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Interactive computer-based interventions for sexual health promotion (Protocol)

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To determine the effects of interactive computer-based interventions for sexual health promotion, considering cognitive, behavioural, biological and economic outcomes.

BACKGROUND

Sexual Health

Sexual health is a major public health challenge throughout the world, with sexually transmitted infection and unplanned pregnancy problematic in most countries (DOH 2001; Tripp 2005; WHO 2004). Human immunodeficiency virus (HIV) prevalence is especially high in sub-Saharan Africa, and epidemics of sexually transmitted HIV are gaining hold in Eastern Europe and Asia (UNAIDS 2004). Sexually transmitted infections (STIs) such as genital chlamydia, gonorrhoea and syphilis are prevalent worldwide, with marked increases in Western Europe in the last decade (Ellis 2004; Nicoll 2002). The UK and the USA have high rates of unplanned teenage pregnancy in comparison with Western Europe as a whole (Chambers 2001). Psychosexual problems such as erectile dysfunction, orgasmic dysfunction and/or lack of sexual desire are also common (Nazareth 2003; Nicolosi 2006), and safe, positive expression of sexuality is often difficult (WHO 2006).

Particular socio-demographic groups are at disproportionate risk of poor sexual health, for example young people (especially disenfranchised youth), men who have sex with men (MSM), refugees, sex workers (especially drug users and street workers) and prisoners (Elford 2003; Ellis 2004; Gray 2002). Sexual health concerns may not be addressed in healthcare encounters because of pressure on health services (White 2005) and patients' and physicians'

reservations about raising complex and potentially sensitive topics (DOH 2001; Gott 2004; Viner 2005).

Sexual Health Interventions

There are many educational programmes designed to promote sexual health, particularly school-based, face-to-face interventions (DiCenso 2002; Peersman 1996). Sexual health interventions are complex interventions in that they have a number of components which may interact with each other and act at different levels simultaneously (MRC 2000). Reviews of health promotion and educational interventions show that simply providing information does not lead to behaviour change (Mellanby 1992; Stephenson 2003). However, the components of successful interventions are not clearly defined (Speizer 2003). Interventions which seem more effective are those which have a theoretical basis (for example drawing upon educational theory and psycho-social theories of sexuality and behaviour change) and those which are targeted and tailored to meet participants' needs (Dubois-Arber 2002; Ellis 2004; Kolb 1984; Wight 1998). Also important seems to be behavioural skills training, for example to increase self-efficacy (the belief in one's capacity to carry out an action) (DOH 2003; Ellis 2004).

Computerised Interventions

Technology such as the internet provides access to increasing quantities of sexual health information (Kanuga 2004; Skinner 2003). There are obvious inequalities in access to internet technology, and this may be especially true for those at higher risk of adverse sexual health, for example children not attending school, sex workers, and

poorer people in general (Dutton 2005; Gray 2002; Kalichman 2005; Norton 2004). It is estimated that 70% of people in North America have access to the internet, 40% of people in Europe, 10% in Asia and the Middle East, and only 4% in Africa (Miniwatts 2006). Access is increasing rapidly worldwide (Kanuga 2004), so there is huge potential for delivery of health promotion via the internet but it is not known whether web-based and other computerised interventions are effective in promoting sexual health. It is also not known what forms of intervention are effective, for which sexual health issues, for which population groups and in which settings.

Computer-based, interactive interventions are feasible, and have been effective in promoting behaviour change in people with chronic diseases such as diabetes or heart disease, leading to improved knowledge, social support, health behaviours and clinical outcomes (Murray 2005; Wantland 2004). Computer-based interventions are also feasible in health promotion contexts such as problem drinking (Linke 2004), smoking cessation (Strecher 1999), and nutrition and physical activity (Patrick 2001). The internet offers potential advantages over face-to-face interventions in that access can be private, repeated, and at convenient times (Kanuga 2004; Skinner 2003). Interactive computer-based interventions can be tailored to meet individual needs, offer individualised feedback, and can promote active learning through interactive elements (Kanuga 2004). Few programmes or modules are evaluated before marketing (Eng 1999): qualitative evaluations of interactive computerised sexual health interventions in schools, community settings and healthcare settings indicate that users like the tailored and interactive elements, and that they readily engage with programmes (Paperny 1997; Thomas 1997).

