

Sexual health promotion for young people delivered via digital media: a scoping review

Julia Bailey, Sue Mann, Sonali Wayal, Rachael Hunter, Caroline Free, Charles Abraham and Elizabeth Murray



**National Institute for
Health Research**

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Abstract

Sexual health promotion for young people delivered via digital media: a scoping review

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Background: Young people are at risk of poor sexual health and are, therefore, in need of comprehensive, effective sexual health education. Young people are confident and constant users of digital technology, such as the internet and mobile phones, and there are many innovative possibilities for sexual health education involving these technologies.

Objectives: To summarise evidence on effectiveness, cost-effectiveness and mechanism of action of interactive digital interventions (IDIs) for sexual health; optimal practice for intervention development; contexts for successful implementation; research methods for digital intervention evaluation; and the future potential of sexual health promotion via digital media.

Design: Literature review of evidence on digital interventions for sexual health for young people, integrating the findings with the views of young people, parents and experts in digital media/sexual health. IDIs are defined as digital media programmes that provide health information and tailored decision support, behaviour-change support and/or emotional support. We focus on sexual well-being for young people aged 13–24 years in the UK.

Results: There are many imaginative IDIs for sexual health promotion, but few interventions address issues that are important to young people, such as sexual pleasure and relationships. It is vital to collaborate with young people and to use Behaviour-Change Theory in designing interventions. We located 19 randomised controlled trials of IDIs for sexual health promotion for young people, finding a moderate effect on sexual health knowledge [standardised mean difference (SMD) 0.54, 95% confidence interval (CI) 0.17 to 0.92], a small effect on confidence (self-efficacy) (SMD 0.11, 95% CI 0.02 to 0.20) and a positive effect on sexual behaviour (odds ratio 1.28, 95% CI 1.01 to 1.61), but no significant effects on safer sex intention or biological outcomes. One study suggests that IDIs may be as good as face-to-face interventions for sexual health knowledge and safer sex intention. There are no existing data on the cost-effectiveness of IDIs for sexual health promotion. The impact of an IDI will be determined by the proportion of the target population reached, intervention efficacy, adoption in a setting, how well it is delivered and maintenance/sustainability. All of these elements must be addressed for IDIs to be successful. More collaboration is needed to capitalise on the knowledge of users and stakeholders, the design and software skills of the commercial sector and the theoretical expertise and evaluation skills of academia.

Conclusions: IDIs are effective for knowledge acquisition and sexual behaviour, and could usefully contribute to sexual health education in schools, in clinic settings and online; however, there are obstacles to overcome, such as access to information technology and ensuring the quality and safety of interventions.

Future work: More evidence is needed on the best designs for interventions (e.g. choice of behaviour-change mechanisms and interactive features) and the best models of delivery (e.g. setting, modes of delivery, methods of facilitation and support for engagement) to improve sexual behaviour, biological outcomes and sexual well-being in a cost-effective way.

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Glossary

Continuous variable An outcome which can take on any value in a range (e.g. variables such as height and blood pressure).

Dichotomous variable An outcome measured by numbers of events out of a total.

Digital intervention Any behaviour-change initiative received by a digital route.

Digital media Information and communications technology (e.g. mobile phones and the internet).

Heterogeneity Variation/difference in outcomes between studies.

Interactive digital intervention A digital media programme that provides sexual health information and tailored decision support, behaviour-change support and/or emotional support for sexual health issues.

Markov model A model used in a health economic evaluation that is a set of discrete health states that a cohort of patients cycle through with specific costs and outcomes attached to each health state.

Odds ratio A measure of the likelihood that one variable is associated with (connected with) another.

Social media (web)sites Websites where users can interact directly with each other.

Standard deviation A measure that is used to indicate the amount of variation or spread in a set of results.

Standardised mean difference A summary statistic that allows the combination of outcomes which might have been measured using different scales (i.e. a measurement of effect: 0.2 = 'small', 0.5 = 'moderate', 0.8 = 'large').

Telehealth The remote exchange of data between a patient at home and their clinician(s) to assist in diagnosis and monitoring.

Viral marketing The dissemination of applications online, from user to user.

Web 2.0 An evolution in pattern of use of the internet, with users uploading their own content (e.g. text, pictures and videos).

List of abbreviations

| | | | |
|--------|---|------|---|
| AIDS | acquired immunodeficiency syndrome | MSM | men who have sex with men |
| BASHH | British Association for Sexual Health and HIV | NCSP | National Chlamydia Screening Programme |
| BCT | behaviour-change technique | NICE | National Institute for Health and Care Excellence |
| BME | black and minority ethnic | OR | odds ratio |
| CD-ROM | compact disc read-only memory | PSHE | personal, social, health and economic (education) |
| CI | confidence interval | QALY | quality adjusted life year |
| EQ-5D | EuroQol EQ-5D | RCT | randomised controlled trial |
| GP | general practitioner | SCT | Social Cognitive Theory |
| HE | health economist | SD | standard deviation |
| HIV | human immunodeficiency virus | SMD | standardised mean difference |
| ICER | incremental cost-effectiveness ratio | SoC | Stages of Change |
| IDI | interactive digital intervention | SQOL | Sexual Quality of Life |
| IM | intervention mapping | SRE | sex and relationships education |
| IMB | Information-Motivation-Behavioural | STI | sexually transmitted infection |
| IT | information technology | TPB | Theory of Planned Behaviour |
| LGBT | lesbian, gay, bisexual and transgender | TRA | Theory of Reasoned Action |

Plain English summary

Many young people experience problems such as sexually transmitted infections and abuse in relationships. Young people in the UK may not get enough sexual health education at school or through health services. We wanted to find out whether or not mobile phones and the internet are good ways to provide sexual health education.

In our research we:

- looked at hundreds of research papers, articles and blogs
- interviewed young people (13–24 years old) and parents of teenagers
- talked to doctors, nurses, teachers and technology experts.

We found that:

- young people want to know more about sex and relationships, including sexual pleasure
- there are interesting ways to learn about sexual health online, such as quizzes, videos, games and virtual worlds
- there are lots of sexual health information websites and mobile phone apps, but most do not give personalised advice
- interactive programmes are effective for learning sexual health facts and can also increase safer sex
- programmes can help people to make decisions or solve problems by giving personalised advice
- programme developers should always involve young people
- programmes that use psychology are the best at encouraging people to make changes to their lives
- not all schools or clinics are ready or willing to provide sexual health information online
- we need to find out the best designs for websites and apps, including how to reach disadvantaged youth, how to change behaviour, what the costs are and which work best in schools and clinics.

Scientific summary

Background

Young people are at risk of poor sexual health and are, therefore, in need of comprehensive, effective sexual health education. Young people are confident users of digital technology, such as the internet and mobile phones, and there are many innovative possibilities for sexual health education. In this report we present the available evidence for the effectiveness and cost-effectiveness of interactive digital interventions (IDIs) for sexual health promotion, what is known about how best to design, develop and implement IDIs and how best to evaluate them. We also comment on the future potential of digital interventions for sexual health.

Methods

This review considers sexual health promotion for young people aged 13–24 years in the UK, defining sexual health in holistic terms to include physical, emotional, mental and social well-being in relation to sexuality. We focus particularly on *interactive* digital interventions, defined as digital media programmes that provide sexual health information and tailored decision support, behaviour-change support and/or emotional support for sexual health issues. We conducted a literature review to locate and synthesise available evidence on digital interventions for sexual health for young people spanning the last 10 years, integrating the findings with the views of key informants (young people, parents and experts in digital media/sexual health).

Results

Evidence on best practice for digital intervention design and development

We identified many examples of IDIs for sexual health promotion, particularly from the USA. Good practice for IDI design and development includes (1) developing an understanding of the target population and their behavioural needs, (2) targeting the modifiable mechanisms of the desired behaviour change through research with users, (3) selecting change techniques that match user needs, (4) implementing techniques in forms that are engaging and promote long-term interest/use among users and (5) ensuring that interventions are feasible and sustainable in an implementation context. Young people should be involved at all stages, and the views of other stakeholders can highlight sexual health needs not identified by young people themselves and help to optimise implementation.

Most IDIs focus on reducing sexual risk-taking behaviour and increasing condom use, with few interventions addressing issues such as sexual pleasure and relationships or cofactors such as alcohol and mental health. There are also gaps for risk groups such as young women after pregnancy, looked-after young people (in institutional care), young people experiencing sexual and domestic violence, young people with learning difficulties and lesbian, gay, bisexual and transgender youths. Promising interventions that have already been developed could be adapted for specific target groups and evaluated in UK settings.

There has been rapid innovation in the development and design of digital interventions. More collaboration is needed to capitalise on the knowledge of users and stakeholders, the design and software skills of the commercial sector and the theoretical expertise and evaluation skills of academia. There is a need for mechanisms to assess whether or not interventions meet defined quality criteria for intervention content and to assess potential risks.

Evidence on effectiveness of interactive digital interventions for sexual health promotion

We located 19 studies which were randomised controlled trials (RCTs) of IDIs for sexual health promotion for young people. We extracted data and (where possible) synthesised the findings from these studies to assess the effectiveness of IDIs. IDIs were delivered in a variety of settings (schools, colleges, health-care settings and online) and targeted heterosexual young people as well as young men who have sex with men.

Are interactive digital interventions effective?

We found that IDIs have statistically significant effects as follows: a moderate effect on sexual health knowledge [standardised mean difference (SMD) 0.54, 95% confidence interval (CI) 0.17 to 0.92], a small effect on self-efficacy (SMD 0.11, 95% CI 0.02 to 0.20) and a positive effect on sexual behaviour [odds ratio (OR) 1.28, 95% CI 1.01 to 1.61], but no significant effects on safer-sex intentions (SMD 0.09, 95% CI -0.01 to 0.19) or biological outcomes (OR 1.18, 95% CI 0.78 to 1.80). There were no data on adverse effects.

Are interactive digital interventions as effective as face-to-face interventions for sexual health?

The results of one study suggest that IDIs may be as good as, or better than, face-to-face interventions for sexual health knowledge acquisition (SMD 0.51, 95% CI 0.11 to 0.90) and intention (SMD 0.46, 95% CI 0.06 to 0.85), but not for self-efficacy (SMD 0.38, 95% CI -0.11 to 0.77). There were insufficient data to draw conclusions about effects of IDIs on sexual behaviour, biological outcomes or adverse effects.

How do interactive digital interventions work?

The existing evidence on this topic is limited, as little trial evidence is available.

These results show that IDIs are effective tools for learning about sexual health, but there is not enough evidence to be sure of the effects on biological outcomes such as sexually transmitted infections (STIs) or pregnancy.

Evidence on methods for economic measurement, analysis and modelling in sexual health

There is very limited health economic evidence which relates directly to digital interventions for sexual health promotion, and so we draw on evidence and guidance regarding (non-digital) sexual health promotion and (non-sexual health) digital interventions.

Sexual health promotion interventions are likely to be cost-effective if the target groups have a high prevalence of STIs and/or if the intervention is relatively cheap. Once an IDI is developed, the ongoing costs can be relatively low and targeting large numbers of people can, in theory, be relatively cheap and easy. However, the level of uptake and engagement with an intervention and the characteristics of target populations might be more instrumental in determining the cost-effectiveness than intervention efficacy alone.

Cost-utility analysis is the type of economic evaluation recommended in the UK (calculating the incremental cost per quality adjusted life year gained), but this may not be the most suitable type of economic evaluation for sexual health intervention evaluation if it does not capture all of the costs and consequences of interest. Cost-effectiveness analyses (e.g. reporting results as cost per STI case detected or cost per pregnancy avoided) may provide more useful information to a decision-maker in a sexual health context. Decision modelling can potentially capture a wider range of information about long-term impacts of an intervention beyond the duration and scope of a RCT. As most of the costs and benefits of sexual health promotion come from the prevention of potentially rare events (e.g. cases of STIs or unintended pregnancies), it is likely that large, observational data sets will play an increasing role in capturing this information.

Further research and consensus are needed on how best to cost intervention development, implementation and maintenance, how to measure health and well-being outcomes in the sexual health promotion field, particularly long-term outcomes, and the best ways to conduct economic evaluations of digital media interventions for sexual health promotion.

Evidence on implementation of sexual health interactive digital interventions for young people

The impact of a sexual health promotion IDI will be determined by its **r**each (proportion of the target population reached), **e**fficacy, **a**doption (within the target setting), **i**mplementation (how well it is delivered) and **m**aintenance (sustainability): RE-AIM.

Sexual health IDIs delivered in settings such as a clinic or the classroom have a captive audience, which enables interventions to be delivered with high fidelity over a defined period of time. In contrast, online interventions can allow private and convenient access and reach populations who may not be linked into mainstream services, but require the user not only to find the intervention but also to stay with it. Mixed delivery through complementary routes (in static settings and online) is most likely to maximise the proportion of the target population gaining access.

The reach of IDIs could be enhanced by linking sexual health promotion interventions with existing digital systems, such as STI testing, or with trusted branded websites or popular social networking sites. Face-to-face recruitment and facilitated engagement (e.g. with teachers or clinicians) also encourage young people to access interventions and are more likely to facilitate continued engagement. More research is needed on how social networking sites, mobile phones and gaming can be harnessed for sexual health promotion.

Using the knowledge of local stakeholders (such as teachers or clinicians) is vital for both successful intervention development and implementation. An effective intervention usually requires some adaptation for local contexts, but care is needed in identifying and preserving the core components so that effectiveness is maintained. Technical support, moderation/monitoring and updating are further challenges for implementing sustainable digital interventions.

There are few national policy levers to drive implementation of sexual health promotion IDIs in practice, and responsibility for health and education is being increasingly devolved to local health care and local authority commissioning groups. An increased emphasis on local cross-sectoral working means that there may be more opportunity for shared initiatives and shared (financial) risk.

Evidence on optimum research design and outcome measurement to evaluate digital interventions

Digital platforms offer quick, convenient and relatively cheap methods for conducting sexual health research. Recruitment via the internet offers opportunities for reaching hard-to-reach, stigmatised populations, although convenience sampling makes sample representativeness more difficult to assess. Online recruitment to trials allows self-registration, online consent, automated randomisation, automated follow-up and online data collection, which can potentially reduce the cost of conducting trials. Using digitally mediated research methods (e.g. computer-assisted self-interviews or mobile phones for data collection) can enhance confidentiality. Requesting several participant identifiers (such as address, telephone number and date of birth) can help to reduce the likelihood of a single participant enrolling in online studies multiple times. Robust measures are needed to ensure the security and confidentiality of data collected using digital methods.

Retention in studies that use digitally mediated research methods (e.g. online trials and longitudinal surveys) can be a challenge. However, the use of multiple strategies, such as offering incentives, sending reminders via text and e-mail and appealing to the altruism of participants, can enhance retention.

Age-appropriate sexual health outcomes should be used in research with young people. If interventions address multidimensional aspects of sexual well-being and other health issues, such as substance use and mental well-being (as users would like), outcome evaluation should also reflect these broader concepts of health. There is a trade-off between producing a specific intervention with clear (narrow) aims and producing an intervention that addresses the complexity of sexual health.

It is difficult to capture impacts on health (e.g. STIs or pregnancy), as these events are relatively rare, especially in younger age groups. It is important to measure determinants of behaviour change (such as knowledge and self-efficacy) to capture shorter-term impacts, and to understand how interventions work. Adequately powered, longer-term studies are needed to assess the impact of digital interventions among young people. Qualitative process evaluations are needed to evaluate how complex interventions work and to assess engagement and implementation in practice.

In conclusion, digitally mediated research methods are acceptable and feasible for recruitment and administration of sexual health research, and there is increasing evidence on how best to ensure good-quality online data and how to maximise retention in studies.

Conclusions: current state of play and future potential of interactive digital interventions for sexual health

There is clear need for better access to sexual health promotion, as many young people in the UK do not currently have access to accurate information about the positive aspects of sex, sexuality and relationships, or sufficient information to assess and minimise risks. Sexual health is a challenging field in which to try to change behaviour because of the complexity of behaviours and social taboos. Public health/medical perspectives on sexual health have tended to focus on negative outcomes rather than the positive dimensions of sex and sexuality and its potential to enhance health and happiness.

Internet access is almost universal for young people in the UK, and sexual health promotion via digital media is a highly appropriate way to reach young people. Accurate information is a vital first step towards sexual self-determination, and digital interventions can meet young people's need for this. We need stronger evidence on the best designs for interventions (e.g. choice of behaviour-change mechanisms and interactive features), evidence on the best models of delivery (e.g. setting, modes of delivery, methods of facilitation and support for engagement) and evidence on cost-effectiveness. More evidence is needed on how to impact on sexual behaviour, on biological outcomes (STIs and pregnancy) and on sexual well-being.

At the time of writing (2015), in the UK there are pockets of local innovation but no co-ordinated national programme to exploit the potential of IDIs for sexual health promotion. Young people have a big appetite for IDIs for sexual health, the commercial sector is keen to exploit opportunities to develop digital media interventions for health and there is political will to deploy IDIs for health. However, there are important obstacles to the widespread implementation of IDIs in clinical settings (e.g. technical issues, access problems and engrained patterns of working), in schools [e.g. lack of compulsory sex and relationships education (SRE), teacher and parent reservations and blocks to websites with sexual health content] and online (e.g. lack of financial incentives to develop or implement freely-available interventions). More research is needed on how to understand obstacles to implementation and how best to address these.

We located many examples of IDIs (mostly from other countries) which were developed with young people's input, which utilise imaginative interactive features and which are underpinned by Behaviour-Change Theory. We did not identify any IDIs which are ready for implementation in the UK, either because evidence of the effectiveness of the intervention was lacking or because interventions shown to be effective in other countries would need to be adapted and evaluated in the UK before implementation.

Collaboration between stakeholders (including young people themselves, developers, academics, educators, parents, teachers, school boards, clinicians, NHS managers and policy-makers) is key to successful design and implementation. We need better mechanisms for bringing together the creative energy of young people and of the commercial sector with academic expertise which can ensure that interventions are theoretically sound and rigorously evaluated before roll-out. We need to ensure that interventions can be developed and evaluated within reasonable time scales while also ensuring that the quality and effectiveness of intervention content is known and that risks to users' privacy and safety are minimised.

Interactive digital interventions have a potentially far reach and, if proven effective, would have significant potential to impact positively on the sexual health of young people in the UK. They could be cost saving, as well as reaching young people who do not currently have access to high-quality SRE (in or outside school). IDIs could usefully form a component of sexual health education in schools, in clinical settings and online.

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Chapter 1 Introduction

In this chapter we give an overview of the sexual health of young people in the UK, and set this report in context in terms of current policy and practice concerning digital interventions for sexual health promotion.

Sexual health of young people in the UK

Relationships, sexuality and sex are central to health and well-being^{1,2} and adolescence is generally a time of learning and exploration, particularly with regard to sexual identity. It is increasingly acknowledged that attending to positive dimensions of sexual health in sexual health education is important not only in terms of increasing the effectiveness of interventions for human immunodeficiency virus (HIV)/sexually transmitted infections (STIs) and pregnancy prevention³ but also for facilitating young people's access to information and resources to allow them to experience fulfilling, pleasurable sexual lives.^{1,2,4} Sexual health can be thought of as:

... a state of physical, emotional, mental and social well-being in relation to sexuality [...] Sexual health requires a positive and respectful approach to sexuality and sexual relationships, as well as the possibility of having pleasurable and safe sexual experiences, free of coercion, discrimination and violence.

Reproduced with permission from the World Health Organization.⁵

Sex and relationships can be sources of pleasure and satisfaction for young people, and there has been an expansion of heterosexual sexual repertoires over time (particularly oral and anal sex).⁶ Young people under the age of 25 years report relatively larger numbers of sexual partners than other age groups and the age of sexual debut is getting younger over time,⁶⁻⁸ so young people are potentially at higher risk of adverse sexual health. For example, young people under the age of 25 years experience higher incidences of genital chlamydia and genital warts than other age groups.^{9,10} A high proportion of 16- to 24-year-olds (51.9% of young women and 43.8% of young men) were not 'sexually competent' at their first sexual intercourse [i.e. with equal willingness of partners, autonomy of decision (not due to peer pressure, drunkenness or drugs), acceptable timing (that it happened at the 'right time') and using a reliable method of contraception] (Dr Cath Mercer, University College London, UK, 2014, personal communication).¹¹ Unplanned pregnancy is associated with lack of sexual competence.¹¹

With regard to young people under the age of 18 years, conception and abortion rates in England, Wales and Scotland are falling over time,¹² although the teenage conception rates in Scotland remain among the highest in Western Europe.¹³ Conception rates are not available for Northern Ireland owing to the lack of complete data on the number of women having abortions.¹⁴ Conception in young people under 18 years old is not necessarily unwanted, but the proportion of unplanned pregnancies among women aged 16-19 years is high, at 45.2%,¹¹ and women aged 16-24 years are more likely to report ambivalence about their pregnancy than older women (approximately 43%).

Particular groups of young people are at higher risk of poor sexual health, for example those who use drugs, teenage parents, incarcerated youths and young people from ethnic minority groups^{9,15,16} There is a strong deprivation gradient, with conception rates in the most deprived areas not falling as fast as those in more affluent areas. Sexual health in Northern Ireland is poor, with high levels of teenage pregnancy and increasing prevalence of STIs. Lesbian, gay, bisexual and transgender (LGBT) young people are at risk of poorer sexual and mental health: for example, young men who have sex with men (MSM) are at greater risk of HIV¹⁵ and women who have sex with both women and men report significantly greater numbers of male partners and higher levels of unsafe sex, smoking, alcohol consumption, intravenous drug use, abortion and STIs.¹⁷ The small quantity of evidence on the health of transgender people suggests that they are at higher risk of adverse sexual health.¹⁸ Intimate partner abuse and non-volitional sex are also issues

for young people^{19,20} and are associated with poor mental health, regretted sex, STIs, distress or worry about sex life, low sexual function, abortion and first pregnancy before 18 years of age.²⁰ Young people may experience sexual problems; premature ejaculation is the most common problem for young men, and for young women the most common problems are lacking interest in sex and having difficulty in reaching orgasm.²¹

A high proportion of young people are not receiving the sexual health services that they need. For example, almost 50% of young women and 75% of young men aged 16–24 years have not been tested for chlamydia in the past year.²² The lowest level of contraceptive use was among those aged 16–19 years, with 64% at risk of pregnancy,²³ and sources of help for sexual problems among young people were predominantly informal (rather than through health services).²¹ There is, therefore, a clear need to improve the sexual health of young people in the UK (and globally).

Sexual health education and health promotion in the UK

Sex and relationships education in schools

In the UK, there is a wide variation in sex and relationships education (SRE) policy and content because each country has its own SRE framework. While SRE is mandatory in schools in England,²⁴ Northern Ireland²⁵ and Wales,²⁶ it is not mandatory in Scotland.

The provision of SRE to young people in England is based on national-level SRE guidance.²⁴ However, curriculum content is determined locally for local authority-run schools or individually for academies, in keeping with the national sexual health policy. Although SRE is mandatory in primary schools in England, it currently focuses only on biology, including puberty, reproduction and fertility. In secondary schools it is mandatory to provide at least basic information on biological aspects of human growth and reproduction, STIs and HIV as part of the National Curriculum for Science.²⁴ However, broader aspects of SRE, including relationships, sexual and domestic violence, same-sex relationships and sexuality, come under the personal, social, health and economic (PSHE) education curriculum and are not mandatory. Independent schools (including private schools and government-funded academy schools) do not have to follow the national curriculum and are not governed by the same statutory obligations as maintained schools. Parents in any school have the right to withdraw their children from all or part of any sex education except teaching on the biological aspects of human growth and reproduction, which are specified in the National Curriculum for Science. This means that while sex education in some schools is excellent, in others children are not offered the information, skills and resources necessary to learn to enjoy safe and pleasurable sex lives.

In Wales, SRE is a compulsory part of the basic curriculum in all secondary schools.²⁶ The Welsh government recommends that primary schools should have a graduated programme of SRE tailored to the age and emotional maturity of the children.²⁷ PSHE has been a compulsory part of the basic curriculum in both primary and secondary schools since 2003. In Scotland there is no statutory requirement for schools to teach sex education. In 2001, the Scottish Executive published a circular on sex education in Scottish schools, which encouraged all schools to provide sex education within a comprehensive programme of PSHE and religious and moral education.²⁸ In Northern Ireland, relationships and sexuality education (RSE) is included on a statutory basis in the school curriculum.²⁵ However, while policy documents are positive about providing comprehensive RSE, in practice there is variable provision in schools.

Across the UK, some schools provide a very well-planned comprehensive SRE curriculum, while in others there is very little provided. Parents or guardians are entitled to withdraw their children from all or part of a planned sex education programme, meaning that many young people receive only minimal SRE.

In recent years there has been a growing call for all children and young people to receive high-quality SRE.^{4,29,30} An Office for Standards in Education, Children's Services and Skills (Ofsted) report has called for

improvement in SRE because over one-third of the primary schools in England did not address issues related to physical and emotional changes during puberty and in secondary schools, and many SRE programmes did not address the impact of relationships, sexuality and pornography on understanding of healthy sexual relationships and safety.³¹ Although pupils had received education on sexual risk and staying safe, they had not developed, for example, assertiveness and negotiation skills. There are also calls to include internet and media literacy in curricula.^{24,32} In addition, teachers may lack expertise in teaching about sex and sexuality, and the assessment of pupils' learning of PSHE may be poor in comparison with other subjects. Experts and researchers in sexual health have also called for the National Institute for Health and Care Excellence (NICE) to resume its work on the modernisation of SRE and to embrace a holistic perspective to focus on relationships, communication and consent in addition to biology.³³ Access to information technology (IT) in schools varies across the UK, with some schools providing IT both within the school and for pupils to access from home, and others providing only minimal IT access.³⁴

Sexual health promotion in clinic and community settings

The provision of sexual health services for young people varies across the UK. Young people may find it hard to access clinic services because of their concerns about privacy and confidentiality and fears about staff being critical or unfriendly.³⁵ The convenience of clinic locations and opening hours is particularly important for young people, who may face restrictions on where they can go and when.³⁵

Sexual health promotion forms a core component of care in sexual health clinics (e.g. as a part of a health advisor role), but the quality and intensity of advice or support is variable. The UK Guidelines on Safer Sex Advice recommend evidence-based behaviour-change interventions for those at higher risk of STIs (including young people), focusing on enhancing communication skills and increasing motivation to adopt safer sexual behaviours.³⁶ Techniques such as motivational interviewing are recommended to increase motivation to adopt safer sexual behaviours, and the guideline recommends that detailed and tailored information on safer sex should form part of all sexual health consultations (in settings such as general practice as well as sexual health clinics). The NICE guidance on one-to-one interventions to reduce STIs and under-18 conceptions recommends that clinicians assess STI risk when the opportunity arises, for example when someone attends for contraception or registers as a new patient.³⁷ The guidance recommends offering advice on STIs and contraception as part of a structured discussion, especially for vulnerable young people who may be at higher risk of poor sexual health, such as those from disadvantaged backgrounds and those who are in or leaving care.

It is difficult to ensure consistent, high-quality delivery of face-to-face, one-to-one behaviour-change interventions by clinic staff, and interventions are costly and time-consuming. Clinics are often overstretched and there is not necessarily funding available to train and mentor staff to ensure the maintenance of high standards of intervention (such as skills in motivational interviewing). In addition, sexual health as a topic can be difficult for both patients and practitioners to broach.³⁸

Outside school and clinic settings, many localities have outreach sex education for young people, but the funding of these programmes is often local and short term, and provision varies across the UK. In community settings, group interventions can be effective, but these tend to be available for specific groups, such as MSM only. Charities such as the Terrence Higgins Trust and Gay Men Fighting AIDS (acquired immunodeficiency syndrome), have embraced digital media for sexual outreach work, including HIV prevention within populations at higher risk of HIV, such as MSM and African migrant groups.

Young people wish to receive sexual health advice from parents, teachers and doctors, as well as online,³⁹ but at the moment sexual health programmes in schools, clinics or the community do not adequately meet young people's needs. Face-to-face interventions are expensive to provide and it is difficult to ensure that interventions are delivered as intended. Digital interventions have the potential to usefully supplement and augment face-to-face teaching and/or health-care provision.

UK policy on digital media for health

There has been an explosion of interest in the use of digital media technology for health over the past decade or so. The NHS has lagged behind other institutions and commercial companies in terms of information and communications technology, but there is now an impetus to address this, to facilitate patient access to information and self-care and to reduce health-care costs.

Digital health: key policy events

There have been important policy commitments to the integration of digital communications into health-care systems. In 2002, the Wanless Report *Securing Our Future Health: Taking A Long-Term View* detailed the spiralling costs of health-care and the importance of self-care, and recommended improving the use of IT in the health service to improve quality and productivity.⁴⁰ This was followed by *Securing Good Health for the Whole Population*,⁴¹ which recommended the development of internet and telephone services to make self-care advice freely available. From 2005, the Connecting for Health programme was introduced to implement the NHS national programme for IT to create a single, central electronic care record for patients and to connect general practitioners (GPs) to hospitals. However, after enormous expenditure, this programme was abandoned after encountering insurmountable technical and security problems. The Innovation, Health and Wealth initiative from 2012 provides policy support for innovation of all types within the NHS, including a roll-out of telehealth and support for electronic care planning.⁴² Under this programme, there are new Academic Health Science Networks, a new legal duty for Clinical Commissioning Groups and the NHS Commissioning Board to promote innovation, a Specialised Services Commissioning Innovation Fund, investment in the Small Business Research Initiative, Innovation Challenge Prizes, new networks with industry and financial incentives (Commissioning for Quality and Innovation). The 3millionlives programme (www.3millionlives.co.uk) is a Department of Health initiative to implement telehealth and telecare services for the 3 million people with long-term conditions and/or social care needs.

The Department of Health's *Digital Strategy: Leading the Culture Change in Health and Care*⁴³ aims to put patients in control of their health and care information, to make services more convenient and more joined up and to promote more transparent sharing of information. The policy proposes implementing the Digital First strategy for health and care to deliver innovation (such as bringing together information and services from across the NHS, public health and social care into a single integrated customer service platform, developing an active community of digital professionals within the health and care system and providing a digital workspace to share best practice, case studies and digital knowledge). The principle of Digital First is that it aims to reduce unnecessary face-to-face contact between patients and health-care professionals, using technology to make access to health care more flexible and convenient for patients and at a lower cost [e.g. online, by telephone, by e-mail or via Skype™ (Microsoft Corporation, Redmond, WA, USA)]. Ideas include pre-assessment or triage (online or by telephone), online booking of appointments, automated appointment reminders, remote follow-up and electronic communication of results and hospital letters.⁴⁴

The proposals in the Department of Health's *Power of Information*⁴⁵ strategy aim to enable patients (in England) to access their GP health records and to book appointments and request repeat prescriptions online, and gives a commitment to making hospital and other records available online. Patients will be able to access information about health and social care services and will also be able to give feedback online. There will be national standards to ensure that locally developed IT systems can exchange information effectively and securely. The strategy also aims to encourage technology use by both patients and staff. The NHS England's *Five Year Forward View*⁴⁶ sets out a much greater commitment to disease prevention and breaking down boundaries between services to provide better co-ordinated and more patient-centred care. The *Personalised Health and Care 2020* policy paper⁴⁷ acknowledges the role of IT in empowering people to take charge of their own health by providing access to medical records and to accredited health and care apps and digital information. It sets out a commitment to facilitating digital information on a person's health and care by 2020 for all NHS-funded services, and access to data on services and

treatment outcomes. The National Information Board is setting the strategy and direction for the health and care system on IT and information, and is monitoring progress (www.gov.uk/government/organisations/national-information-board). The Research and Innovation in Health and Social Care Policy of March 2013⁴⁸ promotes health research and use of new technologies for the development of more effective treatments for NHS patients, and programmes such as Code4Health have been established for knowledge sharing and skill building, to facilitate the development and implementation of digital solutions for health and care.⁴⁹

Sexual health policy and digital health

In England, changes brought about by the Health and Social Care Act 2012⁵⁰ have led to significant alterations in the landscape of sexual health provision, which impact on the potential for use of digital technologies in the statutory sector. Councils have acquired commissioning responsibilities for sexual health under the umbrella of Public Health and, at the same time, greater local autonomy for decisions about how services are configured. Local strategy is driven by Joint Strategic Needs Assessments and services are commissioned from a diverse community of providers by local authorities. National-level policy guidance, support for local health communities and data analyses are provided by Public Health England to drive, but not determine, local decision-making. For local authorities, bringing different areas of health improvement, such as alcohol, drug misuse services and sexual health, under the same roof as other departments, such as education, may mean greater interdisciplinary collaboration. The changing context has brought new opportunities to address the wider determinants of sexual health and for aligning priorities across the health and social care sectors. However, primary care, a significant sexual health provider, is commissioned separately, and different sexual health providers may find themselves competing for rather than collaborating for a local authority tender to provide services.

In Scotland, young people are a priority group in health policy: reduction in unintended pregnancy, harm prevention and integrated approaches to sexual health are important target areas. Relatively high rates of HIV among MSM mean that this has greater priority than some other areas, such as chlamydia screening. Health and social care are integrated, with common budgets and integrated approaches to health care and education. Health care is commissioned almost exclusively from NHS providers, and that has facilitated national-level initiatives such as the National Sexual Health Electronic Patient Record, enabling more integrated approaches to care and sharing across services.

In Wales, care is commissioned from a single provider, with the allocation of resources for sexual health promotion devolved to local regions, much like in England, leading to the potential for variation in provision. Particular national health priorities for young people are safeguarding, identifying and preventing sexual exploitation and addressing domestic violence.

National-level ambitions for sexual health are laid out for England, Scotland, Wales and Northern Ireland (*A Framework for Sexual Health Improvement 2013*;⁵¹ *The Sexual Health and Blood Borne Virus Framework 2011*;⁵² *The Sexual Health Wellbeing Action Plan for Wales 2010–2015*;⁵³ *Progress and Priorities 2014*⁵⁴). The importance of peers and relationships, self-esteem, culture and freedom from coercion in sexual relationships represent key underlying principles for the strategy documents. Wider influences on behaviour, such as drugs and alcohol, as well as the particular needs of risk groups, such as those with learning disabilities or mental health problems, are also highlighted. In England, the sexual health of young people also remains a policy priority, with two out of the three sexual health indicators in the Public Health Outcomes Framework (2012)⁵⁵ being young-person specific – reducing chlamydia among 15- to 24-year-olds and reducing teenage pregnancy. Gender-based violence has become an increasing national policy priority both politically and across education and health policy settings.

Until recently, IT in government policy has been seen as facilitating communication, data storage, data retrieval and analysis, and 'innovation' is conceptualised as changes in the way that services are provided or new treatments for health problems. The main focus of policy initiatives nationally has been on electronic records (increasing access to information for health providers and patients), electronic

communications (e-mail, mobile phones or videoconferencing) and 'big data' (collecting and analysing data sets of patient information), rather than on digital innovations for self-directed health promotion. IT is seen as an important plank in saving NHS resources by reducing the frequency and costs of face-to-face interactions with health providers.⁴⁷ Digital interventions could also help to shift the emphasis from the diagnosis and treatment of conditions to self-care and prevention.⁵⁶

Policy at national level promotes the use of technology and social media for sexual health education and promotion, with a focus on prevention through behaviour-change intervention.⁴ The National Strategy for Sexual Health and HIV⁵⁷ from 2001 mentions the use of multiple channels for helplines (e.g. digital TV and the internet), and encourages the development of technology in clinical decision support systems and computer links between clinical sites to facilitate good practice and shared care. The 2008 Review of the National Strategy for Sexual Health and HIV⁵⁸ does not mention digital media, but the British Association for Sexual Health and HIV (BASHH) and British HIV Association guidelines on safer sex advice³⁶ recommend that digital interventions be considered as an alternative or adjunct to face-to-face interventions.

