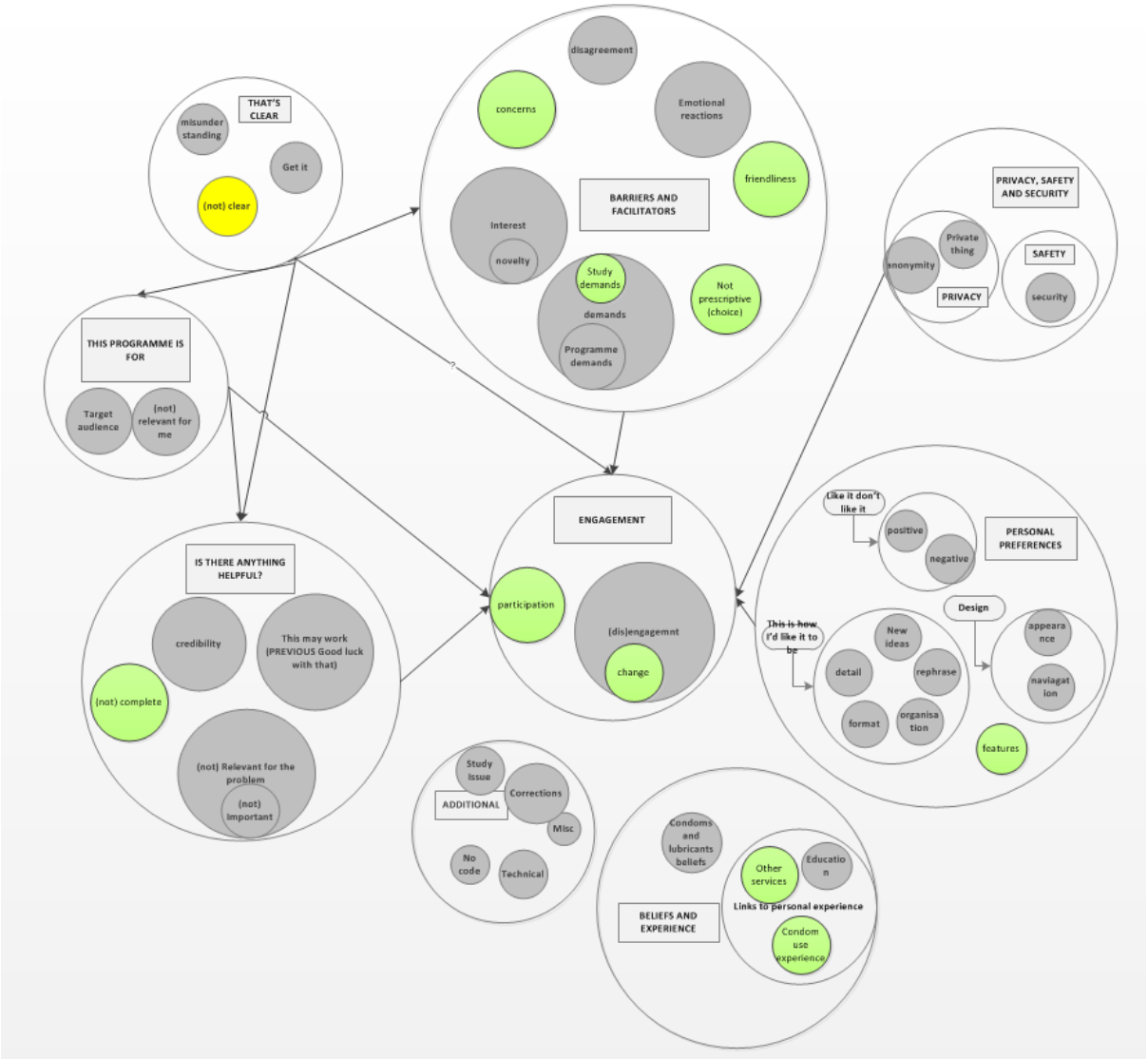

THAT'S CLEAR
misunder standing
Get it
(not) clear
disagreement
concerns
Emotional reactions
friendliness
BARRIERS AND FACILITATORS
Interest
novelty
Study demands
demands
Programme demands
Not prescriptive (choice)
PRIVACY, SAFETY AND SECURITY
anonymity
Private thing
PRIVACY
SAFETY
security
THIS PROGRAMME IS FOR
Target audience
(not) relevant for me
ENGAGEMENT
participation
[dis]engagemnt
change
IS THERE ANYTHING HELPFUL?
credibility
This may work (PREVIOUS Good luck with that)
(not) complete
(not) Relevant for the problem
(not) important
Like it don't like it
positive
negative
PERSONAL PREFERENCES
This is how I'd like it to be
Design
New ideas
detail
rephrase
format
organisation
appearance
navigation
features
Study issue
ADDITIONAL
Corrections
Misc
No code
Technical
Condoms and lubricants beliefs
Other services
Education
Links to personal experience
BELIEFS AND EXPERIENCE
Condom use experience

Figure AL5.

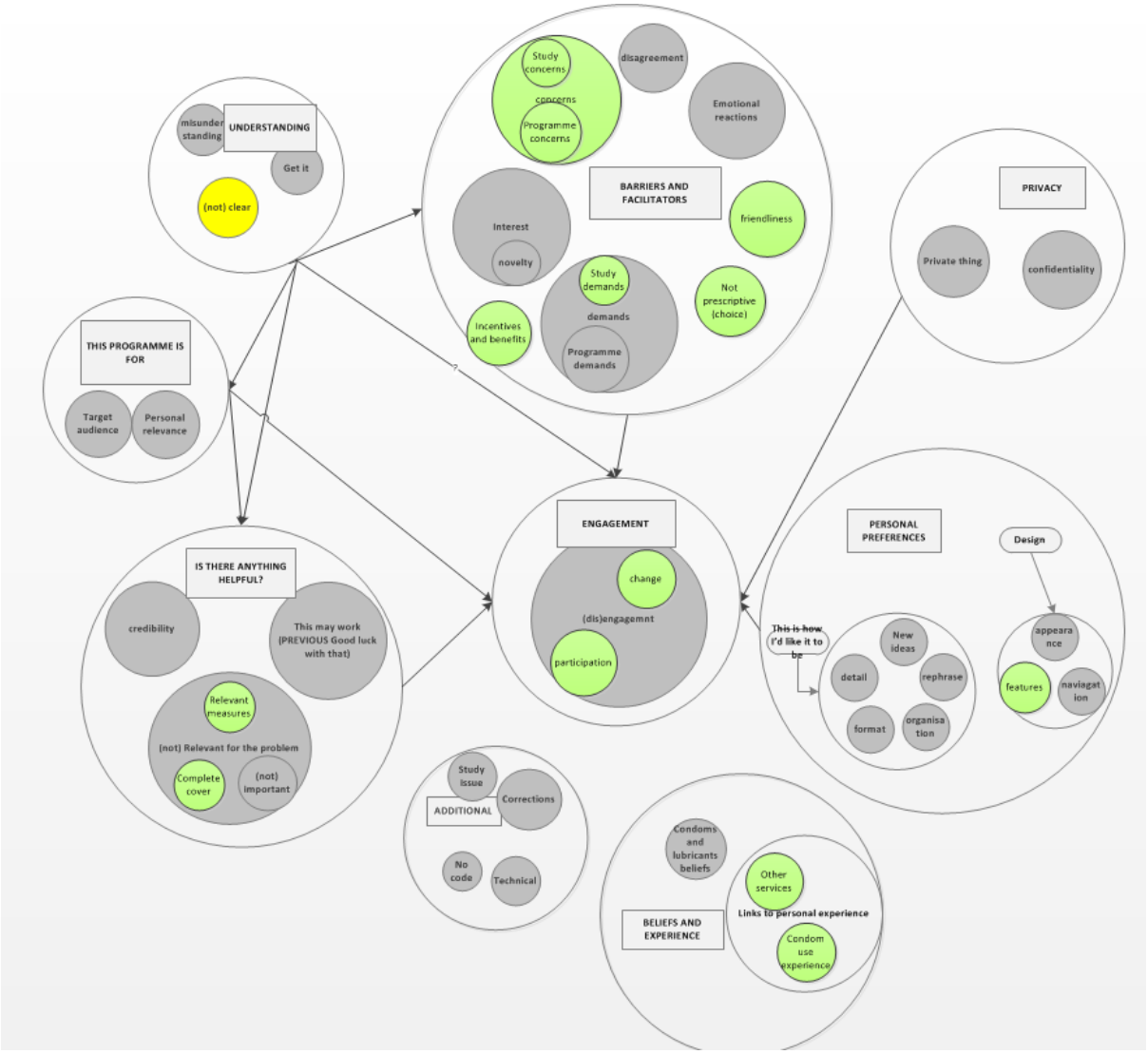

misunder standing
UNDERSTANDING
Get it
(not) clear
Study concerns
disagreement
concerns
Programme concerns
Emotional reactions
BARRIERS AND FACILITATORS
Interest
novelty
friendliness
Study demands
demands
Programme demands
Not prescriptive (choice)
Incentives and benefits
PRIVACY
Private thing
confidentiality
THIS PROGRAMME IS FOR
Target audience
Personal relevance
ENGAGEMENT
change
(dis)engagemnt
participation
PERSONAL PREFERENCES
Design
This is how I'd like it to be
New ideas
detail
rephrase
format
organisa tion
appearance
features
naviagation
IS THERE ANYTHING HELPFUL?
credibility
This may work (PREVIOUS Good luck with that)
Relevant measures
(not) Relevant for the problem
Complete cover
(not) important
Study issue
ADDITIONAL
Corrections
No code
Technical
Condoms and lubricants beliefs
Other services
Links to personal experience
BELIEFS AND EXPERIENCE
Condom use experience

Figure AL6.

