

## Sexual health promotion delivered by digital media: a scoping study

Revised protocol 5<sup>th</sup> October 2012

### Background

Sexually transmitted infections (STI) and unwanted pregnancy are major public health problems which particularly affect young people. There are high social and economic costs, and it is important to identify effective, cost-effective interventions (Christophers 2008).

Digital media for sexual health for young people has great potential because of the reach and popularity of technology such as the Internet and mobile phones (Kanuga 2004).

Digital interventions for sexual health promotion are promising: our Cochrane review (Bailey 2010) shows that such interventions lead to improved knowledge, self-efficacy, intention and sexual behaviour, although more evidence is needed to be certain of effects. There are uncertainties about how best to design, develop and implement digital media interventions (Webb 2010). It is also not clear how best to evaluate digital interventions, for example the optimal design of online trials (Murray 2009), and optimal ways of measuring sexual health outcomes.

Research on digital media for sexual health promotion for young people has accelerated since around the year 2000: a scoping and appraisal of this literature is urgently needed to guide strategic investment in research, development and implementation.

### Summary of research design

This work will **scope**, **appraise** and **synthesise** available evidence on digital interventions for sexual health for young people from published and unpublished literature, integrating the findings with **key informant views** (both professional and lay) (see Figure 1).

### Research objectives

#### Aim

To scope, appraise and summarise evidence on sexual health promotion for young people delivered by digital media, to produce guidance on investment in future research, development and implementation

#### Objectives:

- \* To appraise and synthesise evidence on effectiveness, cost-effectiveness and mechanism of action of digital interventions for sexual health
- \* To determine optimal research methods for intervention evaluation
- \* To determine optimal practice for intervention development and identify 'front running' interventions
- \* To appraise and synthesise evidence on contexts for successful implementation of digital interventions for sexual health
- \* To delineate gaps in available evidence
- \* 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 for sexual health promotion by digital media

### This work will lead to

- \* Systematic summaries of evidence on effectiveness, mechanism of action and cost-effectiveness of digital interventions for sexual health promotion
- \* Recommendations on optimal research design to evaluate digital interventions including online trial methodology and sexual health outcome measurement
- \* Summary of evidence on how to optimise user engagement and intervention implementation
- \* Summaries of evidence on optimal intervention design, development and implementation
- \* Database of available interventions
- \* Comment on the future potential for digital interventions, including recommendations for investment, research and development

### Target population and setting

The target population is **young people aged 13 to 24 years**, to include children of school age (to cover sex education in school) as well as those aged 16 to 24 (who are at higher risk of sexually transmitted infection acquisition and unplanned pregnancy). This work will focus on the impact of digital media for sexual health promotion on young people in the UK.

### Interventions being evaluated

**Digital media** includes technology such as the computer and the Internet, mobile phone, compact disc, video, games, and interactive television. We will use the following definition of **computer-based/digital intervention** (Bailey 2010): '**Programmes that provide sexual health information and one or more of: decision support, behaviour-change support, and emotional support for health issues**'. 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. Interventions may be accessed directly by users (e.g. via the Internet) or provide facilitated access (e.g. by teachers or health professionals). Interventions may be accessed from home, on-the-move, or in settings such as healthcare or education.

Interventions must have the aim of promoting sexual health, defined as '**providing individuals, groups and communities with the tools to make informed decisions about their sexual wellbeing**', with **sexual wellbeing** defined as 'a state of physical, emotional, mental and social well-being in relation to sexuality'.

We will exclude the following types of intervention:

- Simple information packages with no interactive elements;
- Non-interactive mass media interventions such as TV advertisements;
- Interventions targeting health professionals or teachers;
- Computer-mediated delivery of individual healthcare advice (e.g. online physicians), unless part of a wider sexual health promotion package
- Electronic history-taking or risk assessment with no sexual health information or interactive elements;
- Treatment decision aids, unless fulfilling the criteria for interactive computer-based interventions;
- Interventions designed to optimise sexual health care by clinicians;
- Interventions designed to facilitate provider-user communication.

## Research design

This work comprises a **review of literature** to **scope, appraise** and **synthesise** available evidence (Pagliari 2005) on digital interventions for sexual health for young people, integrating the findings with **key informant views** (both professional and lay) (see Appendix, Figure 1). The work falls into five related research topics:

- A. Systematic review and meta-analyses of evidence on effectiveness of digital interventions for sexual health promotion**
- B. Optimum research methodology to evaluate digital interventions**
- C. Optimum intervention design, development and implementation**
- D. Costs, cost-effectiveness, and optimal methods for economic measurement and modelling in sexual health**
- E. Future potential for sexual health promotion via digital media**

### \* **Review of literature**

We will update our **Cochrane systematic literature search** to locate published and unpublished randomised controlled trials (RCTs) of digital interventions for sexual health (for research topic A).