Young people, digital media and sexual health

Globally, there has been a rapid increase in mobile phone subscriptions and a steady increase in internet access and mobile subscriptions.⁵⁹ In 2014, 59% of all citizens in the UK had a smartphone and 84% of adults accessed the internet.⁴⁷ Access to the internet by young people in the UK is almost universal⁶⁰ and most children have access in their own homes and/or at school.⁶¹ However, this does not mean that young people necessarily have open access to sexual health content online: computers may be in shared spaces at home, devices at school or at home may have filtering software installed and it may not be possible to access the internet 'on the go' with some mobile phones or phone contracts.⁶¹ A total of 96% of GP practices have digital clinical record systems but fewer than 4% of patients have been offered online access to their GP records. Only 2% of the population reported any digitally enabled health care in 2014.⁴⁷ The barriers to digital health care include a lack of universal Wi-Fi access, a failure to provide computers or tablets to ward or community-based staff and outmoded security procedures. There are striking variations nationally in patterns of use of digital technology by patients and staff.⁴⁷

Digital media for sexual health promotion for young people has great potential because of the reach and popularity of technology such as the internet and mobile phones.⁶² Young people access the internet for sexual health information, especially if they have a particular concern, and there are now a vast number of websites offering sexual health information and advice [example sexual health websites include Sexperience (<http://sexperienceuk.channel4.com>), SexEtc (<http://sexetc.org>), TheSite (www.thesite.org) and NHS Choices (www.nhs.uk/Pages/HomePage.aspx)]. Types of digital media interventions are evolving fast: in the early days of computer-based education, programmes were presented on computers in specific settings, such as schools⁶³ or clinics.⁶⁴ With wider access to the internet, sexual health interventions can now be made more freely available online.^{65,66} In the early nineties, websites tended to present text-heavy, didactic educational content, which did not allow input from users. Since then, broadband speeds and the reach of the internet have increased hugely, enabling the streaming of audio, video and animation and more interactivity. The advent of Web 2.0 from the turn of the century heralded a huge change from one-way transmission of information on a website to interactions online between website users, for example through chat rooms, bulletin boards and social networking sites such as Facebook (Facebook Inc., Menlo Park, CA, USA), and the posting of site content by users. Digital media interventions have become much more interactive, for example games with feedback,⁶⁷ interactive video stories,⁶⁸ conversations with virtual characters (avatars)⁶⁶ and three-dimensional worlds simulating real-life situations.⁶⁹

Another change in the context for the delivery of digital interventions was the advent of internet access via mobile phones, which became popular in the mid to late 2000s, and the explosion in the development of apps for phones from around 2008. This has meant that the internet and mobile phone apps can potentially be accessed when and where they are wanted. There are increasing numbers of digital

innovations for conditions that lend themselves to quantitative data collection, such as programmes for the self-monitoring of exercise, pulse and blood pressure. However, while there are thousands of apps and programmes available for health problems such as exercise, diet and smoking, there are far fewer available for sexual health, and most of those apps currently available have failed to attract user attention and positive reviews.⁷⁰

There is less scope for harnessing self-monitoring and social networking for sexual health promotion because individuals' sex lives and sexual health are seen as private and potentially embarrassing, and because of the complex, less quantifiable nature of sexual well-being. Some companies' policies [e.g. Apple™ (Cupertino, CA, USA)] block the production of pornographic programmes/apps, and such restrictions may also, under a blanket ban, apply to sexual health apps. Research on digital media interventions has accelerated since around the year 2000, but it is not keeping up with the pace of innovation seen in the commercial sector.⁵⁶

There are increasingly synergies across platforms (e.g. interactive websites related to television programmes) and social dimensions to new media use (e.g. sharing, commenting on or rating digital content).⁷¹ Young people commonly multitask while online, interacting with several programmes or devices at once, and the portability of the internet enhances the likelihood that users are performing non-media activities while they are online.⁷¹ The enhanced convenience and potential ease of access to digital media content may, therefore, be offset by a vast choice of material and competing demands on users' attention.

With increasingly easy access to the internet, there is public debate and concern about children's safety online, for example with regard to the possible exposure of children to sexually explicit material and the online 'grooming' of young people.⁶¹ Websites and apps are increasingly important avenues for people to meet sexual partners, particularly for those over the age of 18 years and for MSM (some examples of dating and hook-up websites are <http://grindr.com>, www.gay.com/ or <https://soulmates.theguardian.com/>). Meeting partners online can be associated with higher-risk sexual activity: for example, MSM who use the internet to meet sexual partners have more partners than MSM who meet partners offline, and may also have higher-risk sex with their partners.⁷² 'Sexting' (the sending of sexually explicit messages and/or pictures) is common among young people⁶¹ and carries the risk of bullying or shaming if the messages are made public.

Many young people have accessed pornography online, either accidentally or intentionally,⁷¹ and this can lead to unrealistic expectations or worries about 'normal' sexual function. Pornography is unlikely to convey positive sexual health messages (e.g. films can show penetrative sex without the use of condoms) and sexual acts are often depicted without showing communication or negotiation between partner(s). The potential harms of the internet to young people may be subtle, for example in unhelpful stereotyped depictions of female and male behaviour and pressures to conform to idealised body types and sizes. In the absence of other sources, pornography may constitute a principal source of information concerning sex and relationships for young people.⁷¹ Media and internet literacy education for children is essential⁶¹ to ensure that they are able to assess the quality and source of material that they encounter and that they can learn how to avoid or minimise possible risks. Access to sexually explicit content online may be controlled by the use of filtering software, but this can also limit young people's access to sexual health educational content.

In this report we use the term 'digital intervention' to mean any behaviour-change initiative received by a digital route (most commonly via the internet or mobile phones). This embraces non-tailored digital media interventions, such as digital media campaigns, and one-way communication, such as text-message reminders. In this review, we have chosen to focus on digital media interventions which are interactive and tailored (meaning that users receive tailored feedback in response to the input of personally relevant data), as active engagement with an intervention and receipt of information that is relevant to the user's own situation is more likely to enhance consolidation of learning and behaviour change.⁷³ We define such interventions as interactive digital interventions (IDIs).

Digital interventions for sexual health promotion

Digital interventions in clinic settings

Figure 1 gives examples of the ways in which sexual health information can be communicated digitally before, during, after or separately from a journey through clinical care.

As shown in Figure 1, digital media interventions may enhance patient **access to information and/or services**. Many digital health tools are already widely used, for example health information online (e.g. the NHS Choices Livewell website: www.nhs.uk/LiveWell/Pages/Livewellhub.aspx), search tools to locate services (e.g. www.nhs.uk/Service-Search/Sexual-health-information-and-support/LocationSearch/734), online symptom checkers (e.g. www.nhs.uk/symptomcheckers/pages/symptoms.aspx), electronic appointment booking (e.g. www.chelwest.nhs.uk/services/hiv-sexual-health/clinics/west-london-centre-for-sexual-health/book-an-appointment), text reminders for appointments,⁷⁴ online test-kit ordering (e.g. www.checkyourself.org.uk for chlamydia testing and www.tht.org.uk/sexual-health/About-HIV/HIV-postal-test for HIV self-testing) and results by text or e-mail.⁷⁵

Digital interventions for sexual health may enhance the reach of clinical services, for example automated text messages to encourage HIV testing,⁷⁶ or an online facility to notify sexual partners of the need for STI testing and treatment (e.g. www.gmfa.org.uk/pn) and online support groups or discussion forums (e.g. www.tht.org.uk/myhiv).

Digital innovations may enhance clinical care, for example electronic triage (with the option of appropriate testing kits being dispensed in the clinic) or electronic history-taking and/or risk assessment prior to an appointment. Electronic decision aids for clinicians are available (e.g. websites to check for HIV drug interactions, such as www.hiv-druginteractions.org), as are those for patient use (e.g. 'My Contraception

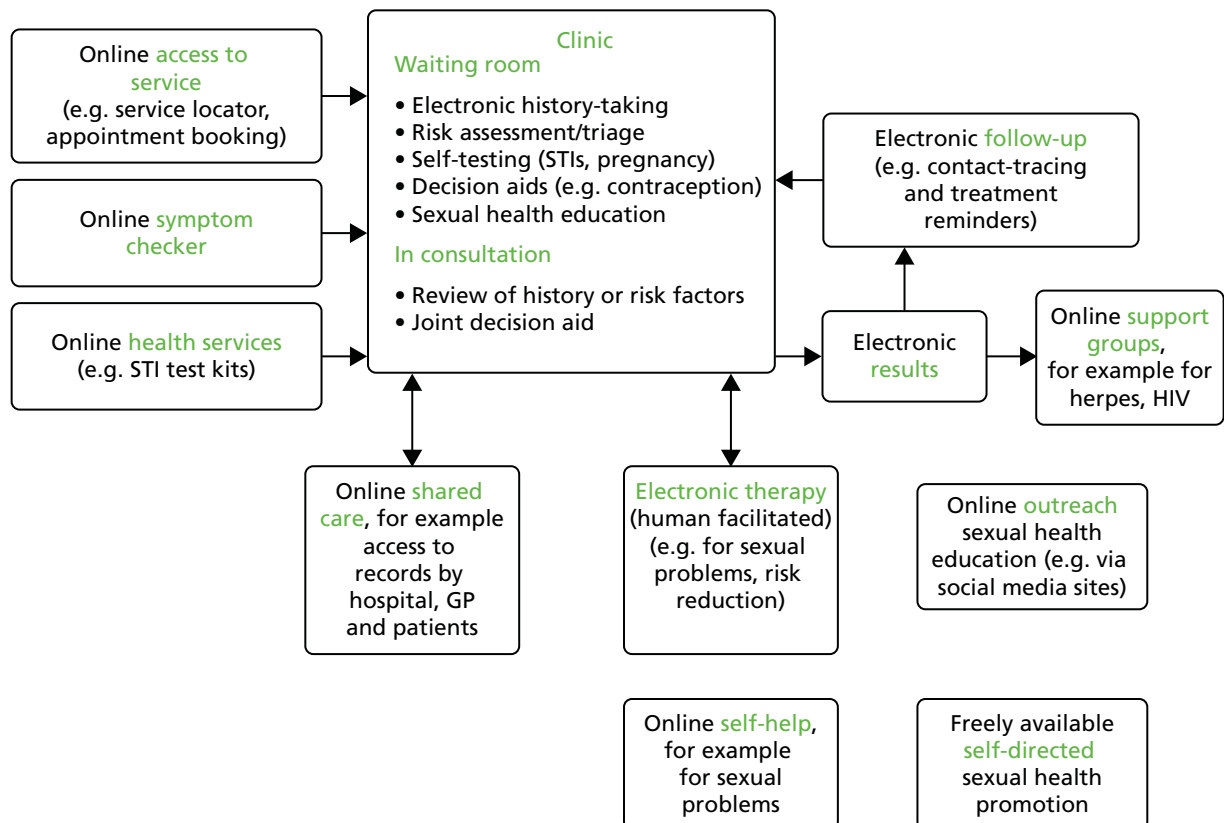


FIGURE 1 Opportunities for digital interventions connected with clinical care.

Tool': www.brook.org.uk/contraception/my-contraception-tool).⁷⁷ Clinician IT systems may also provide links to patient information, which can be passed on to particular client groups.

Digital media (especially mobile phones) can also be used for medication adherence, for example to remind people to take HIV medication⁷⁸ or the contraceptive pill.^{79–81} Text messages or voice messages via mobile phone can be used to support contraceptive choice, uptake and adherence.^{82–84}

Shared **online clinical records** and **online medical consultation** or therapy have not so far been widely available within the NHS, partly because of concerns about confidentiality, data security and medical indemnity for services provided outside routine NHS pathways of care. In contrast, the private sector offers many paid-for services online, including medical advice by e-mail and diagnosis, although these services may disclaim responsibility for the accuracy of information or diagnoses. Online 'Q&A' forums can offer an avenue for advice on sexual problems (e.g. the BASHH 'Health Unlocked' forum at <https://healthunlocked.com/#bashh>).

Digital interventions for **sexual health promotion** may encourage people to use sexual health services, for example text messages to promote STI testing,^{76,85–87} to increase discussion of sexual health with a health-care professional⁸⁷ or to enhance the successful treatment of STIs.⁸⁸ Mobile phones and websites are also feasible ways to reach young people to encourage the use of condoms for safer sex.^{87,89–91}

Online outreach by health educators on social networking sites can target particular populations, such as young people⁹² or MSM, and national health promotion campaigns often have online components (e.g. www.facebook.com/NationalHivTestingWeek).

There are, therefore, a wide range of interventions which can facilitate convenient access to elements of sexual health services or which are designed to enhance aspects of care (such as adherence to medication). However, such digital innovations for sexual health are deployed to a variable extent across the UK, and most innovations associated with health services are designed to enhance the treatment of health problems rather than to address the prevention of sexual ill health.⁵⁶

Digital media interventions in schools

Figure 2 gives examples of the ways in which sexual health information can be communicated digitally before, during, after or separately from school lessons.

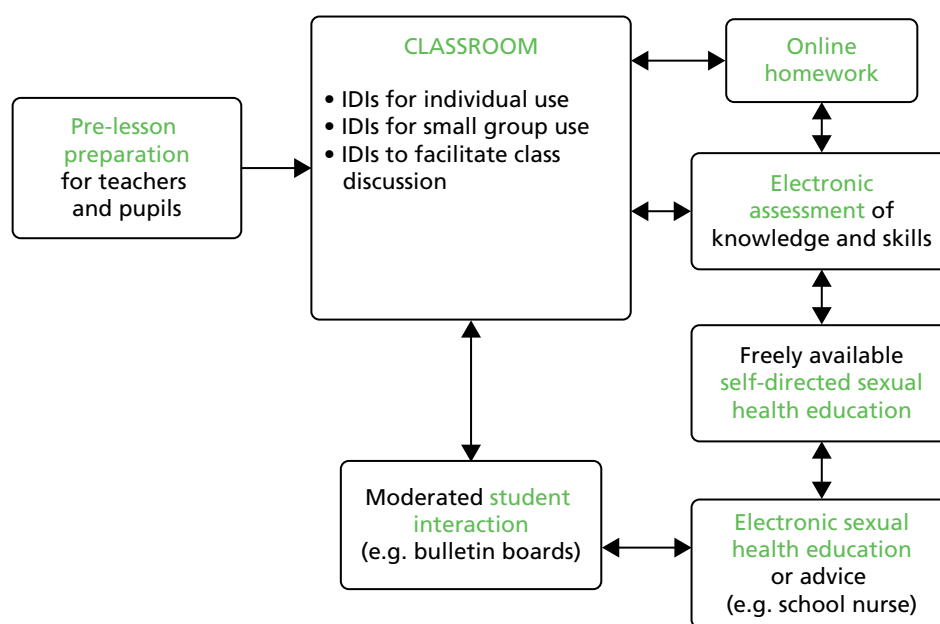


FIGURE 2 Opportunities for digital interventions in schools.

In schools, there are opportunities for digital interventions either in or out of the classroom: IDIs can be self-directed⁹³ or teacher-facilitated during lessons.⁹⁴ Many schools have IT systems which could be used to broadcast health promotion messages on whiteboards or to pupils' phones, for example.⁷¹ Schools may also use online programmes for learning and submitting schoolwork, and could allow access to health promotion interventions from home within these systems, with the use of passwords ensuring access to appropriate content. There are also online sexual health resources for schoolteachers, which could help to address some of teachers' embarrassment or reservations about teaching SRE.

Summary: opportunities for digital interventions for sexual health

There are many possibilities for digital media interventions in clinics or schools (and online), but most of the currently available innovations either do not provide tailored advice or help or are costly in terms of health service staff or health educators. However, self-directed, tailored programmes could be offered in conjunction with other types of digital communications or health tools which are already available and in use.

Why this review now?

Sexual ill-health incurs high social and economic costs⁹⁵ and we need new, effective, cost-effective and engaging interventions which appeal to young people. As young people are 'digital natives', IDIs could be very important modes of delivery for sexual health promotion.⁹⁶ In the UK there are particular contexts which facilitate opportunities for digital interventions for (sexual) health: the widespread and increasing availability of fast and mobile internet, imaginative digital innovations, increasing pressure on health services and on health budgets and the opening up of health-care provision to private (technology) companies.

We have chosen to focus this review to consider sexual health promotion for young people aged 13 to 24 years, as they are at risk of poor sexual health and are frequent and confident users of technology. We focus on the effectiveness and potential of IDIs for sexual health promotion for young people in the UK, particularly IDIs for self-guided use, as these represent the largest potential for low-cost dissemination. In this review we scope and appraise available evidence on effectiveness and cost-effectiveness of IDIs for sexual health,⁹⁷ how best to design, develop and implement interventions⁹⁸ and how best to evaluate them.⁹⁹ We assess the future potential for IDIs for sexual health to guide strategic investment in research, development and implementation in the UK.

Key points

- Being able to have a safe and pleasurable sexual life is central to sexual well-being.
- Young people are at higher risk of STI than older age groups and a high proportion are not protected from unwanted pregnancy.
- Particular subgroups of young people are at higher risk of sexual ill health (e.g. MSM, those in care, drug-using youths, some ethnic minority groups and LGBT young people).
- Comprehensive sex and relationship education is not compulsory in all UK schools, provision varies hugely and parents can withdraw their children from SRE programmes.
- Access to IT in schools is variable.
- Young people value advice from clinicians, but traditional (face-to-face) sexual health care is not meeting young people's sexual health needs, as young people can find it hard to access services, clinicians may lack confidence and health services are under great pressure.
- Young people are 'digital natives', with access to the internet and mobile phones totally integral to their intellectual and social lives.
- There is a wealth of sexual health information available online, and young people are keen to access sexual health resources online.

- There is a policy commitment in the UK to encourage self-care for the prevention and management of health conditions, and digital interventions could facilitate this at a lower cost than face-to-face services.
- Many clinics are using digital interventions to enhance services (e.g. symptom checkers, service locators, appointment booking and digital results and reminders).
- Sexual health services and health promotion initiatives (both digital and face to face) are commissioned locally rather than nationally, and the quality and type of provision varies.
- There are a variety of digital interventions for sexual health promotion which mostly target particular groups (e.g. online sexual health education for MSM and online support groups for those with HIV or herpes).
- There are concerns about young people's safety online and the possible adverse effects of some online content or activities (e.g. grooming, shaming, sexual pressure, impacts on confidence and satisfaction with bodies, sex and relationships).
- Interactive digital interventions have the potential to provide a cost-effective avenue for sexual health promotion which appeals to young people.

Chapter 2 Scoping review methodology

In this chapter we give an overview and details of the methodology that we used to conduct this scoping review. The work comprises a review of literature to find, appraise and synthesise available evidence on digital interventions for sexual health for young people, integrating the findings with key informant views (both professional and lay) (Figure 3).

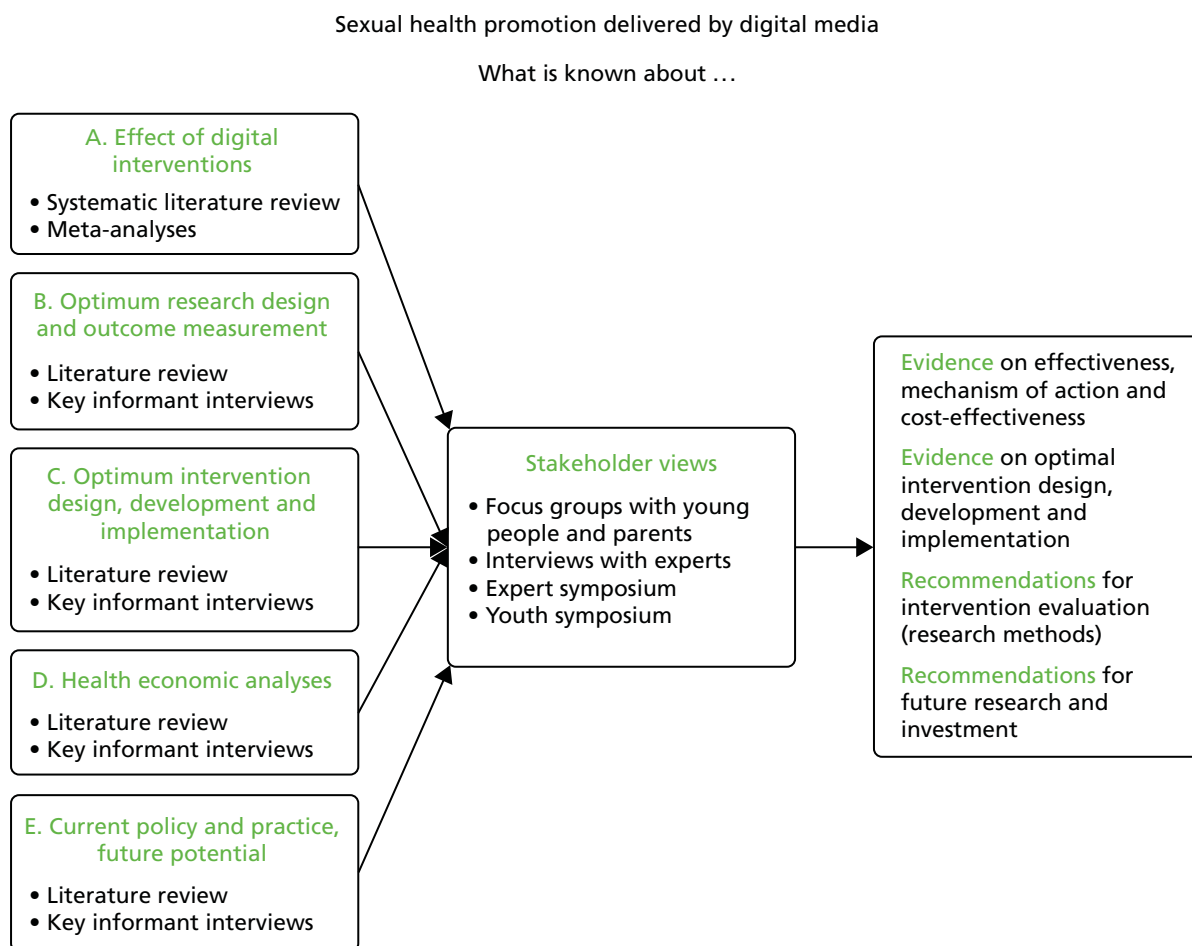


FIGURE 3 Overview of scoping review study design.

Scoping review objectives

- To appraise and synthesise evidence on effectiveness, cost-effectiveness and mechanism of action of digital interventions for sexual health.
- To determine optimal practice for intervention development and identify 'front-running' interventions.
- To appraise and synthesise evidence on contexts for the successful implementation of digital interventions for sexual health.
- To determine the optimal research methods for digital interventions evaluation.
- To provide evidence-based pointers for local and national policy in relation to the adoption and implementation of digital interventions for sexual health.
- To scope the future potential of sexual health promotion by digital media.

Definitions

Definition of sexual health and sexual health promotion

Interventions included in this review were those designed to promote sexual health, defining sexual health promotion as providing individuals, groups and communities with tools to make informed decisions about their sexual well-being. Sexual well-being/sexual health can be thought of as

a state of physical, emotional, mental and social well-being in relation to sexuality [...] Sexual health requires a positive and respectful approach to sexuality and sexual relationships, as well as the possibility of having pleasurable and safe sexual experiences, free of coercion, discrimination and violence.⁵

Definition of interactive digital interventions

Digital media comprises technology such as the computer and the internet, mobile phone, compact disc, video, games and interactive television. Any of these modes of delivery may be used for sexual health education. We used the following definition of IDIs: **digital media programmes** that provide **sexual health information** and one or more of **decision support, behaviour-change support** and **emotional support for health issues**.⁹⁷ Programmes must be '**interactive**', meaning packages that require contributions from users (e.g. entering personal data, making choices) which alter pathways within programmes to produce feedback that is personally relevant to users of the programme. Users may interact with programmes as members of a small group, as well as individually. Our main focus of interest is standalone IDIs accessed directly by users and not composite IDIs which have face-to-face elements as part of their mechanism of action (e.g. input from teachers or health professionals).

Overview of scoping review study design

Focused review literature search

We conducted a **focused review of the literature** on IDIs for sexual health, focusing on **all types of evidence** concerning young people, sexual health and digital interventions in high-income countries over the past 10 years. Particularly where evidence was thin, we also drew on evidence from other (low-income) countries, other age groups, other health conditions and digital interventions that did not strictly meet the definition of 'interactive digital intervention'. We term such interventions 'digital interventions'.

Cochrane literature review

We conducted a separate (but overlapping) **systematic review of the literature** in order to update the Cochrane review 'Computer-based interventions for sexual health promotion',⁹⁷ selecting randomised controlled trials (RCTs) of IDIs for sexual health promotion and extracting and synthesising data in meta-analyses where appropriate. The inclusion criteria for these two literature searches were slightly different (*Table 1*).

TABLE 1 Inclusion criteria for focused review and Cochrane review literature searches

| Inclusion criteria | Focused review | Cochrane review update |
|--------------------|--|---|
| Aims | To map and assess all types of evidence on the topic of digital media interventions for sexual health promotion for young people | To assess the effectiveness, cost-effectiveness and mechanism of action of IDIs for sexual health promotion |
| Target population | Young people aged 13–24 years | Any age |
| Setting | Developed countries (OECD) | Any country |
| Search focus | All types of evidence on digital media and sexual health | RCTs and economic analyses of IDIs for sexual health |
| Timeline | 2002 to April 2013 | 2007 to April 2013 |

OECD, Organisation for Economic Co-operation and Development.

Patient and public involvement

We set up a project user panel of young people aged 16–24 years. The panel members (two male and one female) had previously used the internet for sexual health advice or information, or had previously attended a sexual health clinic. They were recruited via posters and pamphlets put up in three London sexual health clinics and via e-mail sent to Sexpression, a network of students in UK universities involved with SRE. They attended project meetings and received £30 per session of approximately 1–2 hours (including preparation time), and were reimbursed for their travel. Panel members commented on the acceptability of the proposed study procedures and the clarity and language used in research materials such as topic guides and information leaflets. They also helped with the recruitment of young people to focus group discussions by informing young people from their social network about the study. One panel member also commented on the clarity and content of a summary document for circulation to the public.

Focused review methodology

Target population and setting

The target population for this scoping review is young people aged 13–24 years, to include children of school age (to cover sex education in school) as well as those aged 16–24 years (who are at higher risk of STI acquisition and unplanned pregnancy). This review focuses on the impact and potential of digital media for sexual health promotion for young people, focusing on the UK (England, Scotland, Wales and Northern Ireland).

Database searching, selection and categorisation of studies

We searched for all types of evidence on intervention design and implementation, digital research methodology to evaluate IDIs, data on costs, cost-effectiveness and health economic outcomes and future potential for IDIs. We conducted a systematic search of 17 databases, including Cochrane Central Register of Controlled Trials (CENTRAL), Database of Abstracts of Reviews of Effects (DARE), MEDLINE, EMBASE, Cumulative Index to Nursing and Allied Health Literature (CINAHL), British Nursing Index (BNI) and PsycINFO (for a full list of databases, see the Cochrane review⁹⁷). We searched for all types of evidence, that is quantitative evidence, qualitative evidence, theoretical papers, health economic analyses and editorials from 2002 to 2013 (April), which addressed sexual health and IDIs according to the definitions of the concepts specified above. A 10-year period was chosen because technological advances and patterns of use of digital technology change rapidly, rendering earlier interventions less relevant to future health promotion. We included only those studies that were published in English, owing to the cost and time involved in translating materials.

A total of 17,802 unique citations were identified. SW downloaded all of the citations identified by the search into Reference Manager software (Thomson ResearchSoft, San Francisco, CA, USA). Ten per cent of the titles and abstracts were independently double screened by three researchers (SW, SM and Salmaan Khan) as a quality check to establish concordance in screening of citations. Following this, the three researchers each screened one-third of the whole database to identify eligible studies.

The literature of core interest for the scoping review comprised any type of study concerning IDIs for sexual health promotion for young people in high-income countries. We also considered studies of DIs for sexual health from low-income settings; studies of digital interventions for sexual health which did not meet the definition of IDI; studies reporting research methodology; health economic evaluations of non-DIs or non-sexual health IDIs; and digital interventions for health promotion other than sexual health. These papers were considered supplementary literature.

All of the citations on the Reference Manager database were classified as follows:

- 'unclear' – potentially relevant study (i.e. needs further consideration on reading full text)
- yes, core citation
- yes, supplementary citation
- 'no' – does not meet (above-mentioned) inclusion criteria.

Eligible studies were further classified for their relevance to the research topics of interest:

- A: RCTs of effectiveness of IDIs
- B: research methodology
- C: intervention design, development and implementation
- D: health economic literature
- E: future potential for digital interventions
- R: relevant systematic reviews.

The full text of studies classified as 'yes, core' and 'yes, supplementary' were obtained and read by SW or SM to confirm eligibility and to check the preliminary categorisations. Two researchers screened full texts of papers if there was any doubt about eligibility or categorisation. The results of the search are shown in *Figure 4*.

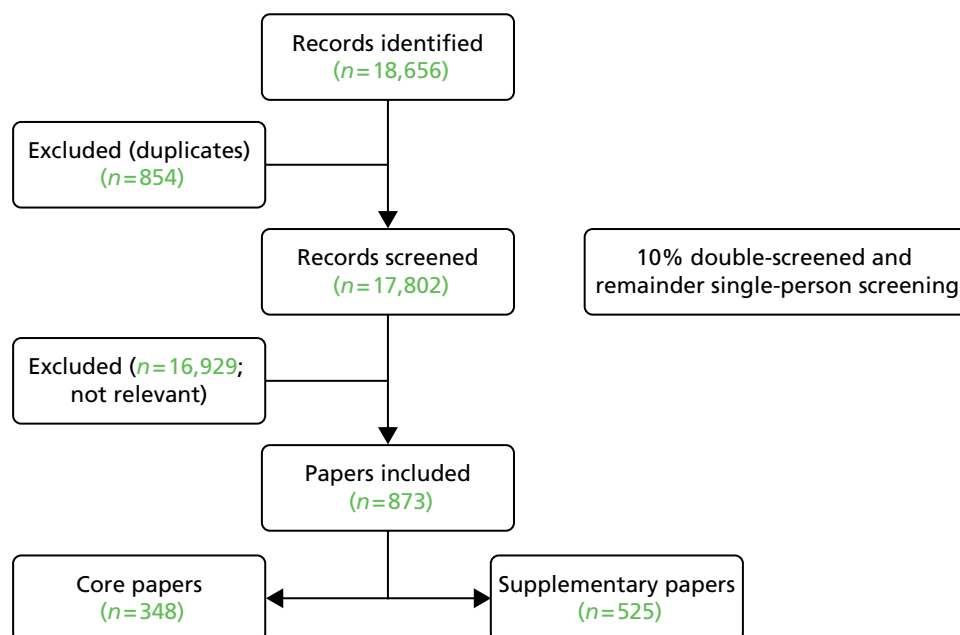


FIGURE 4 Results of searches conducted for the focused review.

Internet search (horizon scanning)

As there can be long delays before the publication of research papers, we conducted a targeted search using the Google search engine (Google Inc., Mountain View, CA, USA) to locate media articles, conference proceedings, web logs (blogs), videos of opinion leaders and interest group discussions for views on the future potential of digital interventions for (sexual) health promotion. As with the focused search, materials of core interest were those concerning young people, digital media and sexual health, but we also collected materials on technological innovations in health fields other than sexual health.

Search for key studies in related fields

To address some of the research questions, we conducted targeted searches for evidence beyond the database of studies on digital/computer-based interventions for sexual health, for example locating key studies on digital interventions in other health promotion fields, such as alcohol, smoking and drug use; sexual behaviour change; human–computer interaction; health economics; and sex education.

Data extraction and analysis

We immersed ourselves in the literature, reading all core and supplementary papers. We extracted data on study characteristics and the key findings of core studies using a Microsoft Excel® sheet (Microsoft Corporation, Redmond, WA, USA), making notes on themes arising from papers. We synthesised the results of RCTs of digital interventions for sexual health promotion, as these provide the best evidence of effectiveness, but did not attempt to synthesise the results of non-randomised quantitative studies. We had planned to conduct a formal meta-synthesis of qualitative themes; however, we identified 873 published papers which were relevant to this scoping review (348 of which were of core relevance in terms of sexual health, digital media and young people) and we also drew on non-peer-reviewed evidence sources, such as online discussion groups and blogs. It was not possible or desirable to formally assess the quality of this number and diversity of sources of evidence. We summarised and synthesised the findings of studies narratively, discussing emergent themes and their significance in the team and with key informants.

We recorded and tabulated details of intervention characteristics, target populations and settings.

We searched for possible ‘front-running’ interventions (i.e. IDIs suitable for implementation in the UK), judging evidence of intervention effectiveness and cost-effectiveness, interventions’ suitability for young people in the UK and the feasibility of implementation in a UK context. We also searched for IDIs which have been developed but have not been evaluated in RCTs, judging their suitability as ‘front running’ according to whether or not they had been designed according to ‘best practice’ principles (see *Chapter 3*). We judged interventions by (a) whether or not they had a clear theoretical underpinning, including clear proposed mechanisms of behaviour change reflected in the content design, and (b) whether or not intervention content was likely to address users’ needs (i.e. users were involved in intervention development in a meaningful way).

We developed a facility for intervention developers or researchers to make details of digital interventions publicly available in a searchable database located on the Sexual Health Research Network website (www.sexualhealthnetwork.org.uk). The database summarises the key characteristics of the IDIs that we located, with details of authors or developers, interventions themselves (if available) and links to any available evaluations.

Cochrane literature review methodology

Types of studies included and timeline

We conducted a systematic literature search to locate published and unpublished RCTs which test the effectiveness and mechanism of action of IDIs for sexual health promotion. This work entailed updating the previous Cochrane review,⁹⁷ which has been renamed ‘Interactive digital interventions for sexual health promotion’, to reflect changes in the way that interventions can now be accessed.

We used Cochrane Collaboration methods to search for eligible RCTs, evaluate their quality and extract and synthesise data. Full details of the methodology used for Cochrane review searches and meta-analyses are available in the published review.⁹⁷ In brief, we updated our comprehensive search strategy, adding new relevant search terms which capture changes in terminology within the e-health field. We searched electronic databases (including CENTRAL, DARE, MEDLINE, EMBASE, CINAHL, BNI and PsycINFO), databases of grey literature for unpublished work, trials registers and reference lists of published studies, and contacted study authors. We had no language restrictions. Details of the full search strategy are available as appendices to the Cochrane review⁹⁷ and on request from the authors. To update the previous review, we ran the search from 2007 to April 2013, locating 15,655 unique citations concerning digital media and sexual health.

Cochrane review inclusion and exclusion criteria

We drew on the definitions of sexual health and IDIs as for the focused review, selecting only RCTs of IDIs for sexual health which exactly met these definitions. We included RCTs of the following types of study:

- IDIs compared with minimal exposure (e.g. usual practice or waiting list) or non-interactive forms of education (e.g. written information, non-interactive computer packages)
- IDIs compared with face-to-face sexual health educational sessions
- studies that compared two or more types of IDI, in order to compare the effects of different designs of intervention
- any type of economic evaluation of IDIs.

Citation screening and data extraction

SW downloaded all the citations identified by the search into Reference Manager software and deleted duplicate references. Two review authors (JB and SW) independently screened all citations, obtained and appraised the full texts of any candidate papers and extracted data using the Cochrane Consumers and Communication Review Group data extraction pro forma.⁹⁷ Study authors were contacted to clarify questions about study methodology and to obtain missing data. The quality of RCTs was judged using the methods recommended by the Cochrane Collaboration. Information about study and intervention characteristics, risk of bias and numerical outcome data were entered into Review Manager software (Cochrane, The Nordic Cochrane Centre, Copenhagen, Denmark), double-checking the accuracy of data entered.

Data analysis

We analysed and present separately the results for studies that compare IDIs with minimal intervention (group 1), those that compare IDIs with face-to-face sexual health education (group 2) and those that compare two or more different designs of IDI (group 3). Separate meta-analyses were conducted for type of outcome (cognitive, behavioural, biological or economic), selecting outcomes to combine using concepts derived from a theoretical pathway for sexual behaviour change¹⁰⁰ (including sexual health knowledge, self-efficacy, intention/motivation, sexual behaviour and biological outcomes). In the full Cochrane review, we present the results of data syntheses for studies involving any age group and setting. In this review, we present the results of data syntheses for RCTs of IDIs for sexual health involving young people (< 25 years of age) in high-income settings only.

