Review 1
Contraceptive advice and provision for the prevention of under 18 conceptions and STIs: a rapid review

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GLOSSARY OF TERMS

Adolescents

This term includes people aged 12-18

Young people

This term includes people aged 18-25

MSM

Men who have sex with men is a broad term and includes gay and bisexual men and those who have sex with men but do not identify themselves as either gay or bisexual.

Relative risk (RR)

This is the ratio of risk in two groups. In an intervention study it is the ratio of the risk in the intervention group to the risk in the control group. A risk ratio of one indicates no difference between the groups.

Odds Ratio (OR)

The ratio of the odds of an event in one group to the odds of an event in another group. An odds ratio of one indicates no difference between comparison groups.

95% Confidence Interval

This is a measure of the precision of an estimated value. For example, the confidence interval of an odds ratio tells us the boundaries within which we can be 95% certain the true value for the population falls. Moreover, if we collected 100 samples, we are saying 95 of these would give rise to an odds ratio within the boundaries of the confidence interval. Wide intervals indicate lower precision and narrow intervals greater precision.

Effect Size

This is a measure of the magnitude of the differences between two variables, also known as a treatment effect. For example, an odds ratio or a relative risk represents the size of the difference in two possible outcomes. There are many different methods of calculating effect size dependant on the properties of the data, whether it is continuous or discrete and the manner in which it is distributed.

ABBREVIATIONS

STI	Sexually transmitted infection
MSM	men who have sex with men
HIV	Human Immunodeficiency virus
GUM	Genitourinary medicine
TAU	Treatment as usual
RCT	Randomised Controlled Trial
OR	Odds ratio
RR	Relative risk
MD	Mean difference
CI	Confidence interval
ES	Effect size

EXECUTIVE SUMMARY

Background

Over the last ten years there has been a large increase in sexually transmitted infections (STIs) and the UK continues to have the highest rate of teenage pregnancy in Western Europe. Government policy has set targets to decrease under 18 conceptions and improve sexual health. The National Institute for Health and Clinical Excellence (NICE) has been asked by the Department of Health to develop public health intervention guidance to reduce the rate of sexually transmitted diseases (STIs), including HIV, and under 18 conceptions. The rapid review presented here is intended to assist with this guidance development by assessing the effectiveness of one to one interventions, with special reference to vulnerable and high-risk groups.

Objectives

The objectives of the review were to:

- To review the evidence of effectiveness of one to one interventions for the prevention of STI (including HIV)
- To review the evidence of effectiveness of one to one interventions for the prevention of conceptions in the under 18s

Methods

Selection criteria

We included systematic reviews, randomised controlled trials and controlled before/after studies of one to one interventions to prevent under 18 conceptions and STIs. This included one to one interventions to provide information or education, advice, therapy, promotion of contraception or condom use, and activities to increase self confidence, self-esteem and to develop skills. Our primary outcomes were conceptions and STIs (including HIV). In addition we looked at secondary outcomes such as condom use, knowledge, number of sexual partners and general sexual risk behaviours. We also included qualitative studies that looked at the process of the interventions (e.g. how and why they do/do not work) and/or those focusing specifically on the user perspective of potential barriers and facilitators.

Data sources

We searched the following electronic databases: AMED, CINAHL, Cochrane Database of systematic Reviews, Cochrane Central Register of Controlled Trials, DARE, EMBASE, HMIC, HTA, IBSS, Psychinfo, PubMed and SIGLE from 1990-November 2005; and we handsearched reference lists from included studies.

Data extraction and quality assessment

Two reviewers independently screened electronic records, extracted data and assessed study quality using specially designed forms. Study quality was assessed using the NICE quality assessment checklists and each study was assigned a quality rating of ++ (best quality), + and – (poorest quality).

Data synthesis

Owing to the wide scope of the research question, and the heterogeneity in interventions, participants, follow up, and outcomes, an overall meta-analysis was not considered to be appropriate. If data were available we calculated relative risks (RR) with 95% confidence intervals. Data are presented in tables with an indication of whether the intervention had a positive effect (+), a negative effect (-) or no statistically significant effect (0). In addition, where possible, forest plots, without a pooled summary statistic, are presented to give a visual representation of the data. Results are presented in two sections, one for the prevention of STIs and one for the prevention of under 18 conceptions.

Main results

We found 62 studies that met our inclusion criteria. Of these, 56 were quantitative and six were qualitative studies.

Additional studies included.

Prevention of STIs

In the initial rapid review we included a systematic review of psychosocial interventions to reduce sexual risk behaviours among drug users (Van Empelen 2003). However, this was a relatively poor quality systematic review that provided little data from the original studies. Therefore, in this update we have included the original studies instead of the systematic review. This is an additional four studies (Gibson 1999a, 1999b, Kotranski 1998, O'Neill 1996).

Prevention of under 18 conceptions

This update of the review includes an additional five studies (Nor 2003, Olds 1997, Olds 2002, Olds 2004, Shlay 2003). These were initially excluded as they did not focus solely on under 18's but included older women as well. However, as literature in this area was scarce and as all the studies included at least 40% of under 20's we have included them in this update. Of these additional studies one looked at contraceptive care in an STI clinic (Shlay 2003) and the rest evaluated home visiting programmes for pregnant women or mothers.

The effectiveness of one to one interventions for the reduction of STIs (including HIV)

Forty-four studies evaluated one to one interventions for the prevention of STIs/HIV infection. Of those, 43 were RCTs, and one was an uncontrolled before/after study. Six studies were graded as having a low risk of bias (++), 11 as having a medium risk of bias (+) and the rest as having a high risk of bias (-). Five qualitative studies that explored barriers and facilitators to the effectiveness of one to one interventions were also included; of these three were graded as having a low risk of bias (++) and two as a medium risk of bias (+).

The quantitative studies included a variety of populations, settings, providers and types of intervention. Many of the populations included were groups at particular risk for STIs/HIV infection. For example: adolescents, MSM, black and minority groups, people with a history of a previous STI, drug users, prisoners and people with HIV. All interventions included safer sex counselling and education of some sort. In 27 studies this was based on some form of theoretical model, and 25 reported that they involved skills development. This included areas such as the development of social skills, self-esteem, self-efficacy or negotiation skills for condom use. Of the qualitative studies one was concerned with the prevention of STI, three with the prevention of HIV and one with the promotion of sexual health.

The main results are presented below:

STIs (including HIV)

(Forest Plot Figures 1, 2 & 3. Effect of one to one interventions on STIs)

Evidence Statement 1.1

In summary the evidence on the effectiveness of one to one interventions for the prevention of STIs is mixed but on balance marginally supports the interventions. There is evidence from Project RESPECT a large (++) US study (Kamb 1998) that both a two session and a four session one to one counselling intervention can reduce STIs in the long and very long term in heterosexuals, and from one (+) study that STIs in men can be reduced in the long term after one 90 minute session (Kalichman). However, the effect appears to decrease over time, with one study finding a reduction in effect after six months (Kamb 1998).

Evidence Statement 1.2

In addition EXPLORE a large (++) US study of ten session one to one counselling for MSM found a 15.7% reduction in HIV infection but this was not statistically significant (EXPLORE 2004). The other studies found no statistically significant effect on STIs but may have been underpowered for this outcome.

Evidence Statement 1.3

Interventions with adolescents appeared to be particularly effective. A subgroup analysis of Project RESPECT (Bolu 2004) found a significant reduction in sexually transmitted infections with both the four and two session interventions versus a didactic control. Although this was the only study to show a statistically significant difference the general trend in this group of studies was towards a reduction in STIs.

Condom use

(*Forest Plot Figures 4&5 Effect of one to one interventions on consistent condom use.)*

Evidence Statement 1.4

Twenty-five studies reported condom use, of which only eight showed a statistically significant increase in condom use in the intervention group compared to the control. However, overall there is weak evidence (that is it is mixed or conflicting but on balance marginally supports) that one to one STI/HIV prevention interventions can increase short and long-term condom use compared to control. Project RESPECT, a large good quality (++) US study found an increase in condom use in both the four and two session counselling intervention groups compared to a didactic control

(Kamb 1998). However, several studies found the effect of an intervention appears to decrease, or disappear over time. Greater uniformity is needed in the way in which condom use is measured in studies.

Unprotected sex

(*Forest Plot Figures 6&7 Effect of one to one interventions on unprotected sex.)*

Evidence Statement 1.5

Fifteen studies reported unprotected sex. Only six studies found a statistically significant difference between intervention and control and in general the evidence is conflicting on whether or not one to one STI/HIV interventions reduce unprotected sex. However, EXPLORE a large high quality (++) US RCT found that there was a 13.9% reduction in unprotected sex at very long term follow up after a 10 session + boosters HIV prevention counselling intervention (EXPLORE 2004). At present there seems to be support for multi-session interventions but conflicting evidence on shorter interventions.

Number of sexual partners/initiation of intercourse

Evidence Statement 1.6

Ten studies reported number of partners, initiation of intercourse, or abstinence as an outcome. No high quality studies reported this outcome; three were graded as (+) and seven as (-). Only two studies, one (+) and one (-) found a statistically significant effect (Downs 2004, Metzler 2000) and in one the effect was not maintained after 6 months (Downs 2004). In summary there is weak evidence that one-to-one interventions for the prevention of STIs/HIV are ineffective in reducing the number of sexual partners or in promoting abstinence. However, it should be noted that the interventions included in this review appeared to be designed to promote safer sexual behaviour rather than abstinence.

Risk taking behaviour/perception of risk

Evidence Statement 1.7

Seven studies measured overall risk taking behaviour (e.g. sexual risk taking scores). One (+) study set in a UK STI clinic found a significant effect on risk perception (James 1998). The remaining six (-) RCTs did not find any significant effect on risk taking behaviour or risk perception (Baker 1994, O'Neill 1996, Deas 2000, Ashworth 1994, Proude 2004, Gibson 1999, O'Neill 1996). However, three of the studies involved HIV prevention for drug users where much of the focus was on safer

injecting and drug use behaviour rather than safer sexual behaviour (Baker 1994, Gibson 1999, O'Neil 1996). In summary, there is little evidence that one to one interventions can reduce risk taking behaviour or perception of risk but the quality of studies is poor.

How does the content of the intervention (what?) influence effectiveness?
(*Forest Plot Figures 9 & 10 Studies with face to face counselling effect on STIs.)*

Evidence Statement 1.8
Nineteen studies compared a theory based/ skills training intervention with a more didactic control. Of those ten measured STIs (Boekeloo 1999, Boyer 1997, El-Bassel 2003, Kalichman 2005, Kamb 1998, Maher 2003, Metzler 2000, Orr 1996, Scholes 2003, Shrier 2001). In general the effects on STIs were mixed. However, Project RESPECT (Kamb 1998) a large (++) US study found that two and four session theory based interventions are more likely to be effective than a didactic control. These interventions were, however, both longer than the control. Further large scale evaluations of theory based interventions are needed to establish which components of interventions are the most effective.

Qualitative studies supported the idea of skills based interventions and found participants wanted practical and psychological strategies to increase self-efficacy for contraception and condom and safe sex negotiation (Choi 2004, Seal 2005).

Does the way that the intervention is carried out e.g. Type/mode of communication, influence effectiveness?
Evidence Statement 1.9
There was a range of types of one to one communication used. The majority of studies evaluated face to face communication between a health care professional, trained counsellor, or health educator and an individual client. Other types of communication evaluated in a few studies included computer assisted interventions, leaflets, personal diaries, and video. Three poor quality studies (-) compared a face to face intervention with a video intervention and found no statistically significant differences (Ashworth 1994, DeLamater 2000, Robert 1990), and one (+) study found no difference between face to face and telephone counselling (Rotheram-Borus 2004). Therefore, there is insufficient evidence to say whether or not face-to-face delivery is superior to other methods of delivery such as telephone, computer

assisted or video based interventions. However, the majority of effective interventions involved face-to-face communication.

Does the effectiveness depend on the job title/position or other factors such as age, gender, sexuality, ethnicity, of the deliverer (leader)? What are the significant features of an effective deliverer (leader)?

Evidence Statement 1.10

Evidence from Project RESPECT a large (++) US study, which found a decrease in STIs and an increase in safe sexual behaviour, suggests that clinic staff do not need extensive experience of counselling to deliver a one to one counselling intervention, but that enthusiasm and motivation are key (Kamb 1998). In a large HIV prevention trial, which reduced HIV and unsafe sex, counsellors had 40 hours of training. Both of these studies highlight the importance of training and quality control (Kamb 1998, EXPLORE 2004). Although qualitative studies reported the importance of peers we found only one evaluation of a one to one peer led intervention. Further research is needed to evaluate different types of leaders for one to one interventions, in particular evaluating the effect of peer-led programmes.

Setting (where?). Does the site/setting of delivery of the intervention influence effectiveness?

Evidence Statement 1.11

The majority of interventions were delivered in a clinic setting of some sort, for example STI/GUM clinics, family planning clinics, primary care clinics and HIV clinics. None of the studies compared one setting with another so there is insufficient evidence to say whether the site/setting of delivery of one to one interventions influences effectiveness. However, the authors of Project RESPECT, a (++) trial which showed a counselling intervention to be effective in reducing STIs and increasing condom use, suggest that STI clinics may be appropriate places to deliver interventions as it is possible those seeking treatment for a STI may be particularly amenable to behaviour change (Kamb 1998).

Does the intensity (or length) of the intervention influence effectiveness/duration of effect?

Evidence Statement 1.12

Evidence is mixed on whether the intensity or length of one to one interventions for the prevention of STIs influences effectiveness. A (++) 10 session HIV prevention intervention for MSM found a significant reduction in unprotected sex and a reduction

in HIV (EXPLORE 2004). However, longer interventions may not necessarily be better than shorter ones. A (++) study (Kamb 1998) found that both a brief two session and an enhanced four session intervention were effective in reducing STIs and increasing condom use, although the four session intervention was marginally more effective than the two session intervention. Two studies evaluated the addition of booster sessions to an intervention. Both, Project RESPECT 2 a (++) study (Metcalf 2005) and a (-) study (Patterson 2003), found no evidence that a counselling intervention with additional booster sessions was more effective, in reducing STIs, than a counselling intervention without booster sessions.

Does the effectiveness vary with age, gender, sexuality, socio-economic status, ethnicity?

Evidence Statement 1.13

Age

A subgroup analysis of Project RESPECT (Bolu 2004) found a significant reduction in sexually transmitted infections in adolescents with both the four and two session interventions versus a didactic control. The intervention was more effective with adolescents than with other age groups. Although this was the only study with adolescents to show a statistically significant difference the general trend in this group of studies was towards a reduction in STIs.

Ethnicity

Evidence Statement 1.14

In 15 studies all or the majority of participants were black, and in the majority of the rest the populations were multiethnic. One important exception is a (++) HIV prevention study which found a 10 session counselling intervention reduced HIV and unsafe sex in MSM (EXPLORE 2004). The majority of participants in this study were white and they reported difficulty in recruiting and retaining black and Hispanic participants. In subgroup analyses of Project RESPECT (Bolu 2004) they found that a four session intervention was more effective than a two session intervention for white participants but that conversly the two session intervention was more effective than the four session intervention for black participants.

Sexuality

Evidence Statement 1.15

Project RESPECT a large (++) US study of a STI prevention intervention included heterosexuals only. They found significant reductions in STIs and an increase in

condom use after a four and two session counselling intervention (Kamb 1998). EXPLORE a large high quality (++) US RCT with MSM found a non significant reduction in HIV and a 13.9% reduction in unprotected sex at very long term follow up after a 10 session + boosters HIV prevention counselling intervention (EXPLORE 2004).

THE EFFECTIVENESS OF ONE TO ONE INTERVENTIONS FOR PREVENTING UNDER 18 CONCEPTIONS?

The effectiveness of one to one interventions for the prevention of under 18 conceptions

(Forest Plot Figure 11. Effect of one to one interventions on pregnancies (includes repeat pregnancies)

We found only twelve studies that evaluated the effectiveness of one to one interventions to prevent conceptions in the under 18s. On the quality assessment score three out of eleven RCTs scored (++), three (+), and five (-), and a controlled study scored (-). In addition, we included three qualitative studies that looked at barriers and facilitators to the prevention of under 18 conceptions. Of these two were graded as (++), and one was graded as (+).

Two studies evaluated the advanced provision of emergency contraception, six looked at health care programmes for pregnant women/ mothers, two looked at contraceptive care and advice in clinics, and two looked at sexual/reproductive health education.

Of the qualitative studies two included information on the prevention of pregnancy in teenagers and one looked at sexual health promotion.

Pregnancy

Eleven studies reported data on pregnancy or repeat pregnancies.

Advanced Emergency contraception

Evidence Statement 1.16

Of the two (++) studies of advanced provision of emergency contraception, one (Gold 2004) found a trend towards a reduction in pregnancies but this was not statistically significant, and the other found a non significant reduction in the pharmacy access group but not advanced provision group (Harper 2005).

Support for pregnant women/mothers

(Forest Plot Figure 12. Effect of one to one home visiting or support for pregnant women/mothers on repeat pregnancies).

Evidence Statement 1.17

Six studies evaluated interventions to support pregnant women or mothers. Although only two of the studies focused solely on adolescents (O'Sullivan 1992, Quinlivan 2003) all included at least 40% of adolescents and focused on disadvantaged, low-income women. There is good evidence that multi-session support and home visiting for disadvantaged low-income pregnant women or mothers can prevent repeat pregnancies with two (+) (Olds 2002, Olds 2004) and one (-) (O'Sullivan 1992) studies showing a significant reduction in repeat pregnancies in the intervention group compared to control. In addition one (-) study (Olds 1997) found a reduction in repeat pregnancies in poor unmarried women, although not in the sample as a whole.

Clinic based contraception care

(Forest Plot Figure 13: Effect of one to one interventions on contraception use).

Evidence Statement 1.18

One (-)RCT and one (2+) non randomised controlled study evaluated contraception advice and support in a clinic based setting (Shlay 2003, Winter 1991). One (Winter 1991) found a significant reduction in pregnancies and the other (Shlay 2003) showed a trend towards a reduction in the intervention group compared to control but this was not significant.

In summary although only four studies showed a statistically significant reduction in pregnancy (O'Sullivan 1992, Olds 2002, Olds 2004, Winter 1991) the general trend was towards a reduction. Therefore, there appears to be evidence that one to one interventions with adolescents can reduce pregnancies. Multi-session nurse home visiting appears particularly effective, especially with low-income disadvantaged women (Olds 1997, Olds 2002, Olds 2004). However, more research, is needed in this area with a focus on the under 18s and studies powered to detect a change in pregnancies.

Contraception use

Evidence Statement 1.19

Seven studies reported contraception use. This was measured in various different ways, including oral contraception, emergency contraception and condom use. Four studies showed a statistically significant effect on contraception use. Two increased oral contraceptive use. These were a (++) RCT (Quinlivan 2003) and a (+) RCT (Danielson 1990) that found one to one interventions with teenagers can improve contraception use in the long term. Of the two (++) studies of advanced provision of emergency contraception one found an increase in the use of EC (Harper 2005) and one an increase in condom use (Gold 2004). In the other studies the general trend was towards an increase in contraception use although one (-) study found the effect on contraception use was no longer significant at 12 months (Winter 1991). Therefore, there is some evidence that one to one interventions with under 18s can increase contraception use. However, further research in this area is needed.

How does the content of the intervention influence effectiveness?

Evidence Statement 1.20

There are few studies evaluating interventions to prevent under 18 conceptions and in general there is insufficient evidence to say whether or not the content of one to one interventions influences effectiveness. However, there is good evidence that multi-session support and home visiting for disadvantaged low-income pregnant women or mothers can prevent repeat pregnancies with two (+) (Olds 2002, Olds 2004) and two (-) (Olds 1997, O'Sullivan 1992) studies showing a significant reduction in repeat pregnancies in the intervention group compared to control.

Does the way the intervention is carried out e.g type/mode of communication, influence effectiveness?

Evidence Statement 1.21

There is insufficient evidence to say whether or not the type/mode of communication of one to one interventions to prevent under 18 conceptions influence effectiveness.

Does the effectiveness depend on the job title/position or other factors such as age, gender, sexuality, ethnicity, of the deliverer (leader)? What are the significant features of an effective deliverer (leader)?

Evidence Statement 1.22

In general there is insufficient evidence to say whether or not the type of leader influences the effectiveness of one to one interventions for preventing under 18 conceptions. However, one (+) US study of home visiting for mothers (Olds 2002) found that nurses were more effective than paraprofessionals in reducing repeat pregnancies.

Setting (where?). Does the site/setting of delivery of the intervention influence effectiveness?

Evidence Statement 1.23

Most interventions were delivered in clinics or via home visiting. There is good evidence that multi-session support and home visiting for disadvantaged low-income pregnant women or mothers can prevent repeat pregnancies with two (+) (Olds 2002, Olds 2004) and one (-) (O'Sullivan 1992) studies showing a significant reduction in repeat pregnancies in the intervention group compared to control, and one (++) study an increase in reliable contraception use (Quinlivan 2003). In addition one (-) study (Olds 1997) found a reduction in repeat pregnancies in poor unmarried women, although not in the sample as a whole.

Does the intensity (or length) of the intervention influence effectiveness/duration of effect?

Evidence Statement 1.24

There is insufficient evidence that the length of clinic based one to one interventions, for the prevention of under 18 conceptions, influences the effectiveness/duration of effect. There is good evidence from one (++) study (Quinlivan 2003) two (+) (Olds 2002, Olds 2004) and two (-) studies (Olds 1997, O'Sullivan 1992) that multi-session one to one interventions may increase effective contraception use and prevent repeat pregnancies.

Does the effectiveness vary with age, gender, sexuality, socio-economic status, ethnicity?

Gender

Evidence Statement 1.25

In summary, there is insufficient evidence to say whether or not gender influences the effectiveness of one to one interventions to prevent under 18 conceptions. Most studies included in the review were aimed at females and there would appear to be a need for further research that evaluates interventions that include, or are specifically targeted at, males.

Socio-economic status

Evidence Statement 1.26

There is good evidence from one (++) study (Quinlivan 2003) two (+) (Olds 2002, Olds 2004) and two (-) studies (Olds 1997, O'Sullivan 1992) that multi-session home visiting or support can be effective in increasing effective contraception use and preventing pregnancies in low-income disadvantaged women.

Conclusions

There is evidence that one to one interventions can reduce STIs and may increase condom use and prevent unsafe sexual behaviours. However, effectiveness decreases over time. A brief US STI prevention intervention, Project RESPECT, delivered in the context of routine health services with existing staff has been shown to be effective (Kamb 1998) in reducing STIs and increasing condom use. Components of Project RESPECT included:

- Client centred intervention tailored to individual's personal risk
- Behavioural goal setting and risk reduction strategies
- Standardised training and structured protocols for clinic staff
- Quality control through observation and feedback

For MSM a multi-session intervention was shown to be more effective than the brief Project RESPECT model (EXPLORE 2004). However, this involved over 10 sessions.

One to one interventions can also improve contraception use and prevent pregnancies in the under 18's. Multi-session interventions involving home visiting appear to be particularly effective in preventing repeat pregnancies in high-risk groups.

Limitations of the review

- Lack of research, in particular there was little UK based research

- In many US studies treatment as usual or control groups received interventions which are more structured and detailed than usual care currently provided in GUM clinics in the UK which makes generalisability to the UK difficult
- Lack of objective primary outcome measures such as incidence of STIs/HIV and conceptions.
- A number of poor quality and underpowered studies

Barriers to implementation

- The provision of resources for multi-session interventions
- Recruitment and retention of participants, particularly for multi-session interventions
- Difficulty generalising current research to a UK setting

Recommendations for future research

There were a number of gaps in the evidence base identified by this review, in particular for the prevention of under 18 conceptions. Overall the effectiveness of many STI and under 18 conception prevention programmes remains in doubt. For this reason further high-quality large scale research is needed with evaluation an integral part of programmes. Areas for future research identified by the review include the following:

Prevention of STIs (including HIV)

- Evaluations aimed specifically at vulnerable groups – e.g young people in or leaving care, young people from some ethnic backgrounds, sex workers, refugees and asylum seekers
- Evaluations of interventions in the UK as most of the included studies were from the USA
- Replication, and evaluation, in the UK of successful US interventions (e.g. Project RESPECT) to evaluate applicability in the UK setting
- Studies large enough to detect a reduction in STIs/HIV infections
- Evaluations of peer-led interventions

Prevention of under 18 conceptions

- Evaluations aimed specifically at vulnerable groups – e.g. young people in or leaving care, young people from some ethnic backgrounds, refugees and asylum seekers
- Evaluations of interventions in the UK as most of the included studies were from the USA
- Studies large enough to detect a reduction in conceptions
- The development and evaluation of one to one interventions in different settings (e.g school based, clinic based)

1. BACKGROUND

Over the last 10 years there have been large increases in many STIs that have contributed to the overall increase in all new episodes. The UK also continues to have the highest rate of teenage pregnancy in Western Europe (United Nations Children's Fund 2001).