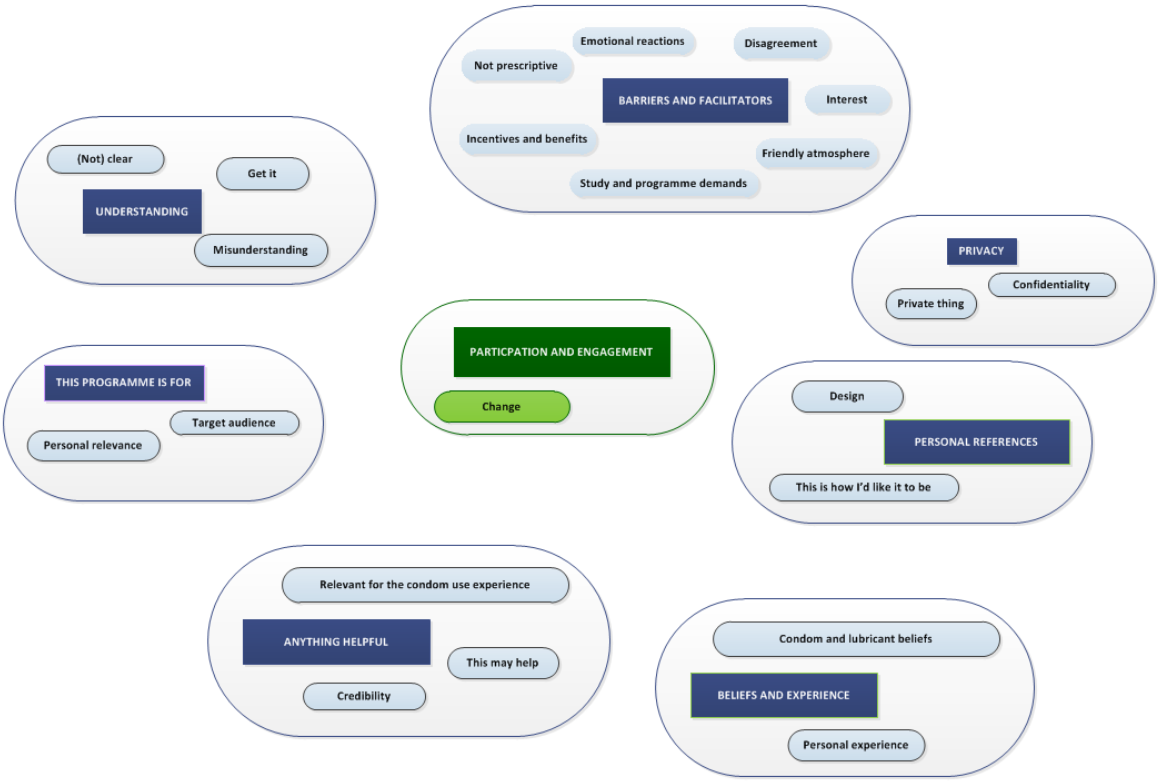

Emotional reactions
Disagreement
Not prescriptive
BARRIERS AND FACILITATORS
Interest
Incentives and benefits
Friendly atmosphere
Study and programme demands
(Not) clear
Get it
UNDERSTANDING
Misunderstanding
PRIVACY
Confidentiality
Private thing
PARTICPATION AND ENGAGEMENT
Change
THIS PROGRAMME IS FOR
Target audience
Personal relevance
Design
PERSONAL REFERENCES
This is how I'd like it to be
Relevant for the condom use experience
ANYTHING HELPFUL
This may help
Credibility
Condom and lubricant beliefs
BELIEFS AND EXPERIENCE
Personal experience

Figure AL7.

Appendix AL

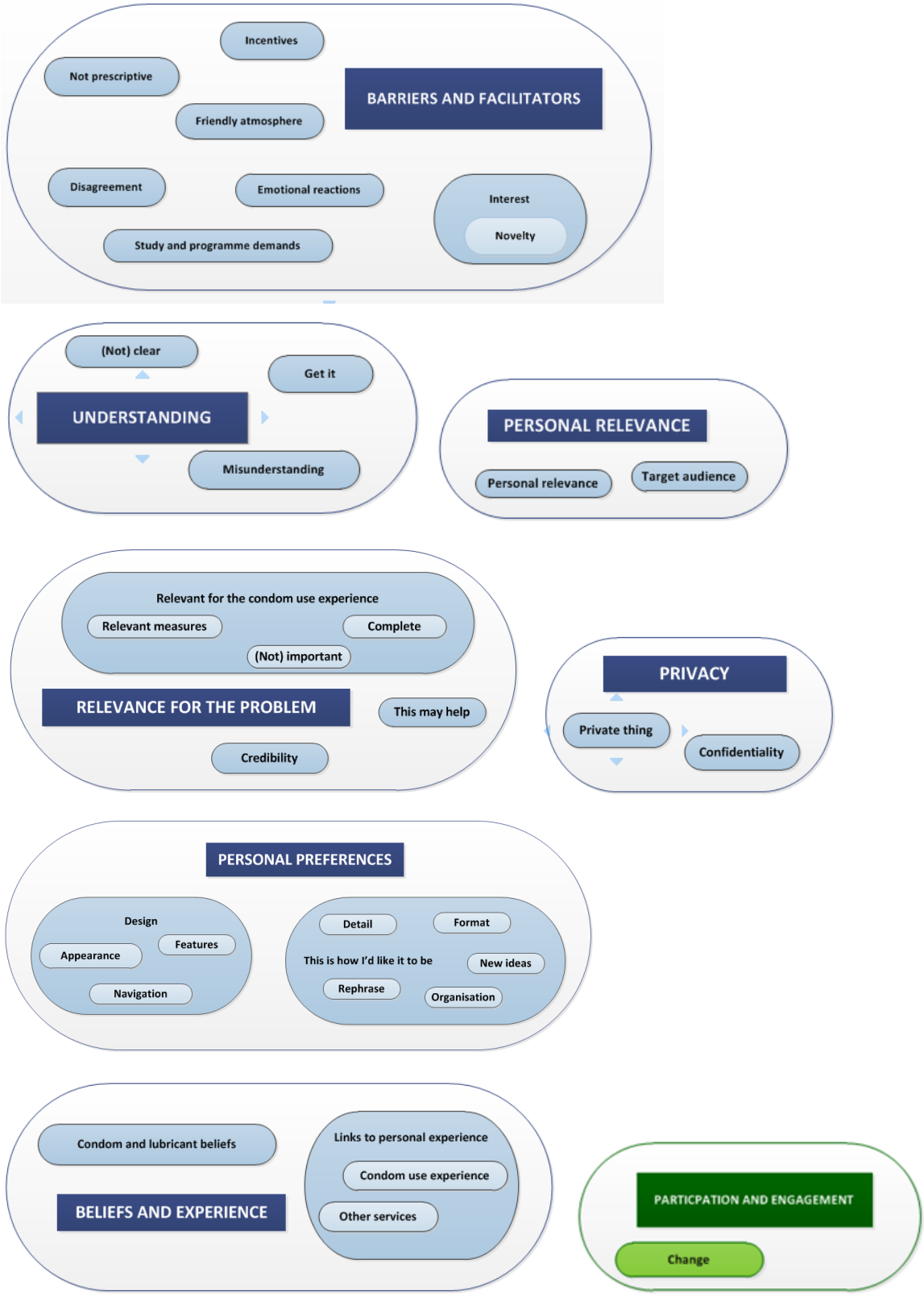


Figure AL8.