We will conduct a **focused, targeted review of evidence**, seeking all types of evidence including quantitative studies, qualitative studies, and theoretical papers on digital/computer-based interventions and sexual health, for evidence on optimum research methodology, intervention design and implementation, and future potential for digital interventions, and data on costs, cost-effectiveness and health economic outcomes (for research topics B, C, D and E).

We will also conduct a highly focused **review of systematic reviews of evidence** on digital interventions in other health promotion fields (e.g. alcohol, drug use), sexual behaviour change, human-computer interaction, and sex education, to learn from these fields regarding optimum research methodology, intervention design and implementation, and future potential for digital interventions (for research topics B, C and E).

### \* **Key informants' views**

We will conduct **interviews with experts and professional stakeholders** on optimum research methodology; intervention design and implementation; and future potential for digital interventions for sexual health promotion

We will conduct **focus groups with young people** to seek their views on design of digital interventions for sexual health promotion, suitable outcome measures, and future potential.

We will hold an **expert symposium** (including e-health and sexual health researchers, policy makers, educationalists, software developers) to discuss areas of controversy concerning optimum research methodology; intervention development, design and implementation; and solicit their views on the future potential for digital interventions for sexual health.

An online **consensus process** will help to prioritise sets of key recommendations for investment in future research, development and implementation.

## Summary of specific research questions and research methods

The research methods applicable to our five research areas are summarised below. The topics and research methods overlap considerably, so for example, there will be **only one focused literature search** which will identify literature relevant for all topic areas, and **only one expert symposium**.

## **A. Systematic review and meta-analyses of evidence on effectiveness of digital interventions for sexual health promotion**

- \* How effective are digital interventions for sexual health promotion?
- \* What features of interventions, participants or settings are associated with efficacy?
- \* What are the effects on health inequalities?

Research methods

- **Systematic literature search** for RCTs of digital interventions for sexual health promotion
- **Meta-analyses**
- **Meta-regression**

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## **B. Optimum research methodology to evaluate digital interventions**

- \* What are the strengths of different research methods to evaluate digital interventions?
- \* What are the challenges of conducting randomised controlled trials of digital interventions?
- \* What are optimal comparators (controls)?
- \* What are the best ways of measuring outcomes (including social and emotional wellbeing)?
- \* How can we maximise the strength and quality of evidence?

Research methods

- **Focused literature search** for qualitative and quantitative evidence on research methodology concerning digital interventions for sexual health promotion
- **Review of reviews** on research methodology from the fields of sexual behaviour change (especially outcome measurement); and e-Health
- **Key informant interviews** (e-Health and sexual health researchers' views on optimum research methodologies)
- **Key informant interviews** (young people's views on suitable outcomes)
- **Expert symposium** (to debate areas of controversy on optimal research methods)

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## **C. Optimum design, development and implementation of digital interventions for sexual health promotion**

- \* What are the barriers and facilitators for successful design, development and implementation?
- \* What is best practice for sexual health digital intervention design and development?
- \* What are the mechanisms of action of digital interventions for sexual health promotion?
- \* Which behaviour change theory and techniques should be incorporated?
- \* What are the merits of alternative models of intervention delivery? (e.g. direct vs. facilitated access)
- \* What are the merits of alternative modes of intervention delivery? (e.g. different technological platforms)
- \* How can intervention access, uptake and adherence be optimised?
- \* Are there 'front running' digital interventions for sexual health suitable for further research?

Research methods

- **Focused literature search** for qualitative, quantitative and theoretical evidence on design, development and implementation of digital interventions for sexual health promotion
- **Review of reviews** on design, development and implementation of interventions from the fields of sex education and sexual behaviour change; human-computer interaction; digital interventions in other health promotion fields (e.g. alcohol, drug use)

- **Key informant interviews** (experts from the fields of e-sexual health research; sexual health policy; sex education and sexual health programme developers)
- **Key informant interviews** (young people's views on digital intervention design and implementation)
- **Expert symposium** to debate areas of controversy on design, development and implementation of digital interventions for sexual health promotion

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#### **D. Costs, cost-effectiveness, and optimal methods for economic measurement and modelling in sexual health**

- \* What are the costs of digital interventions for sexual health?
- \* Are digital interventions for sexual health cost-effective?
- \* What is the scale of possible health and cost benefits?
- \* What are the optimal methods for economic measurement and modelling in a sexual health context?

##### Research methods

- **Focused literature search** for papers which report costs, cost-effectiveness and health economic outcomes for digital interventions for sexual health promotion
- **Key informant interviews** with experts in health economics for their views on optimal methods for economic measurement and modelling
- **Expert symposium** to debate areas of controversy on optimal methods for economic measurement and modelling

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#### **E. Future potential for sexual health promotion via digital media**

- \* What are the barriers and facilitators to future implementation of digital interventions for sexual health?
- \* How should digital interventions integrate with current educational and health promotion practice?
- \* Should sexual health promotion interventions be linked with other digital interventions, e.g. for alcohol and drug use harm reduction?
- \* Where is this field leading?
- \* What strategic investments are needed in future research or implementation to optimise the potential of digital media interventions for young people?