Health economic analyses: methodology

In addition to the databases listed above, we searched health economics databases, including EconLit, NHS Economic Evaluation Database (NHS EED), Cost-effectiveness Analysis Registry, Econpapers, Public Health Interventions Cost-effectiveness Database and The Tufts University Library on Quality of Life, to locate evidence on costs, cost-effectiveness and health economic outcomes of digital interventions for sexual health promotion, encompassing sexual health and digital/computer-based interventions. Papers were assessed against the Drummond *et al.*¹⁰¹ checklist for assessing economic evaluations. Two researchers

(RH and SW) assessed the papers for eligibility. Data were extracted and recorded on costs, consequences, perspective and presentation of uncertainty for each paper identified. We commented on areas of uncertainty or controversy in relation to measuring and collecting costs and consequences for economic evaluations of digital interventions.

Key informants' views

Interviews and focus groups with professional experts and stakeholders

We purposively selected stakeholders who were sexual health youth workers, e-health or sexual health researchers, clinicians, educationalists, policy-makers, intervention developers and digital technology and media experts nationally and internationally. We searched online to map e-health expertise in the UK, and selected expert key informants on the basis of information about their expertise which was available in the public domain (e.g. organisations' or academic websites or contributions to online debates). We selected stakeholders on the basis of their professional position, experience and expertise.¹⁰² We made contact by e-mail initially and sought permission to interview either face to face or by telephone, using semistructured topic guides to seek their views on digital intervention design, development, evaluation, implementation, health economic issues, digital research methodologies and future potential of digital interventions for sexual health. We conducted a total of 28 interviews with expert, professional stakeholders, including e-health and sexual health researchers, policy-makers, educationalists and software developers and digital media experts. We also conducted a workshop on digital media for sexual health promotion, attended by sexual health nurses, teachers and young people from across the UK, and a focus group with researchers working in e-health research (sexual health, alcohol harm reduction, diabetes and other health conditions) (see *Appendix 1*).

Focus groups with young people and parents

We conducted six focus groups with young people between the ages of 13 and 24 years to seek their views on their use of technology, the usefulness of digital interventions for sexual health promotion and future potential. We also conducted a focus group discussion with parents of young people to seek their views on the use of digital interventions for sexual health promotion for young people in schools and other settings. We used semistructured topic guides to seek young people's and parents' views on the role and potential of digitally mediated sexual health information, the design and delivery of digital interventions for sexual health promotion and future potential.

We recruited 42 young people to participate in six focus groups. We sampled purposively by age [young people aged 13–15 years ($n = 21$); 16–19 years ($n = 12$); and 20–24 years ($n = 9$)] and by gender (22 female and 20 male). We recruited the younger age groups (13–15 years) from schools, with the help of teachers. Those aged 16–24 years were recruited from a college by handing out flyers about the research with the help of a sexual health outreach worker and college staff, and via Twitter (Twitter Inc., San Francisco, CA, USA) and snowball techniques (with young people asking their friends). School staff sought consent from the parents of school children in advance. Focus groups were conducted in school/college settings or on University College London premises. All participants were recruited from London. Participants were from different ethnicities, with an equal representation of young people from white backgrounds and non-white backgrounds. Participants were offered a cash incentive of £15 for participating in focus groups.

We held a focus group with parents of teenagers, recruited with the help of schoolteachers ($n = 9$: one male and eight female parents). All participants provided written consent prior to the discussion and received a small token of gratitude for their time and contributions (£15).

Expert symposium

We held an expert symposium with 21 participants (including e-health and sexual health researchers, policy-makers, educationalists and software developers) to discuss areas of controversy concerning intervention design, development and implementation, health economics, digital research methodologies and the place and future potential for digital interventions for sexual health promotion (see *Appendix 1*).

We integrated stakeholder perspectives (young people's, parents' and experts' views) with the findings from our literature review, producing a draft report of findings to circulate to expert symposium participants in advance.

Delegates were asked to:

- comment on and debate emergent findings (the draft scoping review report)
- debate contentious topics and clarify the reasons for lack of consensus
- make recommendations for investment and implementation where there is strong evidence for the effectiveness of interventions
- make recommendations on future research needed to resolve uncertainties on optimal methods for intervention evaluation
- make recommendations on future research needed to resolve uncertainties on the effectiveness and mechanism of action of interventions and effects on health inequalities
- make recommendations for the integration of digital interventions with current sexual health promotion policy and practice in the UK
- make recommendations for the integration of digital interventions with current practice in schools and health-care settings in the UK
- comment on the implications of digital intervention implementation for training and skill development (of researchers, educationalists, health-care workers and young people)
- make recommendations on commissioning priorities
- comment on the future potential for digital interventions for sexual health promotion in the UK
- generate 'blue-sky' innovative ideas to set an agenda for possible future research and development.

Youth symposium

We held a young people's symposium with 23 participants to gather young people's views on sexual health IDI design, aims, targeting and implementation in schools, clinics and online. We recruited young people aged 16–24 years from sixth-form colleges by handing out flyers about the research with the help of a sexual health outreach worker and college staff, and via Twitter and snowball techniques. Twenty-three young people participated in this symposium (see *Appendix 1*). Of these 23 participants, three were recruited via Twitter (i.e. they saw the Twitter feed and contacted the researcher organising the symposium), seven had previously participated in a focus group discussion, one was a user panel member, five were recruited through snowballing and eight were recruited with the help of the college staff. The majority of the symposium participants ($n = 15$) were male and eight were female. Participants were predominantly from non-white backgrounds. They were offered £40 for participation in the half-day symposium. We invited young people to debate the following topics and to make recommendations for intervention design, development and implementation:

- the role of IDIs for sexual health for young people online
- the role of IDIs for sexual health for young people in schools
- the role of IDIs for sexual health for young people in health-care settings
- the future potential of digital interventions for sexual health promotion in the UK
- generation of 'blue-sky' innovative ideas to set an agenda for possible future research and development.

Qualitative data analysis

All focus group discussions and key informant interviews were audio-recorded with participants' permission and transcribed by a professional transcriber. All the transcripts were imported into NVivo 10 (QSR International, Warrington, UK) and were thematically analysed. SW identified emergent themes and developed a coding framework, which was revised in discussion with other members of the research team. We discussed emergent themes in research team 'findings groups' to refine the scope of our topic guides as the project progressed. We compared and contrasted themes within and across data sets.

Group discussions at the expert symposium were audio-taped with participants' permission and delegates were also invited to write down their views. Notes were made from the audio tape, summarising key themes. Experts' and young people's views were used to supplement evidence from the literature review, particularly for topics which are not well covered in academic literature, such as, for example, the realities of young people's lives or of professionals' work, or political contexts.

Prioritisation of recommendations

We had planned to conduct an online consensus process to prioritise sets of recommendations for investment in future research, development and implementation. However, we did not find areas of major disagreement or contention, either between or among expert stakeholders and young people, and so we did not conduct an online consensus process or invite debate on Twitter to help to prioritise sets of key recommendations. Different organisations will wish to make funding decisions based on local contexts or priorities (e.g. taking into account particular at-risk groups or particular clinical settings). We decided, therefore, that it was not useful to try to generate overall orders of priority for our recommendations.

Ethics committee permission

Ethical committee permission for qualitative fieldwork (consultation with young people and parents) was obtained from the University College London ethics committee, reference 2948/002.

Chapter 3 Considerations for the design and development of interventions

In this chapter we summarise the evidence from the literature and key informants about best practice in the design and development of sexual health promotion IDIs. We consider each stage in the process, from identifying the behaviour-change aims, defining the target population and selecting Behaviour-Change Theories and techniques to designing the product.

Chapter aims

- To summarise the literature about the design and development of IDIs for sexual health promotion and propose best practice.
- To discuss mechanisms of action and propose how Behaviour-Change Theory and techniques should be incorporated into intervention design.
- To identify barriers and facilitators to the successful design and development of interventions.

Chapter-specific methodology

We included both qualitative and quantitative studies from the literature, as well as descriptive pieces and text from non-peer reviewed sources for this chapter. We noted and described the elements relevant for design and development of interventions from each paper through narrative review.¹⁰³ We triangulated our findings from the literature with qualitative data from interviews, focus groups and expert symposia. The coding of content, identification of themes and descriptive analysis of the qualitative data was undertaken and related to the literature and especially to the intervention mapping (IM) framework.¹⁰⁴ This framework sets out stages and processes involved in the design, development, implementation and evaluation of evidence-based health promotion interventions. It has been used to develop and evaluate a range of sexual health interventions that have been found to be effective and have been widely implemented.^{105–108} The steps in IM can be summarised as follows, although in practice this is a non-linear and iterative process with different stages occurring concurrently:

- Conduct a **needs assessment** in order to assess important behavioural target areas and risk groups.
- Clarify the programme objectives through identifying desired **behavioural outcomes, determinants** of those behaviours (i.e. the modifiable mechanisms that regulate those behaviours) and thereby specify measurable **change objectives**.
- Using a range of methods and strategies clarify **user perspectives**, identify appropriate **change techniques** and design practical strategies to deliver change techniques in a manner that optimises engagement and impact for the target audience in context.
- **Develop the intervention** through design of materials in accordance with objectives.
- **Assess contexts for implementation** and refine intervention through pilot testing with recipients and implementers.
- **Identify the contexts and determinants of successful adoption**, implementation and sustainability and develop appropriate implementation strategies.
- Design appropriate process and outcome evaluations.

We present a narrative summary of our findings in relation to this framework. Some interventions that illustrate elements of this narrative are described in more depth (see text boxes) where appropriate.

Scope of the literature

Studies that contributed to our current understanding of best practice in intervention design for sexual health promotion IDIs for young people incorporated a range of both qualitative and quantitative designs, as well as descriptive papers. We drew on the literature across the following categories:

- effectiveness studies of any designs, incorporating those included and not included in the systematic review
- studies of the preferred use of different technologies by young people, their main sexual health concerns and how different platforms are used by young people to find sexual health information that they need
- evaluations that identify factors associated with and that may be used for quality assessment of existing sexual health resources for young people
- user and expert views undertaken prior to development or as part of formative evaluation to inform the design and development of particular interventions
- descriptive papers relating to processes in intervention design and development, including concept development, description of theoretical constructs, operationalisation, prototype development and formative and process evaluation.

We reviewed a diverse range of evidence of variable quality. For many sources of evidence, formal assessment of quality was not appropriate (e.g. ideas discussed in online discussion forums). We did not conduct formal quality appraisal, in order to preserve a broad focus on relevant issues and to cover the full scope of this field across a variety of disciplines.

Results

Needs assessment

A needs assessment should be conducted at the outset of intervention development to identify epidemiological need and particular target populations and behaviours to be addressed. There is a pressing need to design interventions that are effective in responding to the high rates of STIs, acquisition of HIV and unintended pregnancies. A number of IDIs designed to improve the sexual health of young people were identified in this review. However, almost all were developed outside the UK (mainly in the USA), which limits their external validity. We identified only one digital intervention for young people that has been developed and evaluated in the UK (Sexunzipped).^{39,109}

Target behaviours

Despite the policy and cultural shift away from traditional biomedical models of sexual health, sexual health promotion IDIs (both evaluated and unevaluated) remain largely focused on behavioural change for HIV and/or STI prevention.^{67,68,110–115} Interventions that mainly target prevention of unintended pregnancy were identified less frequently, even in examples of interventions in which the target population was female.^{67,68,113,116} However, there are good examples of IDIs that take a combined approach to STIs/HIV and pregnancy prevention,^{109,117,118} in keeping with integration as a sexual health policy and practice priority throughout the UK.^{4,57}

Integrated sexual health provision remains poorly defined in both policy and practice. It is usually understood to mean the combined provision of genitourinary medicine and contraception services, variably incorporating prevention, health promotion, sexual dysfunction, sexual coercion and sexual violence, as well as cofactors for sexual risk such as alcohol, substance misuse and mental health. Among sexual health promotion IDIs, this variation is mirrored, with some interventions targeting a relatively narrow and well-defined area of sexual health^{113,119} and a (limited) number of examples of IDIs taking a broader and more integrated approach.^{109,120} Although not necessarily seeking to change multiple behaviours, addressing wider information needs and preferences ('wants') as well as behavioural needs ('needs') is more likely to maximise engagement with interventions, but it is more of a challenge for design (interview, e-health researcher) (see also *Chapter 6*). There are few examples of interventions that address health needs more widely and there is an apparent mismatch between what is being provided and the desires of young people for this broader approach (*Box 1* gives examples of broader approaches).

BOX 1 Broader approaches to sexual well-being

Sexunzipped is a UK-developed, self-delivered internet intervention that addresses three different areas: relationships, sexual pleasure and safer sex.¹⁰⁹ The intervention aimed to take a holistic view of sex and relationships (responding to the findings of the formative research with young people, and what they say they would like).³⁹ It also draws on evidence that suggests that a focus on sexual pleasure may facilitate safer sex behaviour,¹²¹ and is based on the well-being approach to sexual health that underpins the World Health Organization's framework for sexual health promotion.⁵

Health4Uth was developed in the Netherlands and is an internet intervention designed to be delivered to 12- to 18-year-olds in schools over a 45-minute session.¹²⁰ It is primarily a mental health intervention but targets other risk behaviours, such as alcohol and smoking, as well as sexual risk. Participants answer a self-delivered health risk and health well-being questionnaire. Messages tailored to the questionnaire answers are then fed back to the user. Links to websites giving more information on the topics covered are also provided, as well as the opportunity for health-care follow-up.

Target populations

Young people are a high-risk group for poor sexual health outcomes,^{9,10} although sexual behaviours and health needs vary widely across different age bands, genders, ethnicity, marital status, education and socioeconomic backgrounds.^{9,16,122} Certain defined subpopulations are known to be at particular risk, including MSM, some black and minority ethnic (BME) groups, teenagers post-pregnancy and looked-after young people. These subpopulations may also be harder to engage in face-to-face interventions and are, therefore, potentially suited to a targeted online intervention.

Young people are not a homogeneous group and their varying needs both *between* and *within* subpopulations should be taken into consideration in the design and evaluation of IDIs. For example, young black MSM report that they did not receive enough information about gay sexuality when they were growing up and that messages about sexual health are often fear-based rather than promoting lifestyle choices.¹²³ A study comparing younger and older groups of adolescents showed the need to segment interventions by age. Younger groups more commonly sought information about puberty, while older adolescents were more likely to focus on STIs and pregnancy risk.¹²⁴ Different design features as well as content can also draw particular target groups, such as the use of avatars designed to appeal to a younger audience.¹²⁵ Ensuring that the intervention is tailored to the target group while recognising heterogeneity and remaining widely relevant is an inherent design tension. In practice there may be a trade-off between meeting the 'niche' needs of a target population and maximising breadth and reach of the intervention. Good promotional strategies may be the best mechanism for reaching the target group, rather than an overfocus on targeted content. We identified both interventions targeted at young people overall and interventions aimed at particular subgroups of young people. These include interventions targeting young women,^{67,68,113,116} young men,¹²⁶ African Americans,¹¹⁵ younger and/or older age groups,^{67,125} rural youth,¹¹⁷ MSM,^{70,114} substance misusers,¹²⁷ young people with HIV¹¹⁸ and young women with diabetes.¹²⁸ These interventions are closely tailored to the specific needs of the group (*Box 2* gives examples of intervention targeting).

Some population subgroups among young people who may be at higher risk of poor outcomes are relatively poorly served by sexual health promotion IDIs. For example, interventions aimed specifically at young people with a previous unintended pregnancy (abortion or teenage pregnancy), people who have experienced sexual or domestic violence or people for whom the consequences of poor outcomes may be magnified, such as looked-after young people or those with learning disabilities, were not identified in the

BOX 2 Targeting specific populations**Targeted intervention for men who have sex with men: Bowen¹¹⁹**

Rural MSM in the USA have been identified as a group who are isolated from services, who are frequently more stigmatised than their urban counterparts¹²⁹ and who use the internet regularly to meet sexual partners.¹³⁰ A targeted intervention aimed at this group (all ages rather than just younger age groups) was developed in the USA and demonstrated evidence of effectiveness.¹¹⁹ The content and format were initially developed following focus group discussions with potential users and guided by SCT. Content was interactive and included information provision about HIV/AIDS through conversations about living with HIV and discussions about methods for risk reduction between peers. It was delivered as two modules, with a maximum of 7 days between modules, and MSM were recruited to the trial face to face or via internet banners at a popular website. Significant changes in knowledge and attitudes of participants measured over 1 week were seen, although there was insufficient time to measure impacts on behaviour change. Participants also showed high levels of completion and acceptability of the study. In this case, recruitment techniques and inclusion criteria were limited to rural MSM to ensure that participants were all from the target population.

Targeted intervention for younger adolescents: Tortolero⁹⁴

Keep It Real was targeted for younger adolescents pre sexual initiation, building in content about puberty and substance misuse, particularly for young people, as well as general skills building with an overarching goal of delaying sexual initiation. Activities such as peer videos, 'real-world'-style teen series and quizzes were tailored according to sexual experience and gender. Material was also staged for seventh- (12- to 13-year-olds) and then eighth-graders (13- to 14-year-olds), with one building on the other.

SCT, Social Cognitive Theory.

literature. These groups, who are also likely to be less well served by sexual health services, may be among those likely to benefit from IDIs. Examples from practice suggest that work to understand the needs of vulnerable populations, their barriers to accessing sexual health services and difficulties in discussing their concerns, and how IDIs may play a role is already under way in some sectors (interview, voluntary sector provider). However, there is a dearth of published literature in this area.

Planning strategies for reaching the target population are integral to the early stages of intervention design and development.¹³¹ Multiple strategies can be used, including tailoring intervention design, content and delivery mode to the specific identified needs of the group at the outset,³⁹ as well as considering the methods for implementation in the target setting that are likely to optimise reach for the particular group. The potential to adapt existing interventions that work for different target groups or settings (rather than starting intervention development from scratch) has not been well explored. Formative work would be required to identify the active components of an intervention (including change techniques and modes of delivery that may be effective for one audience but not another) so that the content of a successful intervention can be effectively 'translated' from one cultural context¹³² or one target audience to another.¹³³

Use of Behaviour-Change Theory

Assessment of behaviour-change needs

After conducting needs assessment, the desired behaviour-change outcomes and target behaviours for the interventions can be more clearly defined.¹³¹ Selecting change outcomes and using Behaviour Theory to identify the modifiable determinants of the relevant behaviours and the appropriate behaviour-change techniques (BCTs) is associated with greater intervention effectiveness.⁹⁸ Virtually all studies cite the use of theory in their design and development, but there is a lack of explicit detail about the underlying rationale for application of particular theoretical constructs and how the identification of regulatory mechanisms is linked to the selection of particular change techniques.¹³⁴ The IM approach^{104,135} stipulates that needs assessment should guide the identification of (1) modifiable and measurable behaviour-change targets and (2) the regulatory mechanisms or determinants of such behaviours. This allows designers to create logic models for their interventions that can guide the selection of change techniques capable of changing the particular mechanisms underpinning behavioural regulation and change (be these increasing information, developing motivation, learning new behavioural skills or rehearsing behaviours to create new habits).^{104,135} User consultation and cocreation helps to ensure that selected change techniques are delivered and operationalised in a way that is meaningful, engaging and sustainable for users.

Which theory?

A range of different behavioural theories have been selected to underpin sexual health promotion IDIs, including Social Cognitive Theory (SCT),¹³⁶ the Theory of Reasoned Action (TRA), the Theory of Planned Behaviour (TPB)¹³⁷ and Stages of Change (SoC) Theory.¹³⁸ Other models that have been applied include the Intervention-Motivation-Behavioural (IMB) Skills Model,¹³⁹ the Health Belief Model¹⁴⁰ and the Extended Parallel Process Model,¹⁴¹ which uses threat and fear appeal as the proposed mechanism of action. SCT¹⁴² states that the important precursor of safer sexual behaviour is self-efficacy that, in turn, is determined by knowledge, peer norms and outcome expectancies. The TRA states that intention is important, which is a combination of attitude to the behaviour and subjective norms. The SoC Model has also been applied to intervention design.^{143,144} This centres on the idea that behaviours occur along a continuum and may require different risk reduction messages in order to shift from one stage of behaviour to the next.

In reality, the theories that underpin design of these interventions are conceptually overlapping.¹⁴⁵ In most cases, there is little detail given in the literature about how or why a particular theory was selected and how this is translated into the important behavioural determinants for reducing behavioural risk. Some models have been developed to provide a framework for the development of sexual health interventions. For example, the IMB Skills Model¹⁴⁶ includes many of the modifiable determinants specified by SCT and TRA. The IMB has provided the basis for development of safer sex interventions designed to target modifiable determinants specified by the model, including those targeting young people.^{147,148} Albarracín *et al.*¹³³ show how change techniques specified by such theories, including IMB, can enhance the effectiveness of condom promotion interventions, but that particular mechanism-based techniques may be effective for one audience but not another. For example, techniques that can alter normative beliefs may be effective in promoting condom use among young people but may reduce intervention effectiveness for older recipients. These authors found that threat-inducing techniques did not enhance condom promotion for any recipient group, suggesting that theories highlighting fear arousal are not helpful to the design of condom use promotion interventions. Similarly, the use of reverse discourse (using more explicit images and terms) has been shown to have a negative effect¹⁴⁹ and the use of humour can risk reducing the credibility of the message.¹⁵⁰

Rational models for behaviour change may be less applicable, however, in the context of sexual health. Sexual behaviour is influenced by impulse and desire, and social discourses about the spontaneous nature of sexual activity mean that, for example, it may be difficult to discuss and plan sex in advance.¹⁵¹ This means that intervention logic models need to include processes that regulate impulsive and habitual behaviour and that designers need to select change techniques that allow recipients to modify such behaviour patterns.

Application of theory

A transparent, explicit and systematic approach to selecting theory for evidence- and theory-informed intervention design is needed. IM suggests that a careful needs assessment, identifying deficits and competencies within a specified target group in relation to desired change in one or more specified behaviour patterns, should determine the selection of relevant mechanisms (and, therefore, useful theoretical models). Ideally, this is based on empirical evidence, including that generated by meta-analyses of intervention effectiveness. Such work can identify which mechanism-based techniques have enhanced intervention effectiveness and for which groups.¹³³

Once relevant mechanisms of change, such as development of positive outcome expectancies, norms and self-efficacy, are identified, change techniques that have been found to successfully alter these mechanisms can be selected for inclusion in the intervention. How those change techniques are delivered will be determined by what is likely to attract and maintain engagement with the target population. Messages conveyed to users need to be attractive and compelling while retaining fidelity to the underlying behavioural mechanisms. Formative research with users identifies their content and design preferences^{39,68} as well as the likely barriers to adopting the desired behaviours.¹⁵² Involving users more directly with developing narratives for fictional characters^{152,153} or inviting young people to provide content, such as film clips, may increase identification with the message source. This is important because the same technique (e.g. a technique to change normative beliefs) may be more or less effective, not only for different groups of recipients¹³³ but for different sources, depending on how recipients view the source. Thus, mechanism-based technique selection and delivery of such techniques must be carefully tailored to the intervention audiences to optimise behaviour-change effectiveness (Box 3 gives examples of studies that describe the application of Behaviour-Change Theory).

BOX 3 Selecting BCTs in practice

Keeping It Safe: Di Noia⁶⁷

This was a relatively small study describing a promising intervention designed to delay the initiation of HIV risk behaviours among adolescent girls aged 11–14 years. The intervention targeted knowledge, protective attitudes (such as peer norms and partner norms) and risk reduction self-efficacy, incorporating strategies that are of proven effectiveness in these target areas for HIV prevention. It is less clear how the needs of the target population were identified and incorporated. The IDI combined didactic information giving with interactive games, storytelling, scenarios and simulations to develop techniques for managing interpersonal communication. The intervention was effective in increasing both knowledge and risk reduction self-efficacy. Despite a lack of detailed description about how target areas were selected, the study exemplifies the use of techniques matched to the target behavioural outcomes, such as self-efficacy and peer norms.

Men's Safer Sex: Webster¹⁵⁴

The Men's Safer Sex website targets the single behaviour of increasing condom use among men attending sexual health clinics. This paper describes the use of the Behaviour Change Wheel to integrate theory into intervention design. The website content and design were based on a literature review of barriers to condom use, and consultation with both experts and users. Initially, the theoretical domains likely to be important for condom use were identified (e.g. barriers to condom use, such as impact on pleasure, and facilitators to condom use, such as positive identity associated with being a condom user). Intervention functions were decided to address target outcomes (e.g. education to target ways to increase pleasure while using condoms) and relevant BCTs selected for each function. BCTs incorporated into the website design were then coded to make sure that they met the criteria as defined by the BCT taxonomy. Users (men) and experts were consulted extensively throughout the development process.

Repeated piloting of early prototype interventions for design, content, language and usability is needed at a stage where refinement without significant cost is still feasible.^{113,123,128} Other useful insights can be generated through this process. For instance, although the majority of young people have access to the internet, they may be limited by download speeds or network coverage, which will shape both the intervention content and where it can be delivered effectively.

Incorporating the views of young people (e.g. a desire for an online expert question and answer session) may be difficult within cost constraints and a rapidly changing digital field.³⁹ However, cocreation is important for developing an effective intervention that resonates with the audience. It is not always clear from study descriptions how the user views have been incorporated within the design process and, in particular, how this has been triangulated with the theory and evidence to ensure the intervention acts on the mediators of the target behaviour. There are limited insights that can, therefore, be drawn for future intervention development.

Effectiveness of behaviour-change techniques

In one of the largest analyses of how intervention design is associated with effectiveness, Albarracín *et al.*¹³³ combined results from studies of 354 HIV-prevention interventions and 99 control groups, spanning 17 years. The results indicated that interventions involving interaction with recipients were more effective in promoting condom use. The most effective interventions provided information, attitudinal arguments and self-management (or self-regulatory) skills training. In addition, the provision of condoms and HIV counselling and testing enhanced intervention effectiveness. Attitudinal arguments were associated with greater behaviour change (i.e. greater condom use) and results also showed that this effect was mediated (or explained) by changes in attitudes and in normative beliefs. As noted above, arguments targeting subjective and descriptive norms were found to promote behaviour change in audiences under 21 years of age but were associated with less effectiveness among older recipients. The authors offer clear guidelines on which change techniques may be most effective in promoting condom use for which groups using which delivery formats. Further analyses of this kind could accelerate the development of a science of sexual health promotion.

User perspectives

Involving users

As illustrated by the IM perspective outlined above, effective behaviour-change intervention design depends, critically, on the intervention being tailored to the needs of the intervention recipients at a series of key stages. Consequently, as IM advocates, intervention designers have much to gain by co-opting recipients into the design team and cocreating interventions with them.^{155,156} The majority of sexual health promotion IDs identified in the literature have involved users in the process to at least some degree. Here, we provide an overview of this literature and describe the ways in which users have or could be involved in the development process. Qualitative and, to a lesser extent, quantitative user involvement studies were commonly conducted at the outset of development of interventions. Maintaining user involvement throughout the whole process of development, refinement of prototype and implementation is critical for ensuring that the intervention content matches recipient needs, that the selected techniques are appropriate, that modes of delivery will be engaging and facilitate sustained use and that the intervention is attractive, feasible and sustainable in context (interview, e-health researcher).

Face-to-face methods for understanding sexual health needs and user preferences

Clinics are a common source of user recruitment for studies; however, this route for recruitment risks excluding potentially important groups of people who are not accessing services and, therefore, failing to identify the key issues for those at highest risk. Supplementary face-to-face methods, such as observation of young people interacting with technology¹⁵³ or user panels iteratively informing development,¹¹³ can also be used, but online methods are another way of potentially reaching groups who are not accessible by more traditional methods.

Online data for understanding sexual health needs and user preferences

Digital platforms may also be used to seek user views; for example, by soliciting young people's views on intervention design and content by posting prototypes online for comment (interview, youth outreach worker) or by conducting interviews online using instant messaging or Skype¹⁵⁷ or conducting group discussions in virtual world environments, such as Second Life (Linden Lab, San Francisco, CA, USA).¹⁵⁸ Data that are publicly available online through forums, blogs, etc., can provide valuable insights into the needs of young people,^{159,160} in particular hard-to-reach groups, such as LGBT youth, who may not necessarily be reached through traditional routes such as formal support groups or health-care settings.¹⁶¹

User preferences***Preferences for sexual health information***

It is essential that interventions address users' interests, for example in the nature and type of sexual health information content. Formative qualitative studies of user views that precede intervention development have suggested that young people express a preference for sexual health information that presents a holistic view of sex and that incorporates wider elements of relationships, including the emotional aspects, sexual techniques and communication, as well as information about reducing risk.^{39,70,109,159,162} Sexual health interventions are increasingly addressing the context, complexity and reality of young people's sexual lives, for example by addressing communication skills, sexual pressure, etc. However, only one digital intervention was identified that addressed sexual pleasure as a key element of sexual health,¹⁰⁹ despite sexual pleasure and intimacy being major motivators for having sex and also strong factors in choosing not to use condoms for penetrative sex. Authorities such as schools and clinics may feel wary of addressing sexual pleasure as a legitimate topic; however, young people want information on this³⁹ and it is an essential element in giving young people the tools to make genuinely informed decisions about their sexual health.

Young people would also like to access to online health information on a broad range of other topics that are not necessarily specific to sexual health, such as substance misuse.^{70,162} In addition, the inclusion of sexual risk reduction components in the context of wider health issues relevant for youth may represent a more aligned response to their expressed preferences.

Preferences for intervention design

Decisions about design can be made with reference to expressed preferences of users and testing of prototypes. For example, in designing interventions relevant to a target group, culturally specific references are important, but young people do not necessarily wish to be defined by their culture or ethnicity and may prefer sites that portray a range of cultural identities.¹⁶² Recognising heterogeneity within and across groups is important.¹²³ Allowing young people to self-select identities from a range of options offered may also increase perceived relevance and, therefore, increase identification with the message.¹¹³

Credibility of messaging is also frequently cited as important in engaging users.^{123,150} In Bull's¹⁶³ study to develop an intervention targeting condom use, users expressed desire for straightforward information from credible role models and peers through testimonials and personal stories. Negative messaging can inspire fear and defensiveness, although straightforward statistics on consequences of unsafe sex are perceived as useful.¹¹⁴ Campo *et al.*¹⁵⁰ report on the use of humour in intervention design, which can increase the memorability of messages and also prompt message spread. However, caution is needed to avoid generating misunderstanding and reducing credibility. Credibility may also be reduced by the use of 'reverse discourse', which can portray young people's sexual activity as inherently risky or immoral.¹⁴⁹ Formative work with users can to some extent help to identify whether or not there are particular health decisions that are shaped by unique cultural values and norms of the target group and which should be taken into account in intervention design.¹²⁶ Testing content for relevance with the target group helps to define the key messages that work¹⁶⁴ and elicit group-specific content that is perceived as important, such as issues around disclosure for HIV-positive youth,¹¹⁸ sexuality for MSM⁷⁰ or substance misuse for youth in treatment.¹²⁷

Stakeholder perspectives

Stakeholder views

Stakeholders who work with target populations may add value by presenting different perspectives and identifying gaps in information about risk and context not necessarily prioritised by users.¹⁵³ The Mental Models Approach described in one study, in which expert and user views were integrated to ensure that the information gaps were addressed by the intervention,⁶⁸ demonstrates this. Specialist clinical input may be particularly needed in the development of condition-specific interventions and was a key part in the development of both an interactive reproductive health intervention for diabetic girls¹²⁸ and a cervical cancer CD-ROM (compact disc read-only memory) targeted at college students.¹⁶⁵ The views of staff are also needed to understand the ways in which design should take the implementation contexts into account. Staff who care for a particular target group may also be used to review and comment on pilot interventions, as well as indicate potential sites for recruitment to or delivery of the intervention.¹⁶⁴

Collaboration for intervention design

Collaborating partners

The expertise relevant for developing (and evaluating and implementing) digital interventions for sexual health is located in teams and sectors that do not usually work together. An effective, successfully implemented IDI ideally requires collaboration between the following groups:

- **target user group** – to shape the intervention design to meet their needs and expectations
- **stakeholders in the desired setting (clinicians, teachers, parents)** – to advise on models for acceptable implementation of interventions
- **sexual health experts** – to advise on sexual health and public health considerations
- **behaviour-change experts** – to develop and comment on the theory that will underpin intervention content and design in collaboration, particularly, with users
- **human-computer interaction experts** – to advise on interactive intervention design which is user-friendly, engaging and easy to use
- **software developers** – to present a range of innovative, engaging interventions that can be assessed by users as those likely to most engage interest
- **research experts** – to design and conduct good-quality studies to evaluate the effectiveness and cost-effectiveness of interventions
- **marketing and media experts** – to advise on intervention design, marketing and dissemination
- **managers, policy-makers** – to facilitate organisational considerations such as SRE curriculum or care pathways policies and access to the internet.

Crucially, close working between designers, users and behavioural psychologists is needed.¹⁶³ An understanding of which 'active ingredients' determine effects is central to intervention development. The detail of this is likely to rest more on the unique features of the target population identified by the user group.¹⁶⁶ Describing these features clearly is important for replicating interventions and ensuring that the core components are retained, and more work is needed in this area.

Competing and aligned priorities

Priorities, policies, procedures and ways of working in different sectors may be quite different, which can present challenges when collaborating. For example, there is great interest by technology companies in the opportunities presented by the opening up of the NHS to private contracting. For the commercial sector, profit is obviously an imperative, and this means that some innovations will be commercially exploited while 'unprofitable' innovations are less likely to be, regardless of health gain. This, in turn, influences which health interventions are likely to be developed, and for whom. University researchers, clinicians and

private companies will have differing motivations for developing IDIs for health: we need to learn from each other, but advance agreements are needed about intellectual property and the commercial exploitation of IDIs. Market competition may discourage developers from collaboration and the sharing of learning with other companies for fear of losing commercial advantage.

The commercial sector may also have very different processes for intervention design, development and dissemination from those in the public sector. For example, software companies might rapidly develop several prototypes and then drop the ones that are not popular (interview, software developer); within academia, funding supports the development and evaluation of one intervention only. While we describe good-practice guidelines for development from an academic perspective, digital media experts are likely to have a better understanding of how to design interventions that are attractive to young people (interview, e-health researcher). Commercially developed interventions are also emerging at faster rate than in the academic sector, with literally hundreds of interventions (such as mobile phone apps) being produced, particularly in health promotion fields, such as exercise, weight management and alcohol, rather than sexual health.

In clinical practice, the role of private sector provision in all or some parts of care pathways is expanding. The extent of this is locally determined. For example, many diagnostic chlamydia tests are being commissioned from private companies. Tenders may include all or just part of the diagnostic pathways, but this is locally determined [interview, manager, National Chlamydia Screening Programme (NCSP)]. Similarly, there is local variation in how and from whom SRE is commissioned and the degree to which providers have developed or plan to develop 'in-house' digital resources to support delivery. There are examples of interactive face-to-face SRE interventions that are being adapted for digital use, with the potential for both supporting and standardising SRE delivery by teachers (interview, voluntary sector provider).

Although software companies, practitioners and academics work from different design principles and have different pressures and drivers for intervention development, more collaboration is needed to maximise the benefits of combined expertise (interview, e-health researcher). Rigorously designed studies are needed in order to find out whether or not an intervention is effective; however, properly planned, well-conducted research can be very time-consuming. NHS ethical and research and development procedures are very cumbersome and slow, representing a significant barrier to rapid evaluation of technological innovations. There is currently little incentive for the commercial sector to evaluate interventions before release. Software and intervention content may quickly become dated and public sector funding models may not factor in the cost of updating interventions. We need ways of working which can combine the energy for innovation of the commercial sector with the attention for rigorous evaluation offered by academia. Young people could be involved much more actively in the creation of IDIs, not simply in focus groups, for example, but in leading development themselves.