The national target 'to reduce the rate of under eighteen conceptions by 50% by 2010' is a joint public service agreement (PSA) target for the Department of Health (DH) and the Department for Education and Skills (DfES) as part of a broader government strategy for improving sexual health. From 2005/6 primary care trusts (PCTs) are required to provide details of how they will meet this target in their local delivery plans as specified by the DH in *National Standards, local action: health and social care standards and planning framework 2005/6–2007/8* (Department of Health 2004a).

Halving the under 18 conception rate is also a national PSA for local government and a cross-cutting indicator in the local government best value indicator set[1]. The indicator is set out in *Best Value Performance Indicators 2005/6: Guidance Document* (Office of the Deputy Prime Minister 2005). In addition, the reduction of under 18 conceptions and the reduction of STIs among under 16s and 16–19 year olds are targets and indicators in the *Every Child Matters: Change for Children* framework (Department for Education and Skills 2004).

Governement policy supports the delivery of a range of measures for improving sexual health as set out in the public health white paper *Choosing Health* (Department of Health 2004b) including the commitment to implement the chlamydia screening programme throughout England by March 2007. In addition the *National Service Framework for Children, Young People and Maternity Services* (Department of Health 2004c), sets standards to reduce the risk of both teenage pregnancy and acquiring a sexually transmitted infection among young people. These measures

[1]Best value indicators are part of local government's performance management framework. Their purpose is to contribute to and facilitate the efficiency and effectiveness of services and to assist local and central government to monitor, analyse and compare the achievements of local authorities.

also support the government's national teenage pregnancy strategy (Social Exclusion Unit 1999) and the national strategy for sexual health and HIV (Department of Health 2001).

The National Institute for Health and Clinical Excellence ('NICE' or 'the Institute') was asked by the Department of Health to develop public health intervention guidance on reducing sexually transmitted infections (STIs) including HIV and to reduce conceptions in the under 18 age group. The guidance is intended to provide recommendations for good practice that are based on the best available evidence of effectiveness and support measures to achieve the government targets for improving sexual health and reducing the rate of under 18 conceptions.

The rapid review presented in this report is intended to assist with this guidance development.

The scope for the guidance is: how can professionals – and others involved in the delivery of one-to-one direct sexual health interventions – reduce the transmission of STIs, including HIV, and, reduce the rate of conceptions in the under 18s, especially among vulnerable and high risk groups.

In addition to identifying evidence of the effectiveness and cost effectiveness of interventions, the guidance will consider evidence (where found) of the impact on inequalities in health, particularly with reference to social class, ethnicity, sexual orientation and educational attainment.

Previous research has demonstrated that sexual health interventions are more likely to be effective if they:

- use theoretical models
- are tailored and targeted to particular communities
- provide information that is basic, accurate and unambiguous
- use behavioural, communication and social skills training
- make use of needs assessment and formative research

(Ellis & Grey 2004).

Recent syntheses of the effectiveness literature (Swann et al 2004; Ellis et al 2003; Ellis and Grey 2004) have shown that these characteristics are not always present in locally delivered one-to-one interventions. It is for this reason that this scope has prioritised these types of interventions as a focus for the first piece of guidance work in sexual health for the Centre for Public Health Excellence (CPHE).

2. AIMS & OBJECTIVES

The main aims of the rapid review, which were identified by the scope statement, are:

- To review the evidence of effectiveness of one to one interventions for the prevention of STIs (including HIV)
- To review the evidence of effectiveness of one to one interventions for the prevention of conceptions in the under 18's

In addition the scope identified the following research questions, which the review aims to answer:

- What is the aim/objective of the intervention? What is it trying to change?
- What outcome measures are used to assess effectiveness? How valid and appropriate are they?
- Content of the intervention (what?). Does it influence effectiveness?
- Delivery/mode (how?). Does the way it is carried out (the type/mode of communication, for example) influence effectiveness?
- Intervenor (who?). Does the effectiveness depend on the job title/position or other factors such as age, gender, sexuality, ethnicity, of the deliverer (leader)? What are the significant features of an effective deliverer (leader)?
- Setting (where?). Does the site/setting of delivery influence effectiveness?
- Intensity/duration (how much, how long, how often?). Does the intensity (or length) influence effectiveness/duration of effect?
- Target (with who?). Does the effectiveness vary with age, gender, sexuality, socio-economic status, ethnicity?
- Implementation. What are the barriers to implementing effective interventions?

3. METHODS

The rapid review was conducted using methods set out by the NICE Public Health Guidance Methods Manual. This includes guidance about data extraction and quality assessment.

3.1 Inclusion criteria

The inclusion criteria below are based upon those specified in the draft scope.

Types of populations

Based on the priorities/vulnerable groups outlined in the scope, the populations considered by this rapid review were as follows:

Aim 1 - Prevention of STIs

This included the whole population but with particular reference to the at risk groups identified in the scope (e.g. MSM, some black and minority ethnic groups, young people, particularly those affected by poverty and social exclusion and have low educational achievement, and those in and leaving care, plus sex workers and refugee and asylum seekers).

Men who have sex with men (MSM) is a broad term and includes gay and bisexual men and those who have sex with men but do not identify themselves as either gay or bisexual.

Aim 2 - Prevention of under 18 conceptions

This included young people, of both sexes, under the age of 18 (or where the majority of participants were under 18). Particular reference was to be given to those groups at greatest risk of teenage pregnancy (e.g. black and minority ethnic groups, those affected by poverty and social exclusion and have low educational achievement, and those in and leaving care).

Types of interventions

The rapid review considered interventions that provided:

- information provision
- advice
- condom provision
- counselling
- cognitive behavioural therapy and
- activities that increase self confidence, self-esteem and skills development

This could include:

- advice on – and provision of – the range of contraceptive methods including emergency hormonal and non-hormonal contraception, and which address patients' concerns about use and improves understanding and confidence in the use of different methods
- advice on delaying first intercourse or the reduction of number of partners if appropriate
- advice about the use of condoms plus other forms of contraception for the prevention of conception and STIs including HIV
- advice and provision about the use of condoms and other methods of prevention of STIs and HIV for men who have sex with men
- taking key health promotion opportunities, such as at pregnancy testing, pregnancy counselling post abortion and antenatal and post-natal checks, to provide advice about prevention of conception and STIs including HIV, and the provision of a range of contraception methods
- taking key health promotion opportunities, such as at the time of sexual health testing, screening or when giving treatment for STIs and HIV, to provide advice about prevention or re-infection of STIs and prevention of conception where appropriate
- ongoing one-to-one prevention activities for those who are HIV positive
- discussion and offer of post-exposure prophylaxis (PEP) where appropriate
- condom distribution which includes health promotion (for example, the C-Card condom distribution scheme which offers condoms and sexual health advice to young people).

Studies in both NHS and non-NHS settings were considered (e.g. health, education, social services, voluntary, community and independent sectors). As the time line for the review was tight, studies were excluded if the intervention or setting was not relevant to UK.

The review compared one type of one to one intervention against another, and interventions against a control or usual care. We also included studies that compared the intensity or duration of an intervention (e.g one session vs. repeat exposure of the same intervention).

Interventions excluded were:

- Group based interventions including sex and relationship education
- Interventions that evaluated the efficacy of individual contraceptive methods
- Interventions aimed at parents and carers and their involvement in sex and relationship education
- Interventions to address the wider determinants of poor sexual health
- Screening for STIs or HIV (Chlamydia screening is covered by a separate review)

Types of studies

As the main aim of the review was to evaluate the effectiveness of interventions, and because the scope was large, the main focus was on randomised controlled trials. However, we also included some controlled trials or controlled before/after studies, if other study types were not available. Quantitative studies were considered in relation to the hierarchy of evidence set out in table 4.1 of the NICE Public Health Guidance Manual. These are adapted from the Scottish Intercollegiate Guidelines Network (2001). See Table 1 below.

Table 1. Levels of Evidence

Level of evidence	Type of evidence
1^{++}	High-quality meta-analyses, systematic reviews of RCTs, or RCTs (including cluster RCTs) with a very low risk of bias
1^{+}	Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs (including cluster RCTs) with a low risk of bias
1^{-}	Meta-analyses, systematic reviews of RCTs, or RCTs (including cluster RCTs) with a high risk of bias*
2^{++}	High-quality systematic reviews of, or individual, non-randomised controlled trials, case–control studies, cohort studies, controlled before-and-after (CBA), interrupted time series (ITS), correlation studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal
2^{+}	Well-conducted non-randomised controlled trials, case–control studies, cohort studies, controlled before-and-after (CBA), interrupted time series (ITS), correlation studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal
2^{-}	Non-randomised controlled trials, case–control studies, cohort studies, controlled before-and-after (CBA), interrupted time series (ITS), correlation studies with a high risk of confounding bias, or chance and a significant risk that the relationship is not causal*
3	Non-analytic studies (for example, case reports, case series)
4	Expert opinion, formal consensus
*Studies with a level of evidence '–' should not be used as a basis for making a recommendation (see section 7.4)	

In order to explore issues around why and how interventions work, relevant qualitative studies and process evaluations were also included. However, qualitative research was only included if it clearly addressed the process of interventions (e.g. how and why they do/do not work) or focused specifically on the user perspective of barriers and facilitators.

Types of outcomes

The outcomes included in the review were categorised as primary and secondary outcomes and were as follows:

Primary outcomes

- conceptions
- Sexually acquired infection
- HIV

Secondary outcomes

- Contraception use
- Condom use
- Knowledge of contraception methods
- Knowledge of risk of STIs and conception
- Intention to use condoms
- Delay of initiation of sexual intercourse
- Reduction in number of partners
- Participant's experiences

3.2 Search Strategy

The electronic search strategy was developed by the Information Scientist, Reinhard Wentz, with input from Frances Bunn and the NICE project team. We searched for published English language literature from 1990 onwards. Search results were downloaded into Endote and, where possible, duplicates deleted. Full details of the search terms used and databases searched can be found in appendix 1. One of the challenges of this review was searching for and identifying relevant studies. The review scope covers a very large area and as it was difficult to create a search strategy that easily identified one to one interventions while our search strategy was highly sensitive it was not highly specific. In addition, we handsearched reference lists of review articles and studies included in the review.

3.3 Study screening

Our search strategy generated over 15,000 potential citations. Two reviewers independently screened titles and abstracts against the inclusion criteria. Hard copies of potentially relevant papers were obtained and screened double blind against the inclusion criteria. As it was often difficult to judge from abstracts, whether the intervention was group based or one to one we had to obtain the full text of 329 papers. Two reviewers then screened hard copies of papers independently and any disagreements were resolved by discussion.

3.4 Data extraction and critical appraisal

For studies that met the inclusion criteria data was extracted onto a specially designed form (see appendix 2).

Data extracted included

- Type of intervention (including aim, content, mode of delivery, provider (including position, age, gender & race, populations, setting, intensity and duration)
- Type of participants (including age, sex, race)
- Type of outcomes and outcome data
- Type of study design.

Studies were classified by study design using the NICE algorithm (Figure 7.1 Guideline Development Methods) and quality assessed in accordance with NICE Methodology Checklists (appendices B-H Guideline Development Methods). Additional criteria were developed to guide the overall grading of the studies. See Table 2 for the criteria for assessing randomised controlled trials.

Table 2: Quality grading criteria

	NICE quality categories	**Additional quality criteria**
++	All or most of the criteria have been fulfilled. Where they have not been fulfilled the conclusions of the study or review are thought very unlikely to alter.	At least 8 out of 10 questions are well covered or adequately addressed (and 1.2, 1.3 and 1.5 must be well covered or adequately addressed). Follow up must be 60% or above
+	Some of the criteria have been fulfilled. Those criteria that have not been fulfilled or not adequately described are thought unlikely to alter the conclusions.	At least 5 of the criteria have been well covered or adequately addressed (and 1.2, 1.3 and 1.5 must be well covered or adequately addressed). Follow up must be 50% or above
–	Few or no criteria fulfilled. The conclusions of the study are thought likely or very likely to alter.	Two or more questions are poorly addressed, not addressed or not reported. Studies were also classified according to the Levels of evidence in the NICE handbook which are based on the Scottish Intercollegiate Guidelines Network (2001).

Applicability was graded according to the NICE criteria (1-4). These were;
are the results likely to be:
1.Applicable across a broad range of populations and settings
2.Applicable across a broad range of populations and settings assuming they are appropriately adapted
3.Applicable only to populations or settings included in the studies, and broader applicability is uncertain
4.Applicable only to settings or populations included in the studies

Decisions about which grade to assign studies were made taking into account setting, population, study quality and whether there was an adequate description of the intervention which would make replication possible. However, it should be acknowledged that there was still a certain amount of subjectivity about the applicability grading.

Two reviewers independently extracted data and assessed study quality.

3.5 Analysis and synthesis

Owing to the wide scope of the research question, and the heterogeneity in interventions, participants, follow up, and outcomes, an overall meta-analysis was not considered to be appropriate. Instead information is presented about the strength/grade of the evidence and the applicability to the research question/target population in both a narrative and tabular format. Where possible, that is where data were available in the paper, or direct from the author, dichotomous outcomes are presented as relative risks (RR) with 95% confidence intervals. For infection related outcomes and sexual risk behaviours a RR less than one or a negative mean difference (MD) indicates a lower rate of infections or risk taking in the intervention group compared to the control. However, for protective behaviours (such as condom or contraception use) a RR greater than one or a positive MD indicates greater protective behaviour in the intervention compared to the control.

Although a meta-analysis was not considered appropriate, where possible, forest plots, without a pooled summary statistic, are presented to give a visual representation of the data. Forest plots were prepared using the Cochrane software Review Manager (RevMan). Several studies included more than one intervention arm. For outcomes involving these studies two forest plots are presented; one forest plot that shows all arms of the trial, and one forest plot displaying only the most intensive arm of the trial. Data presented in the tables and text are for all follow up time points but for forest plots only the final follow up data available are presented. Forest plots show studies presented by quality with best quality studies (++) at the top of the plots and poorest quality studies (-) at the bottom. Labels at the bottom of the forest plot indicate which way favours treatment and which control.

Not all papers provided the necessary data to include in forest plots, therefore, all data is presented in summary tables in the text and in more detail in the results column of the evidence tables in the appendices. Data in the tables is presented with an indication of whether the intervention had a positive effect (+), a negative effect (-) or no statistically significant effect (0). As a non-statistically significant effect is not necessarily an indication of no effect we have, where possible and when we were unable to calculate relative risks or mean differences, reported effect sizes. For the difference between two means Cohen's d was calculated (.2 = small, .5 = medium, .8 = large); or between several means f (.1 = small, .25 = medium, .4 = large) (Cohen 1988). For difference between two proportions h was calculated (.2 = small, .5 = medium, .8 = large). Additionally, where a chi-square statistic was reported Pearson's C was calculated (.1 = small, .3 = medium, .5 = large). If no data were available to enable us to calculate the above statistics we used the data presented in the paper and reported p values if available (with a p of < .05 taken to be statistically significant). In some instances where we have presented unadjusted relative risks calculated from the raw data we also present adjusted effect sizes reported by the authors.

3.6 Presentation of data

The results (section 6) are presented by main research question: the prevention of STI/HIV (section 6.1) and prevention of under 18 conceptions (section 6.3) and then by outcome. For each outcome a brief summary statement is followed by more detailed information by population group (e.g adolescents, MSM). In addition, data is presented under the other research questions specified by the scope which explore the effect of factors such as intensity and content of the intervention (section 6.2 and 6.4).

Detailed information about individual studies, including data on aim, methods, participants, intervention and results are presented in the evidence tables (appendix 5). Tables in appendix 5 are organised as: prevention of STIs/HIV by population (table 17), prevention of STI/HIV theory based interventions vs. didactic control (table 18), prevention of STI/HIV intensity and duration of STI/HIV prevention interventions (table 19), and prevention of under 18 conceptions (table 20). Information about the qualitative studies is presented in table 21.

4. DESCRIPTION OF STUDIES

We screened 15,326 citations. Of those 325 were deemed to be potentially relevant and we attempted to get the full text. However, we were unable to get full text of 16 papers as the British Library could not obtain them or the reference details were incorrect. We found a further 20 potential records from screening reference lists and these were also obtained. In total we screened the full text of 329 records. Of those 56 quantitative studies met our inclusion criteria. In addition we included six qualitative studies. For a flow chart providing an overview of the selection process see figure 13, appendix three, and for a full list of included studies see appendix four.

The majority of papers excluded were group-based interventions. Other reasons for exclusion were that they included a mixture of one to one and group based components or, as in the case of number of studies involving peer education, it was not clear if the intervention had been delivered one to one or in a group situation (e.g. peer education in a bar). Most systematic reviews were excluded because they did not focus specifically on one to one interventions, or report data for these studies separately. Details of included studies can be found in the Evidence Tables in appendix five.

Study type

We found 54 RCTs, one controlled before after study and one uncontrolled before after study. The uncontrolled study was included because it was the only study we found that evaluated an intervention to promote the female condom. We also included six studies that reported qualitative findings. Some studies were applicable to both research questions and were, therefore, included in both sections. For details of study types by key review question see Table 3.

Table 3: Number of studies included according to design and key questions

Key question	Systematic reviews N=0	Randomised controlled trials N = 54	Non randomised controlled trials N=1	Uncontrolled before after studies N=1	Qualitative studies N= 6
Effectiveness of one to one interventions for the prevention of HIV/STIs	0	43	0	1	Na
Barriers/facilitators to the effectiveness of one to one interventions to prevent HIV/STI	0	0	0	0	5
Effectiveness of one to one interventions for the prevention of under 18 conceptions	0	11	1	0	Na
Barriers/facilitators to the effectiveness of interventions to prevent under 18 conceptions	0	0	0	0	3

5. STUDY QUALITY

5.1 Prevention of STIs (including HIV)

5.1.1 Quantitative studies

Forty-four studies evaluated interventions for preventing HIV or STIs. The studies included a variety of populations, settings, providers and types of intervention. Many of the populations included were groups at particular risk for STIs/HIV infection. For example: adolescents, MSM, black and minority groups, people with a history of a previous STI, drug users, prisoners and people with HIV. For a summary of included studies (including setting, population and content of intervention) see table 4, and for a summary of study quality see table 5.

Aim/Objectives of the interventions

Twelve studies focused on preventing HIV or STIs or a combination of the two in adolescents (Boekeloo 1999, Bolu 2004, Danielson 1990, Deas 2000, DeLamater 2000, Di Noia 2004, Downs 2004, Mansfield 1993, Metzler 2000, Orr 1996, Shrier 2001, Winter 1993). One of those (Bolu 2004) was a subgroup analysis of a larger trial carried out in the general population (Kamb 1998).

Fifteen studies focused on preventing HIV or STIs in the general population where the majority of participants were heterosexual. Five included women only (Artz 2000, Ashworth 1994, Belcher 1998, Oakeshott 2000, Scholes 2003), one men only (Maher 2003) and the rest a mixture of men and women (Boyer 1997, El-Bassel 2003, Evans 2000, James 1998, Kalichman 2005, Kamb 1998, Metcalf 2005, Oliva 2005, Proude 2004). Although we have classified these studies as 'general population' in many instances the participants were high risk groups such as those with a previous STI or other risk factors.

Six studies evaluated interventions for the prevention of HIV in MSM (Dilley 2002, The Explore Study 2004, Gold 1995, Gold 1998, Picciano 2001, Robert 1990).

Eight RCTs focused on the prevention of HIV in drug users (Baker 1994, Deas 2000, Gibson 1999a, Gibson 1999b, Kotranski 1998, Kwiatkowski 1998, O'Neill 1996, Sterk 2003). Two studies (Gibson 1999a, Gibson 1999b) are reported in the same paper (Gibson 1999). Two RCTs evaluated interventions for the prevention of HIV in

prisoners (Grinstead 2001, Martin 2003) and three involved the prevention of transmission in people who were already HIV positive (Patterson 2003, Richardson 2004, Rotheram-Borus 2004).

Location

We found only two studies that had been conducted in the UK (Oakeshott 2000, James 1998). Seven were done in Australia (Baker 1994, Gold 1995, Gold 1998, O'Neill 1996, Proude 2004, Quinlivan, Robert 1990) and the rest in the United States.

Comparisons

One study had no control (Artz 2000), 11 had a no treatment control group (Danielson 1999, DiNoia 2004, Evans 2000, Metcalf 2005, Gold 1995, Gold 1998, Picciano 2001, Robert 1990, Grinstead 2001, Rotheram-Borus 2004, Baker 1994) and four had no treatment or treatment as usual control but compared one type of intervention with another (Downs 2004, Patterson 2003, Richardson 2004, Martin 2003). The rest compared the intervention/s with treatment as usual (TAU). However, in many instances TAU also involved one to one counselling, but in a standard rather than enhanced form.

Sixteen studies involved more than one comparison. With thirteen including three groups (Richardson 2004, Evans 2000, Kamb 1998, Ashworth 1994, Winter 1993, DeLamater 2000, Harper 2005, Rotheram-Borus 2004, El-Bassel 2003, Robert 1990, Gold 1998, Gold 1995, Stark 2003) and three studies including four groups (Kalichaman 2005, Dilley 2002, Patterson 2003).