##### Research methods

- **Focused literature search** for reviews, reports and opinion pieces concerning the future potential of digital interventions for sexual health promotion; and reviews and reports concerning digital interventions in other health promotion fields (e.g. alcohol, drug use)
- **Internet search** to scan the horizon on future potential
- **Key informant interviews** (experts from the fields of e-sexual health research; sexual health policy; sex education and sexual health programme developers)
- **Key informant interviews** (young people's views on the future potential)
- **Expert symposium** to discuss the future potential of digital interventions for sexual health promotion

### **Preparatory work**

#### **Ethical committee permission**

We will seek permission from the UCL Ethical Committee, so that it is in place at the beginning of the project.

#### **Appointment of research associate and two user representatives**

We will appoint staff to these posts

### **Advisory group consultation**

Once we have ethical permission, we will email stakeholders (including e-health and sexual health researchers, policy makers, educationalists, software developers, digital technology and social media experts and user representatives) for their opinions on the scope of the proposed work to ensure that it is judged appropriate and comprehensive. We already have strong links with a large number of experts in the field of digital interventions and/or sexual health: we will review this list to ensure that we contact stakeholders who can represent a variety of perspectives.

### **Systematic literature search for randomised controlled trials of digital interventions for sexual health promotion**

#### *Relevant literature:*

**Sexual health AND Digital/computer-based intervention AND Randomised controlled trials**

We will conduct a systematic literature search to locate published and unpublished **randomised controlled trials** which test the effects of **digital interventions for sexual health promotion**, to address research topic A. This work will entail updating our Cochrane review of Interactive Computer-Based Interventions for sexual health promotion (Bailey 2010). We already have a comprehensive search strategy which captures RCTs of digital interventions for sexual health promotion, and a **database of citations dating from 1985 to 2007**. We will review the trials of digital interventions which were excluded from the previous Cochrane review, i.e. trials of facilitated computer-based interventions (e.g. facilitated by teacher, health professional); and trials of web-based interventions which include an element of computer-mediated human interaction (e.g. 'Ask an Expert'). We will then conduct a comprehensive search from **2007 to date**, adhering to the Cochrane methods for searching, data extraction and data synthesis that we used before (Bailey 2010). We will search electronic databases (including CENTRAL, DARE, MEDLINE, EMBASE, Cumulative Index to Nursing & Allied Health Literature, British Nursing Index, and PsycINFO); databases of grey literature for unpublished work; trials registers; reference lists of published studies; and contact study authors. We will have no language restriction.

Two review authors (JB and the research associate) will independently screen all citations, obtain and appraise the full texts of any candidate papers, and extract data using our data extraction proforma (Bailey 2010). Study authors will be contacted to clarify questions about study methodology and to obtain missing data. The quality of RCTs will be judged using the methods recommended by the Cochrane Collaboration. Information about study and intervention characteristics will be entered onto Excel spread sheets, with numerical outcome data entered into Review Manager software, double-checking the accuracy.

We will describe intervention characteristics narratively, producing a taxonomy of intervention types. We will **identify 'front running' interventions** according to their effectiveness, and the applicability, feasibility and suitability for young people in the UK.

### **Statistical analyses**

Outcome data will be synthesised in **meta-analyses** where appropriate, to estimate the standardised mean differences or odds ratios for the effects of interventions. Separate analyses will be conducted depending upon the **type of comparator** (minimal intervention; face-to-face; or comparisons of different designs of digital intervention) (Bailey 2011); and **type of outcome** (i.e. cognitive, affective, behavioural, or biological) (Bailey 2012).

If we have sufficient good quality data, we will conduct a **meta-regression** to investigate associations with a number of intervention features, for example intervention design (e.g. theory-based; tailored); study participant characteristics (target age group, gender, socioeconomic status), and setting (e.g. school, clinic, or Internet) to report on intervention efficacy for different demographic groups and in different settings (Michie et al 2009).

## **Focused literature search for all types of evidence on digital interventions for sexual health promotion**

*Relevant literature:*

### **Sexual health AND Digital/computer-based interventions**

We will use our comprehensive search strategy (Bailey 2010) to search databases for **all types of evidence** (including quantitative evidence, qualitative evidence, theoretical papers, health economic analyses and editorials) which address **sexual health** and **computer-based/digital interventions** according to our definitions of these concepts. We will search key electronic databases (including CENTRAL, DARE, MEDLINE, EMBASE, Cumulative Index to Nursing & Allied Health Literature, British Nursing Index, and PsycINFO); reference lists of published studies; and contact study authors. Literature will be searched over the last decade (from the **year 2002 to date**). A ten year period has been chosen since technological capabilities and patterns of use of digital technology are rapidly changing, rendering earlier interventions less relevant to future health promotion.

We will download all citations identified by the search into Reference Manager software. Two researchers (JB or SM and the research associate) will independently screen all citations, obtain and **appraise the full texts of any candidate papers to decide on their relevance** to one or more of the research topics B, C, D and E (research methodology, intervention design, development and implementation, health economic literature and future potential for digital interventions).