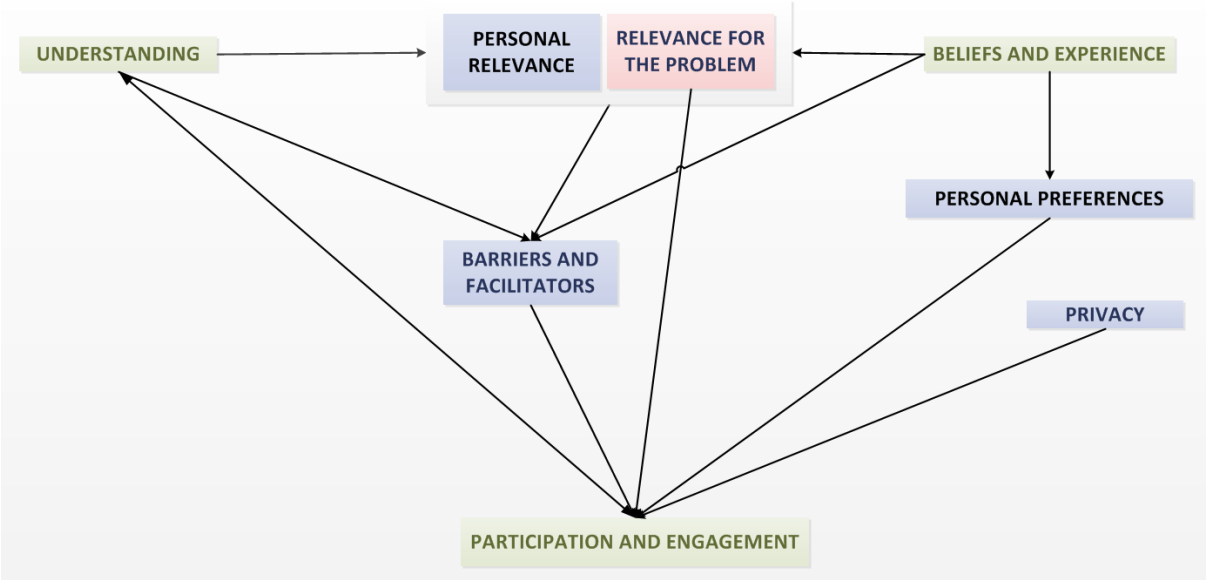

UNDERSTANDING
PERSONAL RELEVANCE
RELEVANCE FOR THE PROBLEM
BELIEFS AND EXPERIENCE
PERSONAL PREFERENCES
BARRIERS AND FACILITATORS
PRIVACY
PARTICIPATION AND ENGAGEMENT

Figure AL9.

Appendix AM

Study 2 Coding Manual

Theme: Understanding	
Code	**Description**
Get it	a participant demonstrates that he understood well the aim, procedure, information or the purpose of the programme or its specific elements (e.g., by summarising the content correctly using own words)
(Not) clear	a participant is not sure or states that he does not know the meaning or purpose of a specific element, programme procedure, or the purpose of the programme, does not know what and/or why he is supposed to do something, asks for confirmation that he understood well, or it's obvious that participant is not entirely sure that he understood well; for example "I don't know," "don't understand", comments about unclear questionnaires items etc. a participant comments that the specific aspect and/or part of the intervention is clear "all is clear", "the content is clear" etc. don't code: - if participant initially demonstrates lack of understanding or clarity but can demonstrate understanding before moving to the next webpage/gaining additional information, - phrase "I can see this" without additional context allowing making interpretation can be interpreted as *get it* or *(not) relevant for the problem*; **code** *no code* - comments referring to the easiness/difficulties to follow the programme; **code** *programme demands* - comments about navigation (not) being clear; **code** *navigation* - participants accurately paraphrasing content of the programme, demonstrating that they understand well the principles of the programme, its procedure, purpose of the specific elements etc. **code** *get it* - suggestions to change the wording of any elements of the programme; **code** *rephrase* - a participant misunderstood the aim, procedure, information or the purpose of the programme or its specific elements

Theme: Personal relevance	
Code	**Description**
(not) Relevant for me	references to the programme and/or its specific elements and/or content being (not) relevant for personal circumstances, a participant explicitly states that the programme or some of its elements are (not) relevant for him personally, or says that it provided answers to his questions or solution for problem(s) he experiences/experienced,
Target audience	references to the target audience of the programme; also when a participants states that the programme is not relevant for him, but may be relevant for others don't code if a participants comments on what others would do when using the programme; **code** *(dis) engagement*

Theme: Relevance for the problem		
Code	**Subcode**	**Description**
(not) Relevant for the problem		references to the programme and/or its specific elements and/or content being (not) relevant for the problem, may include phrases such as "see the point," "does make sense," "answered my questions," "eased my concerns," "it's comprehensive," etc., comments linking programme content with other men condom use experience don't code: - "showed me new perspective," "never thought about it;" **code** *novelty* - "good," 'fine', "I can see this" etc. without additional context allowing making interpretation , can be interpreted as *get it, (not) relevant for the problem* or *positive*; **code** *no code* - "important" or "should be emphasised;" **code** *(not) important*, - comments about relevance of the measures; **code** *participation* - comments about measure(s) being (not) relevant; **code** *participation*
	(not) Important for the problem	references to the programme and/or its elements being (not)important for the problem, comments that some elements, parts of the content should be emphasised or ignored don't code comments that the authors of the programme saw some information as important; **code** *get it, not clear* or *misunderstanding*
	(not) complete	comments about programme covering all aspects relevant to condom use issues or about some important aspect of the issues missing; also comments about measures, information sheet and/or study pages covering all aspects relevant to condom use issues or about some important aspect of the issues missing don't code - comments about the level of detail of the content; **code** *detail* - new ideas related to wider issues such as relationship etc. **code** *new ideas*
	relevant measures	Comments about study measures, information sheet and or other study pages being (not) relevant for the study topic. don't code - comments about the content of the programme; **code** *(not)relevant*
Credibility		references to the website as a credible (trusted) or not credible (untrusted) source of guidance and information, comments regarding programme; authors affiliations, credibility of sources of information etc.
This may help		references to the programme's (or specific elements of the programme) potential (lack of) effectiveness or possible negative effect don't code - comments about concerns regarding technical issues; **code** *technical* - comments regarding factors related to the programme which may hinder the engagement with the programme and/or its effectiveness; **code** *programme demands*

Appendix AM

Theme: Barriers and facilitators		
Code	**Subcode**	**Description**
Disagreement		explicitly expressed disagreement with the programme content or aims
Concerns		comments about concerns related to taking part in the programme, possibility of other users not fully understanding or being able to follow, references to risk associated to taking part in the programme don't code comments regarding the risk related to privacy, anonymity and/or security; **code** *private thing, anonymity and/or security* as relevant don't code comments regarding privacy and data security; code private thing, anonymity or security as relevant
Demands	**Programme demands**	comments regarding factors related to the programme which may hinder the engagement with the programme and/or its effectiveness, for example "too big demand," "task too difficult"
	Study demands	comments about study demands such as completing the questionnaires, registration etc.; references to the programme being easy, not very demanding etc.
Emotional reactions		emotional reactions to the content (observed or declared), jokes about the programme or its elements don't code: expression of curiosity; **code** *interest* comments about feeling (un)comfortable*;* **code** *friendliness*
Friendliness/ friendly atmosphere		Comments regarding the programme atmosphere, its general feel, comfort/discomfort going through the programme etc. don't code emotional reactions to the content; **code** *emotional reactions*
Not prescriptive (Choice)		Comments about having choice, options, making own decision while taking part in the programme don't code comments about general atmosphere of the programme; **code** *friendliness* don't code comments about choice of incentives; **code** *incentives*
Incentives		Comments regarding incentives, preferences of specific incentives, their adequacy etc.
Interest		expressing interest, curiosity, or lack of interest, boredom don't code - phrase "nothing to say" without additional context allowing making interpretation, can be interpreted as treating information as obvious, lack of interest, lack of engagement etc.; **code** *no code* - gazing at or skipping parts of information/pages/elements; **code** *(dis) engagement*
	Novelty	references to the information and/or instruction(s) being well known or new for a participant, comments about programme's similarity/difference to other websites/programmes, references to programme or its element(s) providing a new perspective, for example "I have never thought about it"

Intertwining Theme: Participation and engagement		
Code	**Subcode**	**Description**
(dis) Engagement		references to reasons/motivation to take part in the programme, and/or to follow programme's procedure and/or advice, comments about willingness to stay on the website or to leave it, comments about paying attention to the content or skipping it/gazing through (including information added from observation), remembering information, instruction, advice included in the programme etc. participants' actions or predicted actions of others showing interaction with the prototype such as "I would scroll," "I'll skip," "I'll read carefully" coming back to some of the parts don't code - linking personal experience with the content of the website; **code** *(not) relevant for me* or one of the sub-codes of *links to personal experience* when appropriate - simple actions that may be just description of behaviour and no additional meaning can be assumed, for example "I click next" - "haven't thought about it" without explicit comments regarding rethinking own behaviour; **code** *novelty* - comments regarding participation in the study evaluating the intervention; **code** *participation*
	Change	comments about already reconsidering own practice in response to the information presented in programme don't code - comments regarding belief that taking part in the intervention/any aspect of the intervention could lead to change in condom use behaviour, beliefs and/or attitudes; **code** *this may work*