Table 4: Summary of included quantitative studies (including aim/objectives, setting, population and content of intervention and control)

Study ID	Study type	Specified aim/objective		Setting	Population	Provider	No of sessions		Content of intervention				Content of control
		Prevent STI	Prevent HIV				I	C	Theory based	Skills development	HIV testing & counselling	Safe sex counselling/ education	
Artz 2000	Uncontrolled b/a	Yes	Yes	STI clinic	High-risk females	Nurse clinician						Yes	N/A
Ashworth 1994	RCT		Yes	Community programme	Low income mothers	Community health nurse	1	1				Yes	Leaflets
Baker 1994	RCT		Yes	Community	Injecting drug users	Nurse or psychologist	1	0	Yes			Yes	No intervention
Belcher 1998	RCT		Yes	Community	Low income females	Trained HIV/AIDS counsellor	1	1	Yes	Yes		Yes	HIV education (no skills training or motivation)
Boekeloo 1999	RCT		Yes	Primary care practices	Adolescents	Paediatrician	1	1	Yes	Yes		Yes	Health exam and general HIV/STI education
Boyer 1997	RCT	Yes		STI clinic	High-risk adults	Trained counsellor	4	1	Yes	Yes		Yes	Risk reduction counselling
Danielson	RCT		Yes	HMO offices	Adolescent males	Nurses & physicians assistants	1	0				Yes	No intervention
Deas 2000	RCT		Yes		Adolescent substance abusers	Psychiatrist	1	1	Yes			Yes	Discussion about substance abuse
DeLamater 2000	RCT	Yes	Yes	Social services agencies	Adolescent males	Health educator	1	1	Yes			Yes	Standard care and education (details not specified)
Dilley 2002	RCT		Yes	HIV testing clinic	MSM	Mental health professional	NS				Yes	Yes	Standard HIV test (US federal guidelines)
Di Noia 2004	RCT		Yes	Social services agencies	Adolescent females	Interactive video	1	0		Yes		Yes	No intervention

Table 4 continued: Summary of included quantitative studies (including aim/objectives, setting, population and content of intervention and control)

Study ID	Study type	Specified aim/objective		Setting	Population	Provider	No of sessions		Content of intervention				Content of control
		Prevent STI	Prevent HIV				I	C	Theory based	Skills development	HIV testing & counselling	Safe sex counselling/ education	
Downs 2004	RCT	Yes		Urban healthcare sites	Adolescent females	Interactive video	1		Yes	Yes		Yes	Same content in book or brochure form
El-Bassel 2003	RCT	Yes	Yes	Hospital outpatient clinic	High-risk couples	Facilitators	6	1	Yes	Yes		Yes	HIV/STI education for women alone
Evans 2000	RCT		Yes	University	College students	Interactive video	1	0	Yes	Yes		Yes	No intervention
EXPLORE 2004	RCT		Yes	Not specified	MSM	Trained counsellors	10 +	2	Yes	Yes		Yes	STI/HIV prevention counselling based on Project RESPECT brief intervention
Gibson 1999a	RCT		Yes	Hospital detox centre	Injecting drug users	Health educator	2	1		Yes	Yes	Yes	Brochures
Gibson 1999b	RCT		Yes	Hospital detox centre	Injecting drug users	Health educator	2	2		Yes	Yes	Yes	Standard HIV test counselling
Gold 1995	RCT		Yes	Community	MSM	Researchers	NS					Yes	No intervention
Gold 1998	RCT		Yes	Community	MSM	Researchers	NS					Yes	No intervention
Grinstead 2001	RCT		Yes	Prison	Prison inmates	HIV +ve prisoner	1	0				Yes	No intervention
James 1998	RCT	Yes	Yes	GUM clinic	Adults	Health advisors	1	1	Yes	Yes		Yes	Clinic session with health advisor (content not described)
Kalichman 2005	RCT	Yes	Yes	STI clinic	High-risk adults	Counsellors (no prior experience)	1	1	Yes	Yes		Yes	Information delivered in didactic style

Table 4 continued: Summary of included quantitative studies (including aim/objectives, setting, population and content of intervention and control)

Study ID	Study type	Specified aim/objective		Setting	Population	Provider	No of sessions		Content of intervention				Content of control
		Prevent STI	Prevent HIV				I	C	Theory based	Skills development	HIV testing & counselling	Safe sex counselling/ education	
Kamb 1998	RCT	Yes	Yes	Public health clinic	Heterosexual adults	Counsellors (received intervention training)	E = 4 B = 2	2	Yes	Yes		Yes	Didactic messages designed to approximate TAU in most clinics
Kotranski 1998	RCT		Yes	Community clinic	Drug users	Trained health educator	NS	2	Yes		Yes	Yes	Standard HIV education and counselling
Kwiatkowski 1998	RCT		Yes		Injecting drug users	Counsellors	1-3	1-3	Yes	Yes	Yes	Yes	NIDA standard HIV testing and counselling
Maher 2003	RCT	Yes	Yes	STI clinic	High-risk black males	STI counsellors	3	NS	Yes	Yes		Yes	TAU – not specified
Mansfield 1993	RCT		Yes	Adolescent hospital clinic	Adolescents	Physicians	1	1			Yes	Yes	Risk assessment, condom provision and counselling
Martin 2003	RCT		Yes	Community	Drug using probationers	Counsellors	2	2	Yes	Yes	Yes	Yes	Enhanced version of NIDA standard intervention
Metcalf 2005	RCT	Yes	Yes	STI clinics	Adults	Clinic staff	3	2	Yes	Yes		Yes	HIV education and counselling based on Project RESPECT brief intervention

Table 4 continued: Summary of included quantitative studies (including aim/objectives, setting, population and content of intervention and control)

Study ID	Study type	Specified aim/objective		Setting	Population	Provider	No of sessions		Content of intervention				Content of control
		Prevent STI	Prevent HIV				I	C	Theory based	Skills development	HIV testing & counselling	Safe sex counselling/ education	
Metzler 2000	RCT	Yes	Yes	STI clinic	Adolescents	Clinic staff	5	1	Yes	Yes		Yes	Examination and brief interaction with nurse
Oakeshott 2000	RCT	Yes	Yes	General Practice	Females	Practice nurses and GPs	1	0				Yes	No intervention
Oliva 2005	RCT		Yes	Mobile health clinic	Low income high-risk adults	Counsellors	2	2	Yes	Yes	Yes	Yes	Standard HIV testing and counselling
O'Neill 1996	RCT		Yes	Drug treatment and antenatal clinics	Pregnant injecting drug users	Psychology therapists	5		Yes	Yes		Yes	Standard HIV risk prevention counselling
Orr 1996	RCT	Yes		Family planning clinics	Adolescent females	Researchers	1	1	Yes	Yes		Yes	Didactic sex education
Patterson 2003	RCT		Yes	Project office	HIV positive adults	Trained project staff	1-3	3	Yes	Yes		Yes	Diet and exercise education
Picciano 2001	RCT		Yes	Community	MSM	Trained counsellors	2	0	Yes	Yes		Yes	No intervention
Proude 2004	RCT	Yes	Yes	Family practice	Young people (18-25)	Family practitioner	1	0				Yes	TAU without HIV/STI education
Richardson 2004	RCT		Yes	HIV clinic	HIV positive adults	Clinic staff	1	1		Yes		Yes	Medication adherence counselling
Robert 1990	RCT		Yes	Community	MSM	Not specified	1	0	Yes		Yes	Yes	No intervention
Rotheram-Borus 2004	RCT		Yes	Community	HIV positive substance users	Therapists or social workers	1	0		Yes		Yes	No intervention

Table 4 continued: Summary of included quantitative studies (including aim/objectives, setting, population and content of intervention

Study ID	Study type	Specified aim/objective		Setting	Population	Provider	No of sessions		Content of intervention				Content of control
		Prevent STI	Prevent HIV				I	C	Theory based	Skills development	HIV testing & counselling	Safe sex counselling/ education	
Scholes 2003	RCT	Yes	Yes	Community	Female adults	Booklet	2	NS	Yes			Yes	TAU – not described
Shrier 2001	RCT	Yes		Adolescent hospital clinic	Adolescent females	Health educators	4	1	Yes	Yes		Yes	STI education at discretion of doctor
Sterk 2003	RCT		Yes	Project office in inner city	Low income female crack cocaine users	Health educators	4	2	Yes	Yes		Yes	NIDA standard intervention
Winter 1993	RCT	Yes	Yes	Family planning clinics	Adolescent females	Health educator	1	1	Yes	Yes		Yes	TAU - Condom education

Content of intervention = components of intervention specified in paper
I = intervention, C = control
E = enhanced, B = brief
NS = not specified
NIDA – National Institute on Drug Abuse (USA)
TAU = treatment as usual

Quality score

Seven papers of six interventions scored (++) on the quality assessment (Kamb 1998 (and its subgroup analysis Bolu 2004), EXPLORE 2004, Maher 2003, Metcalf 2005, Dilley 2002, Gold 2004). Eleven RCTs scored (+) on the quality assessment (Kalichman 2005, James 1998, Belcher 1998, Danielson 1990, Downs 2004, Rotheram-Borus 2004, Stark 2003, Kwiatkowski 1999, Scholes 2003, Boyer 1997). The remaining RCTs and one uncontrolled study (Artz 2000) were all graded as (-).

Follow up

We categorised length of final follow up as:

- Not clear – (Richardson 2004) n = 1
- Very short –less than 6 weeks: (DiNoia 2004, Evans 2000, Grinstead 2001, Oliva 2005, Winter 1993) n = 5
- Short -6-12 weeks: (Ashworth 1994, Belcher 1998, El-Bassel 2003, Gold 1995, Gold 1998, Mansfield 1993, Oakeshott 2000, Picciano 2001, Proude 2004) n= 10
- Longer term – over 12 weeks: (Artz 2000, Baker 1994, Boyer 1997, Boekeloo 1999, Deas 2000, DeLamater 2000, Downs 2004, Kalichman 2005, Kotranski 1998, Kwiatkowski 1999, Martin 2003, Metzler 2000, O'Neill 1996, Orr 1996, Patterson 2003, Robert 1990, Scholes 2003, Stark 2003) n= 18
- Very long – 12 months or more: (Danielson 1990, Dilley 2002, EXPLORE 2004, Gibson 1999a, Gibson 1999b, James 1998, Kamb 1998 (and subgroup analysis Bolu 2004), Maher 2003, Metcalf 2005, Rotheram-Borus 2004, Shrier 2001) n = 11

In two of the studies with a very short follow up the assessment was immediately post intervention (Evans 2000, Winter 1993). Of those with a very long follow up three had the final assessment after 12 months. These were 15 months (Rotheram-Borus 2004), 18 months (James 1998), and 48 months (EXPLORE 2004).

Loss to follow up

Attrition rates varied. Four studies had a loss to follow up of over 50% (Artz 2000, Baker 1994, Grinstead 2001, Metzler 2000). Of the four largest studies (Kamb 1998 (++), Metcalf 2005 (++), EXPLORE 2004 (++), Kwiatkoswki 1999 (+)) all, except one (Kwiatkowski 1999) had a follow up of at least 12 months, and attrition rates varied

from 12-34%. Project EXPLORE lost only 15% to follow up despite a final assessment 48 months post intervention.

Study size

The number of participants included in the studies ranged from 60 – 5758. Twenty-six of the quantitative studies had 400 or less participants, ten 400-1000 and four 1000-1500. There were four studies with more than 3000 participants. These included 3297 sexually active 15-39 year olds (Metcalf 2005), 4295 high risk MSM (EXPLORE 2004), 5372 injecting drug users (Kwiatkowski 1999), and 5758 HIV negative heterosexuals aged 14 and over (Kamb 1998).

Study power

Only eight studies reported having done a power calculation (Di Noia 2004, Boyer 1997, James 1998, Kamb 1998 (and subgroup analysis Bolu 2004), Metcalf 2005, Proude 2004, Dilley 2002, The EXPLORE study 2004). Full details of the power calculations are reported in the evidence tables but many of the studies were underpowered, particularly to detect pregnancy or STIs.

Table 5 – Quality assessment details for included quantitative studies

Study ID	Study Type	Study quality	Study size	Power calculation reported?	Length of final follow up	Loss to follow up at final assessment (%)
Artz	Uncontrolled b/a	-	1159	no	6 months	55
Ashworth 1994	RCT	-	217	no	2 months	Not specified
Baker 1994	RCT	-	200	no	3 months	56
Belcher 1998	RCT	+	74	no	3 months	8
Boekeloo 1999	RCT	-	215	no	9 months	8
Bolu 2004	RCT	++	764	Yes – not powered	12 months	Not specified – subgroup analysis
Boyer 1997	RCT	+	399	Yes – not powered	6 months	48
Danielson	RCT	+	1449	No	12 months	18
Deas 2000	RCT	-	60	No	6 months	17
DeLamater	RCT	-	562	No	6 months	Not specified
Dilley 2002	RCT	++	248	Yes – Not powered	12 months	17
Di Noia 2004	RCT	-	205	No	2 weeks	Not specified
Downs 2004	RCT	+	300	No	6 months	14
El-Bassel 2003	RCT	+	217	No	12 months	26.5
Evans 2000	RCT	-	162	No	Immediately post intervention	6
EXPLORE 2004	RCT	++	4295	Yes	48 months	15
Gibson 1999a	RCT	-	295	No	12 months	44
Gibson 1999b	RCT	-	109	No	12 months	40
Gold 1995	RCT	-	138	No	8 weeks	21
Gold 1998	RCT	-	92	No	12 weeks	16
Grinstead 2001	RCT	-	414	No	17 days	57.5
James 1998	RCT	+	492	Yes	18 months	49
Kalichman 2005	RCT	+	612	No	9 months	22
Kamb 1998	RCT	++	5758	Yes	12 months	34
Kotranski 1998	RCT	-	684	No	6 months	30
Kwiatkowski 1998	RCT	+	5372	No	6 months	38
Maher 2003	RCT	++	581	No	12 months	Not specified
Mansfield 1993	RCT	-	90	No	2 months	7.8
Martin 2003	RCT	-	706	No	6 months	40
Metcalf 2005	RCT	++	3297	Yes - underpowered	12 months	12
Metzler 2000	RCT	-	339	No	6 months	53
Oakeshott 2000	RCT	-	1382	No	3 months	24
Oliva 2005	RCT	-	667	No	1 week	Not specified
O'Neill 1996	RCT	-	92	No	9 months	21
Orr 1996	RCT	-	209	No	7 months	46
Patterson 2003	RCT	-	387	No	8 months	45.2
Picciano 2001	RCT	-	103	No	6 weeks	14
Proude 2004	RCT	-	312	Yes	3 months	32
Richardson 2004	RCT	-	886	No	Not specified	44
Robert 1990	RCT	-	159	No	6 months	23
Rotheram-Borus 2004	RCT	+	175	No	15 months	18
Scholes 2003	RCT	+	1210	No	6 months	14
Shrier 2001	RCT	-	123	No	12 months	48
Sterk 2003	RCT	+	265	No	6 months	4

++ = low risk of bias, + = moderate risk of bias, - = high risk of bias

What outcome measures are used to assess the effectiveness? How valid and appropriate are they?

Only a limited number of studies measured one of our primary outcomes. Although in many studies the main aim was specified as the prevention of HIV only one measured new cases of HIV (EXPLORE 2004). Fifteen studies measured incidence of STIs (El-Bassel 2003, James 1998, Kalichman 2005, Kamb 1998, (and it's subgroup analysis Bolu 2004), Boekeloo 1999, Maher 2003, Metcalf 2003, Scholes 2003, Patterson 2003, Downs 2004, Metzler 2000, Orr 1996, Shrier 2001, Boyer 1997). However, many of the studies that measured STIs were underpowered for this outcome. Twenty four studies reported condom use and 14 studies presented data for unprotected sex. Condom use was defined and measured in many different ways and over many different time periods (for example; condom use at last sexual intercourse, consistent condom use, mean condom use). Some studies looked at condom use separately for regular and casual partners and other for vaginal, oral or anal sex separately. Measuring an increase in condom use is not ideal as although condom use may increase there may still be high levels of unprotected sex. Other outcomes related to measures of sexual activity included number of partners and general scores of overall sexual risk behaviours.

Five studies used clinical tests to verify an STI diagnosis (Boyer 1997, Kamb 19980, Maher 2003, Metcalf 2005, Orr 1996). The others relied on self-reported data which included probable or suspected STIs. All other sexual health measures such as condom use, number of partners and unprotected sex were self-reported. This makes recall bias inevitable. There was also a wide variety of ways in which condom use had been defined and this makes comparisons difficult. A number of studies reported several different condom measures some of which were significant and some of which were not, which again makes interpretation problematic. Although most studies collected data by interviewer administered or self-administered questionnaires a few used audio computer assisted self-interviews for the follow up (Kalichman 2005, EXPLORE 2004) which has been shown to yield reliable results in sexual behaviour interviews (Gribble 1999).

5.1.2 Qualitative studies

Aim/objectives of the interventions

Of the qualitative studies one was concerned with the prevention of STI's (Salyers 2005) and one with the promotion of sexual health services within the Bangladeshi community in the UK (Beck 2005). Three studies were concerned specifically with the prevention of HIV transmission (Seal 2000, Choi 2004, Dorfman 1992). These studies included the following populations: heterosexual women (Choi 2004), men who have sex with men (Seal 2000) and female sex workers (Dorfman 1992).
Four studies were exclusively qualitative in nature (Seal 2000; Beck 2005; Salyers 2005; Choi 2004) and one study combined a qualitative user study and quantitative survey as part of a process evaluation (Dorfman 1992). Three studies were graded as (++) (Beck 2005, Seal 2000, Salyers 2005) and two were graded as (+) (Choi 2004, Dorfman 1992).

Methods of data collection included:

- In-depth interviews only (Salyers 2005, Seal 2000)
- In depth interviews and field observation notes (Dorfman 1992)
- Focus groups and in-depth interviews (Beck 2005)
- In-depth interviews plus structured questionnaire (Choi 2004).

Sample sizes were:

- Beck - 58 interviewees (12 individual and 46 as participants in focus groups)
- Choi – 62 interviewees (from 92 enrolled in the study).
- Dorfman – Process and outcome evaluations including the observation data was on 182 female sex workers, plus 42 personal non-commercial sexual partners. 58 in-depth interviews.
- Seal – 72 interviewees.
- Salyers – 48 interviewees.

The majority employed in-depth interviews as the main source of qualitative data collection with participants. However, in most papers, even if methods such as observation and diaries were used, others methods were frequently not fully reported on. The process of analysis was also poorly reported in the majority of studies. Only

one study (Salyers 2005) explicitly employed a theoretical framework, in this case Bronfenbrenner's bio-ecologic model.

Overall there was a paucity of good quality qualitative studies in the areas encompassed by the review.

5.2 Prevention Of Under 18 Conceptions

5.2.1 Quantitative studies

Aim/Objective of the interventions

We found only seven studies of one to one interventions that focused on the prevention of conceptions in the under 18's. Of those, two looked at the provision of emergency contraception (Gold 2004, Harper 2005), two looked at health care programmes for adolescent mothers (O'Sullivan 1992, Quinlivan 2003), one looked at the use of specially developed protocols for adolescents in a family planning clinic (Winter 1991) and one looked at a reproductive health consultation for male adolescents and its effect on contraception use (Danielson 1990). A study of STI education was also included in this section because pregnancy was reported as an outcome (Boekeloo 1999). As literature in this area was scarce we also included an additional five studies that, although they did not focus solely on under 18's, involved study populations where at least 40% of the participants were under 20. Of these studies one looked at contraceptive care in an STI clinic (Shlay 2003) and the rest evaluated home visiting programmes for pregnant women or mothers (Norr 2003, Olds 1997, Olds 2002, Olds 2004).

For details of aims/objectives, setting, type of intervention and study quality see table six.

Comparisons

In the quantitative studies one had a no treatment control group (Danielson 1999), one compared advanced provision of emergency contraception with pharmacy or clinic access (Harper 2005), three compared nurse home visiting and developmental screening with developmental screening only (Olds 1997, Olds 2002, Olds 2004) and the rest compared the intervention/s with treatment as usual (TAU).

Table 6 – Prevention of under 18 conceptions: Summary of population, intervention and study quality

Study ID	Study Type	Study quality	Population	Setting	Intervention	Provider	Study size	Power calculation reported	Length of final follow up	Loss to follow up for final assessment (%)
Boekeloo 1999	RCT	-	Adolescents	Primary care practices	STI education	Paediatrician	215	No	9 months	8
Danielson 1990	RCT	+	Adolescent males	HMO offices	Reproductive health consultation	Nurses & physician's assistants	1449	No	12 months	18
Gold 2004	RCT	++	Adolescent females	Adolescent hospital clinic	Emergency contraception	Not specified	301	Yes (but not powered for pregnancies or STIs)	6 months	36
Harper 2005	RCT	++	Adolescent females	Family planning clinic	Emergency contraception	Not specified	964	PC done for larger study but not for this subgroup analysis	6 months	7
Norr 2003	RCT	-	Low income pregnant women	Prenatal clinic and home	Home visiting	Nurses and health advocates	588	No	12 months	19
Olds 1997	RCT	-	Pregnant women	Prenatal clinic and home	Home visiting	Nurses	400	Yes	15 years	19
Olds 2002	RCT	+	Low income pregnant women	Prenatal clinic and home	Home visiting	Nurses and paraprofessionals	735	Yes	24 months	14.3
Olds 2004	RCT	+	Low income pregnant women	Prenatal clinic and home	Home visits	Nurses	1139	Yes	6 years	46
O'Sullivan 1992	RCT	-	Adolescent mothers	Hospital clinic	Support for adolescent mothers	Multi-disciplinary health care team	243	No	18 months	9
Quinlivan 2003	RCT	++	Adolescent mothers	Antenatal clinic	Support for adolescent mothers	Nurse-midwives	139	Yes (powered for knowledge and adverse neonatal outcomes)	6 months	11
Shlay 2003	RCT	-	Premenopausal women (40% aged 19 or under)	STI clinic	Contraceptive care and counselling	Family planning nurse	877	Yes	12 months	28
Winter 1991	Controlled trial	-	Adolescents	Family planning clinic	Protocols for care of adolescents	Clinic staff	1,256	No	12 months	27

Quality score

Of the 11 RCTs three scored (++) (Gold 2004, Harper 2005, Quinlivan 2003), three (+) (Danielson 1990, Olds 2002, Olds 2004) and five (-) (Boekeloo 1999, Norr 2003, Olds 1997, O'Sullivan 1992, Shlay 2003). One, non randomised, controlled study (Winter 1991) scored (2-).

Follow up

We categorised length of follow up as:

- Longer term – over 12 weeks: (Boekeloo 1999, Gold 2004, Harper 2005, Quinlivan 2003) n= 4
- Very long – 12 months or more: (Danielson 1990, Norr 2003, Olds 1997, Olds 2002, Olds 2004, O'Sullivan 2003, Shlay 2003, Winter 1991) n = 8

Loss to follow up

Attrition rates varied. Eight studies had a follow up rate of over 80% (Boekeloo 1999, Danielson 1990, Harper 2005, Norr 2003, Olds 1997, Olds 2002, O'Sullivan 2003, Quinlivan 2003). The other four studies had losses to follow up of 27% (Winter 1991), 28% (Shlay 2003), 36% (Gold 2004) and 46% (Olds 2004).

Study size

The number of participants included in the studies ranged from 139 – 1,449. Five studies had 400 or less participants (Boekeloo 1999, Gold 2004, Olds 1997, O'Sullivan 1992, Quinlivan 2003), four 400-1000 (Harper 2005, Norr 2003, Olds 2002, Shlay 2003) and three 1000-1500 (Danielson 1990, Olds 2004, Winter 1991).

Study power

Neither of the two largest studies (Danielson 1990, Winter 1991) reported having done a power calculation. Of the others, six reported having done power calculations (Gold 2004, Olds 1997, Olds 2002, Olds 2004, Quinlivan 2003, Shlay 2003) but two were not powered to detect pregnancies (Gold 2004, Quinlivan 2003). One study (Harper 2005) which was a subgroup analysis of adolescents from a larger study of women aged 15-24 (Raine 2005) was not powered to detect pregnancies in the subgroup of adolescents.

What outcome measures are used to assess the effectiveness? How valid and appropriate are they?

Ten studies reported data on our primary outcome of pregnancy (Boekeloo 1999, Gold 2004, Harper 2005, Shlay 2003, Winter 1991) or repeat pregnancy (Olds 1997, Olds 2002, Olds 2004, O'Sullivan 1992, Norr 2003). Other outcomes included condom use, sexual activity, and knowledge. Most of the sexual health measures such as condom use, number of partners and unprotected sex were self-reported, which makes recall bias inevitable. There was also a wide variety of ways in which condom use had been defined which makes comparisons between studies difficult.

5.2.2 Qualitative studies

Aims/Objectives

Of the qualitative studies two included information on the prevention of pregnancy in teenagers (Free 2005, Salyers 2005) and one on the promotion of sexual health services within the Bangladeshi community in the UK (Beck 2005). Although this study was not directly relevant to either the prevention of under 18 conceptions or the prevention of STIs it was included because it was the only qualitative study we found which addressed this ethnic group in the UK.

Of the three qualitative studies two studies were graded as (++) (Beck 2005, Salyers 2005) and one was graded as (+) (Free 2005).

Methods of data collection included:

- In-depth interviews only, (Salyers 2005; Free 2005)
- Focus groups and in-depth interviews, (Beck 2005)

Sample sizes were:

- Beck - 58 interviewees (12 individual and 46 as participants in focus groups)
- Free – 41 interviewees.
- Salyers – 48 interviewees.

As noted in the previous section the majority employed in-depth interviews as the main source of data collection. However, in most papers, even if other data collection methods were used they were frequently not fully reported on. The process of analysis was also poorly reported in the majority of studies. Only one study

(Salyers 2005) explicitly employed a theoretical framework, in this case Bronfenbrenner's bio-ecologic model.

Overall there was a paucity of good quality qualitative studies in the areas encompassed by the review.

6. RESULTS

6.1 The effectiveness of one to one interventions for reducing STIs (including HIV)

The studies included in this review cover a range of interventions in very diverse populations. Several of these groups were identified by the review scope as at particular risk for STIs/HIV. For example, relative to other age groups adolescents are disproportionately affected by STIs (Miller 2004). Other high-risk groups, identified by the scope, included MSM, people in prison, and those living with HIV. Therefore, an overall summary is presented followed by results reported by population (e.g adolescents, general population, MSM, drug users, prisoners/probationers and people with HIV). Results are presented by outcome and by follow up (e.g. very short, less than 6 weeks; short, 6-12 weeks inclusive; long, more than 3 months and less than 12 months, and very long 12 months and over). Results are presented in the evidence tables in appendix five and an overview of findings, by vulnerable population groups is presented in summary table 11.

Results for some studies may be presented more than once as the study includes more than one population. For example a study with people with HIV who are also drug users (Rotheram-Borus 2004), a study that reported subgroup analyses for MSM (Metcalf 2005), and a subgroup analysis of adolescents (Bolu 2004) from a larger study (Kamb 1998).