Two researchers will extract and tabulate data on the study characteristics and findings of included original studies and systematic reviews. We will make judgements on the quality of included studies, and the relevance for young people in the UK. We will use the principles of meta-ethnography to synthesise the findings of qualitative studies (Britten 2002), and summarise the findings of other studies narratively. Provisional conclusions will be presented and discussed in 'findings group' meetings.

### **Search for systematic reviews in related fields**

To address some of the research questions we will go beyond evidence on digital/computer-based interventions for sexual health, to learn from other fields. We will seek **systematic reviews** on digital interventions in other health promotion fields (e.g. alcohol, drug use), sexual behaviour change, human-computer interaction, and sex education.

We will download all citations identified by the search into Reference Manager software. Two researchers (JB or SM and the research associate) will independently screen all citations, obtain and **appraise the full texts of any candidate papers to decide on their relevance** to one or more of the research topics B, C and E (research methodology, intervention design, development and implementation, and future potential for digital interventions).

Two researchers will extract and tabulate data on the study characteristics and findings of included systematic reviews. We will make judgements on the quality of included reviews, and the relevance for young people in the UK. We will summarise the findings narratively, and provisional conclusions will be presented and discussed in 'findings group' meetings.

### **Internet search (horizon scanning)**

Since there is a delay in the publication of research papers, we will also conduct a targeted, focused search using the Google search engine, to locate media articles, web logs or bulletin board discussions of the future potential of digital interventions for sexual health promotion.

## Health economic analyses

### Literature Review:

- Evidence on costs, cost-effectiveness and health economic outcomes encompassing **sexual health and digital/computer-based interventions**
- Economic evaluations of face-to-face interventions for sexual health promotion

We will obtain the full text of all papers identified in the focused literature review (detailed above) that include data on **costs, cost-effectiveness and health economic outcomes** of digital interventions for sexual health promotion. We will also search the following health economics databases to ensure that all economic evaluations of digital interventions have been identified: Econlit; NHS EED (part of the Centre for Reviews and Dissemination); HEED; CEA registry (Cost Effectiveness Analysis) <https://research.tufts-nemc.org/cear4/Home.aspx>; EconPapers <http://econpapers.repec.org>; PHICED (Public Health Interventions Cost Effectiveness Database) <http://www.yhpho.org.uk/PHICED>; and The Tufts University Library on Quality of Life.

Papers will be assessed against Drummond et al (2005) check list for assessing economic evaluations. Two researchers (RH and the research associate) will extract and record data on costs, consequences, perspective and presentation of uncertainty for each paper identified. We will comment on areas of uncertainty or controversy in relation to measuring and collecting costs and consequences for economic evaluations of digital interventions. We will also search health economic databases for **economic evaluations of face-to-face sexual health interventions**, which will be included as comparators in the cost-effectiveness analysis.

### Cost-effectiveness analysis

We will combine information from our meta-analyses on the relative effectiveness of digital interventions for sexual health promotion with information on intervention cost and consequences, including quality of life outcomes, to develop a simple decision analytical model of the likely cost-effectiveness of digital interventions compared to do nothing and to face-to-face sexual health interventions. Cost information will be taken from published studies as well as from our Sexunzipped intervention website and other developed digital interventions (e.g. mobile phone interventions), to assess costs of intervention development and dissemination. We will conduct a deterministic sensitivity analyses to determine how many sexually transmitted infections would need to be prevented for different digital interventions to be cost effective.

Based on the decision analytical models developed and using methodology set out in Briggs et al (2006) we will conduct an expected value of perfect information (EVPI) analysis. Given that all economic evaluations and research contain some degree of uncertainty; that there are costs to implementing an intervention, especially if it is the wrong decision; and that there are costs in delaying the implementation of an intervention in terms of benefits to patients foregone, the cost of uncertainty can be quantified based on the probability that a decision based on the current information is wrong and the cost of a wrong decision. EVPI uses probabilistic, non-parametric methods to estimate the expected net-benefit of implementing an intervention if perfect information was available compared to what is currently known. If the net-benefit of perfect information to the patient population is greater than the cost of conducting future research then future research is likely to be cost-effective. Partial EVPI can also be used to identify which areas of future research would yield the most benefits based on what is currently known (Claxton et al 2004).

## Key informant interviews

### Interviews with professional experts and stakeholders

We will purposively select stakeholders who are e-Health or sexual health researchers, clinicians, educationalists, policy-makers, intervention developers, digital technology and

media experts nationally and internationally, selecting them on the basis of their professional position, experience and expertise (Jones 2005). We will make contact by email initially, and seek permission to interview either face-to-face or by telephone, using semi-structured topic guides to seek their views on optimal intervention design, development, evaluation, implementation and future potential of digital interventions for sexual health. We plan to conduct 40 interviews, ten of which will be with international experts.