Best practice in design

A comprehensive approach to intervention development involves synthesis of evidence about the mediating factors of sexual behaviour, user and expert input about the barriers and facilitators to the target behaviours, identification of relevant contextual factors and a structure for planning behavioural change mechanisms.^{126,131} Few reported studies describe how these separate components can be linked together and operationalised to form the final product. One of the challenges for developing interventions is of retaining fidelity to the behavioural constructs while remain appealing and meaningful to the target audience and adapting for a particular context (see *Chapter 6*). We have proposed a model of best practice in intervention design (see *Appendix 2*) and in *Box 4* we describe three studies which exemplify elements of good practice.

BOX 4 Good practice in intervention design**Intervention designed for an educational setting¹¹⁰**

This HIV-prevention intervention focused on condom use and was delivered in a private room in an educational setting. The intervention was designed using the IMB Model and uses the motivational interviewing technique and the SoC Model for HIV prevention. Although this study does not describe formative work with users about content and design, assessment of contextual barriers, piloting the prototype and acceptability or usability of the intervention, we have selected it because it shows evidence of effect.

The software development was carried out by one of the study authors. Participants in the evaluation study were recruited and the intervention was delivered over two 15- to 40-minute visits, after which the participants returned for follow-up (95%). Following a baseline measure of condom use, participants were provided with tailored material that addressed condom use information, motivation and behavioural skills content. The second part of the material provided motivational content with a tailoring strategy related to the participants' condom use stage of change. The intervention used a mixture of information, quizzes and experiential activities, translating validated theory-based behaviour-change strategies used in face-to-face interventions for digital delivery. At the 4-week follow-up, intervention participants reported greater condom use knowledge and were more likely to carry condoms.

The study authors do not comment on next steps for the intervention or on whether it is designed for delivery in a static setting (which accounts for high levels of completion) or for internet use. The potential for adapting the content of effective, theory-based, face-to-face interventions has not been explored in depth and warrants further investigation.

Intervention designed for online use: Keep It Real¹¹¹

This was a HIV-prevention intervention aimed at young people. The intervention was developed according to best practice processes outlined: needs assessment, user involvement and application of theory. The intervention targeted STI/HIV and pregnancy prevention and was developed from TPB and SCT. Participants completed the five-module intervention over a single 60- to 90-minute session. Attitudes, norms and self-efficacy were selected as the most important aspects for behaviour change. Extensive formative research was conducted with young people to identify ways of operationalising the theoretical constructs in a compelling way. The authors stress the challenges of getting messages across and appealing to a young audience while remaining true to meaning. They solicited user views to develop role models, discuss risks and convey positive outcome expectancies, norms and methods for developing self-efficacy for condom use.

While developed according to best practice principles, this intervention failed to demonstrate effectiveness in the online trial. More information is needed about whether or not a single session provides sufficient intensity and the duration of intervention needed for best effect, as well as optimum contexts for successful delivery, particularly in a UK context.

BOX 4 Good practice in intervention design (*continued*)**Intervention designed for a clinic setting: TIPSS¹¹⁵**

This is a tailored safer sex intervention aimed at 18- to 29-year-old heterosexual African Americans delivered in a clinic setting. The goal was to increase consistent and correct condom use with main and casual sexual partners. It is based on the SoC Model, with individuals staged separately in relation to main and casual partners. The messages recommend different activities for different stages. Formative research for this intervention was through mixed quantitative and qualitative methods. Initially, the theoretical model was tested with the target population by quantitative survey, as well as using this to develop cut-off points for the SoC Model. Two rounds of focus groups were conducted, first to develop content appropriate to the group and then to test out the prototype. The collaboration for development included a technical team, a graphic design team and a research team who developed the intervention iteratively between them. This intervention demonstrated an extensive formative period using principles of codesign and is potentially promising. It is currently being evaluated in a RCT.

Assessing the quality of interventions

We have described good practice for intervention design. However, it is a challenge to keep pace with innovations in the commercial, voluntary and statutory sectors, given the time and costs of a rigorous approach to design. At present, there are inadequate mechanisms to control the quality of digital interventions. Health websites or mobile phone apps can be developed and released quickly, but without any assurance that information is accurate or that a programme has a positive and not a negative impact on health. Hundreds of new apps are produced each week, and these are currently unregulated. There are many more mobile phones apps for smoking cessation, alcohol use and exercise¹⁶⁷ than for sexual health. These apps are rarely based on strategies and BCTs that are known to be effective,¹⁶⁸ and some may cause adverse effects. For example, of 148 apps which claimed to estimate blood alcohol level, most gave inaccurate estimates.¹⁶⁹ This study found that alcohol apps were often used by young people in ways that facilitated risky behaviour. It is, therefore, important to know whether or not digital innovations are used in the way intended and do not have unanticipated adverse effects.

In terms of effectiveness of freely available websites, one study reviewed 21 publicly available interactive safer sex websites.¹⁷⁰ These websites targeted mainly safer sex messages and condom use for teenagers. The types and number of interactive features were highly variable, as were the identified Behaviour-Change Theories that could be applied. The threat of HIV and STIs, a discourse more likely to stigmatise young people,¹⁴⁹ was more commonly featured than promotion of positive reinforcing messages and social norms. Most contained some skills and self-efficacy-building content. Interactive features that were likely to increase enjoyment and, therefore, potentially engagement, were variable in number; however, the number and type of interactive features that optimise behaviour change is not known.

If digital interventions meet the criteria for 'medical devices', they are subject to extensive, detailed product standards and controls on quality. Software that is intended to be used for the diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or handicap or control of conception, can be considered a medical device.¹⁷¹ Although some IDIs could meet the definition for being medical devices (e.g. if they include a symptom checker which suggests a diagnosis), most would not. Devices that simply provide information would not usually be considered medical devices.

It is very hard for users to evaluate the quality of digital resources. The general public trust the NHS brand, and there have been discussions about 'kite marking' online resources (websites) that have been assessed as medically accurate. There are debates for and against trying to do this,¹⁷² and it is practically very

difficult, as there is such a profusion of resource online. It is particularly hard to guarantee medical accuracy in the era of Web 2.0, in which content is often posted by general users rather than by experts (interview, e-health researcher); websites may sometimes provide moderators who pre-approve comments made on bulletin boards, for example, but this is resource intensive. Mobile phone apps which are included in the NHS Health Apps Library have been reviewed to ensure that they are relevant to people living in England, use information from a verifiable or a trusted source (such as NHS Choices), comply with the UK Data Protection Act 1998,¹⁷³ and are unlikely to cause harm to a person's health or condition. However, there are a number of challenges. It is impossible to keep up with the pace of release of new health apps, the intervention content may change after any approval process and it is not clear who should meet the cost of approvals and quality assurance.

In an attempt to address issues of quality, Keller *et al.*¹⁷⁴ used a content analysis approach to assess HIV/STI prevention websites for teenagers. In their study, coding tools were developed and applied to assess communication, information provision and usability (such as currency, authority, readability and objectivity) of the websites. This is the only study that we identified that addressed the concept of developing agreed standards for sexual health promotion digital interventions. The NCSP highlights that the hugely variable quality of publicly available sites for ordering testing kits is, similarly, an issue. As this field has expanded, so the NCSP has developed a quality standard to assess whether or not a digital intervention meets this standard (interview, manager, NCSP). However, it may be that the quality criteria for users differ from those that are perceived by professionals.¹⁷⁵ Although the regulation and quality control of intervention content is very important, this should be proportionate to any potential risks; for example, digital interventions which offer prevention advice or 'find-a-service', but not medical diagnosis or treatment, could be designated 'low risk', so that innovation and implementation is not inhibited by cumbersome, time-consuming approvals procedures.

Security, privacy, confidentiality and ethical concerns about online interventions

The online environment can facilitate enhanced privacy but, on the other hand, it can facilitate the instant, wide sharing of personal information. For example, those seeking advice on a sexual problem via an online agony aunt or a self-help website may choose to remain anonymous by creating a username. On the other hand, dating apps, such as Grindr for MSM, for example, can allow instant access to photographs, location, sexual preferences and drug use, for the purposes of arranging sex. There is sometimes a mismatch between young people's behaviour online (where young people often freely share personal details on social networking sites and have little concern about their privacy or data security)⁷⁰ and adult concerns about privacy, confidentiality and data security.

There is a legal obligation in the UK to safeguard children under the age of 18 years who are at risk of harm.¹⁷⁶ However, it is not clear how this legislation should be enacted in an online context, for example what responsibilities a webmaster has if a child discloses sexual abuse online, especially if they have used a username and their personal details are not known. It can be difficult to determine the maturity of users, who may also be free to lie about their age and could be exposed to age-inappropriate material.^{96,177} These issues raise the question of how and by whom interventions would be monitored in the longer term, and who should meet the cost. There is currently little public discussion of the ethics of automated data collection, for example the implications and potential risks of surveillance via geolocation, etc. There is debate about who owns the data collected by apps and websites, and users may not even know that such data have been collected. There are particular considerations about the potential sensitivity of sexual health-related data online or saved locally on mobile phones. For example, an internet browsing history or a sexual health app on a mobile phone could easily be seen by someone else. The pace of intervention development has outstripped the regulatory framework, but it is not clear what framework would be appropriate, particularly given that the internet is accessible across national borders.

Key points

- Most currently available sexual health promotion IDIs have been developed in the USA and focus on reduction in sexual risk behaviour and/or increased condom use.
- Young people want sexual health education that includes pleasure and relationships and does not just involve biology, safer sex and pregnancy.
- There are hundreds of websites for sexual health, but most of these are not based on Behaviour-Change Theory and do not give personally relevant advice and information.
- A range of interactive and multimedia design features have been used for sexual health IDIs (e.g. quizzes, games, stories, scenarios, virtual characters, animations, video, bulletin boards, 'ask an expert', outreach on social networking sites and online support groups).
- Some topics are missing from sexual health promotion initiatives, for example sexual abuse, alcohol, sexual problems and mental health issues.
- There are no digital interventions specifically for young people in care, young parents, young people with learning difficulties, disabled young people and lesbian and transgender young people.
- Young people should be involved in programme design and development at all stages.
- Sexual health promotion IDIs could be adapted from existing IDIs or developed afresh, consulting with young people to ensure that interventions are attractive and relevant for young people in the UK.
- Programmes should give personally relevant feedback and explicitly use change techniques to influence behaviour patterns.
- Programme development teams should collaborate to bring together people with different skills, for example young people, researchers, psychologists, software developers, human-computer interaction experts and others.
- Programme developers should take into account the views of the recipients, those who will deliver the intervention and those of other stakeholders (e.g. teachers, parents, clinic staff and managers).
- Prototype testing, intervention refinement, usability testing and developing an implementation plan for roll-out are all integral elements of good practice in programme development.
- While the internet has huge potential for sexual health promotion, most interventions are unregulated and there is also the potential for harm online.
- Quality and safety kite-marking is needed so that people know that they can trust programmes and that data will be kept safely.
- NHS evaluation and endorsement of sexual health IDIs is valuable in increasing public trust in sexual health interventions.

Chapter 4 Evidence on effectiveness of digital interventions for sexual health for young people

Chapter aims

- To determine the effectiveness of IDIs for sexual health promotion (in comparison with minimal interventions).
- To determine whether or not IDIs are as effective as face-to-face interventions.
- To determine how IDIs work (i.e. mechanisms of action).

Chapter-specific methods

We conducted a systematic review of literature on RCTs of IDIs for sexual health promotion, the details of which are described in *Chapter 2* and in the full version of the Cochrane review 'Computer-based interventions for sexual health promotion'.⁹⁷ In the full Cochrane review we synthesise the results of RCTs for sexual health promotion for *any age* of participant; we present here the synthesis of data from RCTs conducted among young people only.

Statistical analyses

Where appropriate, we pooled the results of RCTs using a random-effects model, which gives an estimate of the average intervention effect. A random-effects model is more conservative than a fixed-effects model, as it allows for statistical heterogeneity rather than assuming that differences between studies are owing to chance alone.⁹⁷ We used standardised mean differences (SMDs) for continuous outcomes and odds ratios (ORs) for dichotomous outcomes. These measures allow combination of outcomes which may have been measured using different scales, giving averages or ratios which are adjusted by trial size. We comment on the size of SMDs using Cohen's rules of thumb, judging 0.2 to be a 'small' effect, 0.4 to be a 'moderate' effect and 0.8 to be a 'large' effect.¹⁷⁸

Results

The search generated 15,655 unique citations (Figure 5). These were screened for eligibility and full texts of 175 potentially eligible citations were obtained. We excluded 156 citations because these studies were not conducted among young people aged 13–24 years, were not RCTs and/or did not meet our definition of IDI. We extracted data and (where possible) synthesised the findings from 19 studies which were RCTs of IDIs for sexual health promotion for young people (Table 2). Outcome data were collected for a total of 2966 participants who had been randomised to IDIs and 3180 participants who had been randomised to comparator arms (2668 to a minimal intervention, 319 to a face-to-face comparator, such as a lecture or counselling, and 193 to a different design of digital intervention). We excluded Roberto *et al.*,¹¹⁷ as it was a two-school trial. Only 2 of the 19 included studies were categorised as being at low risk of bias in terms of method of randomisation, concealment of allocation and/or loss to follow-up.^{68,143}

Aims and design of interventions

Eight of the 19 included studies focused on HIV prevention^{67,110,111,127,141–143,183} and three focused on STI prevention, including HIV.^{68,112,113} Two studies addressed both STIs/HIV and unwanted pregnancy^{117,181} and two studies focused on the prevention of unwanted pregnancy.^{179,184} One of these studies focused on sexual pleasure and well-being as well as safer sex.¹⁸¹ One study focused on promoting positive sexual communication and preventing sexual assault,¹⁸⁰ one focused on sexual health knowledge and decision-making¹⁶⁶ and one focused on responsible sexual behaviour.⁶³ One study had a focus wider than sexual health, promoting also mental health and the reduction of alcohol and drug use.¹⁸²

All of the interventions were digital and administered either via a computer or online – we located no completed trials of *interactive* (i.e. tailored) digital interventions delivered by mobile phone. Two interventions were delivered using a CD-ROM.^{67,113} Some studies provided feedback based on knowledge tests or behaviour assessment tailored according to answers given.^{67,110,112,117,182,184} Tailoring (individual feedback) was also by gender and ethnicity,¹¹¹ gender,¹¹² ethnicity and sexual experience,¹¹³ risk profile,¹²⁷ adolescent health norms,¹⁸² stage of change,¹⁴³ health behaviours or relationship outcomes and communication skills,¹⁶⁶ perceived threat of HIV/AIDS and perceived self-efficacy to refuse sex.¹⁴¹ Tailored content was also provided through story scenarios or rehearsal of the communication and decision-making process^{63,68,183} and following virtual decisions¹⁸⁰ (e.g. a virtual baby following a decision to have unprotected sex)¹⁷⁹ videos and modelling exercises for skill development^{142,143} and a role-playing game for decision-making skills.¹⁴¹

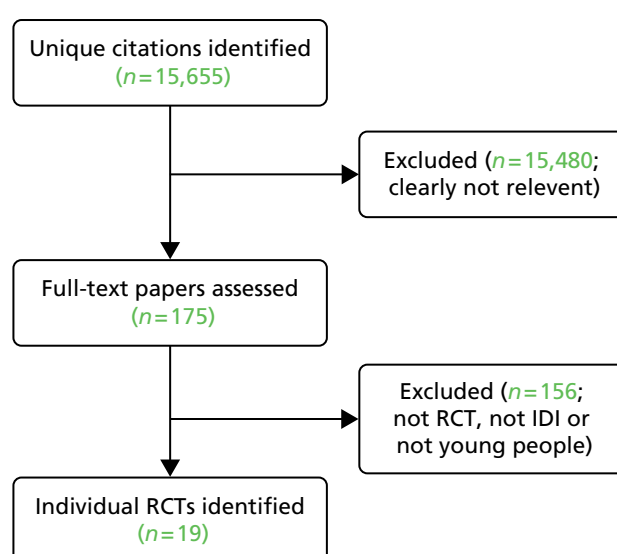


FIGURE 5 Search results: RCTs of IDIs for sexual health promotion among young people.

TABLE 2 Characteristics of included RCTs

| Author and date | Participants and setting | Aim | IDI description | Comparator |
|--|---|--|---|--|
| Alemi <i>et al.</i> 1989 ¹⁷⁹ | Teenagers who had experienced pregnancy Special service programme USA | To prevent adolescent pregnancy | Players asked to decide what the main character should do. Computer responds. Make friendships and relationships with other characters. Unsafe sex leads to a virtual pregnancy and unpredictable baby behaviour. Wrong answers stop the program, and then must ask others | Lecture with same content |
| Avina 2006 ¹⁸⁰ | Female university students (mostly psychology students) USA | To improve women's ability to recognise risk situations and engage in effective behaviours to avoid risk of sexual assault | Developing effective communication skills. Decoding skills, decision skills and enactment to respond effectively. Four scenarios with feedback, and vignettes | Waiting list |
| Bailey <i>et al.</i> 2011 ¹⁸¹ | Young people aged 16–20 years, recruited online in the UK | To give young people the tools to make informed decisions about their sexual well-being | The Sexunzipped interactive website, featuring information, quizzes and decision-making activities with tailored feedback | Information-only website |
| Bannink <i>et al.</i> 2012 ¹⁸² | Secondary school students aged 15–16 years the Netherlands | To reduce alcohol, smoking and drug use and increase safer sex | E-health4Uth arm received computer-tailored health education for nine topics (alcohol consumption, drug use, smoking, sexual behaviour, bullying, mental health, suicidal thoughts, suicide attempts and unpleasant sexual experience) | 1. Outcome assessment only, no tailored messages. Participants could self-refer to a nurse 2. E-health4Uth+ nurse counselling for adolescents at risk of mental health problems |
| Bull <i>et al.</i> 2009 ¹¹¹ | Young people aged 18–24 years recruited online and in a clinic USA | HIV prevention | Keep It Real: online HIV risk assessment and five role model stories tailored by gender and ethnicity | Online HIV risk assessment and text-based generic HIV-prevention information |
| Calderon <i>et al.</i> 2013 ¹⁴³ | Emergency department patients aged 15–21 years USA | To promote safer sex behaviours | All participants viewed a HIV pre-test educational video and were offered a HIV test IDI: HIV post-test counselling video vignettes, tailored by the participant's stage of change while waiting for results. Standard in-person counselling when receiving test results | All participants viewed a HIV pre-test educational video and were offered a HIV test In-person counselling from HIV counsellors while waiting for results |

continued

TABLE 2 Characteristics of included RCTs (continued)

| Author and date | Participants and setting | Aim | IDI description | Comparator |
|--|---|---|---|--|
| Chib <i>et al.</i> 2010 ¹⁴¹ | School children aged 13–16 years Singapore | To test the effect of efficacy of participants' response to high-threat messages about HIV/AIDS | Med Detective interactive multimedia game, conveying messages emphasising high threat of HIV with high-efficacy messages (e.g. emphasising the effectiveness of protective measures) | 1. Interactive game with high-threat messages only 2. Measurement-only control group (data not reported) |
| Cortese and Lustria 2012 ¹⁶⁶ | School children aged 13–17 years USA | To increase knowledge and encourage deeper elaborations of health messages related to sexual health and decision-making | Tailored website focusing on teen sexual health and decision-making | Website with the same basic information (setting life goals, relationships, communication), but no tailored elements |
| Di Noia <i>et al.</i> 2004 ⁶⁷ | Girls from social services agencies USA | To forestall initiation of HIV-related risk behaviours among adolescent girls | Keeping it Safe CD-ROM: information about HIV, game with feedback regarding facts and myths, video personal story of HIV, Four-Step Model of Assertive Responding using scenarios and simulations | Waiting list |
| Downs <i>et al.</i> 2004 ⁶⁸ | Girls recruited from health-care sites USA | To reduce adolescent girls' STI risk | Four domains for content: negotiation, condom use, reproduction and STIs. Characters with choices to make. Cognitive rehearsal in own head | 1. Book with same content 2. Commercially available brochure |
| Evans <i>et al.</i> 2000 ¹⁸⁰ | Students on a college sexuality course USA | To influence HIV prevention behaviours | AIDS Interactive: individual interaction with computer. Stories, role modelling, demonstrations. Video vignettes, rehearsal of communication skills (typing). One hour with computer | 1. Lecture (same content and theoretical principles) 2. 'No intervention' |
| Ito <i>et al.</i> 2008 ¹¹³ | 15- to 19-year-old female adolescent patients attending a family planning clinic USA | To prevent HIV/STIs | Culturally tailored interactive CD-ROM plus standard care (didactic session led by educator). Video clips, cartoons, quiz, games. Tailoring by ethnicity and sexual experience of a virtual host | 30-minute educator-led group didactic session |
| Kann 1987 ⁶³ | Health science students in secondary schools USA | To promote responsible sexual behaviour (decision-making, assertiveness and communication) | Three simulation-based programmes for decision-making, assertiveness and interpersonal communication. Conversations between students and computer. Structured decision-making process | 1. Regular classroom instruction with same content: lectures, discussion and role play 2. No intervention |

| Author and date | Participants and setting | Aim | IDI description | Comparator |
|---|--|---|--|--|
| Kiene and Barta 2006 ¹¹⁰ | Psychology students (university) USA | To increase HIV/AIDS preventative behaviours | Condom use information, motivation and behavioural skills. Goal setting. Tailoring by baseline information, motivation and behavioural skills. Self-selected goals | Nutrition education tutorial (also computer delivered) |
| Klein and Card 2011 ¹⁴² | 14- to 18-year-old African American girls USA | To enhance HIV preventative sexual behaviours | Multimedia SiHLE (Sisters Informing, Healing, Living, and Empowering). Computer-delivered interactive multimedia HIV prevention intervention. Videos, games, quizzes and simulated role-plays | Computer-delivered general health education session on diet and nutrition |
| Marsch <i>et al.</i> 2011 ¹²⁷ | Participants aged 12–18 years attending community-based adolescent treatment for substance abuse USA | Prevention of HIV/STIs | One educator-delivered group session of one hour on HIV/STI prevention as well as access to an interactive, web-based HIV, hepatitis, STI-prevention programme. Tailoring of content by alcohol and drug use and HIV and hepatitis status; quizzes with adjustment of pace and level of content presented. Graphics and animations | Educator-delivered group session on HIV/STI prevention and 15-minute video on HIV prevention |
| Mevisen <i>et al.</i> 2011 ¹¹² | College and university students, aged 18–25 years, heterosexual, in relationships of maximum 6 months The Netherlands | To promote (maintenance of) condom use and STI testing | Justify Your Love: virtual consultant-led STI public clinic. (i) STI risk perceptions, (ii) maintenance of condom use within current relationship and (iii) STI testing. Tailored feedback, reinforcement or counter arguments and subsequent questions according to the participants' responses to prior questions and gender | 1. IDI (non-tailored) virtual STI public clinic, similar sexual risk questions, safe sex advice, information on barriers to condom use and STI testing 2. No intervention |
| Roberto <i>et al.</i> 2007 ¹¹⁷ | High school students USA | To prevent pregnancy, STIs and HIV | Six weekly digital activities and one catch-up week: Sensation-seeking, Truth or Myth, Impulsive decision-making, Risky behaviour, Virtual date, Original refusal line, Radio announcement | Data collection only |
| Van Laar 2000 ¹⁸⁴ | High school students USA | To change irrational beliefs which interfere with effective contraception use | Seven modules addressing irrational beliefs: intent (regarding pregnancy), preparing for sex, condom purchase and carrying, discussion and negotiation of contraception and condom use, peer support. CD-ROM, during school day. Audio through earphones, tailored content according to own dilemmas | Internet-based program focused on altering irrational career beliefs |

Theoretical framework of intervention designs

Interventions were informed by various theoretical frameworks, including the Four-Step Model of Assertive Responding;⁶⁷ SCT;^{142,183} Gender and Power Theory;¹⁴² Decision-Making Process Model;⁶³ Cognitive Restructuring of Irrational Beliefs;¹⁸⁴ Mental Models and Decision Theory;⁶⁸ Information Processing Model of Social Competence;¹⁸⁰ Extended Parallel Process Model;^{117,141} Elaboration Likelihood Model of Persuasion;¹⁶⁶ TRA and SoC;¹⁴³ 'Fluency-Based' Computer-Assisted Instruction;¹²⁷ AIDS Risk-Reduction Model;¹¹² TPB and SCT;¹¹¹ Integrated Model of Behavioural Prediction;¹¹³ Practice in Decision-Making;¹⁷⁹ IMB Skills Model;¹¹⁰ and Integrated Behavioural Model.¹⁰⁹ Some studies drew on a combination of theories.^{63,68,110}

Consumer and stakeholder involvement in intervention development

Several studies involved stakeholders in the process of development of the intervention, including involving community institutions in programme development¹⁷⁹ and expert opinion.^{68,179,180} Several studies also involved user groups in the development of interventions, using various methods, such as focus group discussions,^{39,68,111,117,143,180} surveys,¹¹⁷ pilot testing^{127,183} and semistructured interviews.^{141,181}

Delivery of interventions

Most interventions were delivered to individuals but one was delivered to small groups.¹⁷⁹

Exposure to interventions

The duration and intensity of interventions varied across studies. Some studies involved one single session interaction with the intervention,^{67,113,141,143,166,179,183} while other studies involved multiple sessions or access to interventions over a period of time.^{63,68,110-112,117,127,142,180,184}

Participants and geographical settings

Some studies were conducted only among girls and some included both boys and girls (see *Table 2*). The majority of the studies were conducted in the USA, while two were conducted in the Netherlands, one was conducted in Singapore and one was conducted in the UK.

Study settings

Participants were recruited from the following settings: clinical or treatment settings (including one special service programme for previously pregnant adolescents),¹⁷⁹ a sexual health clinic,¹¹¹ emergency department,¹⁴³ a health-care centre,⁶⁸ a family planning clinic¹¹³ and a community treatment centre for substance abuse.¹²⁷ Some studies recruited from education settings: colleges^{110,112,179,180} and schools.^{63,117,141,166,184} One study recruited from social service agencies⁶⁷ and another relied on referrals from recruited individuals.¹⁵¹ Two studies recruited via social networking sites or online.^{111,142} Two studies recruited participants from multiple settings.^{142,185}

Types of trial design

The majority of the studies were two-arm individual-level RCTs; however, four were three-arm RCTs,^{68,112,141,183} two were two-arm cluster RCTs^{67,117} and one was a three-arm cluster RCT.⁶³

Follow-up periods

Studies varied in length of follow-up period: 2 weeks or less post intervention;^{67,113,141,143,166,179,183,184} 3 weeks to 5 months,^{63,110-112,117,127,142,180,181} and 6 months post intervention.⁶⁸

Outcomes

Outcome data were available from 18 trials but we excluded the trial conducted by Roberto *et al.*¹¹⁷ from meta-analysis because only two schools were randomised to either intervention or control group and, therefore, it is not possible to adjust for clustering effects. For full details of outcome data selection and synthesis please see the methods section of the Cochrane review.⁹⁷ No studies reported economic outcomes. Similarly, no studies measured potential harms apart from reporting any deterioration in measured outcomes.

Analyses

Group 1: studies comparing interactive digital interventions with minimal intervention

For this analysis we combined data from 14 studies that compared the effect of IDIs with minimal interventions. Minimal interventions were defined as non-interactive interventions or non-sexual health comparators, such as waiting lists, leaflets, books or IDIs on non-sexual health topics.⁹⁷ Three studies used 'no intervention' as a comparator,^{63,182,183} two studies used waiting list control groups,^{67,180} and two studies compared IDIs plus standard clinical care with standard care only.^{113,127} In three studies the comparator was a 'placebo': a computer-delivered nutrition tutorial^{110,142} and an IDI about career planning.¹⁸⁴ One study compared IDIs with leaflets or books with the same content⁶⁸ and three used a non-interactive website with generic information.^{111,112,181}

Cognitive outcomes

Sexual health knowledge

Knowledge about STIs, HIV, reproductive health and/or condom use was measured in nine studies.^{63,67,68,110,113,127,142,181,183} However, data from Alemi *et al.*¹⁷⁹ on knowledge were not available and so this study could not be included.

Self-efficacy

Self-efficacy (a person's belief in their capacity to carry out a specific task) was measured in nine studies. Studies used different instruments to measure self-efficacy, including self-efficacy for HIV risk reduction,⁶⁷ safer sex/condom use,^{67,110,112,113,127,142,179,181,183} buying and using condoms¹¹³ and contraceptive use.¹⁸⁴

Intention

Six studies measured behavioural intentions. Intentions to use condoms with a current partner,¹⁸³ at next sexual intercourse,¹¹³ in the future,^{110,127,181} and to maintain condom use¹¹² were measured.

Behavioural outcomes

Nine studies measured behavioural outcomes. These were sexual victimisation,¹⁸⁰ number of protected sex partners in the past 60 days¹¹¹ or past 90 days,¹⁴² condom use with every partner in the past 3 months⁶⁸ or in the past month,¹¹⁰ frequency of condom use,¹⁸² episodes of unprotected sex in the past 3 months,¹⁸¹ consistent condom use with current partner¹¹² and condom use skills demonstrated on a model of a penis.¹²⁷

Biological outcomes

Three studies measured biological outcomes: genital chlamydia (both self-reported and laboratory measured)^{68,185} and self-reported STIs.¹¹¹ In the Sexunzipped study,¹⁸⁵ the overall return for postal chlamydia samples was low, at 42%, so we selected self-reported STI rate for data analysis.

Adverse outcomes

Adverse outcomes were not recorded (except for possible deterioration in outcomes measured).

Group 2: studies comparing interactive digital interventions with face-to-face interventions

Four studies compared IDIs with non-digital face-to-face sexual health interventions. Three studies used a lecture with same sexual health content^{63,180,183} and one study used face-to-face counselling.¹⁴³

Cognitive outcomes

Sexual health knowledge

Two of the four studies in group 2 measured knowledge about STIs, HIV, reproductive health and/or condom use^{180,183} and one measured communication knowledge.⁶³

Self-efficacy

Two studies in this group measured self-efficacy: condom use¹⁴³ and HIV prevention self-efficacy.¹⁸³

Intention

Two studies measured intention: intention to use condoms for vaginal sex¹⁴³ and intention to use condoms with current partner.¹⁸³

Behavioural outcomes

One study in this group measured behavioural outcomes, but these were not clearly defined.⁶³

Group 3: studies comparing two different interactive digital intervention designs

Three studies compared different designs of IDIs for sexual health interventions. One study compared the effect of messages conveying high threat of HIV together with messages which boost self-efficacy, with high-threat-only messages.¹⁴¹ Two studies compared tailored IDIs with non-tailored digital interventions for sexual health promotion.^{112,166}

Cognitive outcomes

Sexual health knowledge

Knowledge on sexual health decision-making was measured by one trial¹⁶⁶ but data were not available.

Self-efficacy

Two studies measured self-efficacy: for saying no to sex¹⁴¹ and for condom use.¹¹²

Intention

One study measured intention: to maintain condom use.¹¹²

Behavioural outcomes

One study in this group measured behavioural outcome: consistent condom use with current partner.¹¹²

Findings

Comparison 1: are interactive digital interventions effective compared with minimal interventions?

Please see the *Glossary* for explanations of the statistical terms used.

Do interactive digital interventions improve sexual health knowledge?

Standard deviations (SDs) were calculated for Di Noia *et al.*⁶⁷ and Evans *et al.*,¹⁸³ allowing us to combine data from seven studies which reported sexual health knowledge outcomes. Data were obtained from authors for Bailey *et al.*¹⁸¹ and Downs *et al.*⁶⁸ Data suitable for analysis were not available for Alemi *et al.*,¹⁷⁹ Kann⁶³ and Marsch *et al.*¹²⁷ Meta-analysis shows a statistically significant positive effect on sexual health knowledge, with a SMD of 0.54 [95% confidence interval (CI) 0.17 to 0.92]. This is a moderate effect size using Cohen's criteria¹⁷⁸ and shows that IDIs for young people have a **significant, moderate effect on sexual health knowledge**. As shown in *Figure 6*, the *I*-statistic was 92%, indicating considerable heterogeneity in the results (i.e. variation in outcomes between studies).

Do interactive digital interventions improve self-efficacy with respect to sexual health?

We combined data from eight studies which reported data on self-efficacy (*Figure 7*), with SDs calculated for Di Noia *et al.*⁶⁷ and Evans *et al.*¹⁸³ Data were obtained from authors for Bailey *et al.*¹⁸² No data were available for Marsch *et al.*¹²⁷ Combining outcomes from studies gave a SMD of 0.11 (95% CI 0.02 to 0.20).

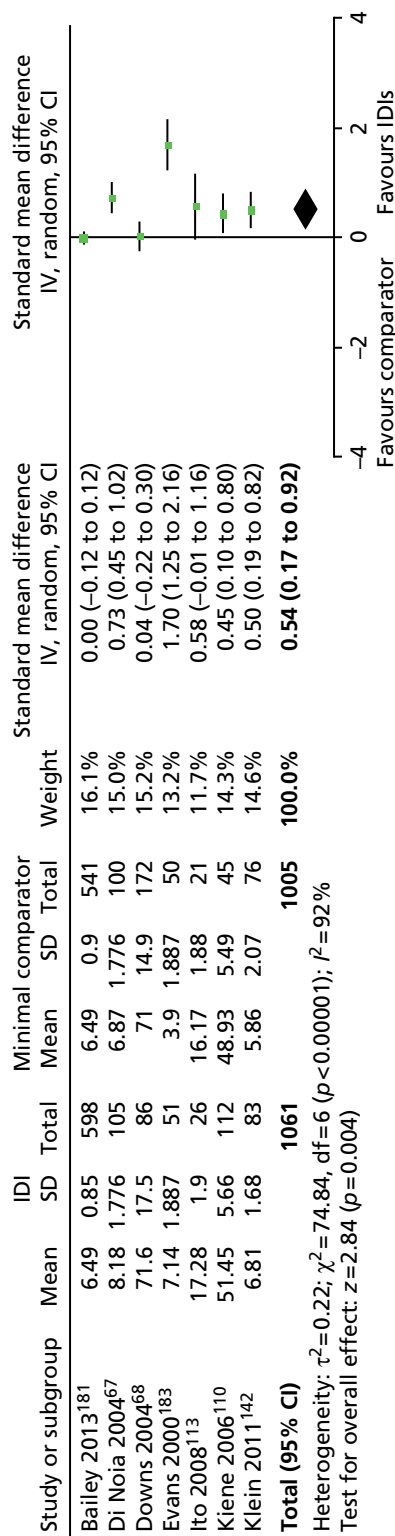


FIGURE 6 Comparison of IDIs with minimal intervention: knowledge. df, degrees of freedom.

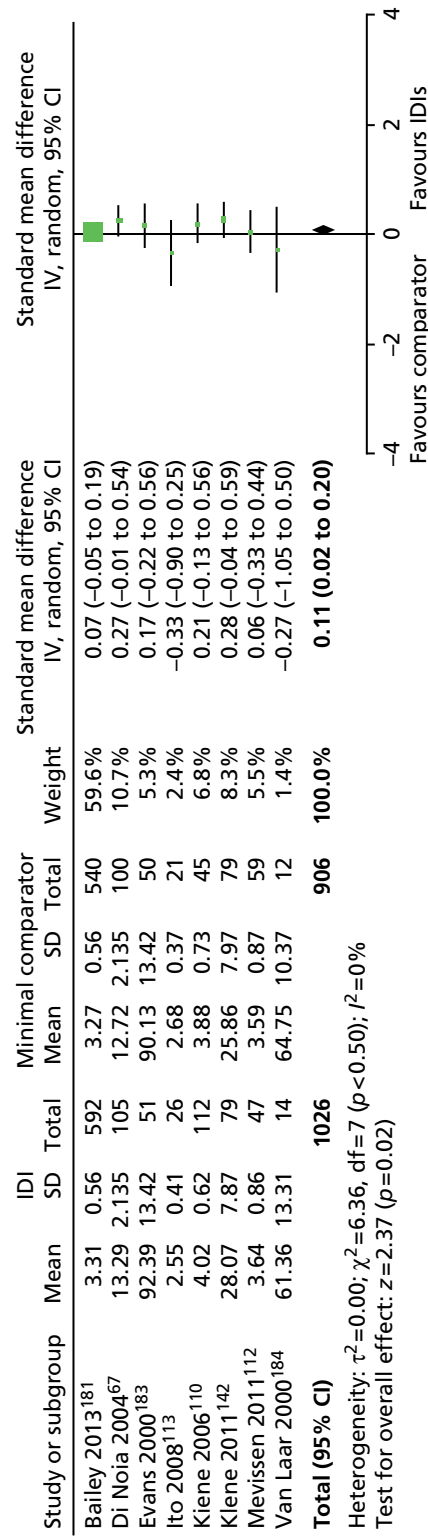


FIGURE 7 Comparison of IDIs with minimal intervention: self-efficacy. df, degrees of freedom.