STIs (including HIV)

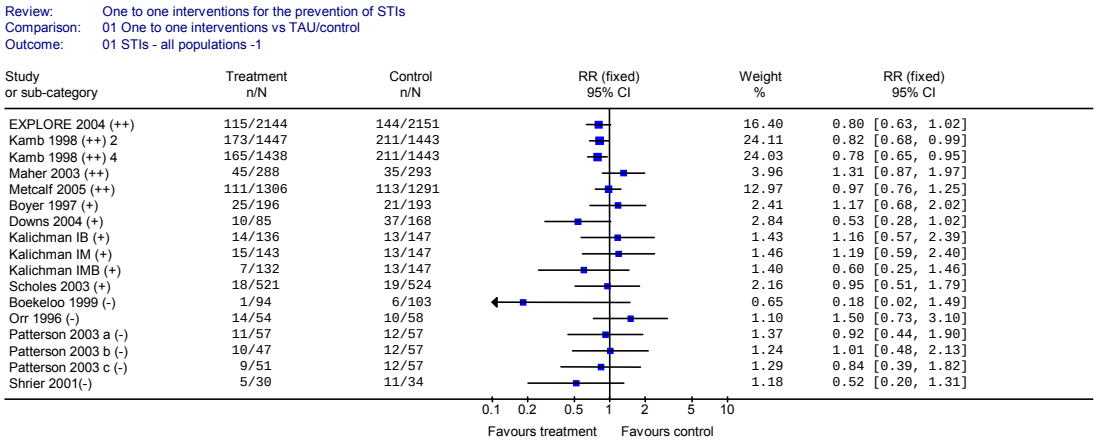
Evidence Statement 1.1

In summary the evidence on the effectiveness of one to one interventions for the prevention of STIs is mixed but on balance marginally supports the interventions. There is evidence from Project RESPECT a large (++) US study (Kamb 1998) that both a two session and a four session one to one counselling intervention can reduce STIs in the long and very long term in heterosexuals, and from one (+) study that STIs in men can be reduced in the long term after one 90 minute session (Kalichman). However, the effect appears to decrease over time, with one study finding a reduction in effect after six months (Kamb 1998).

Evidence Statement 1.2

In addition EXPLORE a large (++) US study of ten session one to one counselling for MSM found a 15.7% reduction in HIV infection but this was not statistically significant (EXPLORE 2004). The other studies found no statistically significant effect on STIs but may have been underpowered for this outcome.

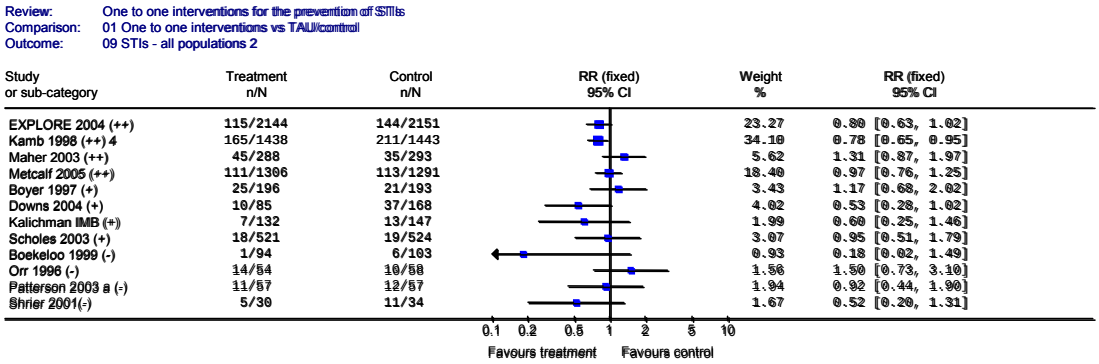
Fifteen studies, looked at the effect of one to one interventions on STIs and HIV infection. Five studies, and one subgroup analysis, with adolescents, eight with the general population, one with MSM and one with people with HIV. A summary of STI results can be seen in table 7. Twelve studies, that reported this outcome, provided data (either from the paper or from contact with the author) that could be used in a forest plot. The forest plots compares intervention with control or treatment as usual (TAU). If available we included definite STI diagnosis (i.e verification through clinical test), otherwise we used reported or suspected STI. Three studies are not included in the forest plot, one which was graded (-) (Metzler 2000) and two graded (+) (James 1998, El-Bassel 2003). None of these three studies found a statistically significant difference but a summary of results from these studies is reported in the text, and in table seven.



Patterson a = comprehensive + boosters, b = comprehensive no boosters, c = brief targeted; Kamb 2 = brief 2 session, 4 = enhanced 4 session intervention; Kalichman IMB = full information, motivational, behavioural, IM =information motivational, IB = information behavioural.

++ = low risk of bias, + = moderate risk of bias, - = high risk of bias

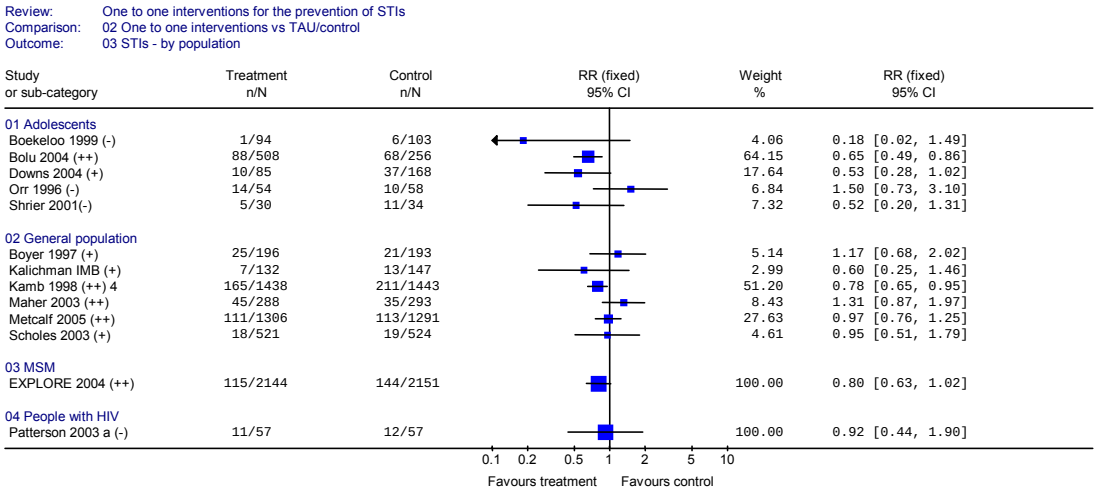
Figure 1: Effect of one to one interventions on sexually transmitted infections – (including all trial arms)



++ = low risk of bias, + = moderate risk of bias, - = high risk of bias

Figure 2: Effect of one to one interventions on sexually transmitted infections – main trial arm only

(This plot includes only one arm per trial – that is the most intensive arm e.g. Kamb 1998 4 session, Kalichman full IMB model)



++ = low risk of bias, + = moderate risk of bias, - = high risk of bias

Figure 3: Effect of one to one interventions on sexually transmitted infections - by population (main trial arm only)

Adolescents

Evidence Statement 1.3

Interventions with adolescents appeared to be particularly effective. A subgroup analysis of Project RESPECT (Bolu 2004) found a significant reduction in sexually transmitted infections with both the four and two session interventions versus a didactic control. Although this was the only study to show a statistically significant difference the general trend in this group of studies was towards a reduction in STIs.

Short term

Two (-) RCTs measured STIs at three months (Boekeloo 1999, Metzler 2000). They found no significant difference in numbers being treated for an STI between a primary care based STI prevention intervention and usual health examination provided by paediatricians (2.2% vs. 4.7%, ES h=.05) (Boekeloo 1999), or in new self-reported STIs after a clinic based behavioural intervention (p=0.76; ES:d=.00) (Metzler 2000).

Long term

Four studies measured incidence of new STIs in the long term. One (+) RCT (Downs 2004) found a significant reduction in STI acquisition when adjusting for baseline rates (OR 2.79, p=.05) and a non-significant reduction in unadjusted rates (RR 0.53; 95% CI 0.28, 1.02). This was a video based intervention for sexually active female adolescents, the majority of whom were African American. The other three (-) studies found no statistically significant differences. These were an RCT of a primary care based intervention (Boekeloo 1999) (treated for a STI: RR 0.18; 95% CI 0.02, 1.49, signs of STI 0.07; 95% CI 0.00-1.26), a clinic based behavioural intervention (Metzler 2000) (new self-reported STIs p=0.24; ES: d=0.01) and a clinic based counselling intervention with a multiethnic high risk population (Orr 1996) (reinfection rates RR 1.50; 95% CI 0.73, 3.10).

Very long term

Two studies measured STIs at 12 months. One (++) RCT (Bolu 2004) found a significant reduction in STIs in both a brief (two session) and an enhanced (4 session) counselling group compared to the TAU control (enhanced: RR 0.65; 95% CI 0.49-0.86, brief: RR 0.66; 95% CI 0.47-0.92) with 9.4 STIs prevented for every 100 people counselled. This study reported results from a subgroup analysis of Project RESPECT (Kamb 1998) and included 764 adolescents counselled in public health clinics in the USA. Another (-) study, of a one-session education intervention for high risk multiethnic female adolescents (Shrier 2001), found a reduction in STIs but this was not statistically significant (RR 0.52; 95% CI 0.20, 1.31). However, this was a small study with high losses to follow up at 12 months.

Table 7: Effect of one to one interventions on sexually transmitted infections

Study ID	Quality score	Target Group	Effect Short	Effect Long	Effect Very long
Adolescents					
Bolu 2004	++	Adolescents			+: Enhanced vs. control RR 0.65 (95% CI 0.49, 0.86) +: brief vs. control RR 0.66 (95% CI 0.47, 0.92)
Boekeloo 1999	-	Adolescents	0: ES:h=0.05	0: RR 0.18 (95% CI 0.02,1.49) (treated for STD); RR 0.07 (95% CI 0.00-1.26) (signs of STDs)	
Downs 2004	+	Adolescent females		+: (adjusted for baseline rates) OR 2.79 (p=0.05) 0: (unadjusted) RR 0.53 (95% CI 0.28,1.02)	
Metzler 2000	-	Adolescents	0: p=0.76; ES: d=.00	0: p=0.24 (ES: d=0.01)	
Orr 1996	-	Adolescent females		0: RR 1.50 (0.73, 3.10))	
Shrier 2001	-	Adolescent females			0: RR 0.52 (95% CI 0.20, 1.31) (self-reported)
General Population					
Boyer 1997	+	Heterosexual adults		0: RR 1.17 (95% CI 0.68, 2.02)	
El-Bassel 2003	+	Heterosexual couples	0: Couples vs. control (p=0.72) Women alone vs. control (p=0.52); ES: d=0.03		
James 1998	+	Adults			0: p=0.26; ES: C=0.03
Kalichman 2005	+	Adults		0: IM RR 1.19 (95% CI 0.59, 2.40) 0: IB RR 1.16 (95% CI 0.57, 2.39) 0: IMB RR 0.60 (95% CI 0.25, 1.46)	
Kamb 1998	++	Heterosexual adults		+: enhanced; RR 0.69 (95% CI 0.54, 0.88) +: brief; RR 0.71 (95% CI 0.58, 0.89)	+: enhanced; RR 0.78 (95% CI 0.65, 0.95) +: brief; RR 0.82 (95% CI 0.68, 0.99)
Maher 2003	++	Males (16-29)			0: RR 1.31 (95% CI 0.87, 1.97)

Metcalf 2005	++	Adults		0: RR 1.06 (0.78-1.44)	0: RR 0.97 (95% CI 0.76, 1.25)
Scholes 2003	+	Young women		0: RR 0.95 (0.51, 1.79)	
MSM					
EXPLORE	++				0: (HIV); RR 0.80 (95% CI 0.63, 1.02)
People with HIV					
Patterson 2003	-	People with HIV	0		0: Comprehensive with boosters vs. diet & exercise control RR 0.92 (95% CI 0.44, 1.90) Comprehensive with no boosters vs. control RR 1.01 (0.48, 2.13) Brief targeted vs. control RR 0.75 (0.34, 1.64) Boosters vs. no boosters RR 0.91 (0.42, 1.95)

Effect score: (+) = positive effect, (-) negative effect, (0) = no statistically significant effect show. Blank columns = data not reported for this time period.

General population

Eight studies measured STIs in studies with general populations.

Short term

Only one study reported short term STIs in this category. This (+) RCT with a high-risk, low income, multiethnic population, compared couple counselling, with women only counselling and a control group (El-Bassel 2003). They found no significant difference in the number of STI symptoms between couple counselling and control (p=0.72), and counselling for women alone vs. control (p= 0.52).

Long term

Five studies measured long term effects on STIs. Two studies found a statistically significant reduction in STIs in the intervention group compared to control. In one large (++) RCT with a heterosexual population, aged 14 and over, (Kamb 1998-Project RESPECT) both the enhanced four session counselling and the brief two session counselling were significantly better than the two session didactic message control at preventing STIs with 30% fewer participants in both groups having a new STI (enhanced RR 0.69; 95% CI 0.54-0.88; brief RR 0.71; 95% CI 0.58-0.89). A (+) study of an information-motivation-behavioural skills intervention (Kalichman 2005) found no overall between group differences in STIs at nine months. They compared three treatment groups: full information, motivational enhancement and behavioural skills (IMB), information and motivational enhancement (IM), information and behavioural skills (IB), with an information only control (IMB vs. control RR 0.60, 95% CI 0.25,1.46; IM vs. control RR 1.19, 95% CI 0.59, 2.40; IB vs. control RR 1.16, 95% CI 0.57, 2.39). However, there was a positive effect for men (adjusted OR 7.3).

The other studies found no statistically significant effect on STIs. Project RESPECT 2 (Metcalf 2005), a (++) study, found no significant effect on STIs (RR 1.06; 95% CI 0.78-1.44). However, in this study the control group received a two session counselling intervention based on the Project RESPECT model, which had previously been shown to be effective (Kamb 1998). In Project RESPECT 2 (Metcalf 2005) the only difference between the groups was that the intervention group received an additional booster counselling session. One study (Boyer 1997) compared four 60 minute skills building sessions with a standard 15 minute counselling session in multiethnic high risk adults attending a STI clinic and found no significant difference in suspected or diagnosed STIs (RR 1.17 (95% CI 0.68, 2.02). One (Scholes 2003)

compared a theory based booklet and safe sex kit with TAU (not specified) in a sexually active multiethnic population and found no difference in diagnosed STIs (RR 0.95; 95% CI 0.51,1.79).

Very long term

Four studies measured the effect on STIs at 12 months and over. The only study to find a positive significant difference in STIs was Project RESPECT (Kamb 1998). In this (++) RCT both the enhanced and brief interventions were still significantly better than control with 20% fewer participants in each group having a new STI (enhanced RR 0.78; 95% CI 0.65-0.95; brief RR 0.82; 95% CI 0.68-0.99).

In the others, three clinic-based counselling interventions, there were no statistically significant differences between intervention and control. In one, with high-risk black males aged 16-29, they compared STI counselling with TAU (Maher 2003). They found no statistically significant difference in risk of a definite STI (RR 1.31; 95% CI 0.87, 1.97). One (+) RCT (James 1998) also found no significant difference in attendance at clinic with a new STI (p=0.26, ES: c=0.03). This study was based in a UK urban GUM clinic and compared a 20 minute individually tailored counselling session with TAU. Over 50% were lost to follow up and the study was probably underpowered to detect STIs. Project RESPECT 2 (Metcalf 2005), also found no significant difference in new STIs (RR 0.97; 95% CI 0.76-1.25).

MSM

One study with high-risk urban MSM measured new cases of HIV infection. This was The EXPLORE study (++), which compared a 10 session behavioural counselling intervention (plus booster sessions) with twice yearly counselling based on the Project RESPECT model. This study involved over 4,000 participants and found a reduction in HIV acquisition of 15.7% at 48 month follow up. However, this was not statistically significant (RR 0.80; 95% CI 0.63-1.02).

People with HIV

One study measured STIs in people with HIV. This (-) RCT (Patterson 2003), evaluated different types and intensities of behavioural interventions to increase safer sex practices. At 12 months they found no significant difference between a brief targeted intervention, a comprehensive intervention, a comprehensive intervention plus a booster session and a diet and exercise information control (comprehensive + boosters vs. control RR 0.92, 95% CI 0.44-1.90; comprehensive vs. control RR 1.01,

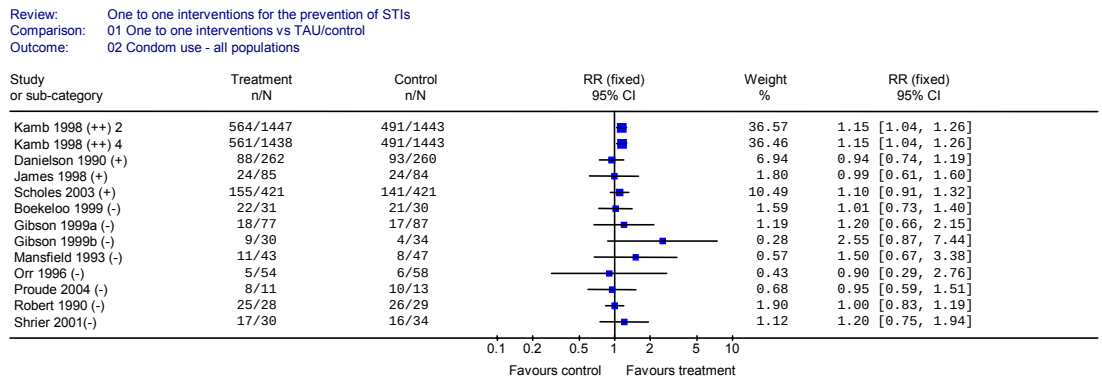
95% CI 0.48-2.13; brief targeted vs. control RR 0.75, 95% CI 0.34-1.64; boosters vs, no boosters RR 0.91, 95% CI 0.42-1.95). In this study, however, only 58% completed the baseline and follow up assessments.

Condom use

Evidence Statement 1.4

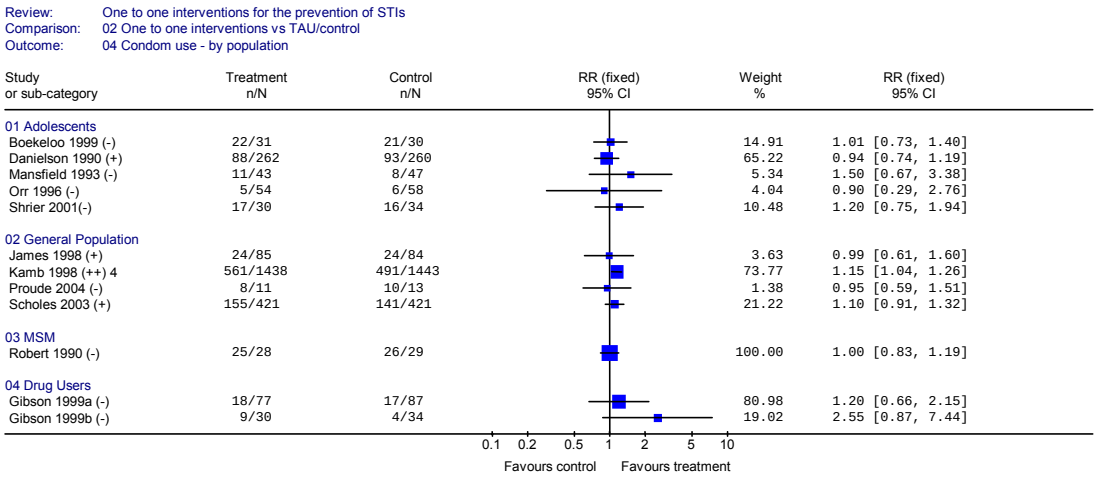
Twenty-five studies reported condom use, of which only eight showed a statistically significant increase in condom use in the intervention group compared to the control. However, overall there is weak evidence (that is it is mixed or conflicting but on balance marginally supports) that one to one STI/HIV prevention interventions can increase short and long-term condom use compared to control. Project RESPECT, a large good quality (++) US study found an increase in condom use in both the four and two session counselling intervention groups compared to a didactic control (Kamb 1998). However, several studies, including Project RESPECT, found the effect of an intervention appears to decrease, or disappear over time. Greater uniformity is needed in the way in which condom use is measured in studies.

Twenty-five studies measured condom use; eight with adolescents, nine with the general population, two with MSM, one with prisoners, and three with drug users. Eleven studies reported consistent condom use as dichotomous data (e.g. always used a condom/ consistent condom use, 100% condom use) and this is summarised in forest plots in figures 4 and 5 below. The rest did not provide data that could be presented in a forest plot and a summary of data for all studies is presented in the text and in table eight.



++ = low risk of bias, + = moderate risk of bias, - = high risk of bias

Figure 4: Effect of one to one interventions on consistent condom use (all trial arms)



++ = low risk of bias, + = moderate risk of bias, - = high risk of bias

Figure 5: Effect of one to one interventions on consistent condom use – by population (main trial arm only)

Adolescents

Short term

Three studies measured condom use in adolescents at short term follow up. Only one (-) study (Boekeloo 1999) found a significant increase (condom use at last vaginal intercourse: RR 1.61; 95% CI 1.09, 2.37). One (+) RCT comparing an hour long video with a brochure, for sexually active female adolescents (Downs 2004) found no significant difference (p=0.57; ES d=.07) and one (-) RCT (Mansfield 1993) found no significant difference in numbers always using condoms between standard and enhanced counselling for adolescents at two months (RR 1.50; 95% CI 0.67,3.38). However, both groups showed an increase in condom use pre to post intervention (p=.001). In this study both groups received clinic based HIV risk counselling but the intervention group received one 20 minute session compared to the control groups ten minute session.

Long term

Six studies measured long term condom use in adolescents (Boekeloo 1999, DeLamater 2000, Downs 2004, Metzler 2000, Orr 1996, Shrier 2001). One (+) clinic based RCT (Orr 1996) found a significant increase in frequency of condom use (RR 1.90 (95% CI 1.19, 3.02) when comparing a STI education intervention provided by a researcher with a nurse delivered TAU STI information session. However, there was no significant difference in numbers who always used a condom (RR 0.90; 95% CI 0.29, 2.76).

The rest of the studies showed no statistically significant effect on condom use. Three of those included populations where at least 75% were African American, two with females (Boekeloo 1999, Downs 2004) and one with males (DeLamater 2000). Of those Boekeloo 1999 found no difference in condom use at last vaginal intercourse (RR 1.01; 95% CI 0.73, 1.40); DeLamater 2000 found no significant effect on condom use with either a face to face intervention or a video compared to a standard education control; and Downs 2004, which also included a video intervention, found no effect on condoms use (ES d=.17). The other two studies compared individual behavioural counselling with TAU in multiethnic populations (Metzler 2000, Shrier 2001). Metzler 2000 found no effect on condom use (p=.96, effect size =.00); and Shrier 2001 no effect on condom use at last sexual encounter (RR 1.10; 95% CI 0.77, 1.58), or on consistent condom use with main partner (RR 1.62; 95% CI 0.88, 2.99) or other partners (60% vs 68%; ES h= 0.21).

Very long term

Two studies measured very long term condom use and found no significant effects (Danielson 1990, Shrier 2001). Danielson 1990 (+) found no difference in condom use at last sexual intercourse (RR 0.94; 95% CI 0.74, 1.19); and Shrier 2001 (-) no difference in condom use at last sexual encounter (RR 0.88; 95% CI 0.57-1.36), or consistent condom use with both main and other partners (main RR 1.31;95% CI 0.68-2.53; other 71% vs 42%, ES h=0.71). In the latter study the control group may also have received condom information and education but this was at the doctor's discretion, was not skills based, and involved less time and sessions than in the intervention group.

General Population

Very short

Four studies measured condom use in the general population at very short term follow up (Artz 2000, Belcher 1990, Evans 2000, Oakeshott 2000).

A (2-) study (Artz 2000) that promoted the use of the female condom to a high risk, largely African American, population found a significant improvement in male or female condom use pre to post intervention (p<.001). However, this was an uncontrolled study with short term follow up only and an attrition rate of over 50%.