Theme: Personal preferences		
Subtheme	**Code**	**Description**
This is how I'd like it to be	**New ideas**	participants' suggestions to add some new elements to the programme (website, kit), only completely new ideas don't code suggestions to add more details; **code** *detail*
	Detail	references to how detail should be the information, requests to provide detailed/more in depth information, instruction, also comments regarding the content being detailed enough, or too many unnecessary details don't code - "emphasize more;" **code** *(not)important* and *rephrase* - too much information/detail to process; **code** *programme demands* - suggestions of changes to the wording of items in the questionnaires; **code**

		rephrase
	Format	comments about format of information presentation (text, video, graphic etc.), suggestions to change format of elements don't code different style, type of picture, picture content; **code** *appearance*
	Rephrase	suggestions to rephrase parts of the content, references to the content not being to the point, straightforward, requests to make the content clearer, easier to understand, swapping plain text with bullet points, suggestions of changes to the wording of items in the questionnaires; etc.
	Organisation	comments regarding the order of presenting information or repeating the same content at different pages; comments regarding availability of programme content at its different stages, for example suggestion that the website should be available before condoms kit is received don't code - suggestion to divide content between more pages, or consolidate on one; **code** *appearance*; - comments about links between pages; **code** *navigation*
Design	**Appearance**	references to the prototype layout, graphics, colours, buttons, appearance etc. (any visual features) don't code - comments about swapping plain text with bullet points; **code** *rephrase*
	Navigation	references to the website navigation, orientation on website, comments regarding easiness/difficulties finding specific content, links, side menu etc.
	Features	references to the website features. comments how the existing ones could be improved don't code new features ideas which are not improvement/change on the existing ones; **code** *new ideas*

Theme: Privacy		
Subtheme	**Code**	**Description**
Privacy	**Private thing**	references to the content of the website, condom kit etc. needed to be seen in private, something that would not be shared with others
	Confidentially	references to the confidentiality when taking part in the study/programme
Safety	**Security**	references to data security, storage, access etc.

Theme: Beliefs and experience		
Code	**Subcode**	**Description**
Condoms and lubricants beliefs		participants beliefs about condoms and lubricants
Links to personal experience	**Condom use experience**	References to condom use experience, references to condom use errors and problems experienced by a participant
	Education	references to previous sex education, sources of information related to correct condom use and/or coping with condom use related problems
	Other services	references to other services, experience with sexual health and online programme, services etc. don't code references to sexual health education; **code** *education*

Additional codes not included in the analysis	
Code	**Description**
Study issue	comments regarding issues related to the study, for example about difficulty to imagining how the exercise would on a printed website prototype
Corrections	comments about errors and mistakes found on the website (typos, grammar mistakes, misprinted parts)
Technical	references to predicted technical problems with use of the programme (software, spam filters etc.)
Miscellaneous	comments not assigned to other codes about issues loosely related to the focus of the study
No code	parts of the transcripts unclear or not enough information to assign a code

Appendix AN

Examples of Study 3 Advertisements

Poster advertisement (A4 format), leaflet advertisement (A6 format), newsletter advertisement

Figure AN1.

Figure AN2.

Department of Psychology University of Southampton poster (A4 format) and leaflet (A6 format) version

Figure AN3.

Figure AN4.

Appendix AN

‘Business card’ advertisement

Figure AN5.

E-mail advertisement /Newsletter advertisement

Title: **Condoms Study**

Would you like to test and rate different types of condoms?

If you are male, age 18 - 69, fluent in English, living in the UK;

want to improve your condom use experience and learn more about condoms

visit eHIS study website to find information about **the online study,** to take part by 31/05/2017.

https://ehis.lifeguidewebsites.org

Study e-mail: ehis@soton.ac.uk

Free condoms and lubricants kit! £5 Amazon voucher!

Donation to charity to thank you for completing questionnaires

Study approved by the Ethics Committee Psychology Department, University of Southampton, ERGO number 24644/25198/26409

Facebook post

Test an online programme helping men to improve their condom use experience. Looking for men age 18-69, living in the UK, fluent in English. Online study, free condoms and lubricants kit. For information and to take part visit: https://ehis.lifeguidewebsites.org e-mail: ehis@soton.ac.uk, ethics number 24644/25198

Figure AN6.

Facebook advertisement

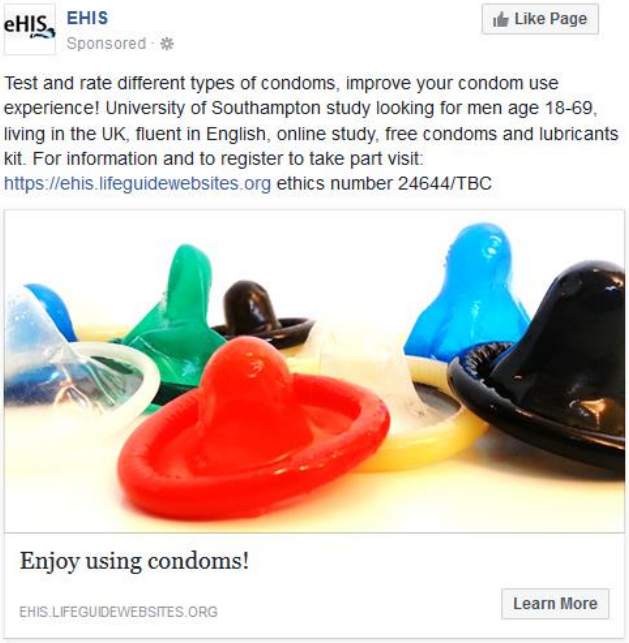


Figure AN7.

Appendix AN

Twitter advertisement

Test an online programme helping to improve men's condom use experience

https://ehis.lifeguidewebsites.org

Figure AN8.

Short study recruitment information for University of Southampton students (approx. 2 min, 1 Powerpoint slide)

Figure AN9.

e-Folio advertisement (Psychology department – University of Southampton)

Title: **Condom Study**

Would you like to test and rate different types of condoms?

If you are male, age 18 - 69, fluent in English, living in the UK;

want to improve your condom use experience and learn more about condoms

visit eHIS study website to find information about **the online study,**

to register and to take part.

https://ehis.lifeguidewebsites.org

Study e-mail: ehis@soton.ac.uk

Sign in to take part by 31/05/2017

Free condoms and lubricants kit! £5 Amazon voucher or up to 32 credits!

Donation to charity to thank you for completing questionnaires

Study approved by the Ethics Committee Psychology Department, University of Southampton, ERGO number 24644

Appendix AO

Study 3 Participant Study Information Sheet Online (adapted from the University of Southampton Ethics templates)

Participant information (compulsory pages):

Participant Information, version 3, 21/11/2016, page 1/2

ERGO Study ID number: TBC

Please read this information carefully before deciding to take part in this research. If you are happy to participate you will be asked to give consent at the end of the information pages.

What is eHIS?

eHIS is a novel programme to encourage men to use condoms more and enjoy it. **(HIS** stands for Homework Intervention Strategy)

What is this study about?

In this study we want to explore whether eHIS programme works as intended, for whom it works and what men think about it. We also want to find whether our way of testing the programme is appropriate.

The study is approved by the Psychology Ethics Committee at the University of Southampton.

Is this programme for me?

This study is for men who would like to improve their condom use experience or learn something new about condoms. It may also be useful for those who have not used condoms before but would like to use them in the future.

Unfortunately, if you have an allergy to latex or non-latex condoms or any type of lubricants, need special software to access the content of the website, or need third person help to access the website you cannot take part in this study.

How much time do I need to take part?

You will need 15-20 minutes to complete the first set of questionnaires before you see the programme, and then two more sets at a later time. Going through the website should take you about 10-15 minutes and then you will be asked to test and rate some condoms over the following 3 weeks (don't worry, you don't have to do every day).

When you are on the website you can stop at any time and come back as many times as you like during the three weeks when you take part in the program.

Who is running this study?

The researcher running this study is Marta Glowacka, PhD student, Trainee Health Psychologist supervised by Professor Cynthia Graham and Professor Lucy Yardley, both from the University of Southampton. You can read more on the Meet the Team page. (link to the optional page "Study team")

What will happen to me if I take part?