Gaps in research

Digital technology such as the internet offers exciting potential for sexual health promotion. There are no known systematic reviews of computer-based modes of delivery for sexual health interventions. Murray and colleagues carried out a systematic review of computer-based interventions for chronic disease (Murray 2005). Coping with chronic disease represents a different context to primary prevention since there is likely to be greater motivation to change in the face of manifest illness (Hobbis 2005). Thorough reviews of sexual health interventions are available. However, these focus on face-to-face interventions by teachers, peers or healthcare providers (Ellis 2003; Ellis 2004; Peersman 1996; Swann 2003), and on interventions for particular target groups for example men who have sex with men (Rees 2004) or women only (Shepherd 1999). Few reviews include interactive computer-based interventions.

It is not known whether a computerised, interactive format is simply another route for delivery of sexual health education, or whether it may work in a different way to face-to-face sexual health education. There is also the potential that internet-based interventions may cause harm: for example for MSM, meeting male sexual

partners via the internet is associated with increased sexual risk-taking (Elford 2001). A systematic review is needed to search for trials of interactive computerised interventions, and to assess their effects in comparison with face-to-face or non-interactive forms of health promotion.

OBJECTIVES

To determine the effects of interactive computer-based interventions for sexual health promotion, considering cognitive, behavioural, biological and economic outcomes.

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

Types of studies

We will include randomised controlled trials (RCTs) (both individual and cluster randomised). Trials could compare interactive computer-based interventions (ICBI) with no exposure, non-interactive forms of education (e.g. written information, non-interactive computer packages), or face-to-face educational sessions (either peer-led or expert) for example.

We will also include trials that compare two or more types of interactive computer-based intervention, in order to compare the effects of different designs of intervention, such as different technological modes of delivery (e.g. personal computer, mobile phone), different theoretical underpinnings, or different styles of presentation (e.g. graphical, audio, video). We will include trials that include ICBI as a component of a multi-component intervention, as long as it is possible to separately identify the effects of the ICBI.

We will include economic evaluations of interactive computer-based interventions which have been conducted alongside RCTs.

Types of participants

We will include users/consumers of any age, gender, sexuality, ethnicity or nationality.

Types of intervention

Interventions must have an interactive computer-mediated design, and an aim of promoting sexual health.

Interactive computer-based interventions

We define 'interactive' as meaning packages that require contributions from users (e.g. entering personal data, making choices) which alter pathways within programmes to produce tailored material and feedback that is personally relevant to users of the programme (Bellis 2002). Users may interact with programmes as members of a small group as well as individually.

Definitions of computer-based interventions are not used consistently in the e-health literature. Adapting the definitions for

'Consumer Health Informatics Systems' (Gustafson 2002) and 'Interactive Health Communication Applications' (Eng 1999) we have defined eligible interventions for this review as interactive computer-based programmes that provide information and one or more of the following: decision support, behaviour-change support, or emotional support for health issues. Programmes should be available directly to users and allow independent access without needing expert facilitation. The internet is likely to be the most common delivery route, although other technologies such as interactive television, mobile telephone, CD-ROM and handheld computers (personal digital assistants) are possible.

An example of an interactive computer-based intervention is the 'Keeping it Safe' CD-ROM utilised with young women in a single 30 minute session. The CD gives information about HIV, an interactive game which provides feedback about HIV facts and myths, a video of a personal story of HIV and a four-step model of assertive responding using scenarios and simulations (Di Noia 2004).

Sexual health promotion

'Sexual health' and 'health promotion' are difficult to define because these concepts are socially and culturally relative (WHO 2004). Risk factors can be seen as individual (e.g. accurate knowledge, beliefs, motivation and skills to change behaviour) and environmental (e.g. socio-cultural norms, the law, availability and access to services) (WHO 2004). It is a complex interplay of these factors that leads to outcomes such as condom use, or acquisition of an STI (Ellis 2004).

We have adapted the Public Health Agency of Canada's definition of health promotion (PHA Canada 2006), taking sexual health promotion to mean strategies for improving the sexual health of the population by providing individuals, groups and communities with the tools to make informed decisions about their sexual well-being.