This is a small effect size using Cohen's criteria,¹⁷⁸ showing that IDIs for young people have a **small but significant effect on self-efficacy**. The I^2 -statistic was 0%, suggesting that there was no statistical heterogeneity.

Do interactive digital interventions increase safer-sex intentions?

We combined data from four studies that measured intention on continuous measurement scales (Figure 8) (SMD 0.09, 95% CI -0.01 to 0.19), which show a **non-significant effect on intention**. Ito *et al.*¹¹³ measured intention as a dichotomous outcome, showing an OR of 5.88 (95% CI 0.60 to 57.30). No data were available for Marsch *et al.*¹²⁷ The I^2 -statistic was 0%, suggesting that there was little statistical variation.

Do interactive digital interventions have an effect on sexual behaviours?

We combined data from four studies that measured sexual behaviour as dichotomous outcomes (numbers of events) (Figure 9). The outcomes combined were condom use^{68,181,182} and number of participants who did not experience sexual victimisation.¹⁸⁰ Data were obtained from authors for Bailey *et al.*¹⁸¹ and Downs *et al.*⁶⁸ The OR following meta-analysis was non-significant (OR 1.18, 95% CI 0.96 to 1.44), showing **no demonstrable effect on sexual behaviour** (measured as number of events). The I^2 -statistic was 0%, suggesting that there was no statistical heterogeneity.

Five studies measured sexual behaviour on continuous measurement scales, with all studies measuring condom use. Data were obtained from authors for Bull *et al.* (clinic and online samples).¹¹¹ The combined SMD was 0.19 (95% CI -0.04 to 0.43), which shows **no demonstrable effect on sexual behaviour** (Figure 10). The I^2 -statistic was 71%, suggesting that there was considerable heterogeneity in study results.

To increase the power to detect an effect, we combined dichotomous and continuous outcomes for sexual behaviour by expressing SMDs as ORs.⁹⁷ This allowed meta-analysis of outcomes from eight studies that measured sexual behaviour. The combined OR was 0.28 (95% CI 0.01 to 1.61), which shows a **significant effect on sexual behaviour** (Figure 11). The I^2 -statistic was 54%, suggesting that there was moderate heterogeneity in study results.

Do interactive digital interventions have an effect on biological outcomes?

Data for biological outcomes were available from authors for three studies.^{68,111,181} As shown in Figure 12, the OR was 1.18 (95% CI 0.78 to 1.80), indicating **no demonstrable effect** on STI diagnoses.

Comparison 2: are interactive digital interventions as effective as face-to-face sexual health interventions?

We combined outcomes from group 2 studies to address the question of whether or not IDIs are as effective as face-to-face interventions, taking studies that compared IDIs with non-digital, face-to-face sexual health education. These trials are equivalence trials, in that it is a positive finding if there is no difference in effectiveness between IDIs and face-to-face interventions.

Sexual health knowledge

We had data available from one study only for the effectiveness of IDIs compared with face-to-face intervention on sexual health knowledge. Evans *et al.*¹⁸³ showed that IDIs had a **significant, moderate positive effect on sexual health knowledge** (SMD 0.51, 95% CI 0.11 to 0.90), compared with a 1-hour lecture on the same content.

Self-efficacy

Data were available from one study only,¹⁸³ which showed **no demonstrable effect on self-efficacy** for HIV-preventative behaviours (SMD 0.38, 95% CI -0.11 to 0.77), compared with a 1-hour lecture on the same content.

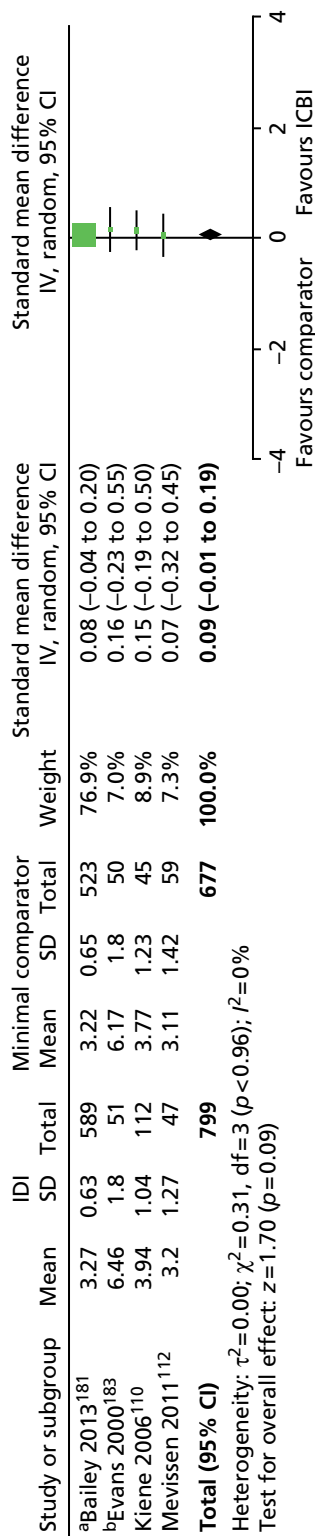


FIGURE 8 Comparison of IDIs with minimal intervention: intention. a, Data from authors; and b, SD calculated from the F -statistic ($F=2.80$). df , degrees of freedom.

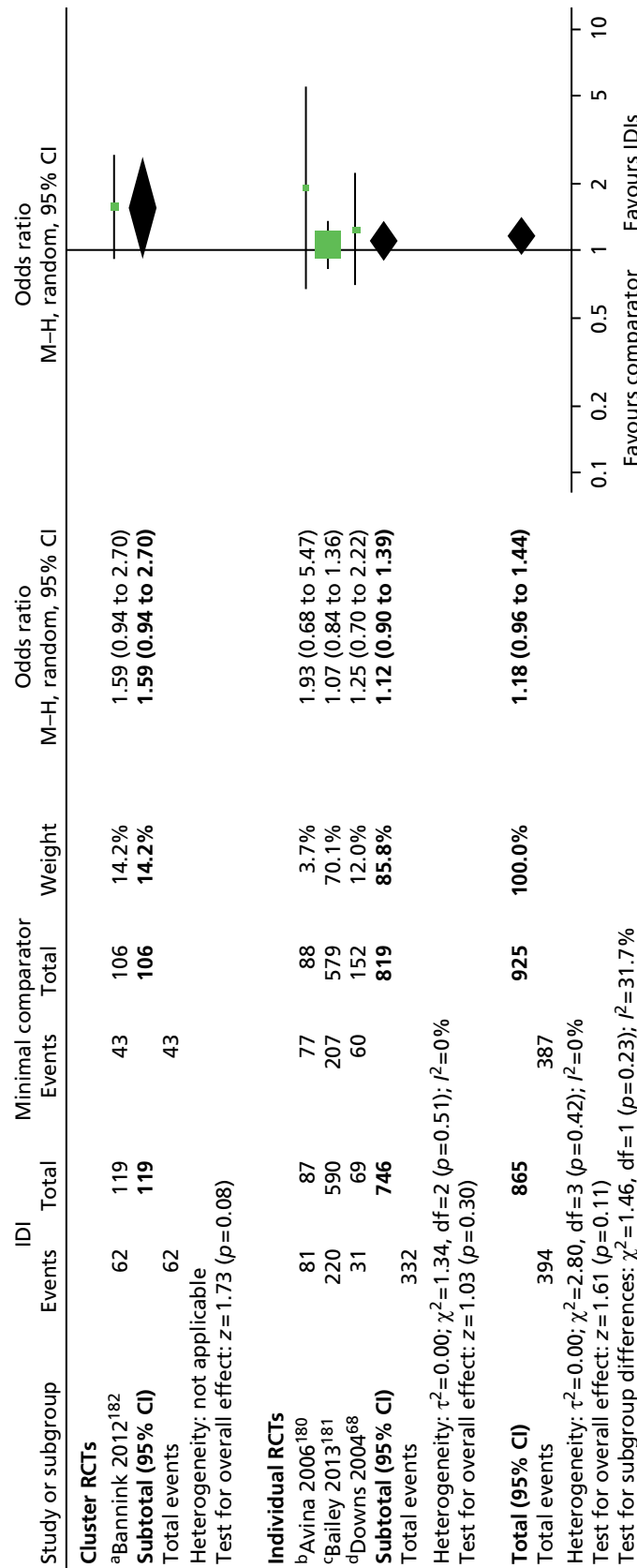


FIGURE 9 Comparison of IDIs with minimal intervention: sexual behaviour (dichotomous). a, Condom use during intercourse 'always'; b, number of participants who did not experience sexual victimisation; c, condom use at last vaginal and/or anal sex; and d, condom use in past 3 months, every time with partner, only for sexually active group. df , degrees of freedom.

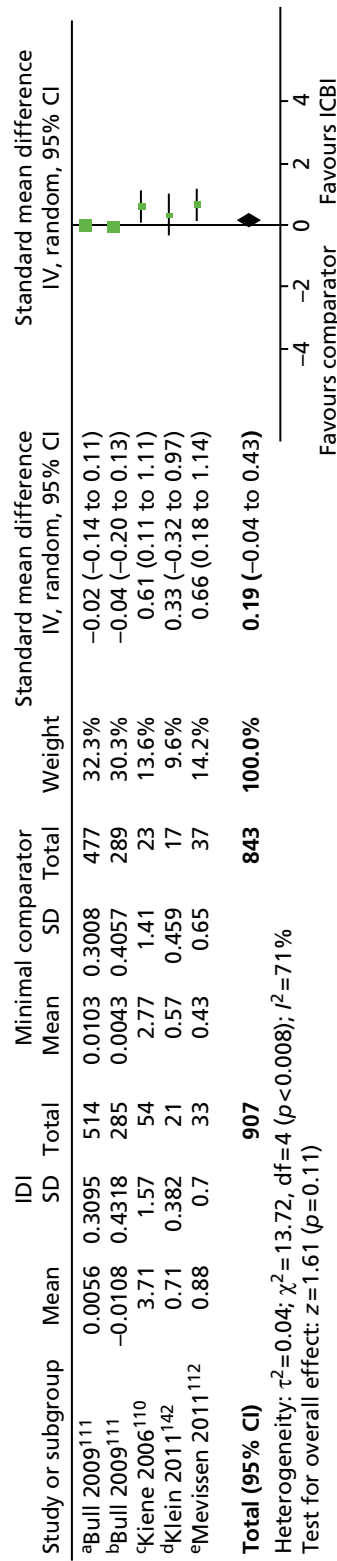


FIGURE 10 Comparison of IDIs with minimal intervention: sexual behaviour (continuous). a, Online sample: change in the proportion of condom-protected sex acts in 60 days; b, clinic sample: change in the proportion of condom-protected sex acts in 60 days; c, condom use in the past 30 days, only those sexually active since baseline; d, condom use in past 30 days; and e, condom use with current partner. df, degrees of freedom.

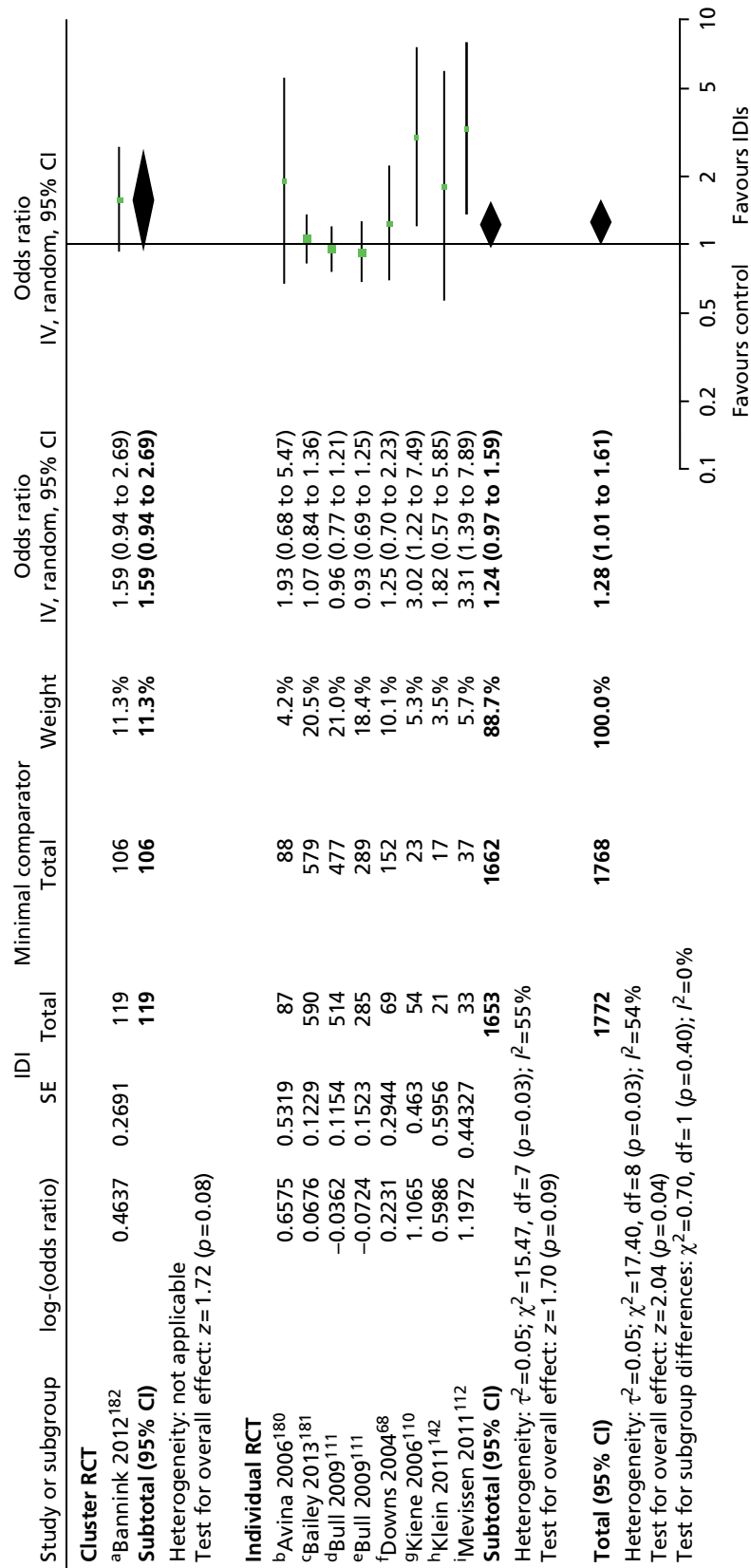


FIGURE 11 Comparison of IDIs with minimal intervention: sexual behaviour (combined). a, Condom use 'always'; b, number of participants who did not experience sexual victimisation; c, condom use at last vaginal and/or anal sex; d, online sample: change in the proportion of condom-protected sex in 60 days; e, clinic sample: change in the proportion of condom-protected sex in 60 days; f, condom use in the past 3 months, every time with every partner, only for sexually active subgroup (data from author); g, condom use in past 30 days; h, proportion of condom-protected sex acts in last 90 days; i, condom use with current partner. df, degrees of freedom; SE, standard error.

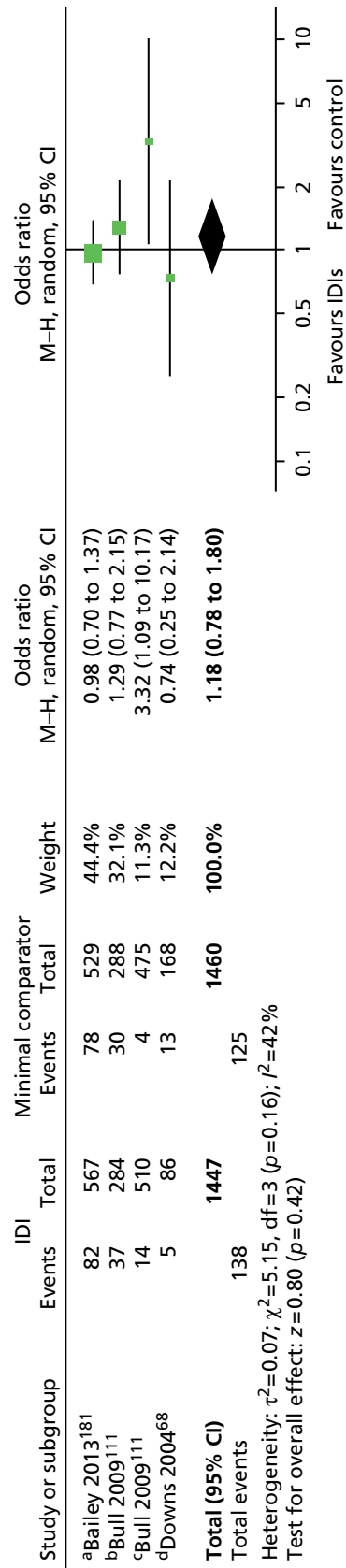


FIGURE 12 Interactive digital interventions vs. minimal intervention: biological outcomes. a, Self-reported STI; b, clinic sample: history of STIs; c, online sample: history of STIs; and d, laboratory chlamydia test. df, degrees of freedom.

Intention

Data available from Evans *et al.*¹⁸³ showed that IDIs had a **small, significant effect on intention** to use a condom with current partner (SMD 0.46, 95% CI 0.06 to 0.85), compared with a 1-hour lecture on the same content in a group.

Sexual behaviour and biological outcomes

There were no studies that evaluated the effectiveness of IDIs compared with face-to-face interventions on sexual behaviours and biological outcomes.

Comparison 3: how do interactive digital interventions work?

Does tailoring improve sexual health knowledge?

Data available from Cortese and Lustria¹⁶⁶ showed **no demonstrable effect on knowledge acquisition** (SMD 0.12, 95% CI -0.20 to 0.44) **or message elaboration** (relating new information to previous knowledge and experience) (SMD 0.29, 95% CI -0.03 to 0.61), comparing a tailored website with a non-tailored website.

Does tailoring improve self-efficacy?

Data from Mevissen *et al.*¹¹² show **no statistically significant difference** between the intervention and control arms for self-efficacy, comparing a tailored with a non-tailored website (SMD 0.07, 95% CI -0.08 to 0.23).

Does tailoring improve intentions?

Similarly, data from Mevissen *et al.*¹¹² showed that there was **no statistically significant difference** between intervention and control for intention (SMD 0.16, 95% CI -0.09 to 0.40).

Does tailoring improve sexual behaviour?

Data available from one study¹¹² showed **no statistically significant difference** in consistent condom use with current partner compared with control (SMD 0.40, 95% CI -0.06 to 0.85) among higher education students aged 18–25 years.

Does tailoring improve biological outcomes?

No studies in this group had measured the impact of tailoring on biological outcomes.

Summary of main results

Are interactive digital interventions effective?

We found that IDIs have statistically significant effects as follows: a moderate effect on sexual health knowledge (SMD 0.54, 95% CI 0.17 to 0.92), a small effect on self-efficacy (SMD 0.11, 95% CI 0.02 to 0.20) and a positive effect on sexual behaviour (OR 1.28, 95% CI 1.01 to 1.61), but no significant effects on safer sex intentions (SMD 0.09, 95% CI -0.01 to 0.19) or biological outcomes (OR 1.18, 95% CI 0.78 to 1.80). IDIs, therefore, seem to positively influence some modifiable determinants of sexual behaviour (knowledge and self-efficacy but not intention). There were no data on adverse effects.

Are interactive digital interventions as effective as face-to-face interventions for sexual health?

Data were available from only one study¹⁸³ on the effectiveness of face-to-face interventions compared with IDIs. The results of this study suggest that IDIs may be as good as or better than face-to-face interventions for sexual health knowledge acquisition (SMD 0.51, 95% CI 0.11 to 0.90) and intention (SMD 0.46, 95% CI 0.06 to 0.85), but not for self-efficacy (SMD 0.38, 95% CI -0.11 to 0.77). There are no data with which to draw conclusions about effects of IDIs on sexual behaviour, biological outcomes or adverse effects.

How do interactive digital interventions work?

The existing evidence on this topic is limited and focuses on the effects of tailoring. Data from one study shows no evidence of effect on knowledge improvement or message elaboration.¹⁶⁶ Another study provides no evidence of effect of tailoring on self-efficacy, intention or sexual behaviour.¹¹²

Key points

Interactive digital intervention effectiveness and mechanism of action

- We located 19 studies which were RCTs of IDIs for sexual health promotion for young people.
- Interventions were evaluated in variety of settings (schools, colleges, health-care settings and online).
- Trials evaluated IDIs for heterosexual young people and young MSM.
- The majority of RCTs were conducted in the USA, with two in the Netherlands and one in the UK.
- Interactive digital interventions are effective tools for learning about sexual health.
- Interactive digital interventions have small but significant effects on self-efficacy, and sexual behaviour.
- There is not enough evidence to be sure of the effects on biological outcomes or to be sure of longer-term impacts.

Recommendations for research

Robust RCT evidence is needed in order to:

- assess the impact of IDIs on biological outcomes and on sexual well-being (e.g. pleasure and relationship and sexual satisfaction)
- evaluate the effects of IDIs in comparison with face-to-face sexual health services or teaching
- evaluate the mechanisms of action of IDIs (e.g. optimal theoretical design, including BCTs, and core components)
- assess optimum exposure, dosage and timing for interventions
- assess the effectiveness of alternative models of intervention delivery (e.g. direct vs. facilitated access, different technological platforms)
- assess longer-term impacts.

Implications for policy and practice

- Interactive digital interventions developed in other countries could be adapted for young people in the UK.
- Interactive digital interventions are effective tools for learning about sexual health.

Chapter 5 Health economic evaluations in sexual health promotion delivered by digital media

Chapter aims

- To conduct a systematic review of economic evaluations of sexual health promotion delivered by digital media and to evaluate available evidence.
- To provide an explanation of economic evaluations in public health.
- To summarise the key methodological issues and literature for health economic evaluations in:
 - digital media
 - sexual health promotion.

Chapter-specific methodology

Expert interviews

Three experts in health economics and either sexual health promotion interventions or public health were interviewed using a topic guide. Interviews were one to one with a researcher who took notes and then transferred the conversation into a document that was used to inform the content of the chapter. The views of the expert interviewees will be referred to as health economist (HE) 1, HE 2 and HE 3.

Literature review

Economic evaluations of sexual health promotion delivered by digital media were sought as part of the main systematic review (see *Chapter 2* for detailed methodology). In addition to the criteria for inclusion (sexual health promotion delivered by digital media), to be an economic evaluation studies had to report costs and consequences of an intervention collected alongside a trial and/or in a decision-analytic model. Systematic reviews and cost of illness studies were excluded. Additional papers were identified through hand-searching references. Papers were checked for inclusion by two researchers. A total of 10 papers were identified as being potentially relevant. Of those 10, one paper was a cost-effectiveness analysis of a non-interactive digital media intervention for sexual health.¹⁸⁶ As so little directly relevant literature was identified, papers which did not fit the inclusion criteria have been used to inform the discussion (i.e. guidance documents on economic evaluations of public health interventions, papers of relevance to economic evaluation of digital interventions and economic evaluations in the sexual health field).

Results: economic evaluations in sexual health promotion delivered by digital media

We found very little evidence about the costs of development, implementation, dissemination, maintenance and adaptation to technological change of digital interventions, and no evidence on the cost-effectiveness of *interactive* digital interventions for sexual health promotion. The one study which was identified as being the most relevant was a cost-effectiveness analysis of a video-based HIV intervention for African American and Latino/a patients in the USA.¹⁸⁶ The intervention was a 20-minute video (VOICES/VOCES, delivered in groups in HIV clinics and designed to trigger group discussion following the video) plus regular clinical care. The control was regular clinical services only. The intervention did not precisely meet our definition of IDI, as it was not tailored or interactive, and was a composite intervention with digital and face-to-face components. However, this was the only economic evaluation of a digital intervention for sexual health promotion identified in our systematic search.

The incremental cost-effectiveness ratio (ICER; see *Economic evaluations in public health*) calculated in the study was cost per quality-adjusted life-year (QALY) gained and was based on trial data and a mathematical decision-analytic model of HIV cases. Participants were tracked through STI surveillance systems to identify new cases of STIs. As condom use was collected only at baseline and not follow-up, a mathematical formula was used to back-calculate annual condom use. This was calculated using data on STI incidence, risk of STI per act of unprotected sex, effectiveness of condoms and number of sex acts in the target population to estimate an individual's annual condom use. Costs and outcomes for the study were from the perspective of STI clinic managers and funding agencies. Costs included the cost of the intervention, including overheads and training, a condom kit for clients and lifetime HIV treatment costs. Uncertainty was tested using one-way sensitivity analysis (varying one variable in the model at a time to see what impact it would have on the results) and threshold analysis (varying one value in the model at a time to see what value it would need to be for intervention costs to equal treatment costs). The results were that the video intervention cost US\$43.30 per client. The intervention was cost saving and resulted in more QALYs gained than regular clinical services. The effectiveness mostly derived from clinic attendees with multiple sexual partners. The key weakness of the analysis was that it was based on an old model of HIV infection, with 1997 levels of cost and effectiveness of treatment.

The focus of this model was cost savings generated from preventing cases of HIV infection: 14 infections (95% CI 3.18 to 126.87 infections) prevented per 9500 intervention recipients. The lifetime cost to treat HIV was taken from Pinkerton and Holtgrave¹⁸⁷ and converted to 1999 USD. The undiscounted, upper estimate of lifetime costs was US\$247,766 (in 1999 USD prices, US\$346,451 when converted to 2013 USD). The lifetime cost to treat a new case of HIV has significantly increased over time, partially as a result of the improved effectiveness of treatment and hence increased life expectancy, but also the increased cost of treatment. The current best estimate of undiscounted lifetime costs to treat HIV in the USA is US\$567,000 (in 2004 USD prices, US\$694,096 when converted to 2013 USD).¹⁸⁸ In addition, the analysis did not include the cost savings from cases of other STIs prevented. If the analysis were updated to include the greater potential cost savings per HIV case prevented and cost savings from other STIs, it is possible that an interactive intervention of similar effectiveness, and the same cost per user, evaluated today could result in even greater cost savings. The intervention described also included the cost of group facilitators. Tailored interventions delivered through a different medium, such as purely online, and with less person contact, could cost even less per user, resulting in even greater potential cost savings. Also to note is that the intervention is specific to the USA and hence the results may not be directly transferable to a UK context.

Sexual health promotion interventions are likely to be cost-effective if the target groups have a high prevalence of STIs and/or if the intervention is relatively cheap. Once an IDI is developed, the ongoing costs can be relatively low and targeting large numbers of people can, in theory, be relatively cheap and easy. However, digital interventions may need substantial marketing budgets to promote effective dissemination. The level of uptake and engagement with an intervention and the characteristics of target populations might be more instrumental in determining the cost-effectiveness than intervention efficacy alone.

Economic evaluations in public health

An economic evaluation is the comparative analysis of costs and consequences of two or more alternative options. The aim is to provide decision-makers with additional information about which option might result in the best outcomes given a budget constraint or limited resources. The results of economic evaluations can influence funding decisions and new technology adoption, so the quality of the methodology used is an important issue. There are a number of different types of economic evaluations, with a common analysis being a **cost-effectiveness analysis**, where the summary statistic is reported as an ICER or cost per outcome gained. The outcome used in the ICER of a cost-effectiveness analysis is generally clinically relevant to the health or social care area in question, such as cost per infection prevented or cost per symptom-free day. Another type of economic evaluation is the cost-utility analysis,

which differs from the cost-effectiveness analysis in that the outcome in the ICER is a compound measure of mortality and morbidity quantified using preferences or risk in a standardised way so as to allow for the comparison of analyses across different disease areas or programmes of work.¹⁰¹

In health technology assessments in developed countries, such as the UK, QALYs are the unit most commonly used as the denominator of the **cost-utility analysis**. QALYs are calculated by weighting each year of life lived using a utility score. Utility scores are anchored so that 1 is perfect health and 0 is equivalent to the state of death. In some models negative scores are possible, representing states that are theoretically worse than death. Multiplying time in a health state by the health state utility value, 1 year of life lived in perfect health is equal to 1 QALY. If a person were to live for 2 years in a health state that is weighted as 0.5 of full health, this is also equivalent to 1 QALY. The utility value, and hence QALYs, are valued independently of a person's age, so 1 QALY is the same for someone who is 18 years of age and for someone who is 80 years of age.¹⁸⁹

The key body responsible for providing advice and guidance on best clinical practice including value for money in England, the National Institute for Health and Care Excellence (NICE), recommends that utility scores are obtained from a random sample of the general population and using a technique called time trade-off to arrive at a measure of preference under uncertainty for a given health state.¹⁹⁰ The generic questionnaire most favoured in the UK is the EuroQol EQ-5D (EQ-5D) and the most common variant used is the three-level version ('no problems', 'some problems' and 'a lot of problems'). This questionnaire consists of five questions concerning (1) mobility (walking about), (2) looking after oneself, (3) doing usual activities, (4) having pain or discomfort and (5) anxiety or depression. Responses to all five questions define 243 distinct health states, each of which has an associated country-specific utility score representing the preferences of a sample of the general population of that country.¹⁹¹ In the UK the score ranges from 1 for perfect health to -0.594: states worse than death (utility values less than zero) are possible with this value set. A five-level version of the EQ-5D is available and preference-based health-state valuations from a random sample of the general population are in the process of being derived.¹⁹²

Although QALYs calculated from the EQ-5D are the recommended outcome for assessments of new health or social care technologies in England, they are not the most suitable outcome in all situations. This will be discussed in more detail below in relation to sexual health promotion. The 2012 *Methods for the Development of NICE Public Health Guidance*¹⁹³ recognised that cost-utility analysis might not be the most appropriate type of economic evaluation in relation to public health. The main disadvantage cited was the narrowness of the analysis, in that a cost-utility analysis tends to include health benefits only. Local governments delivering public health programmes also have priorities and considerations beyond health, such as education, the environment and housing. For example, a local government may be interested in how a sexual health intervention reduces antisocial practices in a local park or improves education outcomes, which are factors that a purely health-focused cost-utility analysis would fail to capture. To accommodate this, NICE's public health methods document makes allowances for more emphasis to be placed on **cost-consequence analysis**, where costs and consequences are reported independently and as descriptive statistics, and **cost-benefit analysis**, where all costs and consequences are reported in monetary units.¹⁹³ Local government and other commissioners might be more interested in **budget impact assessment**, that is, the relative monetary impact on different stakeholders of implementing an intervention, as those who pay for the intervention might not be the same as those who see the monetary benefit. For example, if a sex education programme is implemented in a school, the school is unlikely to see the cost savings of the programme if it reduces the number of STIs among their students (HE 1). **Social return on investment** analyses might also be of interest to some stakeholders. Social return on investment has the advantage that its key aim is to value more than just financial transactions by providing a framework for measuring and accounting for social, environmental and economic costs and benefits. The results of the analysis are then reported as a ratio of £x social value generated for each £1 invested.¹⁹⁴ Given the wide array of potential costs and benefits that can be included when evaluating a public health programme, and the different methodologies available, a 12-point checklist has been published to assist researchers and analysts planning an economic evaluation of a public health programme.¹⁹⁵

Economic evaluations are increasingly being included as part of the design of RCTs; the National Institute for Health Research regularly requests this.¹⁹⁶ In this instance, the costs and consequences required to evaluate the intervention are collected as part of the trial. Although this has the advantages that come with a well-designed RCT, such as the reduction of bias and potentially more robust information, it has some distinct disadvantages: RCTs may not have the follow-up duration required or the sample size necessary to collect information on important costs and consequences needed as part of the analysis. For example, in a trial relating to chlamydia diagnosis and treatment a key consideration might be reducing the risk of infertility in later life. It is unlikely in most chlamydia screening and treatment trials that the follow-up duration will be long enough to capture this information or will have a sufficient sample size to draw clear conclusions on effectiveness.

An additional problem is that in public health trials, including those for sexual health promotion, there is usually a pathway involving modifiable determinants of behaviour change that influence potential impact on health status. For example, determinants of increased condom use include knowledge about how to reduce the risk of acquiring a STI, confidence about ability to use a condom and intention to use condoms in future. Consistent condom use is likely to impact on risk of acquisition of a STI. Research in public health tends to focus on measuring the impact of an intervention on determinant factors, such as knowledge, self-efficacy and intention and sometimes behaviour, whereas the impact on health is sometimes harder to define and measure as part of a trial but is the outcome of interest in most economic evaluations (HE 1). Modifiable determinants are relatively easy to measure, particularly if changes are noted during a trial, but it is hard to draw any conclusions about participants' subsequent behaviour or health, especially over the longer term (HE 1), as there may be only weak correlations with behaviour change and health impact. Changes in behaviour may represent better outcomes, for example reduction in risky sexual behaviour, as this is more closely correlated to health outcomes, such as STI acquisition.²² However, behaviour change can be hard to measure reliably as most behaviours are self-reported. There is not always a direct relationship with change in health status (HE 1), for example use or non-use of condoms will make no difference to STI acquisition if a monogamous couple have both previously been tested and treated for STIs. Little work has been done on valuing the aspects of sexual well-being that young people feel are important, such as satisfaction with relationships and sex life. The limited work on valuing sexual quality of life has been done from an adult perspective.

Health-related outcomes (such as chlamydia, HIV infection or unintended pregnancies) within an economic evaluation are generally the primary outcomes of interest. However, changes may occur a long time after an intervention or STIs may be relatively infrequent in young people¹⁸⁵ and so require a large sample size to draw any conclusions. When this occurs the recommended solution is to develop a **decision-analytic model**. This is a method for combining the best available information from a range of sources to estimate the costs and consequences of a particular health-care technology or intervention.¹⁹⁷ These sources can include other RCTs and combined outcomes from meta-analysis, observational trials and longitudinal cohorts for longer-term outcomes. An additional important source of data for informing decision-analytic models is health-care databases and routinely collected medical information (HE 2, HE 3). If current plans to improve the availability and usability of metadata come to fruition, this type of data is likely to play an even greater role in economic evaluations in the future. There are challenges associated with using routinely collected data in sexual health, though, particularly in relation to patient confidentiality. Unlike in other health-care settings, such as acute or primary care, patient data in genitourinary/sexual health clinics are not linked to other NHS data; only limited data that could be used to identify patients and link their records are held. Provision of details about patient's GP or NHS number to sexual health clinics is voluntary.

Economic evaluations of digital interventions

Digital media interventions are promising for a number of health conditions as the interventions can potentially be delivered cheaply to a wide audience. This may be a particularly important consideration for sexual health interventions delivered in non-health settings. For example, schools are more likely to be supportive of a health-care intervention delivered in a school environment if it costs the school relatively little to run (HE 1). Digital media interventions might be initially expensive to set up, but once set up they are likely to be cheap to run, as delivery to thousands of people may cost the same as to tens of people, depending on the level of additional health-care support provided.¹⁹⁸ Given the cost of treating some STIs, such as HIV, and the cost of unintended pregnancies, if the intervention is relatively cheap it needs to prevent only a small number of events in order to be cost saving. For example, a preconception counselling programme for teens with type 1 diabetes that cost US\$18 per participant only needed to prevent > 0.6 pregnancies per 100 girls in order to be cost saving.¹⁹⁹

A key challenge is how one might apportion the fixed costs that occur as part of the development and implementation of the intervention over the longer term and as a per-person cost, particularly if the costs of developing a technology are costs to one organisation. As technology develops, however, the cost of adapting the intervention to be compliant with advances in technology might also need to be included in the calculation. This cost is likely to be hard to estimate as the speed and extent of technology change is hard to predict. The other consideration is the level of health-care support, as an intervention with more support may be more effective but also more expensive to deliver. At this point economic evaluations may have an important role to play in summarising the extra benefit that could be realised from the additional cost of providing more human support, and may potentially come up with a 'sweet spot' where marginal gains increase more than marginal costs.