After you complete the questionnaires you:

- will see the eHIS website programme
- can order free condoms and lubricant kit

You will be asked to:

- practice condom use for three weeks on your own (without your partner)
- complete on-line condom rating forms,
- complete two more sets of questionnaires, 4 and 10 weeks after you completed the first set of questionnaires

Click here [link to optional page "Study schedule"] to see the study steps in a diagram.

Are there any benefits in my taking part?

- you may learn something new about condoms and see if you are using them correctly (or learn how to use them if you have not used them before)
- you may find a brand of condom or lubricant which works well for you
- get better awareness of sexual health and some aspects of your sexual behaviour - on the website you will find information about services providing advice and support on issues related to sexual health
- the results of this study will be used to inform sexual health researchers and hopefully ultimately improve sexual health services
- you will get a condom kit with a selection of condoms and lubricants
- for each completed set of questionnaires 50p will be donated to one of three health charities (you choose which one)
- after three sets of questionnaires are completed you will get £5 Amazon voucher as a thank you for participation

- students of Psychology at the University of Southampton will have the option of claiming up to 32 credits (no £5 voucher if opt for credits) Click here for more details [link to optional page "Participation credits"]

Are there any risks involved?

When you take part in the programme you may feel uncomfortable or embarrassed answering questions about sexual behaviour and condoms or practicing using condoms - you do not need to give answers to any questions or practice if that may make you feel uncomfortable.

Condom manufacturers warn that using latex condoms may cause irritation or allergic reaction including anaphylactic shock. However, for most people there are no serious risk associated with using condoms (1%-6% of general population and 4%-17% of health workers are estimated to be allergic to latex). Ingredients of non-latex condoms and lubricants may also cause allergic reactions.

How much do you need to know about me?

- there is no need to give us your real name,
- e-mail address to contact you during the study; you may set up an account just to take part in this programme if you want
- a postal address if you want us to send you the condoms and lubricants kit; it can be collected from the University of Southampton
- general information about you (e.g., age range, relationship status), some information about your sexual behaviour and condom use;
- your activity on the website (e.g. number and duration of visits, pages seen etc.) will be recorded,
- your student number if you want to claim credits (Psychology students at the University of Southampton only).

All information you give will be anonymised (information such as e-mail address **will not be linked** to your questionnaires answers or website activity).

Read more about confidentiality and security of your data and what will happen with the study results ... [link to optional page "Your data confidentiality and security"]

What happens if I change my mind?

You can change your mind and leave the study at any time, without giving a reason for your decision. You may also ask us to remove all your data from the study up to 2 weeks after the last set of questionnaires is due to be completed (up to 12 weeks after completing the first set of questionnaires).

What if something goes wrong?

If you have any concerns in relation to the study or if you feel that you have been placed at risk, you may contact the Chair of the Psychology Ethics Committee, University of Southampton, Southampton, SO17 1BJ, email fshs-rso@soton.ac.uk

Do I need to remember all of this information?

All steps of the programme will be explained in detail on further pages. Also, at any time during participation you will have access to all information you read from the eHIS website.

Where can I get more information?

If you would like to find out more about the study, or have some questions that you did not find the answer to, please contact study team at ehis@soton.ac.uk

Participants' information optional pages (accessed through the links from compulsory pages):

- *Study team page*

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Study team

Professor Cynthia Graham

Professor of Sexual and Reproductive Health at the University of Southampton and Co-Director of the Centre for Clinical and Community Applications of Health Psychology (CCCAHP)

Her research interests are in the areas of sexual and reproductive health, including condom use errors and problems. She is a member of the Condom Use Research Team (CURT), involving researchers from Canada, the US and the UK.

Professor Lucy Yardley

Professor of Health Psychology at the University of Southampton and Co-Director of the Centre for Clinical and Community Applications of Health Psychology (CCCAHP)

Her main research focus is on using the internet to support self-management of health. She pioneered the development of the unique 'LifeGuide' open source software for developing web-based intervention and led the 'UBhave' programme to develop software for creating interventions for mobile phones. She has developed and applied the 'person-based' approach to using mixed methods for intervention development.

Marta Glowacka, MSc

PhD student/Trainee Health Psychologist at the University of Southampton

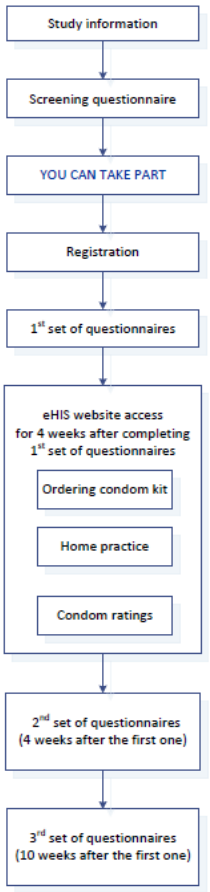
She has been involved in research projects developing and evaluating eHealth interventions. Her research interests focus on small scale on-line programmes and users' experience.

Appendix AO

All photographs used on the website are the work of a photographer **Jacek Niedzielski**.

- *Study schedule page*

Participant Information, version 3, 21/11//2016ERGO Study ID number: TBC



- *Participation credits page*

Participant Information, version 3, 21/11//2016 ERGO Study ID number: TBC

Psychology students at the University of Southampton will have the option to claim up to 32 credits for participation.

Study stage	**Credits**	**Award condition**
Screening	2 credits	Screening completed
Taking part in the programme	24 credits	At least one condom rating completed
Baseline questionnaires	2 credits	Baseline completed
1st follow-up questionnaires	2 credits	1st follow-up completed
2nd follow-up questionnaires	2 credits	2nd follow-up completed

- *Your data confidentiality and security page*

Your data confidentiality and security

Data you provide will be used only for research, and the results will be presented in a chapter of a PhD thesis. **The results** of the study may also be submitted for publication in a scientific journal or presentation at a scientific conference, or be disseminated to general public as a part of educational activities.

The data gathered in this study may be used in future studies analysing anonymised data. Separate ethical approval will be obtained for any future study.

All data will be **anonymised** which means that no information that makes it possible to identify you will be used in any report, publication or presentation. Data such as age range, first three characters of your postcode, or background information (for example, occupation or relationship status) will be used only to describe the sample of people taking part in the study, without any links to any individual.

If you decide not to take part in the study, all data you entered before withdrawal may be used for the analysis unless you ask for them to be removed. You can ask for your data to be removed up to 2 weeks after the last set of questionnaires is due to be completed (up to 12 weeks after you completed the first set of questionnaires).

All data (electronic and hard copy) will be securely stored in line with procedures approved by the Department of Psychology Ethics Committee at the University of Southampton. Data will be stored in a password-protected file, on a password-protected computer and on an encrypted USB drive locked filing cabinet. You will be asked to set your own account using your e-mail address and password. You will use this information to enter the website, complete questionnaires and condom rating forms. Personal information, for example name or address, will not be released to anyone outside the research team or be viewed by anyone other than the researchers and employees of the University of Southampton involved in this project.

Your e-mail address, phone number, postal address and name (if provided) will be deleted after the study is finished and will not be used in any analysis.

Appendix AP

Study 3 Consent Statement

Consent Statement

Thank you for taking the time to read the study information. If you feel that you know enough about the study and want to take part, tick the button below and click next.

By ticking the button, I confirm that I have read and understood information about this study and that I agree to take part and for my data to be used for the study.

I understand that I may withdraw at any time without giving any reason and that data I entered before withdrawal may be used for the analysis unless I ask for them to be removed up to 2 weeks after the last set of questionnaires is due (12 weeks after completing the first set of questionnaires).

For students: If you are a student at the University of Southampton and you choose not to participate there will be no consequences to your grade or to your treatment as a student.

Data Protection

I understand that information collected about me during my participation in this study will be stored on a password protected computer and that this information will only be used for the purpose of this study. All files containing any personal data will be anonymised (Data will be coded for the analysis, and only staff involved in the study would have access to all data).

I give my consent to take part in the study under the conditions stated above.

Appendix AQ

Study 3 Screening Questionnaire

Please answer the questions below to check whether you can take part in the study.

You need to answer all questions in this section to be able to participate.

What is your gender?	male female other
What is your age?	*dropdown list:* below 18, 18 - 25, 26 - 35, 36 - 45, 46 - 55, 56 – 69, 70 or older
Do you have an allergy to any type of condoms (latex or non-latex) or any ingredient of lubricants?	yes no
Do you need screen readers to access the website content?	yes no
Are you fluent in written English?	yes no
Do you live in the UK?	yes no
Do you need other people's help to complete the questionnaire and to go through the website?	yes no
Do you have Internet access to complete the study over the next 3 months?[30]	yes no

[30]Adapted from materials received from the authors, used in studies evaluating the face-to-face version of the KIHIS (R. E. Emetu, personal communication, 2015; C. A. Graham, personal communication, 2016; R. R. Milhausen, personal communication, 2014).
None of the information provided in footnote was displayed to participants – included here for referencing purposes only.