### **Focus groups with young people**

We will invite 36 young people to participate in focus groups. We will sample purposively by age and gender, running six single gender focus groups in age bands 13-15; 16 to 19; and 20 to 24. We will recruit the younger age groups (13-15) from school settings, and the older age groups from a variety of routes including youth clubs and sexual health outreach schemes as well as an advert on the social media website 'Facebook' and via Twitter, recruiting young people who live in or near to London (to ensure reasonable travel times). We will ensure that we include high and low users of digital technology, and we will also hold a focus group with parents of teenagers.

We will 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, suitable outcome measures, and future potential.

We will consult the same participants in a second round of focus groups, to invite young people and parents to comment on the findings of the whole project, and to make recommendations in the following areas:

- *The place of digital interventions within current UK health promotion policy and practice*
- *The place of digital interventions in current practice in schools*
- *The place of digital interventions in healthcare settings in the UK*
- *The future potential for digital interventions for sexual health promotion in the UK*
- *To generate 'blue sky' innovative ideas to set an agenda for possible future research and development*
- *To comment on research methodology (including sexual health and health economic outcome measurement)*

### **Qualitative data analysis**

We will audio-record and transcribe stakeholder interviews and focus group discussions, and analyse them thematically (Bryman 1994) using a coding frame derived from our topic guide, supplemented with codes emerging from the qualitative analysis of interview data. We will discuss emergent themes in research team 'findings groups', to refine the scope of our topic guides as the project progresses.

### **Short report on findings**

We will integrate stakeholder perspectives (young people's and experts' views) with the findings from our literature reviews, producing a short report of key findings to circulate to expert symposium participants.

### **Expert symposium**

The findings from our literature reviews and field work will inform the agenda for a 2 day **expert symposium**. We will circulate the short report to delegates in advance, highlighting areas where there is a lack of consensus in the literature. The agenda for symposium discussions will be shaped by emergent findings, but is expected to focus on three main areas:

- \* Research methodology
  - Health economic assessment
  - Sexual health outcome measurement
  - Challenges in research design (including online trials)

\* Challenges in intervention design, development and implementation

\* Future potential of digital interventions for sexual health promotion

*Delegates will be asked to:*

- Read a short report on findings
- Comment on our emergent findings
- 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 health promotion policy and practice in the UK
- Make recommendations for the integration of digital interventions with current practice in schools and healthcare settings in the UK
- Comment on the implications of digital intervention implementation for training and skill development
- Comment on realistic 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

Discussions will be audio-taped with delegates' permission, and minutes will be taken at the symposium. Notes will be made from the audio-tape, summarising points made during symposium discussions. Lists of expert recommendations will be compiled, removing duplicate suggestions.

### **Consensus process**

We will undertake a modified Delphi technique to seek an expert consensus on our scoping review findings (Hsu 2007). 'Expert' interviewees and expert symposium participants will be invited to participate in the consensus process. An online questionnaire will focus on key areas where there are debates and uncertainties in the literature, asking participants to indicate their agreement with particular views and to prioritise some items (for example to rank competing funding priorities). Space will be provided for comment and to provide rationale for decisions. The results from this questionnaire will be fed back in a second round, with participants asked to justify their choices if their opinions diverge from the majority.

We will post the results of this consensus process online, and invite debate and comment from members of the public on the issues raised, utilising an online discussion board format. This consultation process will be advertised via Facebook and Twitter, with additional debate encouraged on Twitter as well

### **Final report- Sexual health promotion delivered by digital media: scoping exercise and horizon scanning**

The final report will summarise available evidence in the following five principal areas, commenting on the strength of evidence which underpins conclusions, highlighting gaps in knowledge, and providing expert commentary where evidence is uncertain (see also Appendix, Figure 1).

- A. Summary of evidence on effectiveness** of digital interventions for sexual health promotion (also published in full as a Cochrane systematic review)
- B. Summary of evidence on optimum research design and outcome measurement** to evaluate digital interventions for sexual health promotion
- C. Summary of evidence on best practice for digital intervention design, development and implementation** of sexual health interventions for young people
- D. Summary of evidence on optimal methods for economic measurement, analysis and modelling** in sexual health
- E. Comment on future potential** for sexual health promotion for young people via digital media, with recommendations for **investment in research, development and implementation**

Our final report will be for wide dissemination, including policy makers, practitioners and commissioners. We will make the report freely available online, and circulate it using our contact lists and via Twitter, Facebook and the UCL e-Health Unit website.

### **Other research outputs**

- \* Online, publicly available database of available interventions and their evaluations.
- \* Identification of front-running interventions suitable for implementation, or for further research and development
- \* Peer reviewed publications on each of the five main topic areas

### **Socioeconomic position and inequalities**

We will consider the impact of digital interventions on inequalities in health - this is especially important given the 'digital divide' between those with and without access to 'new' technologies (Kanuga 2004). We will conduct a meta-regression within our systematic review of digital interventions to assess whether there is a differential impact on those at higher risk of adverse sexual health (for example, by gender, ethnicity and socioeconomic status of study participants). We will also consider other available qualitative and quantitative evidence on access to digital interventions, uptake and engagement of young people from different demographic and socio-economic groups, and those with physical and learning disabilities.