Careful consideration needs to be given as to who is the target audience for the intervention and how they interact with the relevant technology. In sexual health interventions there is a risk of targeting the 'worried well' or the healthy middle class (HE 3). Addressing the needs of those at higher risk may be challenging, as these people may be from hard-to-reach groups (such as the homeless and people in prison) who do not usually take part in research (HE 2, HE 3) or do not regularly use traditional health-care services and may not have access to digital technology. However, some hard-to-reach high-risk groups, such as MSM, may be relatively easy to reach with digital technology (see *Chapter 6*). Higher-risk groups are likely to represent a more cost-effective group to target, as prevalence of infection is higher and hence the number needed to identify and treat an infected individual is lower (HE 2). In summary, although digital media interventions have the potential to be cost-effective because of scalability, there is a risk that, if uptake of the intervention is low or if the population accessing it is low risk, the benefits seen are likely to be negligible. As a result, the cost-effectiveness of digital media interventions may be more sensitive to the number and characteristics of the target group accessing the intervention than to the magnitude of effectiveness of the intervention itself.

Economic evaluations of sexual health promotion interventions

Many of the economic evaluations of sexual health interventions were conducted prior to NICE guidance, which recommends cost-utility analysis as the preferred output of economic evaluations. The overall consensus among the three experts interviewed was that, although QALYs are the ideal outcome in most economic evaluations so as to facilitate the comparison of the results across disparate programmes of work, sexual health presents specific challenges to calculating and interpreting QALYs because of the difficulties in capturing the impact of changes to sexual functioning or STI prevalence using the generic health-related quality of life scales. In addition, there are also the challenges associated with measuring potentially rare events, such as new STI infections, and capturing changes if most of the decrement to health occurs in the distant future.

Most economic evaluations in sexual health have been cost-effectiveness analyses in which the ICER is the cost per case detected in the case of studies of STIs²⁰⁰ and cost per unintended pregnancy avoided in terms of contraception and abortion services.²⁰¹ This presents problems for economic evaluations of sexual health interventions as it is not clear what value, other than the cost of health care, should be placed on cases detected or unintended pregnancies to allow for comparison with other disease areas or programmes of work. In the case of STIs, such as genital chlamydia, most evaluations also fail to capture any long-term impact of the disease, such as the risk of infertility or ectopic pregnancy.²⁰² Although some sexually transmitted diseases can be asymptomatic, a diagnosis is likely to impact on quality of life and to do so in a range of ways, such as increasing anxiety or affecting the quality of a relationship with a partner, so there does need to be a standardised way to quantify this. A recent systematic review of valuing health states for chlamydia for decision-analytic models found a large number of ways in which the health impact of chlamydia was valued, in terms of both the utility score that was used to calculate QALYs and the duration of different health decrements, such as pelvic inflammatory disease. In studies where health-state preferences were directly elicited, the characteristics of the participants heavily influenced the value that they put on the health state. There is another challenge regarding chlamydia, which is that both men and women can experience infection but women experience the main complications of the disease.²⁰²

A sexual health quality of life measure that has an associated preference-based measure that can be used to calculate QALYs, the Sexual Quality of Life (SQOL) questionnaire, has been reduced to a three-dimension version (SQOL-3D), the three dimensions being sexual performance, sexual relationship and sexual anxiety, with associated preference weights. The SQOL-3D is currently being tested alongside the EQ-5D and other outcome measures in a feasibility trial of an online intervention to improve condom use among men.²⁰³ Future work may focus on developing measures outside the QALY framework, with the capability approach being one way of measuring the impact of public health programmes on health inequalities.¹⁹⁵ The capability approach differs from QALYs in that, unlike QALYs, where the aim is to maximise health and well-being within the population, the aim of the capability approach is to distribute capabilities (defined as the ability to function, given the choice) equally across the population. No measure of capability has been developed specifically for sexual health, but measures such as the ICECAP [ICEpop (investigating choice experiments for the preferences of older people) CAPability measure for adults] have been developed for other adult populations. The measure focuses on asking people whether they 'can' or are 'able to' achieve particular states within the quality of life domains of stability, attachment, autonomy, achievement and enjoyment.²⁰⁴

Collecting cost information in sexual health promotion trials is relatively easy, with the challenge instead being adequate recruitment to trials. This is particularly challenging if the aim is to report differences between intervention and control in preventing new cases of STIs (HE 1, HE 2, HE 3). As most of the work in sexual health promotion is on asymptomatic or disease-free individuals, it can be hard to get the numbers needed to draw clear conclusions about the effectiveness of an intervention. This presents a problem for the cost of the intervention as well, given the number of individuals who need to be seen before a case is detected or prevented. The intervention has to be very cheap or the prevalence of the disease in the population relatively high before the intervention is likely to be cost-effective (HE 2).

The challenges associated with measuring outcomes in sexual health-related trials mean that a common solution is not to rely on trial data alone but to develop decision-analytic models. Most of the earlier decision-analytic models in trials of chlamydia screening and treatment were static, relatively simple models.²⁰⁰ In these models, a cohort of hypothetical individuals, using information only on the average values and variation for the relevant population, has a probability of having an event based on preceding events (in the case of a decision tree model) or has probabilities of moving through different health states (in the case of Markov models). The total costs and benefits of a health-care programme over a given time horizon are then calculated using costs and benefits attributed to the events or health states. The problem with these models when evaluating the cost-effectiveness of STI-related health programmes is that they do not take into account the characteristics of STIs, for example the fact that once contracted the disease can be passed on to others and that even once an individual has been screened and found to be disease free it does not mean that they will remain in this state. The high correlation between parameters and assumptions

about independence in the decision-analytic model structures most commonly used in health economic evaluations (decision trees and Markov models) means that they are not suitable in this area. Instead, more complex mathematical decision-analytic models at a patient level are recommended, such as discrete event simulation or system dynamics at a cohort level (HE 2, HE 3). To evaluate the cost-effectiveness analysis of home-based screening for chlamydia, Roberts *et al.*²⁰⁵ developed a dynamic simulation model of 50,000 virtual people aged between 12 and 62 years. Characteristics of people in the model are based on random draws from expected population values from published data. The strength of this model in evaluating the cost-effectiveness of a STI-related intervention is that people in the model can 'interact': the individuals have partnerships with specific characteristics that can form and dissolve. Individual interactions (e.g. if contraceptive protection is used, if the individual is infected or if they have been diagnosed, treated and are no longer infectious) can be independent events in these models and a better replication of real life.

Further research and consensus is, therefore, needed on how best to cost intervention development, implementation and maintenance; how to measure health and well-being outcomes in the sexual health promotion field; and the best ways to conduct economic evaluations of digital media interventions for sexual health promotion. Although calculating QALYs is usually the preferred approach, this may not be the most appropriate way to measure health and well-being for sexual health. It is necessary to define and value patient preferences in sexual health and develop robust methods for collecting long-term outcomes. As most of the costs and benefits of sexual health promotion come from potentially rare events (such as the prevention of cases of STIs), it is likely that large, observational data sets of routinely collected data will play an increasing role in capturing this information, as they present a potentially cheaper solution to collecting data on a large number of individuals over a longer time horizon. If a decision-analytic model is being developed, as in any area, the model needs to be carefully designed to ensure that it captures the key characteristics of the disease area in question.

There is not a one-size-fits-all approach to economic evaluation: the costs and consequences collected, how they are collected and how they are analysed are dependent on the research question, the population group and the intended audience. There are a number of documents that provide guidance on identifying key issues and designing an economic evaluation.^{193,195} Given the range of methodologies available to researchers and analysts, and the different potential costs and benefits that can be included, this guidance can help to identify what should be collected and how best to analyse and report the results given the research question and the intended audience.

Key points

Economic evaluations in public health

- Economic evaluations are the comparative analysis of costs and consequences of two or more options and provide decision-makers with information about which option might result in the best outcomes given a budget constraint or limited resources.
- Cost-utility analysis, the incremental cost per QALY gained, is the type of economic evaluation recommended by NICE in the UK to allow for the comparison of results across disease areas and programmes of work.
- In public health there is recognition that cost-utility analysis might not be the most appropriate option, as QALYs are potentially too narrow to capture all of the outcomes of interest, in particular non-health outcomes (such as wider behavioural, environmental, education and social functioning outcomes).
- RCTs are generally considered the gold standard in determining the effectiveness of an intervention. However, they may not capture all of the information necessary to adequately assess the cost-effectiveness of an intervention. In these instances, decision-analytic modelling (collating information across a range of published sources) is recommended.
- Mathematical models and published data are needed to overcome some of the limitations of primary data collection.

Economic evaluations of sexual health promotion interventions

- Cost–utility analysis (composite mortality and morbidity) may not be suitable for assessing sexual health interventions as it may be hard to capture the main outcomes of interest, especially as the events, such as STIs, may be rare and costs and outcomes may occur a long time after an intervention.
- Cost-effectiveness analysis, expressed as cost per STI case detected or cost per pregnancy avoided, may be more relevant for assessing sexual health interventions. However, it is not clear what value should be placed on outcomes or how the results compare with cost-effectiveness analyses for other health-care programmes.
- Decision modelling of long-term outcomes allows for the collation of a wider range of information over a longer time horizon. When modelling sexually transmitted disease in particular, careful consideration needs to be given to the type and structure of the model used.
- The cost and effectiveness of medical treatments for diseases is constantly changing, with more effective but more expensive treatments regularly becoming available. As a result, economic evaluations can quickly become out of date in their prediction of costs and QALYs.
- High-quality data on the effectiveness of an intervention at preventing new infections are not always readily available, unless STI surveillance systems are in place.

Cost-effectiveness of interactive digital interventions for sexual health

- Digital media interventions provide a potentially low-cost way to access a large audience. This is mostly because of their scalability, as the main cost is in the initial development of the intervention.
- The high cost of treating STIs, in particular chronic conditions such as HIV, means that a cheap intervention needs to prevent only a few cases before it becomes cost saving.
- In some situations, particularly if the uptake of the intervention is low, cost-effectiveness may be determined by the number of high-risk people accessing the intervention as much as the magnitude of effectiveness of the intervention.
- Targeting those at higher risk of sexual ill-health may be most likely to make an intervention cost-effective.
- Although there is limited evidence, effective sexual health IDIs are likely to be cost-effective.

Recommendations for research

- The costs of development, implementation and maintenance of IDIs should be recorded and reported.
- Evaluations and trials of new interventions should include an appropriately designed economic evaluation to increase the evidence base in this area.
- Work is needed to establish how best to capture and measure outcomes in economic evaluations of sexual health IDIs (e.g. the SQOL scale compared with the generic health-related quality of life scale).
- Work is needed to establish the best ways to collect, value and apportion costs and consequences of IDIs in sexual health over longer time horizons, for example how to capture long-term health costs and consequences of new cases of STIs and how to correctly apportion the initial costs of development and implementation over a longer time horizon and a large number of users.
- The role of sexual health IDIs in reducing health inequalities requires further research.

Implications for policy and practice

- Although there is limited evidence, effective sexual health IDIs are likely to be cost-effective.

Chapter 6 Implementing sexual health promotion interactive digital interventions in real-world settings

In this chapter we discuss what is known about optimum conditions for implementation and the structural barriers and facilitators that affect access, uptake and impact of digital sexual health promotion IDIs.

Chapter aims

- To summarise the literature on engagement, adoption, maintenance and implementation of IDIs for sexual health promotion.
- To identify barriers and facilitators to successful engagement, adoption, maintenance and implementation in different settings.
- To assess the relative merits, as well as some of the problems and risks, of implementing digital interventions.

Chapter-specific methodology

Frameworks

We refer mainly to the RE-AIM framework²⁰⁶ for structuring discussions and identifying the key issues and gaps in the literature that might be important for implementation of sexual health promotion IDIs in clinics, schools or for self-access through the internet. RE-AIM considers reach, efficacy, adoption, implementation and maintenance of interventions as the necessary and important elements contributing to impact. In this context, these concepts are taken to mean the following:

- **Reach** – how well it reaches its target audience. For IDIs this is influenced by factors that affect both **access to** and **engagement with** the intervention.
- **Efficacy** of the intervention on targeted outcomes – this is addressed in *Chapter 4*.
- **Adoption** – the types of setting in which interventions are implemented, the barriers and facilitators to their adoption in different settings and consideration of how they can be adapted appropriately.
- **Implementation** – how well and consistently the intervention is delivered in a particular setting (health and education) by staff and how this should be facilitated and overseen. We also refer to Normalisation Process Theory,²⁰⁷ a conceptual framework that seeks to determine the mechanisms through which an intervention might become embedded within educational and health-care settings.
- **Maintenance** – the factors influencing sustainability of interventions over time at individual, community and organisational levels. At an individual level this includes the degree to which behaviour change can be sustained over time. At an organisational level, this addresses how the use of interventions can be maintained over the longer term, what support would be needed including technical and financial and how institutionalisation of an intervention can be predicted.

In applying these frameworks, we found that the literature was weighted more heavily towards design and effectiveness studies, to a lesser extent towards reach and engagement and was very limited with respect to furthering understanding about the challenges of implementing sexual health IDIs in practice. We were, therefore, inclusive in our approach, incorporating a diversity of study designs and publication types for the narrative synthesis. We included any publication that gave insights into issues for implementation, an approach that precluded formal quality review of each paper. We have also drawn on expert interviews and symposia and user focus group discussions to supplement the literature where appropriate. Data were coded and analysed descriptively in relation to the RE-AIM and Normalisation Process Theory frameworks and triangulated with findings from the literature.

Results

Reach

Digital interventions have the flexibility to be implemented either in a defined setting, such as a school or clinic, or through self-access wherever people are located, via the internet or, for example, a smartphone app. While most evaluation studies have been conducted in school or clinic settings, as most interventions are internet based, there is flexibility about how they might be delivered in practice.

The proportion of the target population reached by the intervention is fundamental to its impact, with a potential trade-off between effectiveness and reach. The population impact of an intervention with relatively low effectiveness can be mitigated if it reaches relatively high proportions of its target population.¹⁴⁴ However, little is known about the factors that might influence the reach of interventions in a real-world context and how this might differ for different target populations. Measures of recruitment to evaluation studies can be only a proxy measure for how well implementation might work (especially as incentives have often been used for research recruitment). In addition, studies from the USA strongly predominate in the literature, limiting the generalisability and learning for UK education and health contexts.

Reach: clinic and educational settings

The settings that have been most studied for sexual health promotion IDIs are schools and clinics, although other environments, such as youth facilities and young parent groups, could also be appropriate (expert symposium).

Clinical settings

Offering interventions in clinical settings has the clear advantage of quick and easy access to a 'captive' audience, compared with purely self-accessed internet interventions.^{113,127,143,144,208} Locations that are frequently accessed by the target population can be identified to maximise reach, using face-to-face methods.^{118,127,153,209} This approach provides straightforward and quantifiable access where coverage and fidelity to the intervention (such as number of visits to the site and dosage) are generally higher and can be more easily measured. Nonetheless, sexual health clinic attendees also often attend on a once-only basis, limiting the opportunity for follow-up access and requiring either that interventions have impact in a single use or that ongoing online interaction is maintained. For example, interventions delivered by text message, initiated from a clinic visit, can continue to be delivered to people wherever they are located. There is, therefore, the potential to sustain and increase motivation for targeted behaviours over a longer time period.

For particular clinic populations, such as young substance misusers,¹²⁷ placing the intervention in the appropriate specialist service is a 'quick win' for reaching those people who are in touch with services. Targeting populations with particular conditions in the clinical setting means that interventions reach them when they are a captive audience.^{118,128} Particular settings may favour the particular sociodemographic groups of interest, for example sexual health clinics can provide easy access to high numbers of young people at relatively high risk, but, again, the advantages may be offset by excluding a proportion of those not in touch with services and who may have the greatest needs. Assessing service-use characteristics of the target population is an essential part of intervention development, as reaching them in a clinical setting is a potentially quick, cheap and easy way to ensure that they are preferentially accessed.

Although there are a growing number of digitalised solutions within the area of sexual health care more broadly, there is little guidance or exploration of what would be needed, by whom and how for this to be an effective approach in practice for the area of sexual health promotion. Recruitment to studies in the clinic is not a good proxy for assuming reach of the intervention, as the research process is facilitated by researchers or clinical staff in a way that is unlikely to be replicated in practice. Additionally, study participants may differ in important but often unquantified ways from the whole-clinic or other target population. More investigation is needed about the strategies and mechanisms that could promote and maximise the reach of interventions in a non-study setting while minimising the impact on clinic flows.

There is increasing interest in online provision of services such as STI testing and emergency contraception provision via the internet, directing people to local face-to-face services where appropriate (interview, sexual health practitioner). Such novel forms of service delivery lend themselves to the provision of online sexual health promotion alongside service delivery.

Educational settings

Educational settings have been studied widely, particularly in the USA, as places where large numbers of young people can be reached in single or repeated sittings.^{94,141,166,210,211} As IDIs for sexual health promotion have been shown to be effective in increasing knowledge (see *Chapter 4*), they may be particularly appropriate for the delivery of school-based sex education. Digital methods in this context have the advantage of ensuring that all topics are covered and delivered similarly across schools. There is scant UK literature in this field and the potential for digital interventions in supporting school SRE provision is underexplored. Sexual health promotion IDIs in school may help to overcome reluctance and embarrassment by teachers to deliver aspects of SRE, especially if students can access programmes outside lesson times, but alternative settings are also needed to provide access for non-attenders or in instances where schools opt out of comprehensive SRE (interviews, education and health practitioners and e-health researcher).

Educational settings have the advantage of allowing virtually universal coverage (assuming parental permission) of a target population who can also be accessed repeatedly, in contrast to many clinical environments. For example, the intervention *It's Your Game: Keep It Real*⁹⁴ was designed for delivery to school students over eight sessions, and the students were largely retained throughout. By implementing interventions in particular schools, such as special educational settings (for pupils with disabilities or demanding behaviour), they can be further targeted to the needs of more disadvantaged populations.²¹¹

Reach: online interventions

Although online delivery depends on active searching and finding by users, this approach has the advantage of allowing interventions to be self-delivered at a self-determined pace and intensity. Offering interventions online may capture harder-to-reach populations who are not in touch with mainstream clinical services.^{112,123,212} Reach can be optimised for self-access by understanding:

- i. the use of **different technologies** by young people
- ii. young people's **sexual health information needs**
- iii. the **promotional strategies** that are likely to be effective
- iv. the appeal of intervention **design** and contexts.

Reports indicate that use of the internet by young people in the UK is almost universal and that most people have access in their own homes.²¹³ Harder-to-reach groups (that may have lower levels of engagement with services) have the equivalent usage of internet and other platforms to non-disadvantaged groups. However, bandwidth and connectivity may be a limiting factor for some young people accessing the internet from home²¹⁴ and the loading time for sophisticated graphics may be unacceptable for those with slower connections.²¹² The reach of interventions to young people is unlikely to be restricted by access to mobile phones or the internet, but is more likely to be limited by the technology itself or by controls by parents or schools. Privacy concerns may also prevent young people from searching for information about sex and sexual health on mobile phones or in public places.

By taking advantage of the range of digital modalities that young people use, interventions can be delivered through a range of formats, making information as widely accessible as possible for both those who do not attend mainstream services¹⁵² or to overcome any restrictions to access. Multimedia formats such as audio and graphics may facilitate access to content for populations with low literacy.^{83,127} Many of the currently available interventions could be adapted for internet, CD-ROM or mobile phone use, maximising their reach.¹²⁷ Selection of the modality for use should be guided by understanding the technology usage of the target population. For example, the preferential use of mobile phone technologies by black MSM groups,⁷⁰ the potential for technology-assisted social interaction games for Hispanic girls¹²⁵

or the use of online sexual networking sites (interview, voluntary sector provider) have all been identified in preference assessments.

Assessing patterns of use of different types of technology, frequency, duration and preferred features and activities is, therefore, integral to intervention design.^{70,162} Formative work suggests that higher-risk groups, such as MSM (and young men in general), may be less inclined to access face-to-face services, but further work is needed to evaluate how successful targeted web-based interventions are in reaching these populations. This has been less well explored in young people and it is not known how applicable some interventions developed for an older target group are likely to be to younger MSM.

Use of technology: mobile phones

Mobile technology provides a high-reach delivery mechanism for health behaviour-change interventions. In the UK mobile phone use is almost universal in the 16- to 24-year-old age group.²¹⁵ As most young people carry their mobile phones with them wherever they go, support can conveniently be delivered wherever people are and whenever it is needed. BCTs and personalised content can be delivered by mobile technology. There is the potential to personalise content according to the demographic characteristics of participants (e.g. gender or age) or their issues in changing behaviour. Content can be further personalised using interactive features. Health behaviour-change interventions delivered by mobile technology can be effective. Once developed, interventions can be low cost.

In lower- and middle-income countries sexual health interventions delivered by text message have achieved high reach. Some trials of interventions in lower- and middle-income countries and in the USA report statically significant and clinically important increases in contraception use.

Many interventions developed to date are, however, unlikely to be optimal, as they do not employ all of the BCTs needed to target the factors influencing behaviour. In the UK, despite high mobile phone ownership and usage and the potential to reach disadvantaged youth,⁷⁰ sexual health promotion delivered by text messages is an under-researched area. A qualitative evaluation of a mobile phone intervention shows that the intervention is feasible and acceptable to young people (*Box 5*).

Young people's mobile phone use is very high, for example for social interaction, to download videos and, potentially, for health information. Young people who received multimedia sexual health information via mobile phones found this very acceptable and it also enhanced peer-to-peer and parent-to-young-person discussions about sexual health.²¹⁷ Initial evaluation of the Trelya fLASH initiative, which uses short textable videos for health promotion around alcohol awareness, also shows this type of intervention to be highly relevant and acceptable to young people, as well as motivating them to think about health behaviours.

BOX 5 Mobile phone texting intervention²¹⁶

In the UK, a theory-based IDI was delivered by text message to young people reporting unprotected sex with more than one partner in the past year or diagnosed with chlamydia. Messages targeted the correct treatment of STIs, including partner notification, avoiding unprotected sex for a week after treatment, condom use and STI testing. The intervention was developed based on factors influencing safer sex behaviours, Behaviour-Change Theory and sexual health expert and user views. Qualitative evaluation of the intervention shows the intervention is highly acceptable. Participants reported that the intervention reduced stigma and helped them to tell partners about their infection sooner and more calmly. Some reported they would not have told their partner about the infection if they had not received the messages. Participants reported that they had learned how to avoid problems with using condoms and explained how sharing messages with partners had enabled them to negotiate condom use. Messages were sometimes saved to reread and shared with younger siblings, friends and partners. A pilot trial of the intervention is in progress.

Further trials are needed to assess the reach of mobile phones compared with that of other platforms in reaching young people with sexual health IDs.

Despite the potential of texting interventions and use of the mobile internet, a systematic review of currently available HIV and STI prevention mobile phone apps shows that these are rarely downloaded or used.⁷⁰ Sexual health tools may be needed once or twice only (e.g. service locators, symptom checkers) and issues of privacy may discourage the downloading of sexual health apps. It may be that apps will be downloaded if they are developed in response to specific issues faced by participants. Such apps could be promoted in clinics or advertised more widely.

Use of technology: social networking sites

The frequent use of the internet by young people for networking both socially and sexually via sites such as Twitter, Facebook and YouTube and dating sites such as Grindr offers opportunities for intervention.¹³⁹ MSM report regularly meeting contacts through digital sexual networks,^{123,212} and this may provide a critical 'teachable' moment to engage with sexual health promotion.^{139,218} However, although more than half of young people surveyed in the USA have looked up health information online,¹²⁷ few (1 in 10) report use of social networking for any health-related issues and even fewer for sexual health-related issues.²¹⁹

Other approaches to exploiting social networking opportunities include development of Facebook pages for communicating health information by health professionals^{92,220} or from the clinical setting.²²¹ However, there was limited success of some of these initiatives in promoting the dialogues with at-risk groups.²²⁰ Attracting young people to relevant sites may be difficult.⁹²

While the reach of social networking sites is expressed in terms of interactions such as 'likes', wall posts and comments, through which peaks and troughs of interaction can be charted, the public nature of social networking sites allows for greater opportunity for more personalised communication. The particular taboos of sexual health mean that social networking for sexual health behaviours or peer support may also not be appropriate. For example, someone increasing their physical exercise could post about this on a social networking site for some moral support and encouragement, but it may not be socially acceptable to report increased condom use in this way. Even if users like programmes and have found them useful, they may not be willing to publicly endorse sexual health apps, which makes it difficult to assess the popularity of sites and reduces the possibilities for viral dissemination of sexual health interventions.

There are ways to minimise the risks of breaches of privacy, confidentiality and data security on social networking sites: groups can be made secret and member-only, with all communications on a group 'wall' or in private messages,²¹⁸ computer algorithms can detect telephone numbers or e-mail addresses to prevent exchange of contact details between site users, moderators can remove private information on bulletin boards or in chat rooms, for example, and can also monitor for bullying online.³⁹

Although there is a lack of literature in this area and a lack of evidence of impact on behaviour, MSM in particular have been successfully engaged with sexual health promotion via social media sites (interview, voluntary sector provider). Exploiting different forms of digital media and their social networking potential across different platforms not only widens reach but may enhance their pro-social impacts (impacts on community and social networks).²²²

Sexual health information needs

Engaging young people in sexual risk reduction behavioural change is a challenge. Sexual behaviour is motivated by enjoyment, with risk to health a secondary concern (researcher, e-health). Interventions may need to adopt a more positive stance in which sexual enjoyment, as well as adverse consequences, is addressed.

Interventions are more likely to be attractive if they reflect the sexual health information needs of young people. Young people do use the internet to seek information about sensitive topics concerning their sexual health,²¹⁹ but many feel that current information available online does not fully meet their needs.³⁹ Analysis of online search threads representing young peoples' sexual health concerns shows that they are interested in a wide range of topics and find a huge range of competing online information of variable quality. Topics include sexual pleasure, puberty, menstruation and transmission and mechanisms of infection. Some of the search terms and strategies used by young people may not generate the best-quality information. In the Sexunzipped study, the most frequently visited content on the website was about sexual pleasure.¹⁸¹ Where they have concerns, young people tend to search using symptoms rather than medical terminology.

Much of our learning about the information needs of young people is also gained from experience within sexual health services. Child sexual exploitation, abuse and violence, as well as mental and emotional health and well-being, are some of the problems for which young people seek help. The views of more marginalised groups are not easily captured and clinic intelligence is another mechanism through which to identify the needs of young people. Increasing the understanding of users and reflecting their common concerns within the content and textual strategies of web-based interventions, as well as through views and experiences of clinic users, will maximise the chance that they will be accessed through young people's web searches.

Promoting access to interventions

One of the main challenges to adoption, particularly of primarily online interventions, is facilitating users to first perceive the need that they might want to address. While young people may actively seek (sexual) health information about specific problems through internet search engines, they are less likely to seek out sexual health promotional materials, and those who do are often those who are best at getting help and least likely to be those in need (researcher, e-health).

Although searches for sexual health-related information may lead to specific sites, users can also be proactively engaged through various promotional 'push' factors, such as face-to-face interventions (in services and elsewhere), word of mouth, flyers,¹¹⁴ banner adverts online or the placing of study descriptions on websites with high usage by target groups.^{139,223} However, these methods are generally deployed in the context of research studies and may be too costly and time-consuming to be sustainable in the long term for intervention implementation. The promotion of a website through online mechanisms and posters and flyers in clinics as part of local-level health promotion activities is a relatively low-cost option.

Integrating digital interventions with ongoing initiatives is one approach. For instance, young people already access well-known organisations and brands that they trust (including the NHS) for the information or services they need, and these avenues could be an important vehicle for the promotion of interventions or to expand access (interview, voluntary sector provider). There are also digitalised sexual health promotion initiatives, such as the 'Come Correct' condom distribution scheme (again a recognised brand), that remain unexploited as a vehicle for superimposing digital sexual health promotion initiatives (interview, voluntary sector provider).

Options for virtual sexual health diagnostics and treatment where the need for face-to-face consultation is replaced are increasingly being explored. This underexplored opportunity for sexual health promotion may represent a vehicle for the integration of more tailored interventions. One example, the eSTI (Electronic Self-Testing Instruments) Research Consortium led by St George's Hospital in South London, is using microfluidics to develop novel point-of-care STI testing and a mobile phone-based diagnostic app that could link provision of results (positive and negative) with sexual health promotion initiatives (interview, sexual health researcher).

Little has been written in the literature about which methods to promote interventions are likely to be most effective in terms of reaching the target population. In practice, statutory budgets are likely to prohibit much investment, and services may find themselves competing with the much more highly resourced commercial sector. There are few studies that specifically examine barriers and facilitators to improving intervention access, which methods are likely to reach particular groups and how people who are reached via the internet or face to face exhibit different levels of risk. A multidimensional strategy is likely to be best but incurs greater costs and may be difficult to sustain in the longer term.

Intervention design features

The design of interventions that are reliant on self-access needs to take account of features of a website likely to facilitate access and adherence. Even if young people are recruited to an intervention, it may be more difficult to keep them engaged over multiple sessions and modules. Young people are likely to be multitasking and instant messaging online, which presents a challenge in terms of maintaining engagement with an intervention.²¹⁴ If interventions require some degree of sustained and repeated engagement²¹⁴ then greater understanding of the factors that facilitate this for sexual health interventions is needed. Building an initial rapport and situating the importance of the intervention may help to maintain engagement and encourage users to return to a site. Ensuring that the intervention website is embedded in sites that are already visited by the target group²¹⁴ or the use of online peer facilitators as an adjunct to self-access²¹⁸ are other strategies.

Complex design features require close collaboration between technical and research teams,²²⁴ as well as input from users about their preferences. The look and feel of a website is important for engagement but, in this rapidly changing field, may quickly become out of date.³⁹ Young people may want social interaction via features such as discussion boards, but non-contribution may alienate young people from using a site.³⁹

Reach: mixed delivery

Many interventions have the flexibility for use either in institutional settings or online, although evaluations commonly centre on those that have been delivered in schools, clinics or in controlled research settings.^{113,120,144,214} In practice, clinics or educational settings can attract users to internet interventions whether or not they were originally designed to be delivered there (*Box 6*).

Reach: engagement

Once a young person finds the sexual health intervention, it is not known which factors will maintain interest or encourage them to visit more than once. It may be easy to attract young people to an online intervention, but engagement tends to fall off over time.²¹² Although participants can be flexible about when they interact, there is little social pressure to return, unlike for face-to-face interventions. In one study, about 20% of those enrolled to one intervention¹¹⁹ did not complete it. One possibility is that this was due to poor internet connectivity. There needs to be a balance between sophistication of the programme and time taken for the intervention to load.¹¹⁹

BOX 6 Self-access or kiosk-based intervention delivery

Bull *et al.*, seeking to capitalise on relative and contrasting advantages of self-access and 'kiosk-based' implementation, studied both modalities.¹¹¹ The research team were more successful in reaching individuals who were at higher risk from the clinic setting than online. However, they failed to demonstrate significant effect of the intervention for either route of recruitment. They conclude that, while the individually delivered intervention in a single session may not be of sufficient intensity for effect, the internet intervention failed owing to fall-off in participant engagement over time. Although the study recruited a relatively diverse sample, the reported proportion of protected sexual acts was 71–83%, suggesting that even this multipronged approach to recruitment may fail to reach the highest-risk groups. However, not enough is understood at this time about the relative advantages of promoting access to interventions in the different ways, nor about the preferences of different groups.

There are challenges for health promotion interventions in both terms of attracting users' attention²¹⁴ and sustaining attention throughout one or multiple sessions, sufficient to be effective. Audiences that are most successfully retained tend to be female, middle class, well educated and have higher income and interventions may, therefore, miss those at highest risk.⁹⁷ There may be an advantage in building trust through face-to-face recruitment, for example in clinic environments,^{143,211} where higher-risk individuals may be more likely to attend. Face-to-face engagement strategies may serve to build rapport and encourage users to stay with the intervention. In a climate where financial pressures require more to be delivered at lower cost, one model is to integrate a facilitator to support users in continued engagement with an online intervention for health promotion. While the active ingredient is in the digital intervention, a health-care assistant provides human interaction to support its delivery. Rather than replace services, this reduces costs, enabling more to be delivered for less and using the health-care setting mechanisms to foster adoption and ongoing engagement (interview, e-health researcher).

Online studies of web-delivered sexual health promotion interventions tend to direct participants to complete the intervention themselves over a finite period, typically 1 week.^{119,139,225}

In social networking interventions, interest tends to decline over time or messages may be downloaded once without further engagement. Different delivery mechanisms may sustain interest, such as videos, quizzes, etc., but this runs the risk of fragmenting the message.⁸⁹ Experience points towards a shorter time frame with a single standalone message; however, evidence of the effectiveness of this approach is lacking.⁸⁹

Interventions delivered by mobile phone can have fewer problems with engagement with the intervention because messages can be delivered to participants wherever they are in order to boost and sustain waning motivation. This makes it imperative that messages are appropriately developed to ensure that they are not irritating or intrusive and that clear instructions are delivered to the participant regarding how to stop receiving messages if they wish. For interventions delivered by text or voice message, participants wanted a friendly, knowledgeable and non-judgemental tone.⁸⁴ They asked for no more than three text messages per day. They also wanted short messages that gave practical advice and support. Participants diagnosed with STIs wanted information to cover what the problem is, what to do about it and where to get help. Messages that provided examples of how others had tackled problems or issues were considered especially helpful.⁸⁸

It is important to assess the usability and perceived relevance of an intervention by the target group.¹²⁰ Users (who completed interventions) tended to rate sexual health promotion interventions highly on usability, attractiveness and enjoyment.^{123,139,142} Completion of an intervention is a more objective marker. One study measured engagement through the number of webpages that were viewed. One-quarter of participants viewed more than 10 pages of the Sexunzipped website (which was available for self-directed use), one-quarter did not view any of the pages and the remainder explored a few pages of website content.¹⁸¹ There was minimal prompting to access the website.

Engagement with content is also an important consideration in maintaining interest and adherence. Users may scan content but it is difficult to assess the degree to which they are actively engaged and processing it. There is a suggestion that individual tailoring does have an independent effect on enhancing elaboration of health promotion messages (i.e. applying messages to personal situations).¹⁶⁶ Understanding which particular elements of tailoring are needed for digital interventions to be effective is an area that needs more work. There is already evidence for factors that moderate the effect of print-based tailored health promotion interventions, such as having more than one intervention with closer follow-up,⁷³ and some of these findings may be applied, with caution, here.

Use of humour is another technique that has been used to attract and maintain attention, although styles of humour, particularly in a sexual health context, differ, can potentially cause misunderstanding and can reduce credibility.¹⁵⁰ Making a message memorable, however, also increases its potential for indirect effect

through either social networking or face-to-face interaction with other young people.¹⁵⁰ In terms of features and operationalising constructs, young people report that they favour sites with built in social interaction features, such as discussion boards.³⁹

Gaming offers another avenue of engagement.¹⁴¹ A novel online gaming environment in which users interact with a virtual sexual health clinic via an avatar with personalised interactive features is currently under investigation.²²⁶ In India, mobile phone-based games promoting HIV awareness through 'Safety Cricket', 'Life Choices' and 'The Great Escape' achieved high reach, with 10.3 million game sessions in 15 months. Their non-randomised evaluation suggested it increased condom use, age at sexual debut and HIV awareness.²²⁷ Although young people frequently game online for entertainment, the acceptability and desirability of gaming for sexual health promotion interventions needs more exploration.