Appendix AR

Study 3 Condom Rating Form[31]

Which condom are you rating? *	dropdown list: condom1[32], condom2, condom3, condom4, condom5, condom6, other
If you used a different condom, please enter the brand, name and type (latex, non-latex etc.)*	
Have you used this condom before?	Yes No

Did you use this condom (Please tick all that apply)	*multiple choice*: for masturbation; with a partner – vaginal sex, with a partner – anal sex, with a partner – oral sex
Did you have an orgasm (cum, ejaculate) while wearing this condom?	Yes No
Did you stop testing the condom before putting it on?	*dropdown list:* I put the condom on, stopped after taking it out of the packet, stopped after trying to put it on

If you stopped before putting the condom on, please try to answer as many questions below as possible. The answers are important to get better understanding of your experience with condoms.

Please indicate whether you disagree or agree with each of the following statements about this condom by ticking the button that corresponds to your answer.

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
I like this condom better than others I have tried.	1	2	3	4	5
This condom feels right for me.	1	2	3	4	5
This condom fits me well.	1	2	3	4	5
I like the texture (how the condom feels).	1	2	3	4	5
I like the shape of this condom.	1	2	3	4	5
I like the way this condom smells.	1	2	3	4	5
It was easy to put this condom on.	1	2	3	4	5

[31]Adapted and modified from materials received from R. R. Milhausen (personal communication, 2012) and C. A. Graham (personal communication, 2016).
[32] Numbers were replaced with labels of the condoms included in the condom kit

This condom was uncomfortable.	1	2	3	4	5
This condom hurt my penis.	1	2	3	4	5
This condom decreased my sensation.	1	2	3	4	5
This condom decreased my sexual pleasure.	1	2	3	4	5
This condom made it difficult to stay hard.	1	2	3	4	5

The length of the condom was	Just right	Too long
The width of the condom was	Just right	Too loose

Did you use a lubricant with this condom?	Yes	No
If yes, did you put the lubricant on the outside of the condom?	Yes	No
If yes, did you put the lubricant on the inside of the condom?	Yes	No

Would you use this condom in the future?	Yes	No	Unsure

Appendix AS

Study 3 Debriefing Sheet (adapted from the University of Southampton Ethics templates)

eHIS Condom Study

Debriefing Statement (Version no 2, 31/10/2016)

The aim of this research was to explore feasibility of the eHIS, engagement with and acceptability of the programme and to find out whether the eHIS has the potential to increase frequency and consistency of condom use and improve condom use experience.

The results of this study will inform further research and hopefully clinical practice.

Once again, the results of this study will not include your name or any other identifying characteristics.

If taking part in this study raised any concerns for you about your sexual health, you can

- find more information on the NHS choices website http://www.nhs.uk/Livewell/Sexualhealthtopics/Pages/Sexual-health-hub.aspx [link on the website and URL on printable page]
- find your local GUM clinic http://www.nhs.uk/chq/Pages/972.aspx?CategoryID=68 [link on the website and URL on printable page]
- or contact your GP for further advice.

If you have any questions or concerns, please also feel free to contact Professor Cynthia Graham, my supervisor, who is qualified Clinical Psychologist C.A.Graham@soton.ac.uk.

You can also contact me at mag1g10@soton.ac.uk.

Thank you very much for taking time to participate in this research.

Marta Glowacka

If you have questions about your rights as a participant in this research, or if you feel that you have been placed at risk, you may contact the Chair of the Ethics Committee,

Psychology, University of Southampton, Southampton, SO17 1BJ. Phone: +44 (0)23 8059 3856, email fshs-rso@soton.ac.uk

If you are interested in the topic, below you can find the references to other studies reporting programme development.

Emetu, Roberta E., Marshall, Alexandra, Sanders, Stephanie A., Yarber, William L., Milhausen, Robin R., Crosby, Richard A., & Graham, Cynthia A. (2014). A Novel, Self-guided, Home-Based Intervention to Improve Condom Use Among Young Men Who Have Sex With Men. *Journal of American College Health, 62*(2), 118-124. doi: 10.1080/07448481.2013.856914

Milhausen, Robin R., Wood, Jessica, Sanders, Stephanie A., Crosby, Richard A., Yarber, William L., & Graham, Cynthia A. (2011). A novel, self-guided, home-based intervention to promote condom use among young men: A pilot study. *Journal of Men's Health, 8*(4), 274-281. doi: 10.1016/j.jomh.2011.06.003

To print this information click here. [link to printable page containing the same information]

Appendix AT

Evaluation Survey

Your opinion about the programme and the website is very important to find out what works well and what needs to be improved. Please tick one option for each of the statements below or enter your answers in the boxes.

The content of the programme was useful for issues linked to condom use.	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
The content of the programme was useful for me.	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
The most useful part of the programme was					
The least useful part of the programme was					
I received all information and/or advice I needed.	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
I trusted the information and/or advice given in the programme.	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
I followed the advice/instructions given, when it was relevant for me.	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
Taking part in the programme fit with my daily life.	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
The information and instructions were clear and easy to follow.	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
I enjoyed using the programme.	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
Was there anything in the programme you liked the most? Why?					
Was there anything in the programme you did not like at all? Why?					
I would recommend this programme to other men.	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
I would like to be able to speak to someone in addition to using the programme (e.g. over the phone, face-to-face etc.).	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
If you would like to tell us more about your experience with the programme, please use the box.					
It was clear what was included in the programme.	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
It was clear when each part of the programme (e.g. condom use instruction, kit order form, condom ratings etc.) will be available.	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree

It was easy to move between the sections of the programme.	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
If you had any problems moving between pages or sections on the programme could you tell us more about it?					
The amount of information on the pages was	Just right		Too much		Not enough
I liked how the website looked.	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
Was there anything in the website design you liked the most? Why?					
Was there anything in the website design you did not like? Why?					
If you would like to share more about your experience with the website, please use the box.					

Appendix AU

Study 3 Data Analysis

Research question	Variables[33] / **Analysis:** Descriptive statistics/narrative summary	Research question	Variables/ **Analysis:** analysis of correlation, comparison between subgroups
	Sample characteristic		
Who was interested in the study? (Baseline (T1) characteristics of participants)	**Demographic characteristics**: age, ethnic background, education, employment/student status, relationship status, relationship type, geographical location. **Sexual activity**: sexual activity type, sexual orientation, had sex previously, number partners in life. **Sexual health and unplanned pregnancy**: previous STI diagnosis, previous HIV diagnosis[34], previous experience of unplanned pregnancy. **Condom use experience:** taught how to use condoms, source of information about using condoms, used condom with a partner, practised using condom previously, condom use experience. **Recent sexual behaviour (in the last 4 weeks):** number of partners. **Recent condom use (in the last 4 weeks):** condom use consistency, frequency of intercourse without condoms, practised using condoms, reasons condoms were used, types of condoms used. **Condom use errors and problems**: condom use errors (M-CUES), condom use problems (M-CUES), condom fit and feel		

[33] Some of the variables were merged to create wider categories for some of the analysis due to low numbers in subgroups or answers overlapping: avoid infection in the last 4 weeks (avoid sti and avoid HIV in the last 4 weeks), sti ever (sti in the last year and in life), pregnancy ever (pregnancy in the last year and in life)

[34] None of the participants reported previous HIV diagnosis; therefore this variable was not included in further analysis.