The other three studies found no statistically significant difference in condom use. One (+) study (Belcher 1990) compared a single session skills building intervention with a standard HIV education session for economically disadvantaged women, the majority of whom were African American. They found no significant difference at one month in condom use (data not reported). One (Evans 2000) compared an interactive computer assisted intervention (CAI) and a no intervention control for American College students and found no difference in intention to use condoms (ES d=.06). The other (Oakeshott 2000) was a UK study that evaluated the effect of condom promotion amongst women attending General Practices for a smear test found no difference in condom use (2% difference; 95% CI -1 to 6%, ES h=.04).

Short term

Four studies measured short term condom use (Belcher 1998, El-Bassel 2003, Kamb 1998, Proude 2004). Three studies found a positive significant effect. One (+) RCT that compared a skills building intervention with an education only control in adults (Belcher 1998) found a significant increase in condom use at thee months ($p<0.05$, ES d=2.26). Another (+) RCT (El-Bassel 2003) found a small but significant increase in the percentage of protected sexual acts in both the couple counselling (ES h=0.24) and a woman alone counselling intervention (ES: h=0.37) compared to a control. There was, however, no difference between couple or women alone counselling (ES: h=0.14). In one (++) RCT (Kamb 1998) both the enhanced or brief Project RESPECT counselling had a significant effect on 100% condom use compared to control (enhanced: RR 1.21; 95% CI 1.09-1.35; brief: RR 1.15; 95% CI 1.03-1.27) at three months. There was no significant difference between the enhanced and the brief counselling (RR 1.06; 95% CI 0.96-1.17). The other study, with young people (aged 18-25) in a family practice setting in Australia (Proude 2004), found no significant effect on short-term condom use (condom use on first occasion of sex with new partner 73% vs. 77%; ES: h=0.12).

Long term

Three studies measured condom use in the general population at long term follow up (James 1998, Kamb 1998, Scholes 2003). In one study the effects were mixed (Scholes 2003). They found that an individually tailored magazine style booklet and safe sex kit had a significant effect on any condom use (OR 1.57; 95% CI 1.18-2.10) and average number of times condoms were used (OR 4.8; 95% CI 1.2-10.7) compared to TAU control, but did not affect consistent condom use (RR 1.10; 95% CI 0.91-1.32). In one (++) study (Kamb 1998), where more than one intensity of

intervention was being compared, there were differences between the interventions with only one reaching statistical significance. Although the effect on condom use at six months was still significant in the enhanced four session counselling group it was no longer statistically significant for the brief two session counselling group. However, the difference between the groups was slight (enhanced RR 1.15; 95% CI 1.04-1.26; brief RR 1.15, 95% CI 1.00-1.25).

One UK based study, comparing a 20 minute individually tailored skills training counselling session and usual care, in an urban genitourinary medicine clinic (James 1998) found no significant difference in those who 'always' or 'almost always' used condoms (RR 0.99; 95% CI 0.61, 1.60) or frequency of condom use with regular partner (ES: c =0.10), or with non regular partner (ES: c= 0.09).

Very long term

Two RCTs measured condom use at 12 months or more in this population and neither found a statistically significant effect. In one (El-Bassel 2003) although an earlier follow up had found a significant effect on the percentage of protected acts, this was no longer apparent at 12 months (data not reported). In Project RESPECT (Kamb 1998) although they had found an effect for brief and enhanced counselling at short term follow up, and for enhanced counselling at long term follow up, neither were significant at 12 months (data not reported).

MSM

Short term

A US (-) study compared telephone counselling with a no treatment control for MSM (Picciano 2001) and found no between group differences in protected oral (p=0.88, ES: d=0.07) or anal sex (p=0.59, ES: d=0.02).

Long term

One study (Robert 1990) found no significant difference in those reporting safer sexual behaviour (including consistent condom use) between individual counselling, a video or a no intervention control for sexually active MSM (counselling vs. control RR 1.00, 95% CI 0.83, 1.19; video vs. control RR 0.88, 95% CI 0.70, 1.10).

Drug users

Long Term

Two studies looked at condom use in drug users at long term follow up. In one study there was a statistically significant effect on condom use. This large study (Kwiatkowski 1998) with injecting drug users compared enhanced AIDS education and counselling (1-3 sessions) with the US National Institute on Drug Abuse (NIDA) standard HIV counselling. They found that the enhanced counselling was statistically significantly better than the standard treatment control in increasing condom use (31% vs. 27%, p=0.04). However, the effect size was small (ES: h=.08) and is not likely to be clinically significant.

The other study (Sterk 2003) compared an enhanced motivation counselling intervention with an enhanced negotiation intervention and a standard treatment control for female crack users. They found no significant effect on condom use for the motivation intervention compared to control (ES: d=0) but there was a small increase in condom use with steady partners for the negotiation intervention (ES: d=0.17). As with the previous study (Kwiatkowski 1998) the control group received the NIDA standard HIV counselling intervention.

Very long term

Only one study looked at condom use in drug users over 12 months. This study, which compared face to face and telephone counselling with a no treatment control for drug users (Rotheram-Borus 2004) found a significant difference in the percentage of protected acts for the face to face group vs. control (p <.01; ES: h= 0.79). However, there were no differences between face to face and telephone (ES: h=0.02).

Prisoners

One (-) RCT compared a peer-led pre-release HIV prevention intervention with a no treatment control for prisoners (Grinstead 2001). They found a significant difference in condom use at first sexual intercourse since release (p=0.05; ES: h=0.37). However, in this study they only followed people up for 17 days and the effect size was small.

People with HIV

Only one study looked at condom use in drug users over 12 months. This study, already reported in the section above on drug users, (Rotheram-Borus 2004) found a

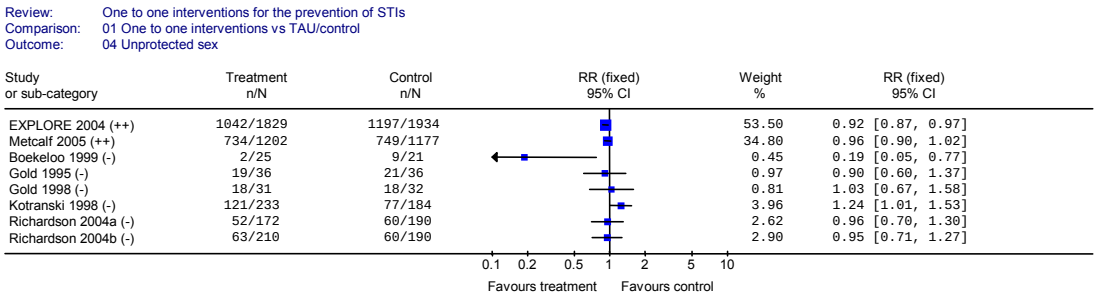
significant difference in the percentage of protected acts for the face to face counselling group vs. a no treatment control (p <.01; ES: h= 0.79).

Unprotected sex

Evidence Statement 1.5

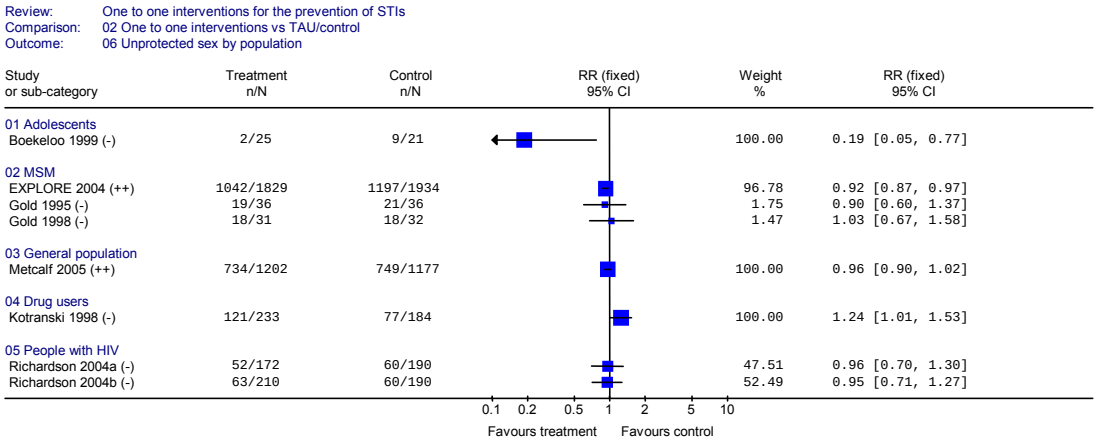
Fifteen studies reported unprotected sex. Only six studies found a statistically significant difference between intervention and control and in general the evidence is conflicting on whether or not one to one STI/HIV interventions reduce unprotected sex. However, EXPLORE a large high quality (++) US RCT found that there was a 13.9% reduction in unprotected sex at very long term follow up after a 10 session + boosters HIV prevention counselling intervention (EXPLORE 2004). At present there seems to be support for multi-session interventions but conflicting evidence on shorter interventions.

Fifteen studies, and one subgroup analysis, reported unprotected sex as an outcome measure. This included one study with adolescents, five studies with the general population, five (and one subgroup analysis) with MSM, two with drug users, and two with people with HIV. One study (Metcalf 2005) is included in two sections (general population, MSM) as they report results for the whole population and a subgroup analysis for MSM. Seven studies provided data (either from the paper or from contact with the author) that could be used in a forest plot (see figure 6). A summary of data for all studies is presented in table eight.



++ = low risk of bias, + = moderate risk of bias, - = high risk of bias

Figure 6: Effect of one to one interventions on unprotected sex (all trial arms)



++ = low risk of bias, + = moderate risk of bias, - = high risk of bias

Figure 7: Effect of one to one interventions on unprotected sex by population

Adolescents

Short term

One study with adolescents (Boekeloo 1999) found a significant reduction in unprotected sex (RR 0.19; 95% CI 0.05, 0.77).

General population

Short term

Three studies measured short term unprotected sex in the general population (Boyer 1997, El-Bassel 2003, Kalichman 2005). Two found a significant reduction in unprotected sexual acts in populations of high-risk heterosexual adults. In one (+) cognitive behavioural skills building intervention to prevent STIs (Boyer 1997) they found a significant reduction in unprotected intercourse in both the intervention and TAU counselling control ($p<0.001$), which was greater in the intervention than control group ($p<.05$; ES: c=.02). In the other (+) relationship based counselling intervention (El-Bassel 2003) they found a significant reduction in the number of unprotected sexual acts at three months. This was significant for women alone and couples compared to information only control. There was no difference between the two interventions (data not reported). The other (+) RCT (Kalichman 2005) found mixed results. They compared three theory based interventions; full information-motivation-behavioural skills model (IMB), information + motivational enhancement (IM), information + behavioural skills (IB) with an information only control. At three months the only positive significant difference was in unprotected intercourse for women in

the IM group (ES: d=0.46). Women in the full IMB group reported more unprotected intercourse than the control (ES: d=0.33).

Long term

Three studies measured unprotected sex, in studies with general populations, at long term follow up (Boyer 1997, Kalichman 2005, Metcalf 2005).

In one, (Kalichman 2005) there were significant six month differences for women in the information motivational (IM) group (ES: d=0.54) and information behavioural (IB) groups (ES: d=0.38) and men in the full-informational motivational behavioural group (IMB) (ES: d=0.29). However, at nine months it was only significant for women in the IM (ES: d=0.20) and IB groups (ES: d=0.28) (Kalichman 2005). In another (+) RCT (Boyer 1997) the significant effect on sexual intercourse without condoms, found at three months had disappeared by six months (no data reported). However, there was a significant reduction in the mean number of sexual partners without condoms ($p<0.01$). In Project RESPECT 2 (Metcalf 2005) they found no statistically significant difference in unprotected sex at nine months (RR 0.96; 95% CI 0.90-1.02).

Very long term

Project RESPECT 2 (Metcalf 2005) attempted to address the problems associated with maintaining the effect of an intervention in the long term by providing an additional booster session. However, this was not found to have a statistically significant effect on unprotected sex compared to the TAU control (data not reported).

MSM

Short term

Three studies measured unprotected sex at short term follow up. (Gold 1995, Gold 1998, Picciano 2001). Two studies by the same authors (Gold 1995, Gold 1998) compared three groups; a self-justification group, a group sent AIDS education posters and a no treatment control, for MSM in Australia. The self-justification part of the intervention involved asking participants to think about recent occasions when they had had unprotected sex and to consider how they had justified this to themselves. In one (Gold 1998) they found no significant difference in unprotected anal intercourse (self justification group RR 1.03, 95% CI 0.67, 1.58; posters RR 1.16, 95% CI 0.78, 1.74). In the other (Gold 1995) they found that there was no significant difference in unprotected anal intercourse (self justification: RR 0.90; 95%

CI 0.60, 1.37; posters: RR 1.07; 95% CI 0.73, 1.55) but a significant difference in those who had more than one incidence of unprotected anal intercourse for the self-justification group compared to control (self justification p<0.05, ES: h=0.53, posters ES h=0.02).

A US (-) study compared telephone counselling with a no treatment control for MSM (Picciano 2001) and found no differences between telephone counselling and a no treatment control in unprotected oral (p=0.19, ES: d=.07) or anal sex (p=0.60 d=0.02). However, both groups showed a significant overall reduction in unprotected oral or anal intercourse. The authors attributed the improvement in the control group to the assessment procedure, which may in itself have had an effect on behaviour.

Long term

Two studies evaluated the long term effects of an intervention on unprotected sex. In one study (Dilley 2002) (++) they compared two types of enhanced HIV test counselling and self justification exercises with standard HIV test counselling for MSM. At six months they found one of the enhanced counselling and self justification groups was significantly less likely to have unprotected anal intercourse than the control group (p = .008) but that in the other intervention group there was no significant difference from the control. In Project RESPECT 2 (Metcalf 2005) they found no statistically significant difference in unprotected sex in a subgroup analysis with MSM (RR 0.91; 95% CI 0.83-1.00).

Very long term

Three studies measured unprotected sex in MSM at 12 months and over. Two studies (Dilley 2002, EXPLORE 2004) found a significant reduction in unprotected anal intercourse in the intervention groups compared to control. One (EXPLORE 2004) reported a 13.9% reduction (95% CI 5.6, 21.5%) in unprotected anal intercourse), and the other (Dilley 2002) statistically significant reductions in all three interventions compared to the control (standard HIV counselling + diary p=.006; standard HIV counselling + self justification exercise p=0.008; standard HIV counselling, self justification + diary, p=0.047). In Project RESPECT 2 (Metcalf 2005) they found no statistically significant difference in unprotected sex in a subgroup analysis with MSM (data not reported).

Prisoners

Long term

In one study (Martin 2003) they evaluated an intervention that was focused on prisoners released on probation (PFI). This was compared with a control that was an enhanced version of the NIDA standard HIV counselling. They found no between group differences in unprotected sex (data not reported) but both groups showed a pre to post reduction in unprotected intercourse.

People with HIV

One study (Richardson 2004) evaluated different ways of providing safe sex counselling. This involved comparing counselling sessions that emphasised the benefits of protective behaviour (gain frame) with those that emphasised the negative consequences of risky behaviour (loss frame). Both were compared with a control that focused on medication adherence. The length of follow up was not specified and there was no significant difference between interventions or intervention and control (gain frame vs. control RR 0.96; 95% CI 0.70, 1.30; loss frame vs. control RR 0.95 95% CI 0.71, 1.27). The other study (Patterson 2003) measured unprotected sex in people with HIV. They compared a brief targeted intervention, a comprehensive intervention and a comprehensive + booster session intervention. They found that all groups reported less unprotected sex pre to post but that the comprehensive + boosters group reported more unprotected sex than the other groups.

Table 8: Effect on incidence of condom use/unprotected sex of one to one interventions to reduce STIs/HIV infection (Intervention/s compared to control)

Study ID	Quality score	Target Group	Condom use	Unprotected sex	Effect Very short	Effect Short	Effect Long	Effect Very long
Artz 2000	2-	Women	Always used		+ (p<.001)	+ (p<.001)		
Belcher 1990	+	Women	% condom use for vaginal sex	Unprotected sex		+: condom use (p<0.02) ES: h=0.55 0: unprotected sex (p<0.06) ES: d = 0.48		
Boyer 1997	+	Heterosexual adults		Sexual intercourse without condoms		+ (p<0.05) ES: C = 0.02	0 (data not reported)	
Boekeloo 1999	-	Adolescents	Condom use at last vaginal intercourse	Yes		+; Unprotected sex RR 0.19 (0.05, 0.77) Condom use +; OR (adjusted) 18.05 (95% CI 1.27-256.03) RR (unadjusted) 1.61 (95% CI 1.09, 2.37)	Condom use 0; OR (adjusted) 1.00 (95% CI 0.31,3.24) RR (unadjusted) 1.01 (95% CI 0.73, 1.40)	
Danielson 1990	+	Adolescents	Condom use at most recent intercourse					0: RR 0.94 (95% CI 0.74, 1.19)
DeLamater 2000	-	Adolescent males	Condom use with casual or steady partner				0; casual partner 0; steady partner	
Dilley 2002	++	High-risk MSM		Unprotected anal intercourse in last 90 days			0: Intervention A vs. control +: Intervention B vs. control (p=0.008) 0: Intervention C vs. control	+: Intervention A (p=0.006) + Intervention B (p=0.001) + Intervention C (p=0.047)
Downs 2004	+	Female adolescents	How often used condoms			0 (p=0.57); ES: d =0.07	0 (p=0.15); ES: d=0.17	
El-Bassel 2003	+	Heterosexual couples	% of protected sexual acts	Unprotected sexual acts		+ Condom use WA vs. control ES: h=0.24; C vs. control ES: h=0.24 + unprotected sex		0 condom use + unprotected sex
Evans 2000	-	College students	Condom intention with current & future partners		Current partner 0: ES: d= 0.06 Future partner 0: ES: d=0.07			

Table 8 continued: Effect on condom use/unprotected sex of one to one interventions to reduce STIs/HIV infection (Intervention/s compared to control)

Study ID	Quality score	Target Group	Condom use	Unprotected sex	Effect Very short	Effect Short	Effect Long	Effect Very long
EXPLORE 2004	++	MSM		Unprotected anal intercourse				+ OR 0.86 (95% CI 0.79, 0.94)
Gibson 1999a	-	Drug users	Condom use all & some of time			All the time 0: RR 1.10 (0.59, 2.02) Some of the time 0: RR 1.27 (0.78, 2.07)		All the time 0: RR 1.20 (0.58, 2.48) Some of the time 0: RR 0.83 (0.46, 1.51)
Gibson 1999b	-	Drug users	Condom use all & some of the time			All the time 0: RR 1.00 (0.34, 2.94) Some of the time 0: RR 1.14 (0.49, 2.66)		All the time 0: RR 2.55 (0.71, 9.14) Some of the time 0: RR 0.96 (0.37, 2.46)
Gold 1995	-	MSM		Unprotected anal intercourse		0: self justification group vs control RR 0.90 (95% CI 0.60, 1.37) 0: Standard vs. control RR 1.07 (95% CI 0.73, 1.55)		
Gold 1998	-	MSM		Unprotected anal intercourse		0: specific encounter grp vs. control RR 1.03 (0.67, 1.58) 0: posters vs. control RR 1.16 (0.78, 1.74)		
Grinstead 2001	-	Prisoners	Used condom first time had sex since release		+ p = 0.05; ES: h = .37			
James 1998	+	Adults (mostly heterosexual)	Always or almost always use condom & Frequency of condom use				Always/almost always use condom 0: RR 0.99 (95% CI 0.61, 1.60) Frequency of condom use 0 regular partner ES: c=0.10 non regular partner ES: C=0.09	
Kalichman 2005	+	Adults		Mean unprotected sex	IMB 0 men, - women IM 0 men, + women IB 0	+ women IM 0 all other groups	IMB 0 IM 0 men, + women IB 0 men, + women	
Kamb 1998	++	Heterosexual adults	100% condom use			+ Enhanced RR 1.21 (95% CI 1.09, 1.35) + Brief RR 1.15 (95% CI 1.03, 1.27)	+ Enhanced RR 1.15 (95% CI 1.04, 1.26) + Brief RR 1.15 (95% CI 1.04, 1.26)	0 (data not reported)
Kotranski 1998	-	Drug users		Unprotected vaginal sex			+: RR 1.24 (1.01, 1.53)	

Table 8 continued: Effect on condom use/unprotected sex of one to one interventions to reduce STIs/HIV infection (Intervention/s compared to control)

Study ID	Quality score	Target Group	Condom use	Unprotected sex	Effect Very short	Effect Short	Effect Long	Effect Very long
Kwiatkowski 1998	+	Drug users	Increased condom use				+ 31% vs 27% (p=0.04); ES: h-0.08	
Mansfield 1993	-	Adolescents	Always use condoms			0; RR 1.50 (95% CI 0.67, 3.38)		
Martin 2003	-	Drug using probationers		% had unprotected sex			0 (not enough data to calculate ES)	
Metcalf 2005	++	Adults		Unprotected sex			0: RR 0.96 (95% CI 0.90,1.02)	0: (data not reported)
Metzler 2000	-	Adolescents	Condom use in past 3 months			0; p=0.94; ES .00	0; p= 0.96; ES: d=0.00)	
Oakeshott	-	Women	Used condoms more since intervention		0: 8% vs 6% ES: h=.04			
Orr 1996	-	Adolescent females	Always & sometimes use condoms				Always 0: RR 0.90 (95% CI 0.29, 2.76) Sometimes +: RR 1.90 (95% CI 1.19, 3.02)	
Patterson 2003	-	HIV positive (mostly males)		Unprotected sexual acts			- comprehensive % boosters vs. other groups 0: other groups. Not enough data to calculate ES	
Picciano 2001	-	MSM	Protected anal & oral intercourse	Unprotected anal & oral intercourse		0: protected anal sex; RR 0.76; p=0.59 0: protected oral sex; RR 1.23; p=0.88 0: unprotected anal sex; White participants RR 1.38; p= 0.60 Minority participants data not available 0: unprotected oral sex; RR 0.66; p=0.19		
Proude 2004	-	Young people	Condom used at first sex with new partner			0: RR 0.95 (95% CI 0.59, 1.51)		

Table 8 continued: Effect on condom use/unprotected sex of one to one interventions to reduce STIs/HIV infection (Intervention/s compared to control)

Study ID	Quality score	Target Group	Condom use	Unprotected sex	Effect Very short	Effect Short	Effect Long	Effect Very long
Richardson 2004	-	HIV positive (over 80% males)		Unprotected anal or vaginal intercourse (follow up not specified)	0 Gain frame vs. control RR 0.96 (95% CI 0.70, 1.30) Loss frame vs. control RR 0.95 (0.71, 1.27)			
Robert 1990	-	MSM	Safer sex behaviour (included consistent condom use)				0: counselling vs. control RR 1.00 (95% CI 0.83, 1.19) 0: video vs. control RR 0.88 (95% CI 0.70, 1.10)	
Rotheram-Borus 2004*	+	Drug using HIV positive males and females	% of protected acts					+ face to face counselling vs. control p=<0.01; ES: h=.79 0 telephone vs. control
Scholes 2003	+	Young women	Consistent condom use				0: 1.10 (0.91, 1.32)	
Shrier 2001	-	Adolescents	Consistent ('always') condom use				0: main partner RR 1.62 (95% CI 0.88, 2.99) Other partner ES: h=0.21	0: main partner RR 1.31 (95% CI 0.68, 2.53) Other partner ES: h=0.71
Sterk 2003	+	Female drug users	Frequency of condom use				0 motivation vs. control ES: d= 0.0 + negotiation vs. control ES: d=0.18	

Effect score (+) = positive effect, (-) = negative effect, (0) = no effect shown

Blank columns = data not reported for this time period

* Some studies appear more than once as they cover more than one population

Number of sexual partners/initiation of intercourse

Evidence Statement 1.6

Ten studies reported number of partners, initiation of intercourse, or abstinence as an outcome. No high quality studies reported this outcome; three were graded as (+) and seven as (-). Only two studies, one (+) and one (-) found a statistically significant effect (Downs 2004, Metzler 2000) and in one the effect was not maintained after 6 months (Downs 2004). In summary there is weak evidence that one-to-one interventions for the prevention of STIs/HIV are ineffective in reducing the number of sexual partners or in promoting abstinence. However, it should be noted that the interventions included in this review appeared to be designed to promote safer sexual behaviour rather than abstinence.