The use, acceptability and potential of different delivery platforms for interactive sexual health promotion interventions remain underexplored in this rapidly changing field. As new forms of social media and their usage for sexual health intervention are likely to outpace detailed investigation, pragmatic evaluation of innovations is needed to generate learning about the modes of delivery that are popular for this type of intervention and the factors that facilitate and inhibit their reach.

Adoption

Sexual health promotion IDIs may be implemented in schools, clinics or any other setting either to complement existing services or to replace elements of the sexual health promotion currently delivered face to face. Aims, likely impacts on current ways of working and anticipated benefits all need to be conveyed to frontline staff in advance in order for adoption to be effective.²⁰⁷ Some adaptation of the intervention to local context is necessary for this process to be successful,²²⁸ however, this can also create tensions where retaining fidelity to theory may be at odds with the needs of context: the 'local adaptation-fidelity' debate.²²⁹ It also assumes an understanding of which of the intervention 'ingredients' are active and must, therefore, be preserved in this process of adaptation. Initiatives arising from stakeholders 'on the ground' in clinic or educational settings have the advantage of being grounded in existing contexts and constraints, but are less likely to be underpinned by Behaviour-Change Theory (interview, e-health researcher).

In a clinical setting, there is huge potential for digital interventions to replace the simpler elements of clinical care, but there is anxiety among stakeholders about how this might threaten important functions of the face-to-face consultation [service providers, SASH (Studies in Adolescent Sexual Health) workshop]. 'Buy-in' from implementing staff is important for the effective implementation of technology, and a significant cultural change is still needed in both clinical and educational settings (interview, voluntary sector provider).

Implementation

We did not identify theory-based sexual health promotion IDIs from the literature that had actually been implemented in original or adapted form in practice in either a research or a real-world health or education setting. However, there are pockets of innovation in this area in both statutory and voluntary sector settings, and there is increasing motivation among some policy-makers and people on the front line for exploring this area further.

Adaptation of face-to-face interventions

One example of a school intervention currently under development aims to combine inputs from users with the expertise and experience of voluntary sector professionals in face-to-face delivery using pre-existing materials to develop a digital intervention. The face-to-face intervention involves young people moving around themed learning zones and participating in a range of facilitated discussions and activities. For example, one area might be about discussing health promotion facts, another about discussing different dilemmas and another about talking about identity and sexuality and challenging some of the myths and preconceptions. This resource is being translated into a series of digital approaches using tablet computers and mobile apps so that it can be delivered using digital media. The resource will then be marketed and promoted to schools and teachers can be trained to use it (interview, voluntary sector provider).

Such initiatives as these, which have been developed in collaboration with stakeholders, potentially have an advantage of being grounded in the direct experience of young people's needs, as well as having an understanding of the context for implementation. Implementers are likely to understand from the outset how the intervention adds value and can drive development in a way that complements existing initiatives. However, less is known about the degree to which face-to-face initiatives can be directly translated and remain effective, how they can be introduced and the settings in which they are likely to be most effective.

While these examples most often hail from the voluntary and commercial sector, the NHS has not kept pace with technological development in other settings. Implementing interventions has often been hampered by difficulties regarding access to the internet and cumbersome processes to enable interventions to interface with current systems (interview, e-health researcher). This is a very real barrier to ensuring that interventions are implemented (and also to evaluation in target settings). Implementation may be easier if a sexual health promotion IDI can be linked with existing digital health systems, especially if systems are meeting particular needs of users or if systems are already integral components of clinical care pathways, for example:

- online symptom checkers
- service locators
- free condom schemes
- internet-postal self-test services (e.g. for chlamydia testing)
- digital results services
- contact tracing by mobile phone or e-mail
- social networking sites (e.g. dating or hook-up websites)
- social support online (e.g. herpes or HIV support groups).

Wider policy-level support and financing

Policy, legislation and standards are important determinants of whether or not an intervention is likely to be implemented. The lack of national mandatory SRE beyond biology, coupled with constraints on health-care and education financing, is a barrier to the provision of comprehensive sexual health promotion interventions in schools or clinics. Similarly, without explicit sexual health promotion standards to drive improvements in this area, perceived upstream preventative initiatives may not take precedence in local priority setting processes.

Local organisations may be reluctant to commission sexual health promotion interventions when they are juggling service imperatives, their organisational capacity to provide, financial barriers and a lack of short-term measurable outcomes. Current sexual health quality standards are based on biomedical outcome measures, such as reduction in teenage pregnancy and STIs.⁵⁵ As there is no performance-managed requirement for service-based sexual health improvement, this significantly reduces the likelihood of adoption of sexual health promotion initiatives. However, some policy-makers and clinicians are prepared to take a longer-term view, recognising the future benefits on sexual ill health and service use (interview, NCSP manager). As sexual health promotion is a cross-cutting issue, potentially linking with other health agendas such as mental health and substance misuse, as well as cross-sectorally with, for example, education, opportunities to share financial risk are already being explored which can make investment more appealing (interview, policy-maker).

Maintenance

Ongoing management and financing digital interventions after implementation has been underexplored. Websites need continuous maintenance and review. Interventions incorporating a social networking element require posts to be checked for accuracy and relevance, as well as provision of moderation of discussions. One approach to moderation via social networking sites has been the use of the peer-led HIV prevention education via Facebook that has been adopted in the HOPE (Harnessing Online Peer Education) study, training peer educators in methods likely to be effective.²¹⁸

Small, regular updates of digital interventions are needed to incorporate new facts and research. The look and feel of a website also dates rapidly, meaning that more major revisions are required. These maintenance issues are costly in terms of financing and time and present a challenge for a low-resource environment.⁸⁹

Key points

- The impact of a sexual health promotion IDI is determined by its **r**each (proportion of the target population reached), **e**fficacy, **a**doption (within the target setting), **i**mplementation (how well it is delivered) and **m**aintenance (sustainability) – RE-AIM.
- Educational and clinical settings provide a captive audience for delivery of interventions but may miss higher-risk individuals who did not attend the services.
- Health promotion interventions should take advantage of the digital devices and functions that the target population most commonly use, such as mobile phones, social networking and gaming.
- Young people are most likely to search the internet for information about pleasure, relationships or symptoms, or to use 'brands' viewed as legitimate, such as the NHS. This should be taken into account in deciding where to place digital sexual health promotion initiatives.
- Implementation strategies should combine online promotion with face-to-face methods in education, clinical or other settings used by young people for maximum impact.
- Engagement with an intervention tends to diminish over time. Face-to-face methods of recruitment and ongoing support encourage continuation, but little is known about the most effective strategies.
- A cultural shift is needed within both education and clinical settings before digital sexual health promotion interventions are widely adopted. Frontline staff need a clear understanding of how interventions will both benefit and impact on current ways of working.
- Adaptation of interventions to local context is needed, but the important core components of an intervention must be preserved during this process.
- Interactive digital interventions could be offered in conjunction with currently existing digital health systems, for example online service locators, online services (for condoms or STI testing), clinic results systems and sexual health or dating websites.
- There are organisational and structural challenges to implementing interventions, particularly in relation to the structure of IT within the NHS.
- There are few national educational and health policy levers to support the implementation of sexual health promotion IDIs. Commissioning decisions are taken locally and do not have a mandated sexual health promotion commitment. However, this is strong policy support for deploying digital technology in health in future.
- Maintenance contracts for updating and maintaining the hardware and moderating social interaction are required in order for sexual health IDIs to be implemented sustainably in practice.
- Implementation studies are needed in order to understand the factors associated with effective implementation of sexual health promotion IDIs.
- Research is needed into the contextual opportunities and constraints for the adoption and implementation of digital sexual health promotion IDIs within education and clinic settings.
- Closer cross-sectoral working between health and social care and voluntary and commercial sectors in this field is needed for shared financing of digital initiatives, as national policy levers and funding options are limited.

Chapter 7 Digital research methods and optimum research methodology to evaluate digital interventions

Introduction

Digital platforms are increasingly used to reach people for research as well as for health care and health promotion. In this chapter we give an overview of digitally mediated research methods, consider specific issues in the evaluation of digital interventions for sexual health promotion and highlight gaps in the evidence in this area.

Chapter aims

The specific aims of this chapter are to explore:

- advantages and disadvantages of digitally mediated research methods
- digitally mediated research methods for evaluation of effectiveness of digital interventions
- optimal comparators (control groups) to evaluate digital interventions
- optimal outcomes (including social and emotional well-being) in sexual health.

Chapter-specific methodologies

The literature reviewed in this chapter includes core papers that address issues related to digitally mediated research methods and methods for evaluation of digital interventions, especially online trials. Where appropriate, we have drawn on literature from other fields, such as digitally mediated research methods in the fields of alcohol harm reduction and smoking.

Digitally mediated research methods

'Digitally mediated research methods' means the use of online and other digital technologies, such as online surveys, text messages and interactive voice response systems for research purposes. The following section highlights the advantages and limitations of digitally mediated research methods compared with other research methods.

Advantages of digitally mediated research methods

Digitally mediated research methods have several advantages compared with face-to-face methods.

Convenience and cost of online recruitment of study participants

It is feasible, acceptable and relatively cheap to recruit research participants online via search engines such as Yahoo! (Sunnyvale, CA, USA) or Google,²³⁰ dating websites^{72,231} or social networking websites such as Facebook.¹⁸⁵ Consent, randomisation and data collection can be fully automated online, which is convenient for participants as well as for researchers.^{111,185} A large number of study participants can be recruited online in a relatively short period of time.^{185,232,233} Online recruitment also makes possible the automated recording and estimation of response rates, for example numbers of people viewing a web advertisement, numbers of people clicking through and numbers of people completing and submitting

data.^{185,232} Digitally mediated research can be administered using technologies such as desktop PCs, laptops, tablet computers and mobile phones, which facilitate access to research at convenient times and locations.²³⁴ With research accounts accessed with a personal login, survey responses can be saved part-way through, allowing participants to return at a later time.^{235,236} An online medium for sexual health research was preferred to other research methods (e.g. face to face or paper) by young people in a UK research study.²³⁷ Adaptive questioning (skip patterns) can reduce the length of a survey and increase its relevance, enhancing the user experience.²³⁶ Data collection via mobile phone apps or by text can allow for more immediate data submission and can, therefore, enhance recall and convenience.

Reaching 'hard-to-reach' populations

Some stigmatised, hard-to-reach populations who are also at risk of sexual ill health may be heavy users of the web and mobile phones in order to meet sexual partners or clients (e.g. MSM or sex workers). The internet has provided a platform to study HIV/AIDS risk behaviours among hard-to-reach populations,²³³ for example via chat rooms on gay websites.²³⁸⁻²⁴⁰ Digitally mediated research methods have facilitated the recruitment of MSM in communities where homosexuality is stigmatised.²⁴⁰ Less is known about the potential for recruitment of young people to research through dating sites.

Audio and digital graphics can improve accessibility among individuals with limited literacy,^{83,241} and in resource-poor settings with limited access to the internet, mobile phones may have much better reach and can be used to collect survey data.²⁴²

Privacy and validity of data

Reporting bias (social desirability bias) is a challenge in studies of 'sensitive' topics such as sexual behaviour, drug use or alcohol use. Participants may be more comfortable entering responses to sexual health questions online than being interviewed face to face.²³⁷ Computer-assisted self-interview²⁴³ and mobile phone-mediated interactive recording systems²⁴⁴ can lead to greater reporting of risky sexual behaviours than traditional methods, such as a pen-and-paper questionnaire, thereby reducing reporting bias. Electronic formats can also improve the internal consistency of data and enhance data completeness by requiring all questions to be answered.²⁴⁵

Challenges of digitally mediated research methods

Several factors may threaten the validity of data collected using digitally mediated research methods.

Sampling bias

Sampling in online research is 'convenience sampling', as it is not possible to randomly sample from the whole population of interest.²³² It can be hard to assess the representativeness of online samples and, therefore, the generalisability of results.²⁴⁰ Clear information about routes and methods of recruitment will help to assess possible recruitment bias and the implications for generalisability.

Validity of data

Accurate data are vital for research. The potential anonymity of the online environment raises concerns about invalid data owing to, for example, multiple enrolment or deliberate falsification.^{233,246} Multiple enrolment has been reported as occurring in an online sexual health survey as well as in online trials of digital interventions for sexual health.²⁴⁶ Multiple enrolment can be minimised by collecting several different personal identifiers (e.g. name, e-mail address, postal address and telephone number), and by requesting information (e.g. date of birth) on different occasions.^{185,231,235} Internet protocol (IP) addresses can be used to check for multiple enrolment. However, shared IP addresses may originate from communal spaces (e.g. a library or shop) and in some households more than one participant may be eligible for participation. Offline contact is another strategy, for example requiring a postal address for the receipt of incentive vouchers¹⁸⁵ or following up with a personal telephone call.²³¹ Where eligibility was in doubt, Bull *et al.*²³¹ asked participants to fax a copy of their driving licence.

There is a risk that participants may rapidly fill in an online survey without responding honestly, simply to obtain an incentive. Appealing to participants' altruistic attitudes and providing them with information about the relevance of accurate data may minimise the submission of invalid data.^{99,235} Young people said that they are more likely to fill in a survey honestly if the research topic is perceived as valuable, and if the questions are seen as relevant to them.²³⁷

Dealing with invalid or suspicious data may increase research costs if incentives are disbursed to individuals who were ineligible or who had already participated, and also for personnel time to deal with this issue.²³⁵ Careful decisions should be made about how to handle potentially invalid data: invalid/suspicious data can be compared with other cases and potential biases assessed and reported.²³⁵ The identification and exclusion of data may reduce the final sample size, so researchers should allow for this in sample size calculations.

Anonymity

Anonymity may be an important factor for participants in online trials addressing sensitive issues. It may be difficult to give incentives to study participants without compromising anonymity.²³² Strategies such as the collection of IP addresses or the use of cookies to track users can be used to ensure that participants fill out a survey only once,²¹² but such strategies may affect participation rates. Therefore, researchers need to carefully consider whether or not forgoing anonymity is a suitable approach for decreasing invalid data, depending on the study's topic, population and available staff resources.²³⁵

Confidentiality

Concerns about privacy and confidentiality can be a barrier to participation in online studies.²³⁰ However, a low occurrence of breach of confidentiality was reported among MSM recruited to an online survey through banner advertisements.²⁴⁷ Breach of confidentiality had occurred when someone had walked into the participant's room while they were completing the survey or reading the e-mail invitation to participate; however, only one participant had concerns about the disclosure. Young people frequently share digital devices³⁴ and so unintentional breaches of confidentiality are a concern for digital research with young people. Researchers should inform study participants of the potential risks to confidentiality and any measures that can be taken to minimise those risks.

Data storage and security

The collection of online data poses the challenge of storing the data securely and maintaining the confidentiality of study participants (e.g. in accordance with the Data Protection Act 1998¹⁷³ and information governance guidelines). Secure Sockets Layer (SSL) encryption was used for data collection in an online study on HIV risks among young MSM²³⁵ to ensure data protection. SSL is a security technology for establishing an encrypted link between, for example, a web server (website) and a browser, which allows sensitive information to be transmitted securely. SSL certificates are issued digitally by trusted certificate authorities and browsers trust only certificates that come from an organisation on the list of trusted certificate authorities. Therefore, researchers should use servers that are authenticated by a certificate authority for data collection and storage. Most e-mail accounts are inherently insecure, so careful consideration should be given to the possible risks of communicating via e-mail and research participants should be made aware of possible risks and of strategies to minimise these. Automated e-mail systems are potentially very convenient for research administration and follow-up, but batch-generated e-mails may be treated as spam/junk mail. Participants should be asked to look out for this and to add study e-mail addresses to lists of acceptable senders.²⁴⁸

Evaluation of effectiveness of digital interventions

This section provides an overview of the challenges and facilitators for evaluation of effectiveness of digital interventions, in particular research using online trials. In this section we discuss the nature and implications of conducting RCTs of digital interventions in an online environment.

Recruitment

Recruitment of young people to online studies is feasible offline (e.g. via health-care settings^{83,88}), at community events²⁴⁹ or entirely online.^{66,119} Online trial procedures can be completely self-directed/automated, for example accessing trial information, establishing eligibility, obtaining informed consent and randomisation to experimental arms. There is a possibility of losing a high proportion of potential participants during all of these stages.⁶⁶ However, several factors can enhance recruitment in online trials: exclusivity (i.e. intervention website access limited to research participants), user-centred design (i.e. involvement of user groups to develop online trial recruitment materials), findability (routing the website through well-known and respected sites), media advertisement and piloting.⁹⁹

Randomisation systems

Robust methods of randomisation in trials are essential to minimise allocation bias. Automated randomisation and concealment of allocation to study arms is technically easy, and can be seamlessly achieved as part of an online trial procedure.^{111,139,185} Automated methods can also enhance the blinding of research personnel. Trials of sexual health interventions delivered by mobile phone have used paper-based data entry combined with remote randomisation systems, or web-based data entry systems which automatically link to a remote randomisation system. The randomisation system can then automatically send text or voice messages according to the group allocation.^{83,88}

Fidelity of digital interventions

It is important to know whether or not an intervention was delivered as intended. Fidelity can be defined as 'the methodological strategies used to monitor and ensure the reliability and validity of behavioural interventions'.²²⁹ There are different components of fidelity; content fidelity refers to whether or not the intervention components were delivered as prescribed, whereas process fidelity refers to the consistency with which intervention content was delivered.²⁵⁰ Using robust study designs to avoid contamination between the study arms and standardised delivery of an intervention can enhance fidelity.

Digital interventions may be self-administered, with private, individual access which can facilitate controlled access to an intervention and reduce the risk of contamination between study arms. However, contamination between study arms can occur, for example if participants show each other text messages²¹⁶ or websites.²³⁷

The standardised format and medium of delivery of IDIs to trial participants ensures fidelity in administration of digital interventions, although, in practice, actual delivery is less controllable. A challenge with self-administered online interventions and short message service (SMS)-based interventions is to ensure that an appropriate dose is delivered and that the intervention is completed. Adequate exposure means engaging with interventions for long enough (or a sufficient number of times) to be able to process the information.²⁰⁶ A lack of engagement can affect intervention fidelity²⁵¹ and underestimate the potential efficacy of an intervention.

Among adolescents who do not have a specific health problem they wish to address, it is a challenge to sustain their interest and, therefore, their exposure to digital interventions. A review of studies showed that theoretical foundation of the intervention, perceived personal relevance to the user, perceived effectiveness, persuasive technologies, credibility and social networking also influence engagement with online interventions.²⁵² Self-regulatory strategies, such as inviting users to commit to revisiting the intervention (if required), by indicating a time when the user might like to revisit, can be used to enhance exposure.²⁵³ As described in *Chapter 3*, design features of interventions can also influence engagement. Thus, it is important to conduct usability testing and involve users in the development of online intervention content and to conduct feasibility testing to avoid technical challenges and ensure smooth access and navigation. Various strategies, such as e-mail reminders to log in for booster sessions¹¹¹ or return for follow-up sessions,⁶⁶ resending intervention messages^{90,120} or giving financial incentives,⁶⁸ have been used to enhance exposure to interventions.

Differential usage of interventions by trial participants can influence the validity and reliability of the trial results. Eysenbach²⁵⁴ suggests that researchers should report raw drop-out proportions at different points in time, as well as 'usage half-life', which indicates after how much time 50% of the participants will have stopped using interventions. Analytics software can automatically record visits to individual webpages¹⁸⁵ or activities, such as writing or responding to posts, updating medication adherence data, viewing articles, etc.²⁵⁵ To ensure exposure, willingness to return to the intervention site at least twice during the study was used as one of the eligibility criteria for study participation.¹¹¹ However, with self-administered digital interventions, it is hard to know how they are used in practice; young people in particular may be multitasking while programmes are open. Defining exposure/usage of digital interventions can, therefore, be a challenge. There is a need to define what constitutes usage/adherence to digital interventions and to develop mechanisms for reliable measurement.

Retention in randomised controlled trials of digital interventions

Trial feasibility is described as the percentage of participants recruited and retained at each assessment point.²⁵⁶ Low levels of retention in trials can affect the power of the study and external validity. A common challenge in online trials is the high proportion of dropouts before completion of the trial.^{230,247,254} However, some online trials have shown higher retention rates, for example 90% at 1 month,²⁵⁵ 72% at 3 months¹⁸⁵ and > 70% in a trial with a follow-up period of 1 year.²³⁹ In a trial of an IDI delivered by automated voice message, 86% follow-up was achieved for self-reported data at 4 months.⁸³ A trial of a digital intervention delivered by text message to increase safer sex behaviours achieved 93% follow-up for self-reported data at 1 month and 86% follow-up for chlamydia tests at 3 months.⁸⁸ Eysenbach has hypothesised that dropout from a trial usually follows the pattern of non-usage of an intervention,²⁵⁴ although this was not substantiated in a trial of a website for alcohol harm reduction, in which greater adherence to the intervention was not necessarily associated with greater retention, especially in the intervention arm, and factors associated with intervention usage and retention in the trial were not similar.²⁵² There is a need to conduct further research to better understand factors influencing retention in trials of digital interventions and engagement with digital interventions. Various strategies can be used to enhance retention in trials of digital interventions, as follows.

Participant contact information and retention

A high proportion of participants' e-mail addresses can be invalid and affect the effective use of strategies such as sending reminders via e-mail to enhance retention.^{65,230} Given the low retention rate in trials despite e-mail reminders, researchers have suggested that participants should be asked to provide an e-mail address that they check at least once per day or to provide an e-mail address that is important to them (e.g. one that they use for financial management).²⁴⁷ Evidence suggests that using multiple ways to contact participants, such as sending e-mails, telephone calls and using multiple reminders, during the follow-up period can enhance retention.^{185,231} In a trial among young MSM, > 80% of those who returned to the study site after receiving multiple reminders did so within two reminders and 98% did so within three reminders.²³⁰ In the Sexunzipped trial with young people, 36% completed an online questionnaire in response to the first e-mailed invitation and 60% responded within five e-mailed reminders. Follow-up was further boosted by sending questionnaires by post. These data suggest that retention in online trials can be a challenge but that follow-up reminders using multiple methods can be used to boost retention.

Incentives

Bull *et al.*²³⁰ offered an incentive to young MSM of a \$50 gift certificate at the end of the 3-month study period, but reported a poor retention rate (15.2%) at 3-month follow-up. Despite a generous level of incentive, non-participants were more likely to be unemployed and have lower levels of education and less likely to have health insurance. In another HIV prevention trial among young people, Bull *et al.*²³¹ offered incentives to participants after submission of baseline data, a 1-month booster session and 2-month follow-up as opposed to at the end of the trial. They also gave additional incentives to participants if they completed the booster session of the intervention and follow-up assessment within 8 hours. A higher value incentive was associated with better retention rates at 3 months than a lower-value incentive in a sexual health promotion trial among young people in the UK.¹⁸⁵

Duration of follow-up

Klein and Card¹⁴² have suggested that the duration/length of computer-administered interventions should be shorter than face-to-face interventions to minimise dropout, but core programme elements and logic models should drive these decisions.²³¹

Methods/venues of recruitment and retention

Enrolling participants face to face and then asking them for commitment to participate in trials can enhance retention among online trial participants.²⁵⁷ Bull *et al.*²³⁰ obtained high recruitment rates through a paid banner advert on a high-volume website, but this was expensive and yielded the lowest retention rates compared with other methods, such as using flyers, e-mail lists, etc. They argue that, if online recruitment reaches a wider population than face-to-face recruitment, the likelihood of recruiting persons who have a high probability of attrition is greater. They raise the question of whether or not high attrition should be considered to be an 'acceptable hazard' of online RCTs. Text messaging may be an alternative to the internet for data collection in digitally mediated trials.²⁴⁷

Recruitment and retention costs

In a sexual health promotion trial among young people, online recruitment was relatively cheap compared with trials conducted in primary care, for example, as the majority of participants were recruited through Facebook at a cost of £8.95 per participant recruited (Dr Julia Bailey, University College London, 2014, personal communication). However, offering incentives to retain people can be expensive: in the Sexunzipped trial, participants were randomised to receive a £10 or £20 voucher for 3-month questionnaire completion and returning a sample for genital chlamydia testing. Those who were offered a £20 voucher were 6–10% more likely to provide 3-month follow-up data than those offered £10.¹⁸⁵ An online trial to reduce alcohol consumption found that 3-month retention rates were higher for the group who were offered a £10 gift voucher versus nothing, at a cost of £52 per additional response.²⁵⁸ Further research in this area might compare this with retention rates and costs for other trial designs to find the method that represents best value for money.

Other challenges

Murray *et al.*⁹⁹ reported that the website for the Down Your Drink study (DownYourDrink.org.uk) had become popular over the years since its launch in 2001. However, three other sites with similar domain names were subsequently created with an intention to make money through advertising (i.e. people clicking on information about alcohol services on these pages were taken to web adverts). The authors suggest that researchers should buy suites of related domain names prior to starting a research program (e.g. *website.com*, *.org*, *.net*, *.co.uk*, etc.) to prevent 'cybersquatting'.

Optimal comparators (controls) to evaluate digital interventions

The choice of comparator (control) group is influenced by the aims of the research, ethical considerations and also pragmatic factors such as cost. To assess the effects of an intervention, the optimal comparator group should be a 'minimal' intervention such as, for example, no-treatment condition, standard care or a leaflet. The choice of minimal intervention can influence the observed effect sizes. For example, comparators such as information-only websites or 'usual internet use' may themselves have an impact, which would, therefore, reduce any observed difference between trial arms. Most studies assess outcomes at baseline and at follow-up. However, simply measuring outcomes may constitute an intervention in itself.^{237,259} Such measurement reactivity may reduce observed differences between trial arms. The size of any measurement effects could be assessed in a RCT which compares a baseline measurement arm with a no-baseline measurement arm, measuring both groups at follow-up to assess the effect of measurement alone (with no other intervention).

While it is important to assess the efficacy of digital interventions, it is also important to assess their effectiveness compared with face-to-face interventions. Such trials are equivalence trials, in that finding evidence of no difference is a positive outcome. RCTs can also evaluate IDIs in combination with a face-to-face component as a composite intervention, for example in the study by Tortolero *et al.*,⁹⁴ who compared an 'IDI-enhanced classroom lesson' with a 'usual classroom lesson'. The choice of comparator, therefore, depends on the research question to be addressed.²⁶⁰ In combining the results of studies in meta-analyses, it is important to consider the nature of study control groups and to combine separately studies which compare IDIs with minimal interventions, those which compare IDIs with face-to-face interventions and those which test composite interventions⁹⁷ (see *Chapter 4*). Answers to questions such as 'what is the effect of self-directed IDIs?', 'what is the effect of facilitated IDIs' and 'are IDIs as good as face-to-face interventions?' will inform public health decisions related to the commissioning of health promotion interventions.²⁶⁰

The comparison of different designs of digital interventions in two-arm trials can provide insights into the mechanism of action of IDIs (e.g. comparing a tailored with a non-tailored website). However, many separate RCTs would be needed to test the multiple components of IDI design. Randomised experimental designs, such as factorial designs, can be used to identify active components of an intervention, active components of intervention delivery and optimal doses for example.²⁶¹ Such research designs can address questions of how IDIs work in order to unpick the active components of IDIs as complex interventions.

Qualitative process evaluations

Qualitative process evaluations are needed to evaluate how complex interventions work and to assess engagement and implementation in practice.¹³¹ Qualitative methods such as simulations can provide insight into possible mechanisms of action of digital interventions, including factors to do with design and delivery, which can impact on uptake and engagement and, therefore, effectiveness.²⁶² Qualitative observation in practice can help to assess patterns of engagement and implementation and to discover unanticipated adverse effects of interventions.¹⁶⁹

Intervention evaluation in practice

It is not always feasible to conduct RCTs to evaluate the effectiveness of digital interventions because of constraints such as time, funding or expertise. The ever-changing nature of technological innovation and the redundancy of old technology makes the use of faster methods of evaluation of digital interventions vital in order to assess their effect on health and cost-effectiveness. Although RCTs are considered the gold standard, despite their limitations other non-randomised methods can be used for evaluation of digital interventions. A pre-post design can capture changes in outcomes following the use of an intervention,^{263,264} although observed changes could be caused by confounding factors. This kind of study design may be appropriate for the evaluation of digital interventions after general release, as data could still be collected from users in situations where randomisation may not be acceptable to users (e.g. when accessing a new app).

Changes in patterns of use of technology have implications for online research design: for example, if interventions involve social networking or content sharing, this makes it harder to define the precise content of a digital intervention. It is also potentially harder to control who has access to an intervention, and to keep control and intervention groups separate, as digital content can be easily shared and young people frequently interact with websites or mobile phones together.³⁴ Some researchers have endeavoured to build on the potential effects of social networking to enhance intervention effects, also recruiting networks of people (as a group) into research.

The commercial sector has a long history of using market research to capture user views and preferences and to optimise user experiences with technology. However, research outside university or health settings is not subject to the same ethical and research governance regulation: an experiment was conducted on the social networking site Facebook in which posts expressing positive or negative emotional states were displayed or blocked from other users' sight, and subsequent posts' emotional content was noted.²⁶⁵ The study was carried out without ethical committee approval and concerns have been raised about the lack of informed consent or opportunity to opt out. A balance needs to be struck between exploiting the utility of easily collected online data and the rights of participants in research.

Measuring sexual health outcomes (including social and emotional well-being)

This section examines some challenges in the measurement of sexual health outcomes.

Nature of outcomes measured for sexual health interventions

The choice of outcomes to measure should reflect the theoretical design of an intervention; in other words, it should reflect the aims of the intervention and capture the behaviours and health outcomes targeted. It is also important to measure the modifiable determinants of behaviour which are specified in hypothesised pathways of action (such as knowledge, self-efficacy, perceived susceptibility and intention), to understand possible mechanisms of action of interventions.²⁶⁶

Researching sexual behaviour is challenging because sex and sexuality are embedded in webs of often contradictory social significance.²⁶⁷ Qualitative research gives access to deeper understandings about sexual behaviour, but does not yield quantifiable estimates of the effect of interventions. Capturing a 'true' picture of sexual beliefs, attitudes and behaviour is challenging with quantitative tools because standardised questionnaires strip away the complexity and context.²⁶⁸ Qualitative research can be conducted online (e.g. interviews by instant message or group discussions in chat rooms), but data from these may be less rich than those which are attainable from face-to-face or telephone interviews. Quantitative data collection (online) is cheaper, quicker and more convenient than qualitative data collection, but qualitative understandings are necessary to be confident that research findings are meaningful.²⁶⁹

Sexual behaviours are often complex. For example, 'condom use' involves many steps: a condom user needs the knowledge of how to use condoms correctly, the confidence to use it without adversely impacting on sexual performance or pleasure, the motivation to use it, to obtain and carry condoms and skills to negotiate with partner(s). 'Condom use' is, therefore, not just one behaviour, but a series of behaviours requiring the involvement of others. In addition, 'condom use' needs to be understood in context; for example, condoms may be seen as less relevant for a monogamous heterosexual couple using the contraceptive pill and with negative STI screens. For these reasons, composite sexual health outcomes which take into account a number of factors may be more meaningful.²⁷⁰

There is a lack of standardised outcome measures, even for behaviours such as condom use or self-efficacy. Few studies capture factors which are important to young people (e.g. measures of sexual well-being), and there is little agreement about how best to capture dimensions of social and emotional well-being, although researchers are turning their attention to these issues.²¹ Interventions may target several health behaviours (e.g. alcohol consumption, drug use and sexual behaviour)¹²⁰ but this may present challenges for measurement, as outcome questionnaires may need to be long and spurious associations may be found simply by chance if large numbers of outcomes are measured.

Behavioural and biological sexual health outcomes may not be appropriate for all age groups. For example, interventions may aim to impact on condom use, but young people may not be experiencing penetrative sex with sufficient frequency to capture changes in condom use. Measuring the determinants of behaviour might be more appropriate (e.g. self-efficacy or intention), and/or over much longer follow-up periods. Age-appropriate outcomes should, therefore, be used in research with young people.

Reliability of outcome measurement

Many outcomes in sexual health are, by their nature, subjectively experienced and so are necessarily self-reported, for example self-efficacy, intention, regret, relationship and sexual satisfaction, etc. Some behavioural outcomes can be measured objectively. For example, a study examining the effectiveness of daily text reminders for adherence to contraceptive pills used both daily diaries and an electronic monitoring device to measure adherence to pills and found that the latter was a better predictor of (lack) of adherence.⁸¹ In another study, actual condom use was established by checking bins in a brothel.²⁷¹ However, methods such as these may be expensive to administer, may pose ethical challenges and may not be feasible practically.

Biological outcomes are the 'gold standard' for measuring impacts on health,⁶⁸ but STI events are relatively rare for most young people and it may be hard to capture acute infections such as chlamydia at single time points, as they may have been acquired but also treated by the time of follow-up.¹⁸⁵ Capturing incident STIs over a given study period through clinic records is likely to be more accurate, but there can be problems in identifying or tracking patients through medical records because of concerns about confidentiality and data security.

Optimal follow-up periods

Most RCTs of IDIs that we located measured the effect of IDIs on outcomes either immediately post intervention or by 3 to 4 months (see *Chapter 4*). One study followed up participants for 6 months.⁶⁸ Measurement at different time points for different outcomes is appropriate; an intervention may have an immediate impact on knowledge, self-efficacy and intention,⁶³ but behaviour change will take longer to emerge (especially if sexual contact is a relatively rare event for a young person) and impacts on biological end-points are likely to take even longer. For example, it could take years to realise the impact of a school educational programme on STIs or unwanted pregnancy. The impacts of interventions could be amplified over time (e.g. as skills are practised) or could diminish: repeated measurements would help to understand the impact of interventions on different outcomes over time,²⁷² and to understand impact on determinants of behaviour change. As noted above, the follow-up periods for educational interventions for school-aged children may need to be long in order to capture changes in behaviour.⁹⁴

Measurement reactivity

The detailed measurement of sexual health outcomes in both an intervention arm and a control arm can prompt reflection about sex and sexual health.²³⁷ A study conducted among MSM showed that the mean number of unprotected anal sex partners in both the study arms declined over time during the 12-month follow-up period.²³⁹ It is difficult to know if this observed decline was caused by real decline in both the study arms (which can potentially suggest measurement reactivity), regression to the mean, or if it was caused by other coincidental factors. Collecting only minimal baseline data prior to allocation to study arms could be one way to minimise measurement reactivity.

Evaluation paradox

There is also an 'evaluation paradox'; if participants know that there is doubt about the effectiveness of an intervention, this can lead to an underestimation of its effects and, hence, a reduced confidence about following advice given during the intervention.²⁷³

Key points

Advantages and disadvantages of digitally mediated research methods

- Research administration via technology such as mobile phones and laptops can be convenient for participants and for researchers.
- Online recruitment can be quick and relatively cheap.
- The internet can help to reach hard-to-reach, stigmatised and at-risk populations.
- Audio-visual features can help to reach participants with poor literacy.
- Digitally mediated surveys facilitate research of sensitive issues, such as sexual health, by offering privacy during data collection.
- Digitally mediated (private) data submission encourages honest disclosure, enhancing the internal validity of data collected online.
- Convenience sampling is used in online research: as the sampling frame is not known it is hard to assess sample representativeness (and, therefore, the generalisability of results).
- Risk of multiple enrolment in online studies can be minimised by using multiple personal identifiers to enhance internal validity of data.
- Researchers should take adequate measures to ensure the confidentiality and security of data collected and stored digitally.
- Study participants should be provided with adequate information about the risks of participating in online research.

Evaluation of effectiveness

- Automated (digital) randomisation and allocation methods can minimise allocation bias.
- Digital interventions, by their nature, offer standardised content, minimising inconsistencies in delivery of intervention content.
- Ensuring exposure to digital interventions as intended can be a challenge. Various digital methods, such as reminders via e-mail, text message, etc., can be used to improve exposure to digital interventions.
- Reliable measures to assess exposure to digital interventions need to be developed.
- Retention in trials of digital interventions conducted solely online is a challenge. Strategies such as offering incentives and using multiple methods of contact can enhance retention in online trials.
- Evaluation of digital interventions is vital for assessing any potential adverse effects.