Sexual well-being can be thought of as "a state of physical, emotional, mental and social well-being in relation to sexuality; it is not merely the absence of disease, dysfunction or infirmity. 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. For sexual health to be attained and maintained, the sexual rights of all persons must be respected, protected and fulfilled". (WHO 2002).

Studies meeting our definition of sexual health promotion could therefore include those aiming to enhance 'life skills' such as decision-making and assertiveness with the aim of enhancing sexual wellbeing, as well as studies aiming to reduce adverse biological outcomes such as STI or unwanted pregnancy. Seeking sexual health care may also improve the sexual health of others, for instance where genitourinary screening or HIV testing result in a reduction in the spread of disease.

We will, therefore, include interventions which facilitate the active seeking of sexual wellbeing, including accessing sexual health services (e.g. vaccination, STI screening, contraceptive advice, psychosexual counselling, etc.), but exclude interventions that aim to optimise health care once in a healthcare setting.

Exclusions

We will exclude the following interventions:

- simple information packages with no interactive elements;
- non-interactive mass media interventions such as TV advertisements;
- interventions designed to be used with others' help (e.g. teacher or health professional);
- interventions targeted for health professionals or teachers;
- computer-mediated delivery of individual healthcare advice (e.g. online physicians);
- 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.

All included interventions must meet the definitions for interactivity, computer-based intervention, and sexual health promotion, as well as being randomised controlled trials (or economic evaluations of trials).

Types of outcome measures

Outcome measures for individual participants can be divided into cognitive, behavioural and biological indices (Stephenson 2003). The first two are generally self-reported, whilst biological outcomes may be measured externally. Whilst self-reported indices are more susceptible to inaccuracy and bias than externally measured outcomes, they give valuable information about the possible mechanisms of action of interventions (Stephenson 2003). Many trials measure cognitive and behavioural indices because biological measurement may be costly to obtain, less acceptable to participants, and trials may need to be very large to detect changes in relatively rare outcomes such as STI or pregnancy rates in lower risk communities. Any meta-analysis in this review will consider these different types of outcomes (cognitive, behavioural and biological) separately since the relationship between them is complex and non-linear (Stephenson 2003); for example, someone may become motivated to use condoms but their partner refuses; or increases in condom use may make little difference to HIV acquisition in populations with low initial prevalence of HIV.

Populations at risk of sexual health problems (e.g. adolescents, MSM), their risk behaviours, and the contexts in which sexual risk occurs are obviously very diverse (Johnson 2001; Stephenson 2003). Similarly, patterns of computer or internet use vary with socio-demographic indices and across cultural and sub-cultural groupings (see 'Background'). However, we postulate that the underlying psychological pathways of behaviour change with interactive computer-based interventions are similar for participants in different contexts. For example, increase in knowledge, change in attitudes, and improvement in skills may be needed to effect behaviour change leading to improved sexual health. The specific context and combination of these factors is likely to be different for different populations, but we postulate that on a theoretical level, interactive computer-based interventions would work in a similar way (Hardeman 2002; Hobbis 2005).

We will extract the following outcomes:

- Cognitive outcomes (e.g. knowledge; self-efficacy (a person's belief in their capacity to carry out a specific action); attitude (overall evaluation of performing a behaviour); sexual satisfaction).
- Behavioural outcomes (e.g. consistency of condom use for vaginal or anal intercourse; partner numbers; sexual activity whilst intoxicated; health seeking behaviour (such as increased STI testing and treatment, uptake of cervical cytology screening); age at first sex, condom use at first sex (young people), consistency of contraceptive use (heterosexual participants); negotiation/communication skills).
- Biological outcomes (e.g. STI rate; HIV acquisition rate; conception rate; abortion rate).
- Adverse effects (data on unintended adverse outcomes attributable to the intervention).
- Economic outcomes (e.g. costs of developing and implementing interactive computer-based interventions; costs and savings for health services or other agencies (such as costs of screening tests and increased use of health services versus costs of untreated STI); costs and savings for users/consumers (such as costs associated with uptake of preventative health services versus costs of unwanted pregnancy)).

SEARCH METHODS FOR IDENTIFICATION OF STUDIES

See: Cochrane Consumers and Communication Group methods used in reviews.