Ten studies used the number of partners/abstinence as an outcome measure. This included six studies with adolescents, two with the general population, one with MSM and one with probationers. Results for the numbers of sexual partners/abstinence are detailed in the text below and are summarised in table 9

Adolescents

Short term

Of the five studies which measured number of partners/abstinence only one (+) RCT) (Downs 2004) found a reduction in sexual activity. This study, which compared a sexual health video with a pamphlet, found a significant increase in abstinence at three months (OR 2.50, p = 0.027). Three (-) RCTs found no difference in the number of partners (DeLamater 2000, Mansfield 1993, Metzler 2000) between groups. However, in one of those (DeLamater 2000), which compared a face-to-face health education session, with a video, or a standard care and education session for black adolescent males, they found a significant increase in the number of partners for both intervention and control groups combined. One (-) study (Boekeloo 1999) found a significant increase in vaginal sex in the intervention group (compared to control) (OR 2.46; 95% CI 1.04, 5.84) although there was no significant difference in vaginal, oral or anal intercourse (OR 1.55; 95% CI 0.73, 3.32).

Long term

Only one study found a significant improvement. This was (Metzler 2000) (-) where there was a significant reduction in the number of partners at six months (p=0.0001).

However, this study, involving high-risk adolescents in a US STI clinic, lost over 50% to follow up. One (-) (Boekeloo 1999) found no difference in vaginal intercourse (OR 1.64; 95% CI 0.81,3.34), or vaginal, oral or anal intercourse (OR 1.56; 95% CI 0.79,3.08), and another (+) study (Downs 2004) found no significant difference in numbers who were abstinent at six months (OR 1.45;p=0.344) although this had been significant at three months.

Very long term (12 months and over)

Only one (+) adolescent study looked at this outcome at 12 months and they found no significant difference in the numbers becoming sexually active (30% vs. 34%; ES: h=0.08) (Danielson 1990). However, the study was not designed to promote abstinence and, as the authors point out, the fact that sexual activity was not greater in the intervention group supported the argument that providing explicit sexual health education to teenagers does not encourage early initiation of intercourse.

General population

Short term

Two studies with the general population found no significant difference in number of partners. One (El-Bassel 2003) found no difference in number of partners at three months for either couple counselling (p=0.36) or women alone counselling (p=0.15), and one (Kalichman 2005) found no between group difference in number of sexual partners.

MSM

Short term

One study (Picciano 2001) found no difference between counselling and a delayed control on number of partners for MSM (RR 0.97; p=0.92).

Drug users

Long term (12-52 weeks)

One study with drug involved male and female probationers (Martin 2003) measured numbers who had multiple partners. There were no between group differences (ES: h=0.10) but both a probation focused intervention and an enhanced version of standard NIDA counselling (ESI) had a significant pre to post reduction (PFI, ES: h=0.34; ESI, ES: h=0.24)

Table 9: Effect on number of partners/abstinence of one to one interventions for the prevention of STIs/HIV infection (Intervention/s compared to control)

Study ID	Quality score	Target group	Outcome measured	Effect short	Effect Long	Effect very long
Boekeloo 1999	-	Adolescents (12-15)	Vaginal intercourse in last 3 months Vaginal, oral or anal intercourse in last 3 mths	0: Unadjusted RR 1.37 (95% CI 0.82, 2.28) -: adjusted OR 2.46 (95% CI 1.04-5.84) 0: unadjusted RR 1.04 (95% CI 0.67, 1.61); adjusted OR 1.55 (95% CI 0.73, 3.32)	0: Unadjusted RR 1.13 (95% CI 0.75, 1.72) 0: adjusted OR 1.64 (95% CI 0.81, 3.34) 0: unadjusted RR 1.16 (95% CI 0.80, 1.67); adjusted OR 1.56 (95% CI 0.79, 3.08)	
Danielson 1990	+	Adolescent males (15-18)	Became sexually active following intervention			0: 30% vs. 34%; ES: h=0.08
DeLamater 2000	-	Adolescent males (15-19)	Number of partners	0: (but increase in both groups pre to post)	0	
Downs 2004	+	Adolescent females	Abstinent (no sexual partners since baseline)	+ OR 2.50 (p=0.027)	0 OR 1.45 (p=0.344)	
El-Bassel 2003	+	High-risk heterosexual couples	Number of sexual partners	0: couple vs. control (p=0.72) 0: women alone vs. control (p=0.52)		
Kalichman 2005		High-risk adults	Number of sexual partners	0		
Mansfield 1993	-	High-risk adolescents	Average number of partners a month	0: MD 0.20 (-0.05, 0.45)		
Martin 2003	-	Drug using probationers	Had multiple partners		0: ES: h=.10	
Metzler 2000	-	High risk adolescents (15-19)	Number of partners in past 3 months	0: p=0.55; ES: .00	+: p= 0.0001; ES .11	
Picciano 2001	-	High-risk MSM	Mean number of partners	0: RR 0.97; p=0.92		

Effect score (+) = positive effect, (-) = negative effect, (0) = no effect shown

Blank columns = data not reported for this time period

Risk taking behaviour/perception of risk

Evidence Statement 1.7

Seven studies measured overall risk taking behaviour (e.g. sexual risk taking scores). One (+) study set in a UK STI clinic found a significant effect on risk perception (James 1998). The remaining six (-) RCTs did not find any significant effect on risk taking behaviour or risk perception (Baker 1994, O'Neill 1996, Deas 2000, Ashworth 1994, Proude 2004, Gibson 1999, O'Neill 1996). However, three of the studies involved HIV prevention for drug users where much of the focus was on safer injecting and drug use behaviour rather than safer sexual behaviour (Baker 1994, Gibson 1999, O'Neil 1996). In summary, there is little evidence that one to one interventions can reduce risk taking behaviour or perception of risk but the quality of studies is poor.

Seven studies used some measure of risk behaviour or perception. This included one in adolescents, three in the general population and one with drug users.

Adolescents

One study (Deas 2000) compared an HIV/AIDS educational motivation intervention for adolescents being treated for substance abuse to TAU and found no effect on total risk behaviour (p=0.840; ES: d=0.06). However, this study had a sample of only 60 of whom 17% were lost to follow up (Deas 2000).

General population

Three RCTs were in the general adult population (Ashworth 1994, James 1998, Proude 2004). Only one (+) study found a significant impact on risk. This was a UK based RCT of an individually tailored counselling session (James 1998) which found a significant impact on participants perception of risk at 18 months (RR 0.21; 95% CI 0.08-0.51). Of the others one (-) study, of nurse education or video compared to control (Ashworth 1994), found no significant effect on intention to engage in AIDS related risk taking behaviours at two months (nurse education vs. control MD 0.10; 95% CI –0.31-0.51; ES: d=0.08; video vs. control MD 0.0; 95% CI –0.42-0.42; ES: d=0.00). One (-) RCT (Proude 2004) found no difference in risk perception at three months between an individualised risk counselling group and TAU control (OR 1.3; 95% CI 0.72-2.4).

Drug users

Five RCTs looked at general sexual risk taking behaviour with drug users (Baker 1994, Deas 2000, Gibson 1999a, Gibson 1999b, O'Neill 1996)).

Two (-) studies evaluated single session educational motivational interventions for drug users (Baker 1994, Deas 2000) and looked at sexual risk behaviours. One (Baker 1994) compared a cognitive behavioural motivational intervention with a no treatment control for injecting drug uses and found no difference in an overall sexual risk score (MD 0.14; 95% CI –1.18-1.46; ES: d=0.05). The other (Deas 2000) compared an HIV/AIDS educational motivation intervention for adolescents being treated for substance abuse, compared to TAU and found no effect on total risk behaviour (p=0.840; ES: d=0.06).

Two (-) studies of HIV prevention counselling involving individualised problem solving and exploration of high risk practices (Gibson 1999a, Gibson 1999b) found no significant differences in those at sexual risk at three (RR 1.27, 95% CI 0.78, 2.07; RR 2.00, 95% CI 0.17, 23.00) or 12 months post intervention (RR 0.82, 95% CI 0.48, 1.40; RR 0.38, 95% CI 0.04, 3.83). However, in one (Gibson 1999a) both intervention and control groups showed a pre to post intervention reduction in those at sexual risk (p=0.001). Both these studies had small sample sizes and high losses to follow up. A theory based five session HIV prevention intervention for pregnant women who were injecting drug users (O'Neill 1996) also found no significant difference in overall sexual risk behaviour in the intervention compared to control group at nine months post intervention (MD 0.07; 95% CI -0.38, 0.53) although both groups had reduced risk scores pre to post.

<u>Knowledge/attitudes</u>

In summary evidence is mixed on whether one-to-one interventions can improve sexual health related knowledge.

Adolescents

Very short term

Two (-) adolescent studies measured knowledge or attitudes at very short term follow up (Di Noia 2004, Winter 1993). One (Di Noia 2004) found a significant difference in HIV/AIDS related knowledge in multiethnic adolescent females after a computer

assisted intervention compared to control, but the effect size was small (p<.001; ES d=0.12). One (Winter 1993) found no difference in condom knowledge (p=0.69; ES d=0.10) but participants in a contingency planning condition (which explored barriers and facilitators to condom use) had a significantly more positive attitude towards condoms when compared to a direct experience intervention (p=.006; ES: d=0.35) or a standard condom education control (p<.011; ES: d=39).

Long term

Two RCTs with adolescents looked at the long term effect on knowledge, neither found a statistically significant effect. One (-) study (Deas 2000) found no significant difference in HIV/AIDS knowledge (p=0.440; ES d=0.24) and one (+) study (Downs 2004) found no significant difference in STI knowledge (data not reported).

Very long term

One (+) study of a reproductive health consultation for adolescent males (Danielson 1990) found a significant difference in knowledge about preventing STIs in the intervention group compared to the control (OR 1.98 p<.001).

General population

Very short term

Three studies looked at short term effects on knowledge or attitudes in the general population (Evans 2000, Belcher 1998, Oliva 2005). Of the (+) studies one of a computer assisted instruction (Evans 2000) was significantly better than a lecture or the no intervention control at improving HIV related knowledge immediately post intervention (CAI vs. control p<0.01; ES d=0.86, CAI vs lecture p<0.01; ES f=0.72). However, the other evaluation of a single session skills building HIV intervention (Belcher 1998) found no significant difference in HIV/AIDS knowledge (ES d=0.00). However, follow up was immediately post intervention. A (-) study with a high-risk population (Oliva 2005) found a significant increase in positive attitudes towards condom use after a mobile health clinic intervention.

Short term

Two studies measured HIV related knowledge at short term follow up. A (-) RCT of nurse education or video intervention (Ashworth 1994) for low income mothers had no effect on AIDS/HIV knowledge at two months (nurse education MD 0.60 (-0.28, 1.48), video MD 0.70 (-0.13, 1.53). The other study a (+) single session skills building

HIV risk reduction intervention (Belcher 1998) had no significant effect on HIV/AIDS knowledge at three months (ES d=0.20).

Table 10: Effect on knowledge of one to one interventions for the prevention of STIs/HIV infection (intervention compared to control)

Study ID	Quality score	Target Group	Effect Very short	Effect Short	Effect Long	Effect Very long
Adolescents						
Danielson 1990	+	Adolescent males				+: knowledge about preventing STIs OR 1.98 (p<0.001) +: Knowledge about AIDS OR 1.28 (p<0.05)
Deas 2000	-	Adolescent substance abusers			0: HIV/AIDs knowledge p=0.440; ES: d=0.24	
Downs 2004	+	Adolescent females			0: STI knowledge (data not reported)	
Winter 1993	-	Adolescents	0: condom knowledge p=0.69			
General population						
Ashworth 1994	-	Low income mothers		0: AIDS/HIV knowledge ES: d=0.20		
Belcher 1998	-	Low income females	0: HIV/AIDS knowledge ES: d=0.00	0: HIV/AIDS knowledge ES: d =0.20		
Evans	+	College students	+: knowledge p<0.01; ES: d=0.86			
Oliva 2005	-	Low income adults	+: attitudes towards condoms			

Effect score (+) = positive effect, (-) = negative effect, (0) = no effect shown

Blank columns = data not reported for this time period

Table 11: Summary presentation of findings for vulnerable populations

Adolescents

Prevention of STI/HIV Adolescents					
Study defined by author/s date	**Definition of one to one intervention**	**Intermediate outcomes**	**Long term outcomes**	**Quality grading**	**Comment (evidence statement)**
Boekeloo 1999 (Addresses both research questions – prevention of STIs and under 18 conceptions)	Skills based safe sex education (theory based) (STI)	Sexual intercourse - Condom use + Treated for an STI 0	Sexual intercourse 0 Condom use 0 Treated for an STI 0	-	Evidence that skills based safe sex education has no long term effect on sexual intercourse, condom use, or treatment for STI, although impact on sexual activity and condom use is short lived
Bolu 2004 (subgroup analysis of Kamb 1998)	Interactive enhanced counselling including behavioural goal setting (theory based)		STI +	++	Evidence that enhanced counselling or brief counselling is effective in preventing STIs, although enhanced counselling is not more effective than brief counselling.
Danielson 1990 (addresses both research questions – prevention of STIs and under 18 conceptions)	Safe sex counselling/education	Not reported	Sexual activity 0 Condom use 0 Knowledge about preventing STIs + Knowledge about AIDS +	+	Evidence that reproductive health consultation has no effect on sexual activity or condom use in men. There is evidence of a positive effect on knowledge about preventing STI and AIDS at 12 months
Deas 2000	HIV/AIDS educational motivation	Knowledge on HIV/AIDS 0 Total risky behaviour 0 (sexual and drug related)		-	Evidence that HIV/AIDS educational motivation counselling has no effect on knowledge or preventing sexual and drug related risky behaviours
DeLamater 2000	Safe sex counselling/education	Condom use with casual partner 0 Condom use with steady partner 0 No of partners 0		-	Evidence that health educator has no effect on sexual risk behaviour (condom use or no of partners) among black adolescent males.

Table 11: Summary presentation of findings continued

Prevention of STI/HIV Adolescents					
Study defined by author/s date	**Definition of one to one intervention**	**Intermediate outcomes**	**Long term outcomes**	**Quality grading**	**Comment (evidence statement)**
Di Noia 2004	Computer mediated skills based education on HIV	2 weeks outcomes HIV/AIDS related knowledge + Self-efficacy for HIV risk reduction +		-	Evidence of a small effect on knowledge and little effect on self-efficacy in this study with very short follow-up and low quality
Downs 2004	Skills based safe sex counselling/education (theory based)	STI acquisition + Condom use 0 STI knowledge 0 Abstinent 3 months +, 6 months 0		+	Evidence of no effect in females on condom use or abstinence at 6months although some effect on abstinence at 3 months and on STI acquisition at 6months. There is insufficient evidence on STI acquisition.
Mansfield 1993	HIV testing & counselling, safe sex counselling/education and condom advice	Always use condoms 0 Average number of partners a month 0		-	Evidence of no effect of intervention on consistent use of condoms and very small effect on number of partners
Metzler 2000	Skills based safe sex education (theory based)	New self reported STIs 0 Condom use 0 No of partners in last 3 months +		-	Evidence of some effect in the number of partners, more in men compared with women but no effect in new STIs or condom use
Orr 1996	Skills based safe sex education and condom advice (theory based)	Reinfection rates 0 Frequency of condom use +		-	Evidence that the behavioural intervention is effective in increasing condom use in high risk females but no effect on reinfection rates

Table 11: Summary presentation of findings continued

Prevention of STI/HIV Adolescents					
Study defined by author/s date	**Definition of one to one intervention**	**Intermediate outcomes**	**Long term outcomes**	**Quality grading**	**Comment (evidence statement)**
Shrier 2001	Skills based safe sex education and condom advice (theory based)	Recurrent STI Not reported Condom use 0	Recurrent STI 0 Condom use 0	-	Evidence that the behavioural intervention is ineffective in preventing recurrent STIs or condom use in females
Winter 1993	Skills based safe sex education and condom advice (theory based)	Mean no of condoms + Attitude towards condoms + Condom knowledge 0		-	Evidence that the intervention is moderately effective in increase of condoms with some effect on positive attitudes and no effect on knowledge.

MSM

STIs MSM					
Study defined by author/s date	**Definition of one to one intervention**	**Intermediate outcomes**	**Long term outcomes**	**Quality grading**	**Comment (evidence statement)**
Dilley 2002	Enhanced HIV test counselling	Unprotected anal intercourse: 0 for intervention one; + for intervention two	Unprotected anal intercourse: +	++	Evidence that a single session counselling intervention can reduce unprotected anal intercourse in MSM.
EXPLORE 2004	Enhanced 10 session HIV prevention counselling		HIV infection: 0 Unprotected anal intercourse: +	++	Evidence that 10 session HIV prevention counselling can reduce unprotected anal intercourse and may reduce HIV infections in MSM.
Gold 1995	Safer sex promotion intervention (including use of self-justification exercises)	At least one incidence of unprotected anal intercourse: 0 More than one incidence of unprotected anal intercourse +		-	Weak evidence that a safer sex intervention focusing on self-justification reduced unprotected sex but this was only in those who had more than one incidence of unprotected anal sex in MSM.

Table 11 continued: Summary presentation of findings

Prevention of STI/HIV MSM					
Study defined by author/s date	**Definition of one to one intervention**	**Intermediate outcomes**	**Long term outcomes**	**Quality grading**	**Comment (evidence statement)**
Gold 1998	Safer sex promotion intervention (including use of self-justification exercises)	At least one incidence of unprotected anal intercourse: 0 More than one incidence of unprotected anal intercourse: 0		-	No evidence that an intervention using self-justification exercises can reduce unprotected sex in MSM
Picciano 2001	Telephone based safer sex counselling	Unprotected sex: 0 Mean number of partners: 0		-	No evidence that a telephone counselling intervention is effective in reducing unprotected sex or number of partners in MSM
Robert 1990	AIDS education intervention Compares, face to face counselling, video and control.	Condom use: 0 Safer sexual behaviour: 0 (overall measure)		-	No evidence that face to face counselling was better than a video or that either was better than control in increasing condom use.

Drug Users

STIs Drug users					
Study defined by author/s date	**Definition of one to one intervention**	**Intermediate outcomes**	**Long term outcomes**	**Quality grading**	**Comment (evidence statement)**
Bolu 2004 (subgroup analysis of Kamb 1998)	Enhanced and brief interactive STI/HIV counselling		STI (enhanced 0; brief +)	++	Evidence that a brief counselling intervention may prevent STIs in a subgroup analysis of drug users.
Baker 1994	Brief cognitive behavioural counselling intervention (based on motivational interviewing)	Sexual risk (overall score for past month) 0		-	No evidence that a single session behavioural intervention reduced sexual risk behaviours.
Deas 2000	Brief educational motivational intervention	Risky behaviour: 0 (included sexual and drug related behaviours) HIV/AIDS knowledge: 0		-	No evidence that a single session behavioural intervention reduced sexual risk behaviours in adolescents.

Table 11 continued: Summary presentation of findings

Prevention of STI/HIV Drug users					
Study defined by author/s date	**Definition of one to one intervention**	**Intermediate outcomes**	**Long term outcomes**	**Quality grading**	**Comment (evidence statement)**
Gibson 1999a	Counselling with individualised problem solving and exploration of high risk practices	Condom use: 0 Number of sexual partners: 0 Sexual risk : 0	Condom use: 0 Number of sexual partners: 0 Sexual risk: 0	-	There is no evidence that an individualised counselling intervention was more effective than educational brochures but both groups showed a pre to post improvement on a number of measures.
Gibson 1999b	Pre and post test HIV counselling with individualised problem solving and exploration of high risk practices	Condom use: 0 Number of sexual partners: 0 Sexual risk: 0	Condom use: 0 Number of sexual partners: 0 Sexual risk: 0	-	There is no evidence that brief counselling with HIV testing reduces HIV risk behaviour. However, the study was small with high loss to follow up.
Kotranski 1998	Individual level HIV risk reduction counselling		Unsafe vaginal sex: 0 Number of sexual partners: 0	-	There is no evidence that an HIV risk reduction counselling intervention reduces HIV risk taking behaviours in drug users.
Kwiatkowski 1999	Personalised AIDS education and condom promotion	Condom use: +		+	Evidence of small statistically significant increase in condom use (due to large sample) but intervention unlikely to be clinically significant.
Martin 2003	Cognitive behavioural skills based HIV prevention pre and post test counselling intervention for drug using probationers	Had some unprotected sex: 0 Mean number of partners: 0		-	There is no evidence that a probationer focused behavioural intervention is any better than an enhanced version of the NIDA HIV counselling. There was evidence that men in both groups showed a pre to post counselling reduction in unprotected sex and number of partners. Effects were less clear for women.
O'Neill 1996	Cognitive behavioural HIV prevention counselling for pregnant drug users		Sexual risk: 0	-	There is no evidence that a five session HIV prevention counselling intervention reduces sexual risk in comparison to a usual HIV counselling control.

Table 11 continued: Summary presentation of findings

Prevention of STI/HIV Drug users					
Study defined by author/s date	**Definition of one to one intervention**	**Intermediate outcomes**	**Long term outcomes**	**Quality grading**	**Comment (evidence statement)**
Rotheram-Borus 2004	Face to face or telephone HIV prevention counselling to reduce risky sexual behaviour in drug users with HIV		Percentage of protected acts	+	There is evidence that an 18 session face to face or telephone counselling intervention may increase condom use in drug users with HIV compared to a no treatment control.
Sterk 2003	Culturally specific HIV counselling for female crack cocaine users	Condom use with regular partner (motivation intervention 0, negotiation +) Number of paying partners (motivation intervention 0, negotiation +)		+	Evidence that an intervention focusing on the development of negotiation skills had some effect: increasing condom use, and reducing the number of paying partners. A motivational intervention did not have a significant effect on either outcome.

Prisoners

STIs Prisoners					
Study defined by author/s date	**Definition of one to one intervention**	**Intermediate outcomes**	**Long term outcomes**	**Quality grading**	**Comment (evidence statement)**
Grinstead 2001	Peer-led pre-release HIV prevention intervention for male prisoners	Used a condom first time had sex since prison release: +		-	There is evidence that a peer-led intervention for prisoners had an effect on very short term condom use.
Martin 2003	Cognitive behavioural skills based HIV prevention pre and post test counselling intervention for drug using probationers	Had some unprotected sex: 0 Mean number of partners: 0		-	No evidence that a probationer focused behavioural intervention is any better than an enhanced version of the NIDA HIV counselling. Evidence that men in both groups showed a pre to post counselling reduction in unprotected sex and number of partners. Effects less clear for women.

Table 11 continued: Summary presentation of findings

People with HIV

STIs People with HIV					
Study defined by author/s date	**Definition of one to one intervention**	**Intermediate outcomes**	**Long term outcomes**	**Quality grading**	**Comment (evidence statement)**
Patterson 2003	Behavioural counselling interventions to promote safer sex in people with HIV		Unprotected sex	-	No evidence that a single session comprehensive intervention with booster sessions was better than a comprehensive intervention or a brief intervention without boosters in reducing unprotected sex.
Richardson 2004	Brief safer sex skills building counselling for people with HIV (emphasised gain frame or loss frame messages)	Follow up not specified Unprotected intercourse (0 people with one partner at baseline, + people with more than one partner at baseline)		-	There is some evidence that a brief message emphasizing the negative effects of risky behaviour may have had an effect in people who had two or more partners at baseline. However, there was no significant effect on the overall sample.
Rotheram-Borus 2004	Face to face or telephone HIV prevention counselling to reduce risky sexual behaviour in drug users with HIV		Percentage of protected acts	+	There is evidence that an 18 session face to face or telephone counselling intervention may increase condom use in drug users with HIV compared to a no treatment control.

Intermediate = up to and including 6 months, Long term = over 6 months
Effect (+) = positive effect, (-) = negative effect, (0) = no statistically significant effect; NIDA = US National Institute of Drug Abuse

6.2 OTHER RESEARCH QUESTIONS

6.2.1 How does the content of the intervention (what?) influence effectiveness?

Evidence statement 1.8

Nineteen studies compared a theory based/ skills training intervention with a more didactic control. Of those ten measured STIs (Boekeloo 1999, Boyer 1997, El-Bassel 2003, Kalichman 2005, Kamb 1998, Maher 2003, Metzler 2000, Orr 1996, Scholes 2003, Shrier 2001). In general the effects on STIs were mixed. However, Project RESPECT (Kamb 1998) a large (++) US study found that two and four session theory based interventions are more likely to be effective than a didactic control. These interventions were, however, both longer than the control. Further large scale evaluations of theory based interventions are needed to establish which components of interventions are the most effective. Qualitative studies supported the idea of skills based interventions and found participants wanted practical and psychological strategies to increase self-efficacy for contraception and condom and safe sex negotiation (Choi 2004, Seal 2005).