Measuring sexual health outcomes

- The choice of outcomes measured should reflect the theoretical design of an intervention, including hypothesised pathways of action.
- Few studies capture factors which are important to young people (e.g. measures of sexual well-being).
- Age-appropriate sexual health outcomes should be used in research with young people.
- Composite outcomes may be more accurate (e.g. contexts for condom use, including duration and type of partnership, history of STI testing, use of other types of contraception, etc.).
- Suitable outcomes to capture the costs and cost-effectiveness of IDs are needed.
- Long-term follow-up data are needed to assess any intermediate impacts on determinants of behaviour change and the persistence of intervention effects.
- Biological outcomes are the 'gold standard' for measuring impact on health, but STI events are relatively rare and may be hard to capture at single time points.
- Study designs should allow for the effect of potential measurement reactivity (the effect of measurement itself).

Implications for research

- Mechanisms for intervention evaluation could be planned at the intervention development stage, for example baseline and follow-up questions and user views on an intervention in practice.
- Online (quantitative) research methods can be convenient for participants and researchers, and relatively cheap.
- Digitally mediated data collection (e.g. by mobile phone or by computer) can enhance participant privacy and data accuracy.
- Randomised controlled trial procedures can be conducted entirely online (recruitment, informed consent, registration, random allocation, data collection and automated follow-up).
- Robust measures are needed to guard against multiple enrolment in online studies and to ensure the confidentiality and security of digitally collected and stored data.
- Multiple strategies can tackle the challenge of retaining participants in online studies over time (e.g. incentives, reminders and different methods of contact).
- Adverse effects of interventions should be actively monitored before and after implementation of an intervention.
- Qualitative evaluations are needed to understand sexual behaviour, to evaluate how complex interventions work and to assess engagement and implementation in practice.

Chapter 8 Discussion

Limitations of scoping review methodology

Quality of the body of evidence

We located a vast quantity of literature through our searches: 348 'core' papers and 525 'supplementary' papers, as well as online sources. We appraised all RCTs of IDIs according to Cochrane Collaboration quality criteria: only two of the 19 included RCTs were categorised as being at low risk of bias in terms of method of randomisation, concealment of allocation and/or loss to follow-up. For some studies, papers did not contain sufficient information to judge quality; in these cases we contacted authors, but contact was not always possible, especially for studies conducted 15 or more years ago. The uncertainty about the quality of the studies included in the meta-analyses reduces confidence in the results.

There were few studies (and few randomised participants) contributing to analyses of IDIs in comparison with face-to-face comparators, such as a lecture or counselling, and analyses of IDIs in comparison with a different design of digital intervention. Decision-makers may wish to know (a) whether or not interventions are effective and (b) whether or not interventions can usefully replace or supplement face-to-face interventions.²⁶⁰ There is evidence that digital interventions for sexual health are effective (especially for knowledge acquisition), but evidence on whether or not IDIs could be as good as face-to-face interventions is lacking. We did not conduct meta-analyses of studies of composite, human-facilitated IDIs (e.g. teacher-facilitated IDIs), but examples of these are given to demonstrate a variety of possible models of design and delivery.

This scoping review is a broad review of evidence, differing from a systematic review by including primary data (the opinions of young people, experts and evidence from sources such as the internet). In the rapidly evolving field of digital interventions, many relevant debates are conducted online rather than published in peer-reviewed journals. We extracted relevant themes from diverse sources of evidence and synthesised ideas narratively instead of carrying out a formal qualitative synthesis of data. This was to capture ideas which could offer fresh insight into issues that were not necessarily captured by formal qualitative studies. It was not necessary to find a particular viewpoint reflected in multiple pieces of evidence for it to lend insight into relevant issues.

Sampling

We selected expert key informants on the basis of information about their expertise which was available in the public domain (e.g. publications, organisational websites or contributions to online debates). Our sampling will, therefore, be biased towards those who have an interest in digital intervention development or evaluation. Participants for the school focus groups (young people and parents) were identified by schoolteachers, and a convenience sample of college students was recruited. The young people invited to focus groups and the youth symposium were from London; our workshop on digital media for sexual health promotion was attended by nurses, teachers and young people from across the UK; and expert key informants were from across the UK. The sample might have included people with strong opinions for or against the use of digital media for sexual health promotion. The views of opponents of use of digital media for sexual health promotion were aired in the workshop, but these are likely to be under-represented in the literature we located and in online debates, as enthusiasts are more likely to publish than those who may have reservations about the place of digital technology for health.

Generalisability

This review focuses on the UK, but the findings are applicable to other settings, especially countries with the resources and infrastructure that can support digital technology. Many of the issues raised are of relevance for digital interventions for health issues other than sexual health.

Summary of findings

Evidence on best practice for digital intervention design and development

We identified many good examples of IDIs for sexual health promotion, particularly from the USA. Good practice for IDI design and development includes (1) developing an understanding of the target population and their behavioural needs, (2) targeting the modifiable mechanisms of the desired behaviour change through empirical research with users, (3) selecting BCTs that match user needs, (4) implementing techniques in forms that are engaging and promote long-term interest/use among users and (5) ensuring that interventions are feasible and sustainable within an implementation context. Young people should be involved at all stages, including needs assessment, the design stages and prototype testing and to inform delivery and implementation in different settings so that the relevance of both the actual intervention and how it is delivered is maintained. The views of other stakeholders may also address important sexual health needs not identified by young people themselves and help to optimise implementation.

Most identified IDIs focus on reducing sexual risk behaviour and increasing condom use, with few interventions addressing issues that are important to young people, such as sexual pleasure and relationships, or cofactors that may influence risk behaviour, such as alcohol and mental health. There are also some notable gaps for risk groups such as young women after pregnancy, looked-after young people (in institutional care), young people experiencing sexual and domestic violence, LGBT youth and young people with learning difficulties. Promising interventions that have already been developed could be adapted for specific target groups and evaluated in different UK settings.

There is rapid innovation in the development and design of digital interventions in the commercial and service sectors, as well as in the academic sector. The guiding principles for design and the drivers for intervention development vary widely between sectors. More collaboration is needed to capitalise on the design and software skills of the commercial sector, the knowledge of users and stakeholders and the theoretical expertise and evaluation skills of academia. There is a need for mechanisms to assess whether or not existing interventions meet defined quality criteria for intervention content quality and to assess potential risks.

Evidence on effectiveness and mechanism of action of digital interventions for sexual health

We located 19 studies which were RCTs of IDIs for sexual health promotion for young people. We extracted data and (where possible) synthesised the findings from these studies to assess the effectiveness of IDIs. IDIs were delivered in a variety of settings (schools, colleges, health-care settings and online) and targeted heterosexual young people as well as young MSM.

Are interactive digital interventions effective?

We found that IDIs have statistically significant effects as follows: a moderate effect on sexual health knowledge (SMD 0.54, 95% CI 0.17 to 0.92), a small effect on self-efficacy (SMD 0.11, 95% CI 0.02 to 0.20) and a positive effect on sexual behaviour (OR 1.28, 95% CI 1.01 to 1.61), but no significant effects on safer sex intentions (SMD 0.09, 95% CI -0.01 to 0.19) or biological outcomes (OR 1.18, 95% CI 0.78 to 1.80). IDIs, therefore, positively influence some modifiable determinants of sexual behaviour (knowledge and self-efficacy but not intention). There were no data on adverse effects.

Are interactive digital interventions as effective as face-to-face interventions for sexual health?

Data were available from only one study¹⁸³ on the effectiveness of face-to-face interventions compared with IDIs. The results of this study suggest that IDIs may be as good as, or better than, face-to-face interventions for sexual health knowledge acquisition (SMD 0.51, 95% CI 0.11 to 0.90) and intention (SMD 0.46, 95% CI 0.06 to 0.85), but not for self-efficacy (SMD 0.38, 95% CI -0.11 to 0.77). There were insufficient data to draw conclusions about effects of IDIs on sexual behaviour, biological outcomes or adverse effects.

How do interactive digital interventions work?

The existing evidence on this topic is limited as little trial evidence is available.

Summary

These results show that IDIs are effective tools for learning about sexual health, but there is not enough evidence to be sure of effects on sexual behaviour or biological outcomes.

Evidence on methods for economic measurement, analysis and modelling in sexual health

There is very limited health economic evidence which relates directly to digital interventions for sexual health promotion, so we draw on evidence and guidance regarding (non-digital) sexual health promotion and (non-sexual health) digital interventions.

Sexual health promotion interventions are likely to be cost-effective if the target groups have a high prevalence of STIs and/or if the intervention is relatively cheap. Once developed, the ongoing costs of IDIs can be relatively low and targeting large numbers of people can, in theory, be relatively cheap and easy. However, the level of uptake of and engagement with an intervention and the characteristics of target populations might be more instrumental in determining the cost-effectiveness than intervention efficacy alone.

Cost-utility analysis is the type of economic evaluation recommended in the UK (calculating the incremental cost per QALY gained). However, this may not be the most suitable type of economic evaluation for sexual health intervention evaluation if it does not capture all of the costs and consequences of interest. Cost-effectiveness analyses (e.g. reporting results as cost per STI case detected or cost per pregnancy avoided) may provide more useful information to a decision-maker in a sexual health context. Decision modelling can potentially capture a wider range of information than a RCT as well as long-term impacts of an intervention beyond the duration and scope of the latter. As most of the costs and benefits of sexual health promotion come from potentially rare events (such as the prevention of cases of STIs or prevention of unintended pregnancies), it is likely that large, observational data sets will play an increasing role in capturing this information.

Further research and consensus is needed on how best to cost intervention development, implementation and maintenance; how to measure health and well-being outcomes, particularly long-term outcomes, in the sexual health promotion field; and the best ways to conduct economic evaluations of digital media interventions for sexual health promotion.

Evidence on implementation of sexual health interactive digital interventions for young people

The impact of a sexual health promotion IDI will be determined by its **r**each (proportion of the target population reached), **e**fficacy, **a**doption (within the target setting), **i**mplementation (how well it is delivered) and **m**aintenance (sustainability) – RE-AIM.

Sexual health IDIs delivered in static settings, such as a clinic or the classroom, have a captive audience which enables interventions to be delivered with high fidelity over a defined period of time. In contrast, online interventions can allow private and convenient access, and reach populations who may not be linked into mainstream services, but require the user not only to find the intervention but also to stay with it. Mixed delivery through complementary routes (in static settings and online) is most likely to maximise the proportion of the target population gaining access.

The reach of IDIs could be enhanced by linking sexual health promotion interventions with existing digital initiatives, such as STI testing, or with trusted branded websites or commonly used social networking sites. Face-to-face recruitment and facilitated engagement (e.g. with teachers or clinicians) also encourage young people to access interventions and are more likely to lead to continued engagement. More research is needed on how social networking sites, mobile phones and gaming can be harnessed for sexual health promotion.

The introduction of any new intervention into an existing setting requires frontline staff and management to believe that there are additional benefits compared with the current arrangements. Using the local knowledge and intelligence of local staff is vital for both successful intervention development and successful implementation. An effective intervention usually requires some adaptation for local contexts, but care is needed in identifying and preserving the core components so that effectiveness is maintained. Technical support, moderation/monitoring and updating material are further challenges for implementing sustainable digital interventions.

There are few national policy levers to drive implementation of sexual health promotion IDIs in practice and responsibility for health and education is increasingly devolved to local health care and local authority commissioning groups. However, an increased emphasis on local cross-sectoral working means that there may be more opportunity for shared initiatives and shared (financial) risk.

Evidence on optimum research design and outcome measurement

Digital platforms offer quick, convenient and relatively cheap methods for conducting sexual health research. Recruitment via the internet offers opportunities for reaching hard-to-reach, stigmatised populations, although convenience sampling makes sample representativeness more difficult to assess. Online recruitment to trials allows self-registration, online consent, automated randomisation to trial arms, automated follow-up and online data collection, which can potentially reduce the cost of conducting trials. Using digitally mediated research methods to administer surveys (e.g. computer-assisted self-interviews or mobile phones for data collection) can enhance confidentiality. Requesting several participant identifiers (such as address, telephone number and date of birth) can help to reduce the risk of multiple enrolment. Robust measures are needed to ensure security and confidentiality of data collected using digital methods.

Retention in studies which use digitally mediated research methods can be a challenge (e.g. online trials and longitudinal surveys). However, using multiple retention strategies, such as offering incentives, sending reminders via text and e-mail and appealing to the altruism of participants, can enhance retention. Digital interventions, by their nature, offer consistent content, which can be standardised as intended. There is a need to develop mechanisms to ensure the standardisation of exposure to digital interventions to measure intervention use.

Age-appropriate sexual health outcomes should be used in research with young people. If interventions address multidimensional aspects of sexual well-being and other health issues, such as substance use and mental well-being (as users would like), outcome evaluation should also reflect these broader concepts of health. There is a trade-off between producing a specific intervention with clear (narrow) aims and producing an intervention which addresses the complexity of sexual health. The theoretical design of the intervention and the hypothesised mechanism of action will dictate which outcome measures are the most suitable.

It is difficult to capture impacts on health (e.g. STIs or pregnancy) as these events are relatively rare, especially in younger age groups. It is important to measure determinants of behaviour change (such as knowledge and self-efficacy) to capture shorter-term impacts and to understand how interventions work. Adequately powered, longer-term studies are needed to assess the impact of digital interventions among young people. Qualitative process evaluations are needed to evaluate how complex interventions work and to assess engagement and implementation in practice.

In conclusion, digitally mediated research methods are acceptable and feasible for recruitment and administration of sexual health research, and there is increasing evidence on how best to ensure good-quality online data and how to maximise retention in studies.

'Front-running' interactive digital interventions suitable for young people in the UK

We did not find 'front-running' IDIs which are suitable for implementation in the UK (judging on the basis of intervention effectiveness, cost-effectiveness, suitability for young people in the UK and the feasibility of implementation in a UK context).

We identified five IDIs for young people with RCT evidence of effectiveness which were all developed and evaluated in non-UK settings: four in the USA^{110,142,183,274} and one in the Netherlands.¹¹² All of these IDIs focused on HIV prevention, mostly recruiting in educational settings. However, all of these studies were very small scale, randomising around 100 people or fewer into each arm of RCTs, and so there is less confidence about the strength of evidence. There are no available data on cost-effectiveness for these interventions. Many of the interventions identified in our search were underpinned by Behaviour-Change Theory and involved users in development, but it is difficult to judge the quality of these interventions as it is not known exactly how to deploy theory effectively, or which models and mechanisms for user involvement in intervention design are the most effective (see *Chapter 3*). The choice of a suitable intervention will depend on the needs of the target audience and on the choice of setting for implementation; as we have noted, 'young people' are not a homogenous group, and it is unlikely that any one intervention could meet the specific needs and preferences of different target populations in different settings. We identified a large range of IDIs which utilise imaginative multimedia and interactive features with different populations of young people in different settings (see *Chapters 3 and 4*), which could be adapted for particular target groups of young people in the UK (see Sexual Health Research Network database: www.sexualhealthnetwork.org.uk).

Implications for policy and practice

Evidence from our literature review and consultation with stakeholders points to ways to increase the likelihood of successful development and implementation of IDIs for sexual health.

Intervention design and development

- Collaboration with target populations is essential in order to design accessible, attractive and engaging IDIs which meet young people's needs and wants.
- Implementation and engagement with interventions should be considered from the outset, with interventions developed in collaboration with all stakeholders.
- Sexual health promotion IDIs could be adapted from existing IDIs or developed afresh to make them relevant for young people in the UK.
- Collaborations which link young people's views, public health expertise, the dynamism and creativity of industry and rigour offered by academia could help to optimise intervention design.
- Protocols and examples of 'best practice' in IDI design and development and models for interdisciplinary collaboration could usefully be shared.

Interactive digital intervention aims and target populations

- IDIs are effective for knowledge acquisition and could address young people's need for sexual health information in clinics, in schools and online.
- Young people express a preference for integrated models of sexual health which focus on sexual well-being as well as disease and physical health.
- Sexual health promotion IDIs could form part of health promotion interventions that address other linked health issues, such as alcohol, mental health and smoking.

Interactive digital intervention evaluation

- Mechanisms for intervention evaluation could be planned at the intervention development stage, for example baseline and follow-up questions or user views on an intervention in practice.
- Online (quantitative) research methods can be convenient for participants and researchers, and relatively cheap.
- Digitally mediated data collection (e.g. by mobile phone or by computer) can enhance participant privacy and data completeness.
- Randomised controlled trial procedures can be conducted entirely online (recruitment, informed consent, registration, random allocation, data collection and automated follow-up).
- Robust measures are needed to guard against multiple enrolment in online studies and to ensure the confidentiality and security of digitally collected and stored data.
- Multiple strategies can tackle the challenge of retaining participants in online studies over time (e.g. incentives, reminders and different methods of contact).
- Adverse effects of interventions should be actively monitored before and after implementation of an intervention.
- Qualitative evaluations are needed to evaluate how complex interventions work and to assess engagement and implementation in practice.
- Tiered ethical committee approval processes could facilitate more rapid evaluation of health promotion interventions with low risk of harm to health.

Interactive digital intervention implementation

- Interactive digital interventions could be offered in conjunction with currently existing digital systems, for example online service locators, online services (e.g. for STI testing), clinic results systems or dating websites.
- Education in internet and media literacy could help to reduce the risks of exposure to harmful online content.
- NHS endorsement of sexual health IDIs would be valuable in increasing awareness of interventions and public trust.
- Closer cross-sectoral working between health and social care and voluntary and commercial sectors could help to share any financial risk.
- A quality assurance system could include criteria for assessing the accuracy of content. A tiered system could apply for interventions with different possible risk (e.g. health promotion websites vs. medical devices for diagnosis or treatment).
- A quality assurance system could help users to judge possible risks associated with online data collection (e.g. privacy, confidentiality and informed consent for the use of data).
- Budgets need to include funds for marketing, maintaining and updating IDIs.

Gaps in evidence concerning digital interventions for sexual health for young people

Here, we highlight the gaps in existing evidence and outline groups of research questions which together address questions of how to design, evaluate and implement IDIs which are effective in improving young people's sexual well-being.

Can interactive digital interventions have a long-term impact on sexual behaviours, sexual well-being and biological outcomes?

- Effect of IDIs on sexual behaviour, biological outcomes (pregnancy, HIV and other STIs) and sexual well-being (e.g. pleasure and relationship and sexual satisfaction).
- Effectiveness of digital interventions for particular problems, including intimate partner violence, repeat abortion and sexual problems.
- Effects of IDIs on inequalities in health.
- Longer-term outcomes (6 months or longer).

What component features of an interactive digital intervention are most likely to be associated with beneficial outcomes in populations in need?

- The best designs for IDIs, for example theoretical underpinning including BCTs and core components.
- Effectiveness of interventions for particular groups, for example school-aged children, young MSM, disadvantaged youth and BME groups.
- Effectiveness of interventions which target multiple health problems, including drug and alcohol use and mental health, as well as sexual health.
- Optimum intervention design to maximise young people's interest and engagement.
- Optimal settings and modes of delivery of IDIs for different populations.
- Understanding the potential of features such as social media and gamification for health promotion.
- Optimum exposure, dosage and timing for interventions.

How can interactive digital interventions for sexual health best be delivered to populations in need?

- The effectiveness of alternative models of intervention delivery (e.g. direct vs. facilitated access, different technological platforms).
- The best methods and costs of reaching, engaging and retaining young people with interventions (particularly reaching populations in greatest need).
- How to target and reach neglected at-risk populations (e.g. young people post pregnancy, looked-after children, young people with learning difficulties).
- Barriers and facilitators to implementing IDIs for sexual health promotion online, in clinics and in school settings.

What are the optimal methods of economic measurement for sexual health?

- Appropriate sexual health-related costs and consequences to use in economic models and analysis, and in particular what outcomes should be used.
- How best to proportion the cost of a digital intervention (development, implementation and maintenance) over the longer term in order to calculate the mean cost per person.
- How best to quantify health outcomes that occur a long time after the digital intervention.

What are the costs and cost-effectiveness of interactive digital interventions for sexual health?

- The costs of different models of implementation.
- The costs of disseminating and maintaining digital interventions for sexual health.
- Which digital media interventions might represent the best value for money in sexual health promotion?
- The role of digital media interventions in reducing health inequalities.
- Best ways of measuring sexual well-being outcomes (including social and emotional well-being).
- Optimal outcome measurement instruments to capture the complexity of sexual behaviour.
- Best ways of measuring sexual behaviour (e.g. condom-use outcomes).
- Optimal outcome measures for young people which are appropriate for their stage of sexual development.

What are the best ways of enhancing data validity in online research?

- Assessment of potential recruitment bias with online recruitment.
- Best methods of minimising potential fraud or dishonesty with online recruitment.
- Best methods of assessing and enhancing data validity.
- Potential size of measurement reactivity (change prompted by measurement alone).
- Best methods of enhancing retention in trials of digital interventions for sexual health.
- Best methods of assessing meaningful exposure to IDIs.

Conclusions: current state of play and future potential of interactive digital interventions for sexual health

There is a clear need for better access to sexual health promotion, as many young people in the UK do not currently have access to accurate information about the positive aspects of sex, sexuality and relationships, or sufficient information to assess and minimise risks. Sexual health is a challenging field in which to try to change behaviour, because of the complexity of behaviours and the social taboos concerning openly acknowledging sex and sexuality. There is a complex interplay of physical, social, psychological and environmental factors impacting on sexual health, with community, family and peer viewpoints being incredibly important in influencing beliefs and behaviour. Public health/medical perspectives on sexual health have tended to focus on negative outcomes and sexual ill health rather than the positive dimensions of sex and sexuality and its potential to enhance health and happiness.

Accurate information/knowledge is a vital first step towards sexual self-determination, and digital interventions can meet young people's need for this. We need stronger evidence on the best designs for interventions (e.g. choice of BCTs and interactive features), evidence on the best models of delivery (e.g. setting, modes of delivery, methods of facilitation, support for engagement) and evidence on cost-effectiveness. More evidence is needed on how to impact on sexual behaviour, on biological outcomes (STIs and pregnancy) and on sexual well-being.

Internet access is almost universal for young people in the UK, and sexual health promotion via digital media is a highly appropriate way to reach young people from a range of demographic groups. At the moment in the UK (in 2015), there are pockets of local innovation but no co-ordinated national programme to exploit the potential of IDIs for sexual health promotion in clinics, in educational settings or online. Young people have a big appetite for IDIs for sexual health, the commercial sector is keen to exploit opportunities to develop digital media interventions for health and there is political will to deploy IDIs for health. However, there are important obstacles to the widespread implementation of IDIs in clinical settings (e.g. technical issues, access problems, engrained patterns of working), in schools (e.g. lack of compulsory SRE, teacher and parent reservations, blocks to websites with sexual health content) and online

(e.g. lack of financial incentives to develop or implement freely available interventions). More research is needed on how to understand obstacles to implementation and how best to address these.

We located many examples of IDIs which were developed with young people's input, which utilise imaginative interactive features and which are underpinned by Behaviour-Change Theory (see database on the Sexual Health Research Network website). However, we did not identify any IDIs which are ready for implementation in the UK, either because evidence of effectiveness is lacking or because interventions shown to be effective in other countries would need to be adapted and evaluated in the UK before implementation.

Key to successful design and implementation is collaboration between stakeholders (including young people themselves, developers, academics, educators, parents, teachers, school boards, clinicians, NHS managers and policy-makers), to ensure that IDIs engage young people and are effective in improving their sexual health and well-being. We need better mechanisms for bringing together the creative energy of young people and of the commercial sector with academic expertise which can ensure that interventions are theoretically sound and rigorously evaluated before roll-out. We need to ensure that interventions can be developed and evaluated within reasonable time scales while also ensuring that the quality and effectiveness of intervention content is known and that risks to users' privacy and safety are minimised. Mechanisms for quality and safety testing and certification are needed to ensure that IDIs can be delivered with minimal risk of harm.

Interactive digital interventions have a potentially far reach and, if proven effective, would have huge potential to impact positively on the sexual health of young people in the UK. They could be cost saving, as well as reaching young people who do not currently have access to high-quality SRE (in or outside school). IDIs are effective for knowledge acquisition and sexual behaviour, and could usefully form a component of sexual health education in schools, in clinic settings and online.

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Contributions of authors

Julia Bailey and **Sue Mann** jointly led the research.

All co-authors (**Julia Bailey**, **Sue Mann**, **Sonali Woyal**, **Rachael Hunter**, **Caroline Free**, **Charles Abraham** and **Elizabeth Murray**) contributed to planning the research and overseeing the research conduct.

Sonali Woyal conducted the literature searches with **Julia Bailey** and **Sue Mann**.

The Cochrane review was updated by **Julia Bailey** and **Sonali Woyal**.

Citations for the scoping review were screened by **Sonali Woyal**, **Sue Mann** and **Julia Bailey**.

Sonali Woyal conducted focus groups.

Sonali Woyal, **Sue Mann** and **Julia Bailey** conducted individual interviews with stakeholders and facilitated symposiums with young people and expert stakeholders.

Sonali Woyal, **Sue Mann** and **Julia Bailey** contributed to the analysis of qualitative data.

Julia Bailey, **Sue Mann**, **Sonali Woyal** and **Rachael Hunter** wrote the first draft of the report, and all authors contributed to the final report.

Data sharing statement

Anonymised qualitative data from interviews and focus groups are available from the authors.

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Appendix 1 List of stakeholders consulted

Professional stakeholders

Individual interviewees and participants at the Expert Symposium, The King's Fund, London, UK, 29 May 2014:

- Rob Andrews, Interactive Designer, Art Director & Information Architect, Digital Life Sciences, UK
- Jim Ang, Lecturer in Multimedia/Digital Systems, University of Kent, UK
- Dr Steve Baguley, Consultant Sexual Health and HIV Physician and chairperson of BASHH Scotland
- Dr Katherine Brown, Reader in e-Health and Wellbeing intervention, Coventry University, Coventry, UK
- Dr Rita Browne (chairperson of the adolescent sexual health special interest group), BASHH
- Dr Michael Brady, Medical Director, Terrence Higgins Trust and Sexual Health and HIV consultant, King's College Hospital, London, UK
- Analia Lemmo Charnalia, Business Manager, Social Enterprise, University College London, London, UK
- Natalie Collyer, Campaign and Web Manager, Brook
- Mark Clements, Maldaba, London, UK
- Dr Kevin Dunbar, Director, NCSP, Public Health England
- Andrea Duncan, Programme Manager, Sexual Health Team, Department of Health, UK
- Dr Claudia Estcourt, Reader in Sexual Health & HIV, Barts and the London School of Medicine and Dentistry, London, UK
- Dr Rebecca French, Senior Lecturer in Reproductive & Sexual Health, London School of Hygiene and Tropical Medicine, London, UK
- Lorenzo Gordon, Maldaba, London, UK
- Alison Hadley, OBE, Director, Teenage Pregnancy Knowledge Exchange, University of Bedfordshire, Luton, UK
- Damien Hampton, Head of Technology, Digital Life Sciences, UK
- Justin Harbottle, Terrence Higgins Trust
- Joe Hayman, PSHE Association
- Lorna Hobbs, PhD student, e-Health Unit, University College London, London, UK
- Johnny Hunt, independent consultant, SRE
- Dr Louise Jackson, Health economist, University of Birmingham, Birmingham, UK
- Dr Evelyn Kerr, Consultant Sexual and Reproductive Health, Faculty of Sexual and Reproductive Health, Royal College of Obstetricians and Gynaecologists, London, UK
- Dr Karen Lorimer, Senior lecturer, Glasgow Caledonian University, Glasgow, UK
- Dr Catherine Lowndes, Epidemiologist, Public Health England
- Dr Anatole Menon-Johansson, Clinical Director, Brook
- Dr Henry Potts, University College London Centre for Health Informatics & Multiprofessional Education, London, UK
- Luke Raskino, Founder iBehave, Health Behaviour Change through Tech
- Dr Tariq Sadiq, Reader, Centre for Infection & Immunity, St George's, University of London, London, UK
- Bhupendra Sheoran, Deputy Director of YTH (Youth, Tech and Health), San Francisco, CA, USA
- Robin Vickers, Executive Director and Founder, Digital Life Sciences, London, UK
- Christopher Vincent, UCL Interaction Centre, University College London, London, UK
- Harry Walker, Policy and Parliamentary Manager, Family Planning Association and Brook
- Dr Rosie Webster, Research Associate, e-Health Unit, University College London, London, UK
- Dr Joseph Wherton, Global Health, Policy and Innovation Unit, Barts and the London School of Medicine and Dentistry, London, UK
- Jamia Wilson, Executive Director, YTH (Youth, Tech and Health), San Francisco, CA, USA.

Young people

Participants at the Youth Symposium on Digital Media and Sexual Health, London, UK, 10 July 2014:

- Abiola Adedeji
- Alejandro Brussian
- Brandon Ryan
- Brandon Twumasi
- Dylan Corbett
- Egypt Payne
- Eric Parchment
- Ifeanji Ejindu
- Jeffrey Silva-Pereira
- Jessica Bailey
- Jessica Lowe
- Jody Williams
- Joe Sombi
- Levi Crawford
- Nathan Cornelius
- Rachael Hinds
- Ray Marcelino
- Rhamel Gyarteny
- Richard L Mosinghi
- Salma Nizami
- Sharn Carby
- Simi (surname withheld)
- Stella Anarhunan.

Appendix 2 Proposed model of best practice for intervention design and development

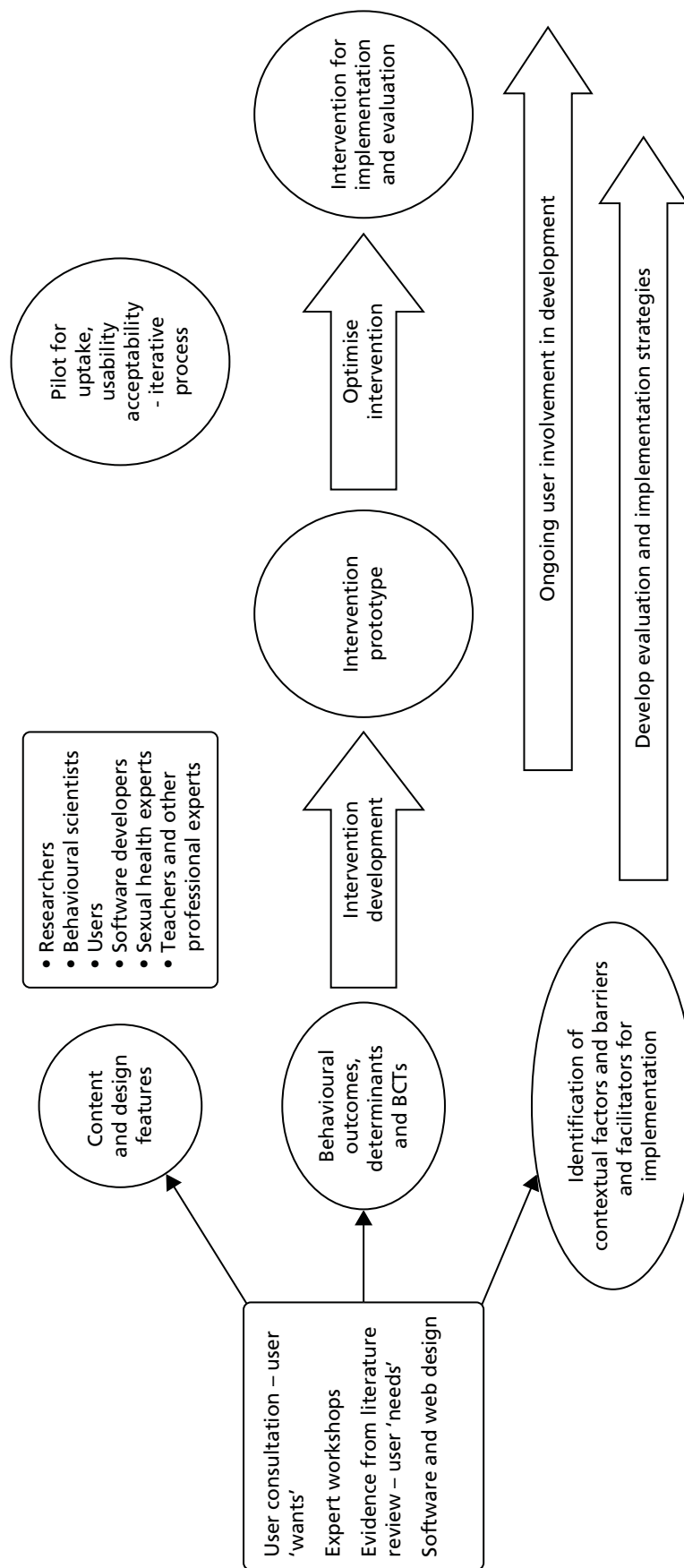


FIGURE 13 Proposed model of best practice for intervention design and development.

Appendix 3 Other sources of data

1. Innovation in Sexual Health Conference Workshop. Digital media for sexual health promotion: setting an agenda for investment in research, development and implementation. SASH Health Interventions, Coventry, UK, 12 February 2013. Facilitated by JB and SM.
2. Yth Live Conference, San Francisco, CA, USA, April 2013.
3. Yth Live Conference, San Francisco, CA, USA, April 2014.
4. Medicine 2.0, Conference, London 2013 (and past conference abstracts www.medicine20congress.com/ocs/index.php/med/med2013#).
5. University College London Festival of Digital Health, July 2014, UK.
6. UK Digital Health LinkedIn Group.
7. E-Health Unit focus group: June 2014, Royal Free Hospital, London, UK.
8. District Health technology network meetings (formerly iBehave; formerly Gamify MyHealth) (www.meetup.com/DistrictHealth/).
9. National Coalition of STD Directors. National Guidelines for Internet based STD and HIV prevention (www.ncsddc.org/Internet_Guidelines).
10. NESTA (National Endowment for Science Technology and the Arts). Innovation programmes (www.nesta.org.uk/).
11. The Lifestyle Elf. Blog which highlights advancements in lifestyle research (www.thelifestyleelf.net).
12. iMedicalApps. Physician reviews of medical apps: www.imedicalapps.com.
13. Sexual Health Innovations. Projects which use digital technology to promote sexual health and well-being (www.sexualhealthinnovations.org).
14. Youth Health Talk. Website with real-life discussions on youth related health issues – sexual health, substance abuse, alcohol. DIPEX Charity (www.youthhealthtalk.org).
15. The King's Fund Telehealth evidence database (<http://kingsfundlibrary.co.uk/telehealth>).
16. Go-On UK. UK Digital Skills Charter. Interactive website to improve digital knowledge and skill (www.go-on.co.uk).
17. Startupbootcamp. Europe's leading accelerator program for startups (www.startupbootcamp.org/blog/potential-of-digital-health-investments-in-europe.html).
18. Healthcare IT News (www.healthcareitnews.com).
19. Health IT Buzz. Office for the National Coordinator for Health Information Technology (ONC) (www.healthit.gov/buzz-blog).
20. Mobile Future. Webinar: Digital Health – The Intersection of Innovation and Healthcare (<http://mobilefuture.org/resources/digital-health-the-intersection-of-innovation-and-healthcare>).
21. The Future of Digital Healthcare. Digital Life Sciences. Blog, Robin Vickers (www.digitallifesciences.co.uk/the-future-of-digital-healthcare-introduction).
22. The Kay Centre for e-Health Research (www.cgu.edu/pages/8884.asp).
23. E-health Impact. European Commission Information Society (www.ehealth-impact.org/index.htm).
24. World of Health IT. Conference abstracts (www.ehealthnews.eu/wohit).
25. Digital Health Coalition (<http://digitalhealthcoalition.org/about-us-digital-health-coalition>).

A decorative graphic consisting of numerous thin, parallel green lines that curve from the left side of the page towards the right, creating a sense of movement and depth.

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