### **Proposed sample sizes**

#### **Focus groups**

We will invite 36 young people and 6 parents of teenagers to participate in focus groups. The views of young people and parents will help us to ensure that we have not overlooked factors which are important priorities for young people. We will consult the same people again to feedback our findings

#### **Expert stakeholder interviews**

Forty participants will provide a diverse range of perspectives, whilst also being a realistic number of interviews to analyse in a relatively short time scale.

#### **Expert symposium**

We will invite 20 experts and stakeholders to participate in our expert symposium (plus 7 of our research team). Participants will be mainly from the UK, since a principal agenda topic

concerns recommendations for research, development and implementation of digital interventions in the UK. Twenty-seven participants will allow for a diverse range of participants whilst being a small enough number to have meaningful discussions.

### **Ethical arrangements**

Ethical committee permission is required to conduct interviews with professional stakeholders and to conduct focus groups with young people. We will ensure that we adhere to best practice for obtaining informed consent, with excellent written and verbal information about the project and the implications of participating. Data will be kept confidential (on password protected university computers), in accordance with the Data Protection Act 1998, and any quotations in reports and publications will be attributed anonymously.

#### **Focus groups with young people**

Parental permission will be required to hold focus groups with young people under the age of 16. We will facilitate focus groups with young people sensitively, laying ground rules for mutual respect between participants. Data will be kept confidential and not disclosed to others including teachers, parents or others, except in the case of disclosure of illegal or abusive behaviour. We will have a written protocol for this eventuality, and will make clear to participants the legal limits of confidentiality if participants under 18 disclose that the health, safety or welfare of themselves or others are at grave risk (DfES 2006). We would initially seek to persuade a young person to disclose the risk to a responsible adult themselves. We will consult with at least one other member of the project advisory panel before disclosing risk to any third parties, and keep the young person informed.

#### **Interviews with professional stakeholders**

We will ensure that there are clear agreements about the publication or dissemination of any information which may be commercially or professionally sensitive.

### **Research Governance**

University College London (UCL) is the nominated sponsor for this study.

#### *Steering committee*

We will hold steering committee meetings every 3 months throughout the project. All co-applicants and two young people will be invited to steering committee meetings. The committee's role will be to review and monitor the conduct and progress of the project, ensuring that the proposed work is accomplished on time and within budget, adhering to ethical principles, high quality research governance, and to the law.

#### *Advisory Group*

We will invite eight people with a diverse range of interests in the field of digital media for sexual health promotion to be on an advisory group (including e-health and sexual health researchers, policy makers, educationalists, software developers, digital technology and social media experts and user representatives). The group will be consulted for their opinions on the scope of the proposed work to ensure that it is judged appropriate and comprehensive, and will be consulted on the specific direction of the research as the project progresses. We will consult by email and telephone to keep the costs low.

#### *Findings groups*

We will also hold monthly research team 'findings groups' (from month 6 onwards), to discuss emergent findings and check the progress of the research.

#### *Data monitoring and ethics committee*

This proposal is a scoping study, with data comprising quantitative and qualitative evidence from literature reviews, and qualitative data from stakeholder interviews. The project will be registered at UCL under the Data Protection Act 1998, and full ethical permission will be

sought for to seek stakeholder views. We are not proposing to have an external data monitoring and ethics committee.

### Project timetable and milestones

Months	Tasks	Milestones
<b>-3 to 0</b>	Staff recruitment UCL ethical permission Research governance permissions	1 <sup>st</sup> February 2013 Research associate recruited User representatives recruited UCL ethical permission, data protection registration, insurance cover in place
<b>1-2</b>	Literature search	1 <sup>st</sup> April 2013 Completed literature searches, selection of relevant papers for inclusion
<b>1-9</b>	Topic A	1 <sup>st</sup> November 2013 Cochrane review effectiveness of digital interventions for sexual health promotion submitted to the Cochrane Collaboration
<b>1-9</b>	Topic B	1 <sup>st</sup> November 2013 Summary of evidence on optimum research design and outcome measurement
<b>1-6</b>	Topic C	1 <sup>st</sup> July 2013 Summary of evidence on intervention design, development and implementation
<b>1-6</b>	Database of interventions	1 <sup>st</sup> July 2013 Online database of available interventions developed 'Front running' intervention/s identified
<b>1-12</b>	Topic D	1 <sup>st</sup> February 2014 Summary of evidence on costs, cost-effectiveness, outcome measurement and development of decision analytical model
<b>6-9</b>	Topic E	1 <sup>st</sup> November 2013 Summary of future potential for sexual health promotion for young people via digital media
<b>10-11</b>	Focus groups with young people	1 <sup>st</sup> January 2014 Qualitative synthesis of young people's views on sexual health promotion for young people via digital media
<b>12</b>	Short report	15 <sup>th</sup> January 2014 Circulate short report on findings to experts
<b>13</b>	Expert symposium	1 <sup>st</sup> March 2014 Qualitative synthesis of professional stakeholder views on sexual health promotion for young people via digital media
<b>14</b>	Focus group re-consultation	1 <sup>st</sup> April 2014 Young people's comments on findings collated
<b>15</b>	Online consensus survey	1 <sup>st</sup> April 2014 Online consensus survey instrument ready for use
<b>15</b>	Stakeholder opinions	1 <sup>st</sup> May 2014 Invitation to comment on findings and recommendations closed.
<b>16-18</b>	Final report	31 <sup>st</sup> July 2014 Scoping report, published online: Sections: 1) Summary of available evidence and gaps in knowledge on efficacy of digital interventions for sexual health 2) Evidence on optimal research design to evaluate digital interventions 3) Evidence for successful intervention design, development and implementation 4) Evidence on optimal methods for economic measurement, analysis and modelling in sexual health 5) Comment on the future potential for digital interventions, including recommendations for investment, research and development