Changing behaviour is a complex process that can not be directly correlated to educating or informing people. The importance of using skills based, tailored interventions based on theoretical models has already been documented (Ellis 2004). Many studies tried to address this issue by evaluated theory based or skills training interventions. These interventions included components such as role-playing, condom demonstration, the use of motivational techniques and the development of social and negotiation skills. They addressed issues around self-efficacy, self-esteem, attitudes and norms.

Twenty-seven studies used some form of theoretical model or practice to inform the development or delivery of the intervention. The most quoted models were the social cognitive/learning theory, which was used in eight studies (Evans 2000, James 1998, Kamb 1998, Boekeloo 1999, Patterson 2003, Stark 2003, Metzler 2000, Shrier 2001) and a motivational-behavioural approach that was used in seven studies (Kalichman 2005, Picciano 2001, Baker 1994, Metzler 2000, O'Neill 1996, Shrier 2001, Belcher 1998). Nineteen studies compared a theory based/ skills training intervention with a didactic information/education control (Boekeloo 1999, Belcher 1998, Boyer 1997, Deas 2000, El-Bassel 2003, James 1998, Kalichman 2005, Kamb 1998, Kwiatkowski

1998, Maher 2003, Martin 2003, Metzler 2000, Oliva 2005, Orr 1996, Robert 1990, Scholes 2003, Shrier 2001, Sterk 2003, Winter 1993). See table 18, appendix five for details of studies that compare a theory/model based intervention with a didactic control.

Of those studies that compared a theory based/skills training intervention with a more didactic information/education control ten measured the incidence of STIs. Of those only one study, (++) Project RESPECT (Kamb 1998), found a significant difference, with both the enhanced and brief interventions being significantly better than the control group. However, this was the only study that reported being powered to detect differences in STI acquisition. Seven studies provided data that could be presented in a forest plot (figure 8).

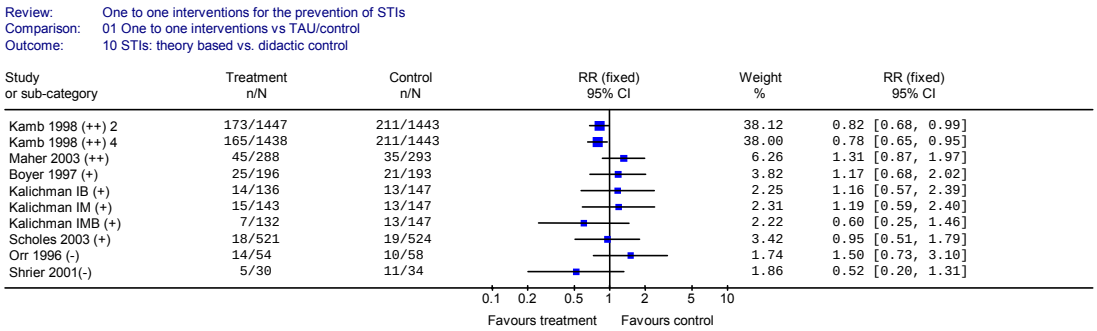


Figure 8: Theory based intervention vs. didactic control effect on STIs (all study arms)

Sixteen studies comparing a theory based intervention with a more didactic control measured the effect on condom use. Effects were mixed. Four (-) studies found no significant effect on condom use. Five, out of six, studies found an increase in condom use in the short term (++) (Kamb 1998), (+) (Belcher 1998, Boyer 1997, El-Bassel (-) (Boekeloo 1999) and three, out of nine, in the long term (++) (Kamb 1998) (+) (Kwiatkowski 1998), (-) (Orr 1996). One (+) study (Sterk 2003) found that a negotiation intervention was significantly better than the control but that the motivation intervention was not.

Interpreting the effect of theory based/skills training interventions is complicated by the fact that in most of these studies the intervention is not only different in content but also in duration and/or intensity. In addition, although the evidence is not robust, there seems to be some indication that raising people's awareness of risk, even if that merely entails detailed assessments and follow up, without an intervention, can

have an impact on sexual risk behaviour. Several studies found a pre to post improvement for all groups combined, although there were not necessarily between group differences (e.g. Boyer 1997, DeLamater 2000, Martin 2003, Picciano 2001, Robert 1990).

The idea of skills based programmes is supported by the qualitative studies. They found that women did not like consultations that focused on risk or made them feel as though they were being 'told off'. This made them reluctant to access services in the future (Free 2005). Indeed, in general the qualitative studies found that participants did not identify a need for education about health risks, but rather wanted practical and psychological strategies to increase self-efficacy for contraception, and condom and safe sex negotiation. Interventions needed to address issues around intimacy, dating and sexual negotiation (Choi 2004, Seal 2005).

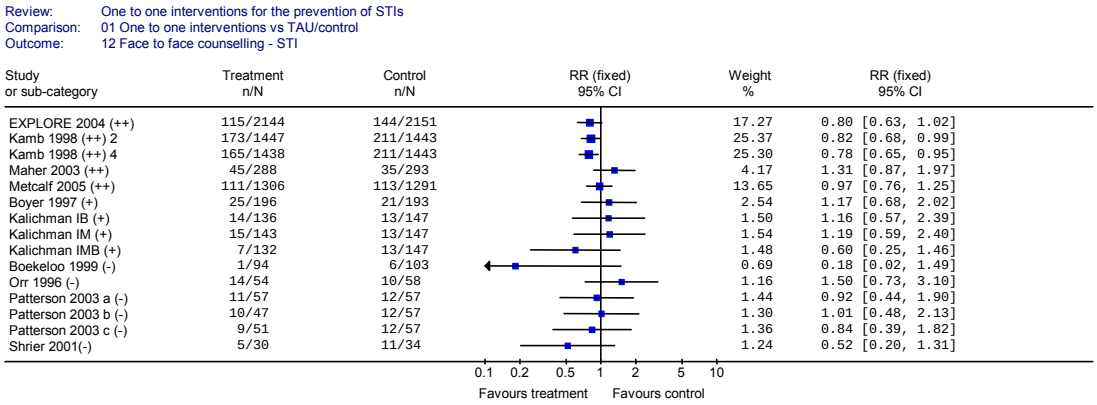
6.2.2 Does the way that the intervention is carried out e.g. Type/mode of communication, influence effectiveness?

Evidence statement 1.9

There was a range of types of one to one communication used. The majority of studies evaluated face to face communication between a health care professional, trained counsellor, or health educator and an individual client. Other types of communication evaluated in a few studies included computer assisted interventions, leaflets, personal diaries, and video. Three poor quality studies (-) compared a face to face intervention with a video intervention and found no statistically significant differences (Ashworth 1994, DeLamater 2000, Robert 1990), and one (+) study found no difference between face to face and telephone counselling (Rotheram-Borus 2004). Therefore, there is insufficient evidence to say whether or not face-to-face delivery is superior to other methods of delivery such as telephone, computer assisted or video based interventions. However, the majority of effective interventions involved face-to-face communication.

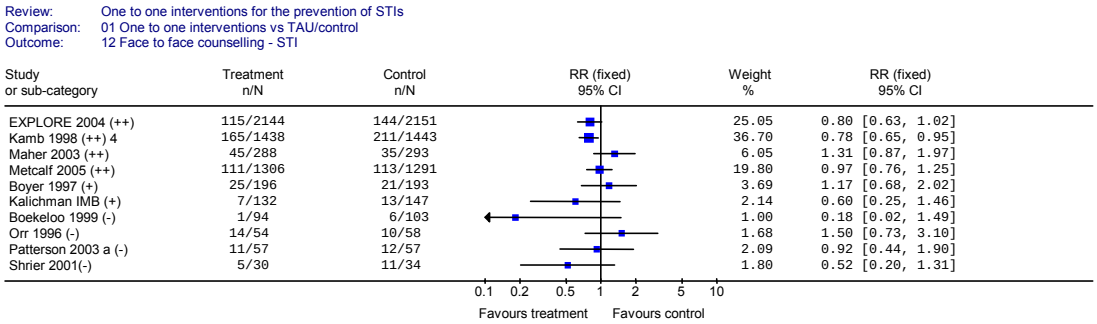
There was a range of included interventions. Two studies looked at computer assisted interventions (Evans 2000, DiNoia 2004), one leaflets and written material (Scholes 2003) and two diaries and posters for MSM (Gold 1995, Gold 1998). Several studies used a video intervention either as the main intervention (Downs 2004) or compared to face to face (DeLamater 2000, Robert 1990, Ashworth 1994), and two used telephone counselling, which was compared to a no treatment control

(Picciano 2001) or to face to face (Rotheram-Borus 2004). However, the majority of studies included in the review evaluated some form of face-to-face intervention. Ten studies evaluating face to face interventions provided data on STIs that could be presented in a forest plot (figures 9 & 10)



++ = low risk of bias, + = moderate risk of bias, - = high risk of bias

Figure 9: Studies with face to face counselling – effect on STIs (all study arms)



++ = low risk of bias, + = moderate risk of bias, - = high risk of bias

Figure 10: Studies with face to face counseling – effect on STIs (main study arm only)

Most studies focused on one mode of delivery only; however, nine studies compared one type of communication with another. These included:

Face to face vs. Video

Three (-) studies compared a face to face vs. video intervention (Ashworth 1994, DeLamater 2000 Robert 1990). None found any significant between group differences.

Video vs. a booklet

A (+) study of an hour-long interactive video (Downs 2004) compared to a booklet found that there was a significant reduction in STIs and an increase in knowledge at six months in the video group.

Computer assisted instruction vs. lecture

One study (-) comparing interactive computer assisted instruction (CAI) vs. a lecture found a significant difference in knowledge (Evans 2000) in the CAI group. However, assessments were immediately post intervention so there is no way of knowing if the effect was lasting.

Couple counselling vs. counselling women alone

One (+) study (El-Bassel 2003) compared couple counselling with counselling women alone for the promotion of safe sex behaviour in high-risk heterosexual couples. They found that although both groups were significantly better than a brief information control there were no significant differences between counselling couples or women alone.

Face to face vs. telephone counselling

One (+) study (Rotheram-Borus 2004) compared face to face and telephone counselling. They found no significant difference between face to face and telephone counselling. However, face to face counselling was significantly better than a no treatment control group. However, this was a relatively small study where many participants were not engaged in risk behaviours at baseline making an effect harder to detect.

Self-justification exercises vs. posters

Two (-) studies by the same authors, (Gold 1995, Gold 1998) evaluated an exercise where MSM were asked to think about recent incidents of unsafe sex and what their self-justification process had been. This was compared to a group who were mailed safe sex education posters. There were no significant differences between the groups.

6.2.3 Does the effectiveness depend on the job title/position or other factors such as age, gender, sexuality, ethnicity, of the deliverer (leader)? What are the significant features of an effective deliverer (leader)?

Evidence statement 1.10

Evidence from Project RESPECT a large (++) US study, which found a decrease in STIs and an increase in safe sexual behaviour, suggests that clinic staff do not need extensive experience of counselling to deliver a one to one counselling intervention, but that enthusiasm and motivation are key (Kamb 1998). In a large HIV prevention trial, which reduced HIV and unsafe sex, counsellors had 40 hours of training. Both of these studies highlight the importance of training and quality control (Kamb 1998, EXPLORE 2004). Although qualitative studies reported the importance of peers we found only one evaluation of a one to one peer led intervention. Further research is needed to evaluate different types of leaders for one to one interventions, in particular evaluating the effect of peer-led programmes.

For the majority of face-to-face counselling interventions the provider was a health care professional of some sort (e.g. doctor, nurse, clinic health care worker) or a trained counsellor/health educator. In one study (Grinstead 2001) the intervention was delivered by a peer counsellor (an HIV +ve prison inmate) and in one some of the project workers were former drug addicts or sex workers (Oliva 2005). Many interventions also had providers from the same ethnic background as the majority of participants (e.g. Ashworth 1994, Belcher 1998, DeLamater 2000).

In the Project RESPECT study (Kamb 1998) the intervention was provided by health department staff members, most of who did not have advanced degrees or lots of experience in interactive counselling. The authors suggest that motivation and enthusiasm were the most important characteristics of those delivering the intervention. In the EXPLORE (++) study counsellors had 40 hours of training. Both studies highlight the importance of quality control to ensure the intervention is delivered correctly; for example through recording and assessing sessions. Another study (Begley 2002) identified staff training and motivation as key areas for improvement.

From the qualitative studies it emerged that peers and female friends were important sources of support and discussion about sexual health, and that peer delivered

interventions may be preferred (Salyers 2005, Dorfman 1992, French 2000). However, we found only one quantitative study that evaluated a peer delivered one to one intervention. Other peer-education interventions we found were excluded because it was not clear that the intervention had been delivered in a one to one fashion (e.g. peer education for gay men in gyms or bars). More research is needed to evaluate the effectiveness of peer delivered one-to-one interventions. Where interventions are delivered by trained health care professionals/providers a non-judgemental approach was considered by participants to be very important (Free 2005).

6.2.4 Setting (where?). Does the site/setting of delivery of the intervention influence effectiveness?

Evidence Statement 1.11

The majority of interventions were delivered in a clinic setting of some sort, for example STI/GUM clinics, family planning clinics, primary care clinics and HIV clinics. None of the studies compared one setting with another so there is insufficient evidence to say whether the site/setting of delivery of one to one interventions influences effectiveness. However, the authors of Project RESPECT, a (++) trial which showed a counselling intervention to be effective in reducing STIs and increasing condom use, suggest that STI clinics may be appropriate places to deliver interventions as it is possible those seeking treatment for a STI may be particularly amenable to behaviour change (Kamb 1998).

Many of the interventions were delivered in clinics of some sort. This included: STI/GUM clinics (Artz 2000, Boyer 1997, Maher 2003, Kalichman 2005, James 1998, Metzler 2000), hospital clinics (Mansfield 1993, El-Bassel 2003, Shrier 2001), family planning clinics (Orr 1996, Winter 1993), primary care clinics (Boekeloo 1999, Kamb 1998, Metcalf 2005, Oakeshott 2000, Proude 2004), HIV clinics (Dilley 2002, Richardson 2004) and a mobile health clinic (Oliva 2005).

Other locations included: Research project related offices (Ashworth 1994, Evans 2000, Patterson 2003, Stark 2003), health care sites (Downs 2004, Danielson 1990, Kwiatkowski 1999), psychiatric in-patient unit (Deas 2000) and prison (Grinstead 2001).

In two studies the setting was not clear (EXPLORE 2004, Martin 2003), and the rest were community based (DeLamater 2000, Scholes 2003, Gold 1995, Gold 1998, Robert 1990, Rotheram-Borus 2004, Baker 1994, Oliva 2005, Belcher 1998, DiNoia 2004, Picciano 2001).

None of the studies compared one site/setting with another and so it is difficult to make judgements about their relative effectiveness. Many of the interventions were delivered to high-risk groups, for example those who had had a previous STI, or were currently attending for STI treatment. STI/GUM clinics may be appropriate places to deliver interventions as it is possible that those individuals who seek STI testing and treatment may be particularly amenable to behaviour change (Kamb 1998). We found no one to one school based interventions to reduce STIs in adolescents. Interventions in school appeared to be group based or, if they did contain a one to one component it was embedded within a group based intervention.

Only two of the included studies were conducted in the UK. One (+) study based in GUM clinic in Nottingham (James 1998) and one (-) study in a general practice setting in London. The majority of studies were based in the USA where different health care systems may make generalisation to the UK difficult.

6.2.5 Does the intensity (or length) of the intervention influence effectiveness/duration of effect?

Evidence Statement 1.12

Evidence is mixed on whether the intensity or length of one to one interventions for the prevention of STIs influences effectiveness. A (++) 10 session HIV prevention intervention for MSM found a significant reduction in unprotected sex and a reduction in HIV (EXPLORE 2004). However, longer interventions may not necessarily be better than shorter ones. A (++) study (Kamb 1998) found that both a brief two session and an enhanced four session intervention were effective in reducing STIs and increasing condom use, although the four session intervention was marginally more effective than the two session intervention. Two studies evaluated the addition of booster sessions to an intervention. Both, Project RESPECT 2 a (++) study (Metcalf 2005) and a (-) study (Patterson 2003), found no evidence that a counselling intervention with additional booster sessions was more effective, in reducing STIs, than a counselling intervention without booster sessions.

The majority of studies involved a single session, six involved between 1-3 sessions (Maher 2003, Scholes 2003, Picciano 2001, Kotranski 1998, Kwiatkowski 1999, Martin 2003), seven 3-6 sessions (El-Bassel 2003, Kamb 1998, O'Neill 1996, Stark 2003, Metzler 2000, Shrier 2001, Boyer 1997) and two more than six sessions (EXPLORE 2004, Rotheram-Borus 2004). Many studies had time-matched comparisons. However, a number of studies compared different numbers of sessions. These were: Boyer 1997, Downs 2004, El-Bassel 2003, EXPLORE 2004, Kamb 1998, Kwiatkowski 1999, Maher 2003, Metzler 2000, Patterson 2003, Picciano 2001, Scholes 20003, Shrier 2001, Stark 2003. See table 19, appendix five for details of studies comparing different durations and intensities of interventions.

It is not easy to make judgements about the effect of the intensity or duration of the intervention. In many cases not only was the intensity and duration of the intervention different but the content also. However, looking at data from some of the (++) studies a longer intervention was not necessarily better. For example in the Project RESPECT study (Kamb 1998) both the brief two session intervention and the enhanced four session intervention were effective in reducing new STIs in comparison with the control. However, the effect decreased over time. In Project RESPECT- 2 (Metcalf 2005) they attempted to address the problem, identified by the earlier Project RESPECT study (Kamb 1998), of maintaining the effect of an intervention in the long term. They evaluated the addition of a booster session six months after the original intervention, but found it made no statistically significant difference to STI acquisition or incidence of unprotected sex compared to the two session Project RESPECT counselling. In a (-) study (Patterson 2003) participants in the intervention that included booster sessions were more likely to have unprotected sex than participants in the groups without booster sessions. However, in the (++) Project EXPLORE study they did find a longer more intensive intervention more effective in reducing unprotected anal intercourse and HIV acquisition for MSM. They compared a 10 session (+ boosters) intervention with the two session Project RESPECT model.

The dilemma for decision makers is balancing the effectiveness of an intervention against applicability and cost. For example a UK based (-) study (Oakeshott) was designed to be brief, cheap and pragmatic so that it could be included in routine GP or nurse consultations. However, this intervention was not shown to be effective in increasing condom use. In one study (Begley 2002) the authors note that a one

contact intervention made establishing rapport, commitment and trust difficult. However, this study was excluded because it did not meet our inclusion criteria and the quality was poor. On the other hand the two session Project RESPECT intervention was found to be effective (Kamb 1998), reducing STIs at six and twelve months and increasing condom use at six months.

6.2.6 Does the effectiveness vary with age, gender, sexuality, socio-economic status, ethnicity?

In the scope for the review a number of populations at high risk for STIs were identified. These were: MSM, some young men and women, some black and minority ethnic groups, people who are living with HIV, people in prisons and youth offending institutions, young people in or leaving care, commercial sex workers, refugee, asylum seekers and migrants. In addition we identified drug users as a high risk group for STI/HIV. Where we have identified evaluations of interventions in these groups they are reported in the main results section and summarised briefly below (adolescents, MSM, black and minority ethnic groups, prisoners, sex workers, and drug users). However, we found no evaluations that specified populations of young people in or leaving care, or refugees, asylum seekers and migrants.

Age

Evidence Statement 1.13

A subgroup analysis of Project RESPECT (Bolu 2004) found a significant reduction in sexually transmitted infections in adolescents with both the four and two session interventions versus a didactic control. The intervention was more effective with adolescents than with other age groups. Although this was the only study with adolescents to show a statistically significant difference the general trend in this group of studies was towards a reduction in STIs.

Twelve studies evaluated one to one interventions that were addressed specifically at adolescents.

We found six studies that evaluated the effect on STIs (no studies measured HIV). Of those, two found a reduction in STIs (Bolu 2004, Downs 2004). One comparing an interactive video to a booklet control (Downs 2004); and Project RESPECT (Bolu 2004) that compared enhanced and brief counselling with a TAU control. In one (Bolu 2004) 9.4 STIs were prevented for every 100 people treated.

Overall nine studies looked at the effect of one to one interventions on the use of condoms or unprotected sex. Only two studies (Boekeloo 1999, Bolu 2004) found a statistically significant effect on condom use. In one this was at 12 months post intervention (Bolu 2004). In the other (Boekeloo 1999) the effect was significant at three month follow up but not by nine months. In summary there is insufficient evidence to say whether or not one to one interventions can increase condom use in adolescents.

Six studies with adolescent populations looked at the number of partners/abstinence as an outcome. Only one found a decrease in number of partners (Downs 2004). This was at short term follow up only, by nine months the effect was no longer significant. One study found an increase in vaginal sex in the intervention group (Boekeloo 1999) and one an increase in the number of partners for both groups pre to post intervention (DeLamater 2000). In summary there is little evidence that one to one interventions reduce the number of sexual partners of adolescents or promote abstinence. However, it should be noted that the interventions appeared to be designed to promote safe sexual behaviour rather than abstinence.

One (++) study (Kamb 1998) found that the STI counselling prevention intervention was particularly effective in the subgroup of adolescents compared to the study population as a whole (Bolu 2004). Another study found that the effects of the intervention were stronger among those not sexually active at baseline (Danielson 1990). Therefore, it may be better to intervene early before adolescents become sexually active. However, another study (Project EXPLORE 2004) found younger MSM harder to recruit and retain in the intervention than older men.

Gender

There was insufficient evidence to say whether the effectiveness of one to one interventions for preventing STIs varies by gender**.**

Of those studies including men and women five studies reported results for men and women separately (Kamb 1998, Kalichman 2005, Metcalf 2005, Metzler 2000, Martin 2003). Overall the effects of interventions on different genders were mixed. In Project RESPECT (Kamb 1998) they found that the counselling intervention was effective for both men and women. However, in Project RESPECT 2, which included booster sessions, they found no significant effect for either men or women (Metcalf

2005). Metzler 2000 found a significant difference in the number of sexual partners for men but not for women. In one study of three different risk-reduction counselling models compared to a control (Kalichman 2005) there was a mixed effect with one model being more effective for men (full information-motivation-behavioural skills model) and the other models being more effective for women (motivational enhancement and behavioural skills). For STIs this study showed a reduction in men but not women. The authors were unable to account for the differences in intervention effects in men and women and suggest that further research is needed to identify the most and least effective elements of HIV risk-reduction counselling for women.

One qualitative study, which looked at the issue of dual contraceptive protection (Salyers 2005), found that the promotion of dual protection was particularly important for women living in material and social deprivation. However, dual protection was generally perceived as a backup method for pregnancy prevention rather than to prevent STIs. A qualitative study of female condom use (Choi 2004) found that relationship power dynamics affected condom use. Women found it useful to have multiple methods of introducing and negotiating condom use available to them. This was reflected in a number of the quantitative studies where interventions included condom negotiation and role-playing of strategies to introduce condoms to sexual partners.

Ethnicity

Evidence Statement 1.14

In 15 studies all or the majority of participants were black, and in the majority of the rest the populations were multiethnic. One important exception is a (++) HIV prevention study which found a 10 session counselling intervention reduced HIV and unsafe sex in MSM (EXPLORE 2004). The majority of participants in this study were white and they reported difficulty in recruiting and retaining black and Hispanic participants. In subgroup analyses of Project RESPECT (Bolu 2004) they found that a four session intervention was more effective than a two session intervention for white participants but that conversly the two session intervention was more effective than the four session intervention for black participants.

In 15 studies all or the majority of the participants were black or Hispanic (Artz 2000, Ashworth 1994, Belcher 1998, Boekeloo 1999, DeLamater 2000, Di Noia 2004, Downs 2004, El-Bassel 2003, Kalichman 2005, Kotranski 1998, Mansfield 1993,

Maher 2003, Martin 2003, Stark 2003, Oliva 2005). Because some of the UK's black and minority ethnic populations are disproportionately affected by poor sexual health the results of these studies are summarised below in table 12. However, none of these studies were conducted in the UK. In four studies all or the majority were white (Dilley 2002, EXPLORE 2004, Picciano 2001, Winter 1993) and in the rest the populations were multiethnic.