We have designed a four-part search strategy. Firstly, we will search electronic bibliographic databases for published work; secondly, we will search the grey literature for unpublished work; thirdly, we will search trials registers for ongoing and recently

completed clinical trials. Finally, we will search reference lists of published studies and contact authors and e-health research groups to check for more trials.

All databases will be searched from their start date. There will be no limitations by date or language.

Electronic database searching

Electronic bibliographic databases to be searched include:

- Cochrane HIV/AIDS, STD, Fertility Regulation, and Consumers and Communication Review Groups' registers of trials;
- *The Cochrane Library* (Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials (CENTRAL), DARE, NHSEED (NHS Economic Evaluation Database), Health Technology Assessment Database);
- Medical electronic bibliographic databases: MEDLINE, EMBASE, CINAHL, and British Nursing Index, using an Ovid platform;
- Social science: Sociological abstracts, Web of science (science and social science citation index), HMIC, PsycINFO, Communication Abstracts;
- Education databases: ERIC (Educational Resources Information Centre), Campbell Collaboration databases (C2-SPECTR; C2-PROT; C2-RIPE), British Education Index; Public health databases: Bibliomap, DoPHER, TRoPHI, CDC Health Promotion and education database;
- Other databases: AIDSLINE (National Library of Medicine), and POPLINE.

Grey (unpublished) literature

We will search for grey literature via the following sources:

- Australasian Digital Theses Program <http://adt.caul.edu.au/>
- Networked Digital Library of Theses and Dissertations <http://www.ndltd.org>
- UMI ProQuest Digital Dissertations <http://wwwlib.umi.com/dissertations/>
- Index to Theses <http://www.theses.com/> (Great Britain and Ireland)
- Dissertation Abstracts (North American and European theses) via British Library

Ongoing and recently completed clinical trials

Ongoing and recently completed clinical trials will be sought via the following research registers:

- National Research Register, International Register of Controlled Trials;
- National Institute of Health clinical trials database;

- ReFer (Research Findings register, DOH);
- African Trials Register.

We will also locate and contact study authors through trials registers, research groups, and unpublished sources, to obtain details of unpublished trials.

Searching reference lists

Finally, we will search reference lists of published studies and contact authors and e-health research groups to check for more trials.

Search strategy

The search strategy comprises three overlapping concepts:

- 1) Study design filter (Robinson 2002)
AND
- 2) Computer/internet-based applications
AND
- 3) Sexual health.

We will use the following MEDLINE (Ovid) strategy:

1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. randomized controlled trials.sh.
4. random allocation.sh.
5. double blind method.sh.
6. single blind method.sh.
7. or/1-6
8. animals/ not (human/ and animals/)
9. 7 not 8
10. clinical trial.pt.
11. exp clinical trials/
12. (clinic\$ adj25 trial\$).ti,ab.
13. ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj25 (blind\$ or mask\$)).ti,ab.
14. placebos.sh.
15. placebo\$.ti,ab.
16. random\$.ti,ab.
17. research design.sh.
18. (latin adj square).tw.
19. or/10-18
20. 19 not 8
21. 9 or 20
22. Comparative study.tw.
23. exp Evaluation studies/
24. Follow-up studies.sh.
25. Prospective studies.sh.
26. (control\$ or prospectiv\$ or volunteer\$).tw.
27. Cross-over studies.sh.
28. or/22-27
29. 28 not 8
30. 9 or 21 or 29

31. (Computers or microcomputers or computers, handheld).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
32. (Internet or local area networks).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
33. Computer Communication Networks/
34. Medical Informatics/
35. Medical Informatics Applications/
36. Decision Support Techniques/
37. Educational Technology/
38. Audiovisual Aids/
39. (Decision trees or decision aid\$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
40. (Software or software design).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
41. Telecommunications/
42. Multimedia/ or Health Education/
43. (CD-ROM or Compact disks or cd-rom or CDROM).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
44. Computer-Assisted Instruction/
45. Public Health Informatics/
46. User-Computer Interface/
47. (Cellular phone or Cellular telephone or (Mobile phone or Mobile telephone) or (Cell phone or Cell telephone)).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
48. (Electronic mail or e-mail or email).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
49. Hypermedia/
50. Video Games/
51. (Video recording or DVD).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
52. Computer Graphics/
53. (World wide web or world-wide-web or www or world-wide web or worldwide web or website\$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
54. Internet/
55. (Online or on-line).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
56. (Chat room\$ or chatroom\$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
57. (blog\$ or web-log\$ or weblog\$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
58. (bulletin board\$ or bulletinboard\$ or messageboard\$ or message board\$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
59. Interactive health communicat\$.mp. [mp=title, original title, abstract, name of substance word, subject heading word]
60. interactive televis\$.mp. [mp=title, original title, abstract, name of substance word, subject heading word]
61. interactive video\$.mp. [mp=title, original title, abstract, name of substance word, subject heading word]