16-18	Dissemination	31 <sup>st</sup> July 2014 Two articles submitted for publication in peer-reviewed journals
16-18	Dissemination	31 <sup>st</sup> July 2014 Presentation of findings at national and international conferences

### Expertise

Our team has internationally recognised expertise and strong track records in e-health research (JB, EM, CF), sexual health research (JB, JS, EM, CA, CF, SM); sexual health clinical work (JB, EM, JS, CF, SM); collaboration with users (JB, EM, CF); intervention design (JB, CA, CF, EM, JS) developing and applying models of behaviour change (CA, EM, JB); developing and evaluating interactive computer-based interventions (JB, EM, CF); developing and evaluating complex interventions (JB, EM, JS) sexual health outcome measurement (JS, CA, JB); qualitative methodology (JB, EM, CA); statistical meta-analyses (RM) and economic assessment and modelling (RH).

Our previous systematic reviews and policy reviews form the starting point for this programme of work: (Interactive Computer-Based Interventions for Sexual Health Promotion by JB, EM, RM RP et al.; The Effectiveness of Mobile Health Technologies for Improving Health and Health Services by CF et al.; and the 2008 Review of the National Strategy for Sexual Health and HIV, co-authored by SM). We have strong links with other e-Health groups nationally and internationally, charitable organisations, NHS clinical services and policy-makers, and we also have successful mechanisms for soliciting user views.

### Roles (see also Figures 1 and 2)

**Dr Julia Bailey:** Principal Investigator – will coordinate the study, directly supervise the Research Associate, conduct quantitative systematic review and meta-analyses, review optimum research methodology including outcome measurement, (Topics A and B), co-facilitate focus groups, convene expert symposium, co-write final report.

**Dr Sue Mann:** Co-applicant - contribute to study protocols, synthesise literature and conduct stakeholder interviews on contexts for successful design, development, and implementation (Topic C) and policy, practice and future potential (Topic E). Co-convene expert symposium, co-write final report.

**Dr Elizabeth Murray:** Co-applicant - contribute to study protocols, co-convene expert symposium, advise JB

**Professor Charles Abraham:** Co-applicant - contribute to study protocols, synthesise literature on mechanism of action (Topics A and C), co-convene expert symposium

**Miss Rachael Hunter:** Co-applicant - contribute to study protocols, conduct economic literature review and analyses (Topic D)

**Dr Caroline Free:** Co-applicant - contribute to study protocols, co-convene expert symposium

**Professor Richard Morris:** Co-applicant - conduct statistical analyses for systematic review and meta-analysis (Topic A)

**Mr Richard Peacock:** Collaborator - literature review strategy planning

**Professor Judith Stephenson:** No cost collaborator - advice on sexual health intervention development and evaluation including outcome measurement, contribute to expert symposium.

### Research associate

18 months full time - systematic literature searching and evidence synthesis for all topics; gather and analyse young people's views through focus groups; assist with the running of the expert symposium; analyse and collate data and contribute to reports and papers. The

research associate will be directly supervised by JB, and will also work with other members of the team including SM, CA and RH.

### **Members of the Public**

We will invite applications from two young people to sit on our steering group. Their role will be to ensure that the research plan and conduct takes into account young people's agendas and priorities. We remunerate user representative, and reimburse their travel expenses.

Focus groups with young people are an essential component of our research design: the findings from four focus groups with young people will inform the agenda for our expert symposium, and will feed into the final report.