	Condom use related cognitions: condom use self-efficacy, condom use attitudes		
Took part in previous eHIS studies	previous studies		
Computer competence[35]	computer competent		
	Study feasibility		
Which method of recruitment was the most effective?	Types of advertisements participants responded to. Where the advertisements were seen.	Were participants from specific groups more likely to respond to different types of advertisements?	**advertisement type** (Chi-square) x **demographic characteristics:** age, ethnic background, education, employment/student status
What was participants' motivation to take part in the study?	Motivation: fun to take part, curiosity, free condoms, to learn more about condoms, to get better at using condoms, to enjoy using condoms more, to find help with condom use problems, to support charity, to receive voucher, other[36]	Did participants with different characteristics have different motivation to take part?	**motivation**[37] (Chi-square, t-test, Mann-Whitney test) x **demographic characteristics**[38]: age, ethnic background, education, employment/student status, relationship x **sexual activity:** sexual activity type, sexual orientation x **condom use experience:** taught how to use condoms, practiced using condoms previously, used condom previously with a partner, condom use experience x **recent (in the last 4 weeks) condom use at T1**: condoms use

[35] All but two participants declared that they were competent computer users, therefore this variable was not included in further analysis.
[36] 'Other' category not included in further analysis due to low numbers.
[37] For 'seeking help with condom use problems' motivation, part of the analysis could not be completed due to not meeting assumptions of the test (due to low numbers), these were: ethnic background, sexual activity type, condom use consistency, previous STI diagnosis, previous experience of unplanned pregnancy, using condom with a partner previously.
[38] For charity donation and voucher only demographic characteristics were explored.

			consistency, frequency of sex without condoms, reasons condoms were used (avoid infection, avoid pregnancy), number of partners x **condom use errors and problems at T1:** condom use errors, condom use problems, condom fit and feel x **condom use related cognitions**: condom use self-efficacy, condom use attitudes x previous STI diagnosis x previous unplanned pregnancy
How many participants chose study credits?	Credits		
Were charities chosen for donation? What charities were chosen?	Charity choice at T1, T2, T3.		
Did participants complete study measures?	Frequency of missing answers.		
Did participants complete the study follow-ups?	T2, T3 completed.	Were there differences between those who completed follow-up measures and those who dropped out?	**Dropout** (Chi-square, Mann-Whitney test) **x demographic characteristics:** age, ethnic background, education, employment/student status, relationship status x **motivation**: fun to take part, curiosity, free condoms, to learn more about condoms, to get better at using condoms, to enjoy using condoms more, to find help with condom use problems, to support charity, to receive voucher x advertisement type x **engagement with the intervention**: number of completed ratings, visits to the websites, number of return visits to the eHIS website

Intervention feasibility – participants engagement

How did participants engage with the intervention? An overview of eHIS usage.	Visits to specific categories of pages (yes/no) and number of these visits: all visists to the website, core pages only, core and at least one optional page, all return visits, return visits with seeing ratings page only, return visits with seeing optional pages only, return visits with seeing ratings and at least one optional page, return visits with seeing only menu page.	Were participants baseline characteristics associated with the number all visits to the eHIS website?	**all visits to the websites** (Mann-Whitney test, Kruskal-Wallis test, Kendall's Tau) x **demographic characteristics**: age, ethnic background, education, employment/student status, relationship status x **sexual activity**: sexual activity type, sexual orientation, had sex previously, number of partners in life x **recent (in the last 4 weeks) sexual behaviour at T1:** number of partners x **recent (in the last 4 weeks) sexual behaviour at T2**: number of partners x **recent (in the last 4 weeks) condom use at T1**: condom use consistency, frequency of intercourse without condoms, practised using condoms, reasons to use condoms (avoid infection, avoid pregnancy, longer sexual intercourse) x **condom use experience**: taught to use condoms, used condoms with a partner previously, practised previously, condom use experience x **condom use errors and problems at T1:** condom use errors, condom use problems, condom fit and feel x previous STI diagnosis x previous unplanned pregnancy x **condom use related cognitions**: condom use self-efficacy, condom use attitudes x **motivation:** fun to take part, curiosity, free condoms, to learn more about condoms, to get better at using condoms, to enjoy using condoms more, to

			find help with condom use problems, to support charity, to receive voucher x provided phone number
Which optional pages were visited?	Optional pages seen (yes/no), number of visits to the optional pages /number of participants.	Were there differences between those who saw at least one optional page and those who saw none?	**Seen at least one optional page** (Chi-square, Mann-Whitney test, t-test) x **demographic characteristics:** age, ethnic background, education, employment/student status, relationship status x **sexual activity**: sexual activity type, sexual orientation, number of partners in life x **recent (in the last 4 weeks) sexual behaviour at T1**: number of partners x **recent (in the last 4 weeks) sexual behaviour at T2** number of partners x **recent (in the last 4 weeks) condom use at T1**:condom use consistency, frequency of intercourse without condoms, reasons to use condoms at baseline (avoid infection, avoid pregnancy) x previous STIs x previous unplanned pregnancy x **condom use experience**: taught how to use condoms, used condoms previously with a partner, practised using condoms previously, condom use experience x **condom use errors and problems:** condom use errors, condom use problems, condom fit and feel x **condom use related cognitions**: condom use self-efficacy, condom use attitudes **x motivation**: fun to take part, curiosity, free condoms, to learn more about condoms, to get better at using condoms, to enjoy using condoms more, to find help with condom use problems, to support charity, to receive voucher

Did participants order the kit?	kit order		
Did participants use lubricants during practice?	lubricant used		
Did participants complete ratings? How many ratings were completed?	ratings completed (yes/no), number of completed ratings	Were there differences between those who completed at least one rating and those who did not complete any?	**completed at least one rating** (Chi-square, Mann-Whitney test, t-test) x **demographic characteristics**: age, ethnic background, education, employment/student status, relationship status x **sexual activity** : sexual activity type, sexual orientation, numbers of partners in life, had sex previously, x **recent (in the last 4 weeks) sexual behaviour at T1**: number of partners x **recent (in the last 4 weeks) sexual behaviour at T2**: number of partners x **recent (in the last 4 weeks) condom use at T1**: consistency of condom use, frequency of sex without condoms, practised using condoms, reasons to use condoms (avoid infection, avoid pregnancy, longer sexual intercourse) x **condom use errors and problems**: condom use errors, condom use problems, condom fit and feel x previous STIs diagnosis x previous unplanned pregnancy x **condom use experience**: taught how to use condoms, used condoms previously with a partner, practised previously, condom use experience x **condom use related cognitions**: condom use self-efficacy, condom use attitudes

			x motivation: fun to take part, curiosity, free condoms, to learn more about condoms, to get better at using condoms, to enjoy using condoms more, to find help with condom use problems, to support charity, to receive voucher x provided phone number
Did participants practise alone or with partners?	practised alone (yes/no)	Were there differences between those who used condoms on their own, with partners or both?	**practised alone** (Chi-square, Mann-Whitney test, t-test) x **demographic characteristics**: age, ethnic background, education, employment/student status, relationship status x **sexual activity**: sexual activity type , sexual orientation, numbers of partners in life x **recent (in the last 4 weeks) sexual behaviour at T1**: number of partners x **recent (in the last 4 weeks) sexual behaviour at T2**: number of partners x **recent (in the last 4 weeks) condom use at T1**: reasons to use condoms (avoid-infection, avoid pregnancy) x **condom use errors and problems**: condom use errors, condom use problems, condom fit and feel x **condom use experience**: taught how to use condoms, used condoms previously with a partner, practised previously, condom use experience x **condom use related cognitions**: condom use self-efficacy, condom use attitudes **x motivation**: fun to take part, curiosity, free condoms, to learn more about condoms, to get better at using condoms, to enjoy using condoms more, to find help with condom use problems, to support charity, to receive voucher
Did participants use other condoms that the one included in the kit?	Own condom used		

Did participants opt in to receive text reminders?	provided phone number (yes/no)	Were there demographic differences between those opting to receive text and those who did not?	**Provided phone number** (Chi-square) x **demographic characteristics**: age, ethnic background, education, employment/student status, relationship status
Did participants cancel automated e-mails?	cancellations number		
Did participants contact the study team? What was the characteristic of e-mail contacts?	e-mails number, issues covered in the e-mails		

Intervention acceptability	
	Analysis: Descriptive statistics/narrative summary
Was the intervention acceptable for participants?	**Acceptability**: personal relevance, relevance for the problem, following the intervention, convenience, usefulness (most-least useful), preferences (most, least liked, design), enjoyment/atmosphere, recommendation, ease of use/usability (clarity, structure, navigation), amount of information, trustworthiness, additional content, additional usability, completeness (survey and searching for additional information)

Preliminary effectiveness	
	Analysis: ANOVA, paired t-test, Friedman's ANOVA, Wilcoxon signed ranks test
Was there a significant change in… - frequency of sex without condoms?	T1/T2/T3 change, T1/T2 change, T1/T3 change, T2/T3 change (Friedman's ANOVA, Wilcoxon signed ranks test)
- consistency of condom use ?	T1/T2/T3 change, T1/T2 change, T1/T3 change, T2/T3 change (Friedman's ANOVA, Wilcoxon signed ranks test)
- condom use experience ?	T1/T2/T3 change, T1/T2 change, T1/T3 change, T2/T3 change (ANOVA, paired t-test)

- condom use self-efficacy?	T1/T2/T3 change, T1/T2 change, T1/T3 change, T2/T3 change (Friedman's ANOVA, Wilcoxon signed ranks test)
- condom use errors (M-CUES)?	T1/T2/T3 change, T1/T2 change, T1/T3 change, T2/T3 change (Friedman's ANOVA, Wilcoxon signed ranks test)
- condom use problems (M-CUES)?	T1/T2/T3 change, T1/T2 change, T1/T3 change, T2/T3 change (Friedman's ANOVA, Wilcoxon signed ranks test)
- condom use errors and problems (Condom fit and feel scale)?	T1/T2/T3 change, T1/T2 change, T1/T3 change, T2/T3 change (ANOVA, paired t-test)
- condom use attitudes	T1/T2/T3 change, T1/T2 change, T1/T3 change, T2/T3 change (ANOVA, paired t-test)