62. Interactive technology.mp. [mp=title, original title, abstract, name of substance word, subject heading word]
63. Interactive multimedia.mp. [mp=title, original title, abstract, name of substance word, subject heading word]
64. E-health/ or electronic health/ or ehealth.mp. [mp=title, original title, abstract, name of substance word, subject heading word]
65. Consumer health informatic\$.mp. [mp=title, original title, abstract, name of substance word, subject heading word]
66. Virtual reality.mp. [mp=title, original title, abstract, name of substance word, subject heading word]
67. (surf\$ adj4 web\$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
68. (surf\$ adj4 internet).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
69. or/31-68
70. (Intercourse or Unprotected intercourse).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
71. (Contraception or contracepti\$ behavio?r or contraception-barrier).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
72. (Contraceptive devices, male or contraceptive devices, female).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
73. (Rubber dams or dental dam\$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
74. (Contraceptives-oral or contraceptives, oral, combined or contraceptives, oral, hormonal or Contraceptive pill).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
75. (contraceptives, postcoital or contraception, post-coital or morning-after pill or emergency contraception).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
76. Intrauterine Devices/
77. (Condoms or condoms-female).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
78. ((Reproductive adj behavio?r) or Coitus).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
79. (Sexual adj health).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
80. (Safe sex or safer sex or unsafe sex).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
81. Sexual Abstinence/
82. Sexuality/
83. Sexual Partners/
84. (Pregnancy, unplanned or pregnancy, unwanted or teen\$ pregnancy or pregnancy in adolescence or unplanned pregnancy or unwanted pregnancy).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
85. (Unplanned conception or unwanted conception or teen\$ conception or adolescent conception).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
86. (Abortion, induced or termination of pregnancy).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
87. Sexually Transmitted Diseases/
88. Sexually transmitted infection\$.mp. [mp=title, original title, abstract, name of substance word, subject heading word]
89. (Sexual behavior or sexual behavio?r).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
90. Sex Education/
91. (Sex counseling or sex counselling).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
92. (HIV or AIDS or Human immunodeficiency virus or Acquired immune deficiency syndrome or HIV antibodies or AIDS serodiagnosis or HIV infections).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
93. (Hepatitis A or Hepatitis B or Chlamydia trachomatis or chlamydia or Gonorrhea or Neisseria Gonorrhoeae or gonorrhoea).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
94. (pelvic inflammatory disease or Trichomoniasis or papillomavirus infections or papillomavirus infections or papillomavirus vaccines).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
95. (syphilis or herpes genitalis or Chancroid or granuloma inguinale or condylomata accuminata or Bacterial Vaginosis).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
96. (Cervical cancer or uterine cervical neoplasms).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
97. (Cervical intra-epithelial neoplasia or uterine cervical dysplasia).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
98. Orgasm/
99. Libido/
100. Reproductive Rights/
101. Sexual Dysfunctions, Psychological/
102. Sexual Dysfunction, Physiological/
103. Dyspareunia/
104. Impotence/
105. Rape/
106. Sexual satisfaction.mp.
107. Sexual pleasure.mp.
108. Sexual assault.mp.
109. Sexual problem.mp.
110. or/70-109
111. 30 and 69 and 110

METHODS OF THE REVIEW

We will download all citations (including their abstracts) identified by the search into Reference Manager software. Two review authors will independently screen titles and abstracts for relevance using the criteria discussed above (i.e. randomised controlled trials of interactive computer-based interventions which aim to promote sexual health). These two review authors will then independently screen the full text of all candidate studies to determine eligibility.