## Sexual health promotion delivered by digital media: a scoping study

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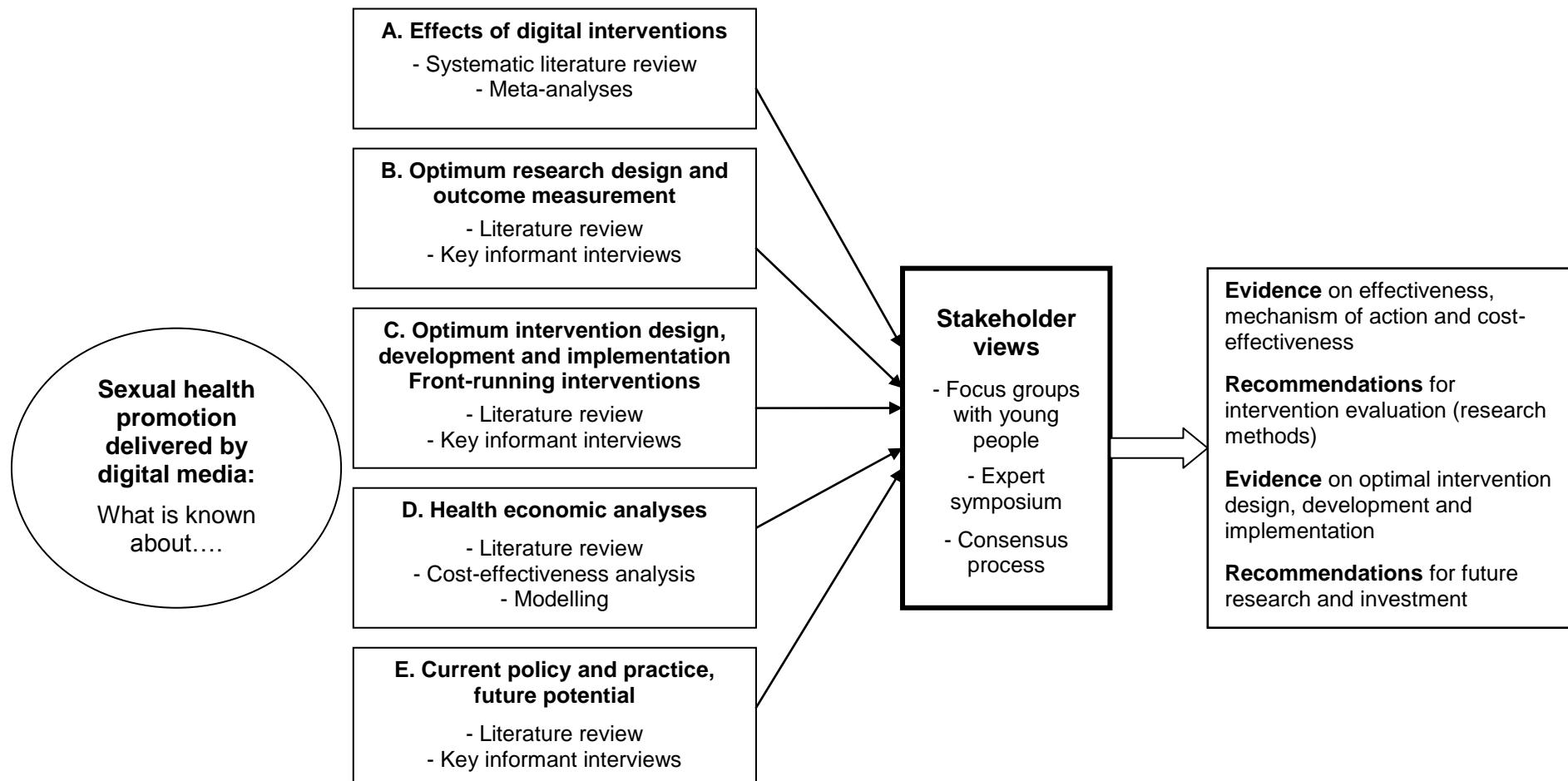
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**Appendix: Figure 1. Research topics for sexual health promotion delivered by digital media: scoping study**



**Appendix . Figure 2. Sexual health promotion delivered by digital media – tasks and timelines**

Month	1	2	3	4	5	6	7	8	9	10	11	12	
Tasks	A. Systematic review, meta-analyses and meta-regression on effects of digital interventions for sexual health promotion JB, RM, EM, research associate										<b>Focus groups</b> with young people. SM, JB, research associate	<b>Collate findings, circulate report to experts</b>	
	B. Optimum research methodologies including sexual health outcome measurement. Literature reviews, Key informant interviews. JB, research associate												
	C. Review of evidence on optimum intervention design, development and implementation including mechanism of action. Front-running interventions. Literature review, Key informant interviews. SM, CA, research associate					E. Future potential for sexual health promotion via digital media. Literature review, Key informant interviews. SM.					Qualitative <b>data analysis</b> and <b>information collation</b> . JB, SM and research associate		
	D. Health economic analyses: literature review on costs, cost-effectiveness, optimal methods for measurement and modelling RH, research associate												

Month	13	14	15	16	17	18
Tasks	Expert Symposium	Focus group re-consultation with young people	Consensus process for stakeholder recommendations	<b>Write up and dissemination</b>		
	Qualitative <b>data analysis</b> and <b>information collation</b> . JB, SM and research associate					