Appendix AV

Significant Associations between Participants' Characteristics and Type of Motivation to Take Part in Study 3[39]

Motivation	Characteristic at baseline	*n*	Significant associations with motivation to take part in the study			
				p		
fun	age (18-25)	136	χ^2 (1) = 5.238	.022	*w* = .20	more likely
fun	had experience of unplanned pregnancy	135	χ^2 (1) = 3.902	.048	*w* = .17	less likely
enjoy using condoms more	taught how to use condoms previously	132	χ^2 (1) = 4.182	.041	*w* = .18	less likely
enjoy using condoms more	lower condom use experience score at baseline	112	*t*(110) = 2.294, 95% CI [.33, .45]	.024	*r* = .21	more likely
curiosity	had experience unplanned pregnancy	135	χ^2 (1) = 5.769	.016	*w* = .21	less likely
learning	had experience unplanned pregnancy	135	χ^2 (1) = 4.838	.028	*w* = .19	less likely
learning	never used condoms with a partner before	135	χ^2 (1) = 5.560	.018	*w* = .20	more likely
learning	non-heterosexual men	123	χ^2 (1) = 6.597	.010	*w* = .23	more likely
improving skills	never used condom with a partner	135	χ^2 (1) = 7.407	.006	*w* = .23	more likely
improving skills	lower self-efficacy score at baseline	135	*t*(133) = 3.124, 95% CI [1.01, 4.49]	.002	*r* = .26	more likely
improving skills	higher fit and feel score at baseline	114	*t*(112) = -2.801, 95% CI [-5.44, -.93]	.006	*r* = .26	more likely
improving skills	not sexually active	135	χ^2 (2) = 7.045	.030	*w* = .23	more likely
improving skills	more condom use problems at baseline	108	*U* = 982.50, *z* = -2.167	.030	*r* = -.21	more likely
help with condom use problems	using condoms to avoid infection	121	χ^2 (1) = 4.235	.040	*w* = .19	more likely
help with condom use problems	more condom use errors at baseline	109	*U* = 614.00, *z* = -2.198	.028	*r* = -.21	more likely
help with condom use problems	lower self-efficacy score at baseline	135	*t*(133) = 3.978, 95% CI [2.15, 6.41]	.000	*r* = .33	more likely
help with condom use problems	higher fit and feel score at baseline	114	*t*(112) = -3.065, 95% CI [-7.02, -1.51]	.003	*r* = .28	more likely
receiving condoms	lower condom use experience score	112	*t*(110) = 2.16, 95% CI [.02, .45]	.030	*r* = .20	more likely
receiving condoms	practiced using condoms previously	134	χ^2 (1) = 10.004	.002	*w* = .27	more likely
charity	students	136	χ^2 (1) = 5.974	.015	*w* = .21	more likely
voucher	not employed	136	χ^2 (1) = 5.181	.023	*w* = .20	less likely
voucher	students	136	χ^2 (1) = 10.470	.001	*w* = .28	more likely

Analysis: Chi-square, t-test, Mann-Whitney test

[39] For full list of variables included in the analysis see Appendix AU

Appendix AW

Condom use related outcomes (T1, T2, T3)

	T1				T2				T3			
	n	*M*	*SD*	range	*n*	*M*	*SD*	range	*n*	*M*	*SD*	range
Condom use experience	111	18.12	4.94	8-35	25	18.84	4.01	12-27	21	18.76	5.89	10-33
Condom use attitude	132	18.25	6.31	5-35	36	18.89	6.68	6-32	29	19.21	6.30	7-34
Condom use self-efficacy	131	24.97	5.14	13-35	36	27.25	4.47	16-34	30	27.87	4.93	18-34
Condom use errors	109	3.47	1.87	0-8	25	2.48	1.26	0-5	22	2.64	1.59	0-7
Condom use problems	108	2.83	2.04	0-7	25	2.00	1.66	0-6	22	1.64	1.81	0-6
Condom use fit and feel	114	26.46	6.00	15-42	35	25.74	4.53	19-40	23	24.52	5.34	16-39

Appendix AX

T1-T2 Change in Condom Use Behaviour and Related Outcomes

Outcome	n[a]	T1		T2		T1 – T2				
		Mdn	*IQR*	*Mdn*	*IQR*	*T*		*r*	*p*	
Condoms use consistency[b]	23	33.33	57.14	66.67	100.00	20		.42	.003*	
Frequency of sex without condoms[b]	23	4.00	10.00	3.00	6.00	58.50		.29	.046	
Condom use self-efficacy[b]	36	26.00	7.75	28.00	4.75	103		.34	.003*	
Condom use errors[b]	21	4.00	2.50	2.00	1.50	17.50		.41	.005*	
Condom use problems[b]	22	3.00	2.00	2.00	2.25	26.50		.25	.105	
									95% CI	
		M	*SD*	*M*	*SD*	*t*	*r*	*p*	*LL*	*UL*
Condom use experience[c,d]	23	4.07	0.54	4.29	0.44	*t*(22) = -2.450	.46	.023**	-0.41	-0.03
Condom use attitude[c]	36	18.44	6.22	18.89	6.68	*t*(35) = -0.794	.13	.433	-1.58	0.69
Condom use fit and feel[c]	28	23.68	5.64	23.57	4.03	*t*(27) = 0.105	.02	.917	-1.95	2.16

Note. [a]number of cases (pairwise). [b]Wilcoxon signed ranks test with Bonferroni correction applied (critical level of significance = .0167). [c]Dependent samples t-test. [d]Square root transformation for the analysis.

*p < .0167

** p < .05

Appendix AY

T1-T3 Change in Condom Use Behaviour and Related Outcomes

Outcome	n[a]	T1		T3		T1 – T3		
		Mdn	*IQR*	*Mdn*	*IQR*	*T*	*r*	*p*
Condoms use consistency[b]	19	33.00	66.67	75.00	93.33	23	.34	.035
Frequency of sex without condoms[b]	19	3.00	4.00	1.00	8.00	26.50	.31	.058
Condom use self-efficacy[b]	30	25.50	8.50	28.00	7.00	31	.49	.000*
Condom use errors[b]	19	3.00	3.00	2.00	2.00	26	-.28	.091
Condom use problems[b]	19	3.00	2.00	1.00	3.00	4	.50	.001*

									95% CI	
		M	*SD*	*M*	*SD*	*t*	*r*	*p*	*LL*	*UL*
Condom use experience[c,d]	20	4.03	0.60	4.24	0.63	*t*(19) = -2.815	.54	.011**	-0.37	-0.05
Condom use attitude[c]	30	18.53	6.86	19.36	6.25	*t*(29) = -1.104	.20	.279	-2.38	0.71
Condom use fit and feel[c]	20	24.60	5.83	22.79	3.98	*t*(19) = 1.961	.41	.065	-0.12	3.74

Note. [a]number of cases (pairwise). [b]Wilcoxon signed ranks test with Bonferroni correction applied (critical level of significance = .0167). [c]Dependent samples t-test. [d]Square root transformation for the analysis.

*p < .0167

** p < .05

Appendix AZ

T2-T3 Change in Condom Use Behaviour and Related Outcomes

Outcome	n[a]	T2		T3		T2 – T3				
		Mdn	*IQR*	*Mdn*	*IQR*	*T*		*r*		*p*
Condoms use consistency[b]	14	67.50	81.25	79.17	95.00	13.50		.12		.289
Frequency of sex without condoms[b]	14	2.00	4.25	1.00	8.00	22		.1		.488
Condom use self-efficacy[b]	22	29.00	5.00	28.00	6.00	51.50		-.23		.069
Condom use errors[b]	14	2.00	2.00	2.00	2.00	22.50		0		.609
Condom use problems[b]	14	1.00	2.25	1.00	2.00	3.50		.36		.055
									95% CI	
		M	*SD*	*M*	*SD*	*t*	*r*	*p*	*LL*	*UL*
Condom use experience[c,d]	14	4.45	0.50	4.43	058	t(13) = 0.332	.09	.745	-0.1	0.14
Condom use attitude[c]	22	20.09	6.82	19.85	6.26	t(21) = 0.300	.07	.767	-1.42	1.89
Condom use fit and feel[c]	16	23.13	4.03	22.19	3.89	t(15) = 1.576	.38	.136	-0.33	2.21

Note. [a]number of cases (pairwise). [b]Wilcoxon signed ranks test with Bonferroni correction applied (critical level of significance = .0167). [c]Dependent samples t-test. [d]Square root transformation for the analysis.

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