We will develop a data extraction form based on the data extraction template of the Cochrane Consumers and Communication Review Group, to include details of study methods, participants and settings, informed consent, consumer involvement, funding source for study, theoretical framework, description of interventions and controls, study quality (see below) and outcomes (including reported adverse outcomes). We will pilot the template with five eligible studies and refine it as required.

We will judge the quality of studies by assessing study validity on the basis of a number of criteria:

Selection bias (non-random selection of control and intervention groups)

We will record and assess the quality of procedures to assign participants randomly to intervention or control groups, and to conceal allocations until the point of allocation.

Performance bias (differences in participant experience other than the intervention)

We will record and assess the adequacy of procedures to blind participants, and those who administer interventions, as to who received interventions.

Attrition bias (differences in drop-out rates)

We will record overall losses to follow-up, and record differential drop-out rates between control and intervention groups. We shall also note whether studies conducted intention-to-treat analysis.

Detection bias (systematic differences in outcome assessment)

We will record whether outcome assessment was blinded.

We will also record other quality criteria including baseline imbalances between groups, whether validated outcome scales were used, and the duration of follow-up. The quality assessment will be used in interpretation and discussion of the results.

Two review authors will extract data independently from included studies using the data extraction form, entering data into separate Excel charts. Disagreements will be resolved through discussion with a third review author. We will contact the authors of included studies for missing data. One review author will transfer data from Excel software into RevMan software, with a second review author checking the accuracy of data transfer.

We will tabulate available data to produce a descriptive synthesis of trials. This will inform the quantitative data synthesis, allowing

assessment of clinical heterogeneity, methodological heterogeneity and heterogeneity in types of outcomes, allowing a determination of whether formal meta-analysis is possible and appropriate. These decisions will be reviewed at a project steering group meeting.

If appropriate, we will pool the results of RCTs using a random-effects model with standardised mean differences (SMDs) for continuous outcomes and odds ratios for binary outcomes (in other words to derive adjusted averages or ratios for trials which have been combined). If studies have not accounted for the effects of clustering in trial designs, we will adjust standard deviations by the design effect, using intra-class coefficients if given in papers, or using external estimates obtained from similar studies (Ukoumunne 1999).

We will analyse and present separately the results for studies that compare intervention to no intervention (or minimal intervention), those that compare intervention to alternative forms of sexual health education (e.g. face-to-face teaching), and those that compare two or more types of interactive computer-based intervention.

Separate meta-analyses will be conducted for different outcome types (cognitive, behavioural, biological). We will assess heterogeneity using the I^2 statistic (to check whether combining different trials is valid) (Higgins 2003). We will conduct sensitivity analyses in order to investigate possible sources of heterogeneity. Factors to be considered include studies' quality (possible bias in study design) and socio-demographic factors which could act as effect modifiers (for example age, gender, sexuality and socioeconomic status).

Data on unintended adverse outcomes attributable to the intervention(s) will be combined statistically where possible (reporting separately cognitive, behavioural and biological adverse outcomes).

We will present and discuss our findings by type of outcome, in other words cognitive, behavioural and biological and then discuss any sources of heterogeneity in the findings. The findings from economic evaluations of RCTs will be synthesised narratively in order to comment on the economic effects of interactive computer-based interventions in comparison with no intervention.

Consumer participation

'Consumers' for interactive computerised interventions include members of the general population who access the internet seeking sexual health information, website designers, and potentially also parents, teachers, clinicians or policy makers who may wish to recommend suitable websites to others. Members of the consumer advisory group comprise two sexual health website users, one website designer, one teacher who is also a parent of teenagers, and one person who is a sexual health policy-maker.

Consultation with the consumer advisory group has helped to refine the aims of the systematic review to contribute consumers'

perspectives to the 'Background' section of the review in order to ensure that the purpose and priorities of the review matches the priorities of consumers. The consumer advisory group will be consulted again once the search has been conducted and data provisionally analysed, to help with interpretation of the results of quantitative synthesis of studies, and to help shape the discussion and conclusion sections of the review by considering the implications of findings.

POTENTIAL CONFLICT OF INTEREST

There are no known conflicts of interest.

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COVER SHEET

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