Of those with a mixed population, two, (Kamb 1998 (and it's subgroup analysis Bolu), Metzler 2000) reported results for different ethnic groups separately. In one (Bolu 2004) they found all ethnic groups benefited but that the enhanced counselling intervention was more effective for white participants and the brief counselling intervention for black participants. In Metzler 2000 the number of partners was not significant for either minority men or women. In one (++) study of counselling for MSM they found it harder to recruit and retain black and Hispanic participants (EXPLORE 2004).

One qualitative study (Beck 2005) explored issues relevant to the promotion of sexual health services within the Bangladeshi community in the UK. Four main themes emerged as impacting on access to services. These were: Confidentiality concerns, relevance of services to the community, problems with discussing sexual issues and problems with previous experiences of health promotion. Community values regarding sex outside of marriage were an important underlying factor in participant's responses. Although some people acknowledged that sex outside of marriage occurred this was universally reported as something that would bring shame and stigma to the individual if it became known. This stigma also affected the use of sexual health services. The authors recommended that health promotion workers established links with existing community networks to provide services but that they also needed to ensure they addressed the needs of those who were younger and more marginalised.

Table 12: Summary presentation of findings - Ethnic minority groups

STI/HIV Ethnicity					
Study defined by author/s date	**Definition of one to one intervention**	**Intermediate outcomes**	**Long term outcomes**	**Quality grading**	**Comment (evidence statement)**
Artz 2000	Safe sex counselling/education on promotion of condom use	Male or female condom used during 100% intercourse + Male or female condom never used during intercourse 0		2-	Evidence that skills based safe sex education is effective in increased use of condom during intercourse.
Ashworth 1994	Safe sex counselling/education	AIDS/HIV knowledge 0 Decreased intent to AIDS risk taking behaviour 0		-	Evidence of a very small effect on knowledge and no effect on risk taking behaviour in low income mothers.
Boekeloo 1999	Skills based safe sex education (theory based) (STI)	Sexual intercourse - Condom use + Treated for an STI 0	Sexual intercourse 0 Condom use 0 Treated for an STI 0	-	Evidence that skills based safe sex education has no long term effect on sexual intercourse, condom use, or treatment for STI, although impact on sexual activity and condom use is short lived
Belcher & Kalichman 1998	Skills based safe sex education (theory based)	HIV/AIDS knowledge 0 Intention to use condom 0 Condom use + Unprotected sex 0 %vaginal sex occasions in which condoms used +		+	Strong evidence that the intervention is effective in increasing condom use with some effect on unprotected sex in economically disadvantaged females. The effect is negligible in increasing knowledge of AIDS and intention to use condom
DeLamater 2000	Safe sex counselling/education	Condom use with casual partner 0 Condom use with steady partner 0 No of partners 0		-	Evidence that health educator has no effect on sexual risk behaviour (condom use or no of partners) among black adolescent males.

Table 12 continued: Summary presentation of findings - Ethnic minority groups

STI/HIV Ethnicity					
Study defined by author/s date	**Definition of one to one intervention**	**Intermediate outcomes**	**Long term outcomes**	**Quality grading**	**Comment (evidence statement)**
Di Noia 2004	Computer mediated skills based education on HIV	HIV/AIDS related knowledge + Self-efficacy for HIV risk reduction +		-	Evidence of a small effect on knowledge and little effect on self-efficacy in this study with very short follow-up and low quality
Downs 2004	Skills based safe sex counselling/education (theory based)	STI acquisition + Condom use 0 STI knowledge 0 Abstinent 3 months +, 6 months 0		+	Evidence of no effect in females on condom use or abstinence at 6months although some effect on abstinence at 3 months and on STI acquisition at 6months. There is insufficient evidence on STI acquisition.
El-Bassel 2003	Skills based safe sex counselling/education (theory based)	Unprotected sexual acts + Protected sexual acts + STD symptoms 0 Sexual partners 0	Unprotected sexual acts + Protected sexual acts 0	+	Evidence of some effect in reducing unprotected sex and increasing protected sex in low income women. There is no effect on STD Symptoms or sexual partners in the short term, with insufficient evidence of effectiveness for long-term outcomes.
Kalichman 2005	Skills based safe sex counselling/education (theory based) and condom advice	Intervention 1 Unprotected intercourse men + Women -/0 Intervention 2 Unprotected intercourse men 0 Women + Newly diagnosed STI No of sexual partners 0	Intervention 1 Unprotected intercourse men 0 Women 0 Intervention 2 Unprotected intercourse men 0 Women + Intervention 2 Newly diagnosed STI Men+ No of sexual partners 0	+	There is evidence of some effect of interventions in men and women in reducing unprotected intercourse and a strong effect in preventing new STIs in men only with little effect on number of sexual partners
Kotranski 1998	Individual level HIV risk reduction counselling		Unsafe vaginal sex: 0 Number of sexual partners: 0	-	There is no evidence that an HIV risk reduction counselling intervention reduces HIV risk taking behaviours in drug users.

Table 12 continued: Summary presentation of findings - Ethnic minority groups

STI/HIV Ethnicity					
Study defined by author/s date	**Definition of one to one intervention**	**Intermediate outcomes**	**Long term outcomes**	**Quality grading**	**Comment (evidence statement)**
Maher 2003	Skills based safe sex counselling/education and condom advice by STI counsellors		Definite STI 0 Possible STI 0 More than 1 STD 0	++	Evidence that the intervention is not effective in reducing STIs among high risk STI clinic patients
Mansfield 1993	HIV testing & counselling, safe sex counselling/education and condom advice	Always use condoms 0 Average number of partners a month 0		-	Evidence of no effect of intervention on consistent use of condoms and very small effect on number of partners in high risk females
Martin 2003	HIV testing & counselling, safe sex counselling/education and condom advice	Unprotected sex 0 Multiple partners 0		-	Evidence of no effect of intervention in reducing sexual risky behaviour.
Oliva 2005	HIV testing & counselling, safe sex counselling/education and condom advice (theory based)	Attitudes towards condoms			Evidence of more positive attitudes but follow-up data is poor.
Sterk 2003	Skills based safe sex counselling/education and condom advice (theory based)	Condom use 0 Paying partners 0			Evidence of no effect of intervention for most sexual risk behaviours

Sexuality

Evidence Statement 1.15

Project RESPECT a large (++) US study of a STI prevention intervention included heterosexuals only. They found significant reductions in STIs and an increase in condom use after a four and two session counselling intervention (Kamb 1998). EXPLORE a large high quality (++) US RCT with MSM found a non significant reduction in HIV and a 13.9% reduction in unprotected sex at very long term follow up after a 10 session + boosters HIV prevention counselling intervention (EXPLORE 2004).

Fourteen studies focused on preventing HIV or STIs in the general population where the majority of participants were heterosexual. Six studies evaluated interventions for the prevention of HIV in populations that were specifically MSM. This included two (++) studies (Dilley 2002, The Explore Study 2004) and four (-) studies (Gold 1995, Gold 1998, Picciano 2001, Robert 1990).

Only one study measured new cases of HIV. This was The EXPLORE study (++), which compared a 10 session behavioural counselling intervention (plus booster sessions) with twice yearly counselling based on the Project RESPECT model. This study involved over 4,000 participants and found a reduction in HIV acquisition of 15.7% at 48-month follow up. However, this was not statistically significant. Six studies with MSM evaluated condom use or unprotected sex and three found a significant effect (Dilley 2002, EXPLORE 2004, Gold 1995). The EXPLORE study found a 13.9% reduction in unprotected sex at 48 months.

We included one qualitative study that considered the views, experiences and needs for HIV prevention interventions in MSM (Seal 2000). Barriers to participation included programmes that overtly targeted gay men, language barriers, and emphasis on HIV education. Recommendations for one-to-one HIV prevention interventions were that HIV education should be embedded in the context of other issues faced i.e. dating, emotional intimacy, development of relationships, self-esteem, self-love, self-care, pessimism regarding one's future, coming out issues, safer sex negotiation and communication, alcohol and elicit drug use, and gaining acceptance amongst one's peers, family members and society as a whole. These issues among high-risk populations were also found in the quantitative studies. For

example in one (++) RCT they found high levels of heavy drinking, drug use and depression among the participants (EXPLORE 2004).

Other high risk populations

Sex workers

No studies specifically addressed the needs of sex workers although two studies performed subgroup analyses of those participants who had a history of exchanging sex for drugs or money (Bolu 2004, Sterk 2003). In one (Sterk 2003) they looked at the effect of a motivation or negotiation intervention on the number of paying partners for female Crack Cocaine users. They found the negotiation intervention was the most effective when compared to a TAU control or the motivation intervention. The negotiation intervention included skills training and the development of tailored negotiation and conflict resolution styles. In all groups combined there was a 41% reduction in number of paying partners for vaginal sex and a 50% reduction in paying partners for oral sex (pre to post). In Project RESPECT (Kamb 1998) 21% of the overall sample at baseline had exchanged sex for drugs or money. In the subgroup analysis (Bolu 2004) the brief two session counselling intervention significantly reduced STIs compared to the control ($p<0.05$). Further research is needed with this high risk vulnerable group.

One qualitative study considered female sex workers understanding of HIV prevention and the acceptability of peer based prevention counselling (Dorfman 1992). Through establishing rapport and relationships they found that peer educators in one-to-one situations were well received. Women found alternative, practical and explicit strategies for incorporating safer sex into their work and private lives valuable and acceptable. Peer educators/field workers who return to their own communities can more easily gain access and function as positive role models. A (-) study of a mobile health clinic for preventing STIs and HIV in a high-risk population (Oliva 2005) used project workers many of whom were former sex workers or drug addicts. They found these project workers made a useful contribution to developing effective counselling strategies.

Drug/substance users

Of five studies that measured condom use one found a small significant effect that is unlikely to be clinically significant (Kwiatowski 1998), one a significant difference in face to face counselling vs. control (Rotheram-Borus 2004) and one a difference in a negotiation intervention but not a motivation intervention for female crack cocaine users (Sterk 2003). The other two found no significant difference in condom use (Gibson 1999a, Gibson 1999b).

The five studies that looked at general risk behaviours (Baker 1994, Deas 2000, Gibson 199a, Gibson 1999b, O'Neill 1996) found no significant differences between intervention and control. There is, at present, little evidence for the effectiveness of one to one interventions to prevent risk taking behaviour in drug users. More research is needed

Prisoners/Probationers

We found only two (-) RCTs that evaluated one-to-one interventions in prisoners/probationers. One (Grinstead 2001) compared a peer-led pre-release HIV prevention intervention, to reduce HIV risk behaviour, with a no treatment control. The other (Martin 2003) used a focused counselling intervention for probationers to reduce HIV/AIDS risk behaviour.

Grinstead 2001 found a significant difference in condom use at first sexual intercourse since release. However, follow up was for only 17 days. Martin 2003 found no significant difference between the intervention and control groups in unprotected sex at six months. However, the intervention was compared with a control that was an enhanced version of the NIDA standard HIV counselling. Both groups also showed a significant pre to post change in mean number of unprotected sex acts. There was, therefore, a reduction in high-risk sexual behaviours in both groups but no between group differences.

People with HIV

Two (-) RCTs (Patterson 2003, Richardson 2004) and one (+) RCT (Rotheram-Borus 2004) evaluated interventions to prevent transmission in people with HIV. Only one study looked at the incidence of STIs (Patterson 2003). They found no significant difference between a brief targeted intervention, a comprehensive intervention, a comprehensive intervention plus a booster session and a diet and exercise

information control. All three studies included unprotected sex as an outcome. Effect on condom use was limited. In one study (Patterson 2003) they found that all groups combined had less unprotected sex pre to post. However, those in the group with the most sessions (comprehensive + booster) reported significantly more unprotected sexual acts than those in the other groups. In a study that compared gain frame and loss frame counselling interventions with a medication adherence control there were no significant differences in condom use (Richardson 2004). The third study, which compared face to face and telephone counselling with a no treatment control (Rotheram-Borus 2004), found a significant difference in percentage of protected acts for the face-to-face group vs. control. There was no significant difference between face-to-face and telephone, or telephone vs. control.

There is insufficient evidence to say whether one-to-one counselling interventions have an effect on STIs or condom use in people living with HIV. No studies measured the transmission of HIV

6.2.7 Implementation. What are the barriers to implementing effective interventions?

There are a number of potential barriers to implementation. One of the most significant is the time and resources required. For example Project EXPLORE although shown to be effective involved over ten sessions and may be difficult to implement. On the other hand the brief two session Project RESPECT model was designed to be implemented at low cost with existing personnel in the context of routine US health services.

The other problem with lengthy interventions is whether you can recruit and retain participants. In many of the studies those recruited were only a fraction of those eligible to participate. It is unclear whether it was being part of a study, or participating in the intervention itself, that deterred people from enrolling. Although in the EXPLORE study they had high visit retention (87% standard group, 83% intervention group) they found it harder to get black, Hispanic, younger men and those of lower socioeconomic status to enrol in the study and they were less likely to be retained. Project EXPLORE included a ‘high risk’ population which the authors say may limit generalisability. They may also have been a more motivated group as they responded to adverts and invitations to join the project. Many of the studies

used a monetary incentive to get patients to come back for assessments or intervention sessions, which again may have implications for applicability.

Another barrier to the implementation of effective interventions is the issue of stigma. In one qualitative study with MSM (Seal 2000) participants felt that programmes that overtly targeted gay men would result in decreased participation. Particularly among non-gay identified or closeted young MSM. Stigma was also an issue for the Bangladeshi community in the study by Beck et al (2005). The stigma attached to sex outside of marriage, and the discussion of sexual issues in general, may lead to reluctance to access services.

One of the barriers to implementing effective interventions in the UK is the lack of previous research on which to base services. Nearly all of the relevant interventions had been developed and evaluated in the US and further research is needed to establish applicability for the UK. In addition there was an overall lack of clarity about what constitutes a one to one intervention. We found no coherent idea of what is meant by one to one interventions and it did not seem to be a term used widely in practice. From our searches of the literature, much of which we excluded from this review, it seemed that one to one was often examined in relation to group work with one to one as the TAU control or embedded within a larger group based model. However, studies from America around HIV/AIDS counselling do seem to be establishing more of a coherent programme of work with several studies assessing the Project RESPECT model (Kamb 1998, Metcalf 2005, EXPLORE 2004).

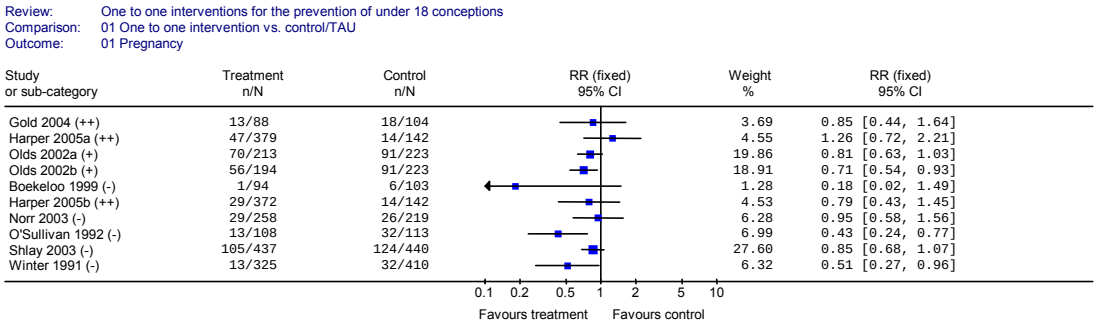
6.3 THE EFFECTIVENESS OF ONE TO ONE INTERVENTIONS FOR PREVENTING UNDER 18 CONCEPTIONS?

We found only twelve studies that evaluated the effectiveness of one to one interventions to prevent conceptions in the under 18s. On the quality assessment score three out of 11 RCTs scored (++), three (+), and five (-), and a controlled study scored (-). In addition, we included three qualitative studies that looked at barriers and facilitators to the prevention of under 18 conceptions. Of these two were graded as (++), and one was graded as (+).

Two studies evaluated the advanced provision of emergency contraception, six looked at health care programmes for pregnant women/ mothers, two looked at contraceptive care and advice in clinics, and two looked at sexual/reproductive health education. Results are presented by outcome and intervention, and are presented in tables 13 & 14 and summarised in table 15.

Pregnancy

Eleven studies reported data on pregnancy or repeat pregnancies. Of these nine provided data that could be presented in a forest plot (Figure 11). Although only three studies showed a statistically significant reduction in pregnancy (Olds 2002b, O'Sullivan 1992, Winter 1991) the general trend was towards a reduction in pregnancies. Data from all studies is presented in table 13.



Harper a = advanced provision, Harper b = pharmacy access

++ = low risk of bias, + = moderate risk of bias, - = high risk of bias

Figure 11: Effect of one to one interventions on pregnancies (includes repeat pregnancies)

Table 13: Effect of one to one interventions on pregnancy/repeat pregnancy

Study ID	Quality	Outcome	Short	Long term	Very long term
Boekeloo 1999	-	Got someone pregnant or been pregnant	0: RR 0.23 (95% CI 0.01, 4.73)	0: RR 0.18 (95% CI 0.02, 1.49)	
Gold 2004	++	Pregnancy		0: RR 0.85 (95% CI 0.44, 1.64)	
Harper 2005	++	Pregnancy		0: advanced provision RR 1.26 (95% CI 0.72, 2.21) 0: pharmacy access RR 0.79 (95% CI 0.43, 1.45)	
Olds 1997	-	Repeat pregnancy			+: p = 0.03
Olds 2002	+	Repeat pregnancy			2002 a 0: RR 0.81 (95% CI 0.63, 1.03) 2002 b +: RR 0.71 (95% CI 0.54, 0.93)
Olds 2004	+	Repeat pregnancy			+: ES: d=0.22, p<0.01)
O'Sullivan 1992	-	Repeat pregnancy			+: RR 0.43 (95% CI 0.24, 0.77)
Norr 2003	-	Repeat pregnancy			0: RR 0.95 (95% CI 0.58, 1.56)
Shlay 2003	-	Pregnancy Unintended pregnancy			0: RR 0.85 (95% CI 0.68, 1.07) 0: RR 0.86 (95% CI 0.61, 1.21)
Winter 1991	-	Pregnancy			0: RR 0.51 (95% CI 0.27, 0.96)

Effect score (+) = positive effect, (-) = negative effect, (0) = no effect shown

Advanced Emergency Contraception

Evidence Statement 1.16

Of the two (++) studies of advanced provision of emergency contraception, one (Gold 2004) found a trend towards a reduction in pregnancies but this was not statistically significant, and the other found a non significant reduction in the pharmacy access group but not advanced provision group (Harper 2005) compared to clinic access control.

Two (++) studies evaluated the effect of providing advanced, or easier access to, emergency contraception (Gold 2004, Harper 2005). One study of advanced provision (Gold 2004) found a reduction in pregnancies but this was not statistically significant (RR 0.85; 95% CI 0.44, 1.64). In the other (Harper 2005) they found no statistically significant differences in the advanced provision group (RR 1.26; 95% CI 0.72, 2.21), or in the pharmacy access group (RR 0.79; 95% CI 0.43, 1.45).

Support for pregnant women/mothers

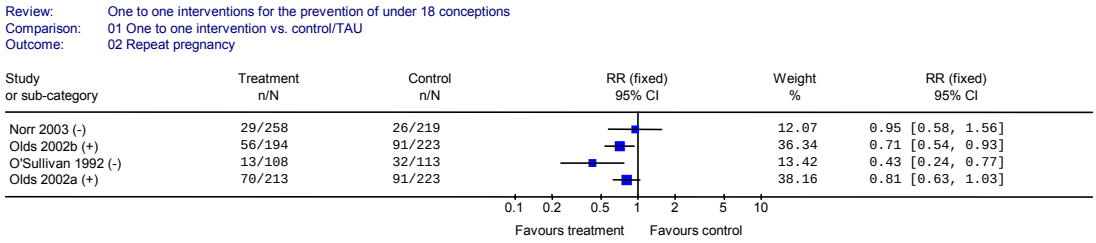
Evidence Statement 1.17

Six studies evaluated interventions to support pregnant women or mothers. Although only two of the studies focused solely on adolescents (O'Sullivan 1992, Quinlivan 2003) all included at least 40% of adolescents and focused on disadvantaged, low-income women. There is good evidence that multi-session support and home visiting for disadvantaged low-income pregnant women or mothers can prevent repeat pregnancies with two (+) (Olds 2002, Olds 2004) and one (-) (O'Sullivan 1992) studies showing a significant reduction in repeat pregnancies in the intervention group compared to control. In addition one (-) study (Olds 1997) found a reduction in repeat pregnancies in poor unmarried women, although not in the sample as a whole.

Of the six studies that evaluated interventions to support pregnant women or mothers five provided data on repeat pregnancies (Olds 1997, Olds 2002, Olds 2004, O'Sullivan 1992, Norr 2003). Three studies (Olds 2002, Olds 2004, O'Sullivan 1992) found a significant reduction in repeat pregnancies. Of those one evaluated a health care programme for adolescent mothers (O'Sullivan 1992) and found a significant reduction in repeat pregnancies at 18 months (RR 0.43 (95% CI 0.24, 0.77). In the other two trials (Olds 2002, Olds 2004) they evaluated the effect of nurse home visiting and developmental screening, compared to screening alone, on pregnant

women with no previous live births. Both found a statistically significant reduction in repeat pregnancies in the group that received nurse home visiting (Olds 2002 RR 0.71; 95% CI 0.54, 0.93; Olds 2004 ES d=0.22, p<0.01) although visits by paraprofessionals, evaluated in one study, (Olds 2002) did not show a significant reduction in repeat pregnancies (RR 0.81; 95% CI 0.63. 1.03). In an earlier study by Olds (Olds 1997) they found no reduction in repeat pregnancies in their overall sample but there was a significant reduction in a subgroup of women with low socio-economic status (p=0.03). One study (Norr 2003) found no difference in repeat pregnancies between a nurse home visiting programme and usual well-child clinic visits (RR 0.95; 95% CI 0.58, 1.56).

Four of these studies provided data on repeat pregnancy that could be presented in a forest plot (Figure 12). Data from all five studies can be seen in table 13.



++ = low risk of bias, + = moderate risk of bias, - = high risk of bias

Olds 2002a = paraprofessionals, Olds 2002b = nurses

Figure 12: Effect of one to one home visiting or support for pregnant women/mothers on repeat pregnancies

Clinic based contraception care

Evidence Statement 1.18

One (-)RCT and one (2+) non randomised controlled study evaluated contraception advice and support in a clinic based setting (Shlay 2003, Winter 1991). One (Winter 1991) found a significant reduction in pregnancies and the other (Shlay 2003) showed a trend towards a reduction in the intervention group compared to control but this was not significant.

Two studies looked at the provision of contraception advice or care in clinic settings. One controlled trial (2+) of specially developed family planning protocols for adolescents (Winter 1991) found a significant difference in pregnancy at 12 months (RR 0.51; 95% CI 0.27, 0.96). The other (-) study (Shlay 2003) compared medical

screening and enhanced individual contraception counselling with contraception education without counselling. They found no statistically significant differences in pregnancy (RR 0.85; 95% CI 0.68, 1.07) or unintended pregnancy (RR 0.86; 95% CI 0.61, 1.21).

The other study that provided data on pregnancy was a (-) RCT of a 45 minute counselling session with a paediatrician (Boekeloo 1999). They found no significant differences in self-reported pregnancies at three (0% vs. 1.9%, ES: h=0.04) or nine months (1.1% vs. 5.9%; ES: h=0.10).

Contraception use

Evidence Statement 1.19

Seven studies reported contraception use. This was measured in various different ways, including oral contraception, emergency contraception and condom use. Four studies showed a statistically significant effect on contraception use. Two increased oral contraceptive use. These were a (++) RCT (Quinlivan 2003) and a (+) RCT (Danielson 1990) that found one to one interventions with teenagers can improve contraception use in the long term. Of the two (++) studies of advanced provision of emergency contraception one found an increase in the use of EC (Harper 2005) and one an increase in condom use (Gold 2004). In the other studies the general trend was towards an increase in contraception use although one (-) study found the effect on contraception use was no longer significant at 12 months (Winter 1991). Therefore, there is some evidence that one to one interventions with under 18s can increase contraception use. However, further research in this area is needed.

Seven studies reported contraceptive or condom use. Results are presented in the text below and in table 14. Six studies provided data on contraceptive use that could be presented in a forest plot (Figure 13).

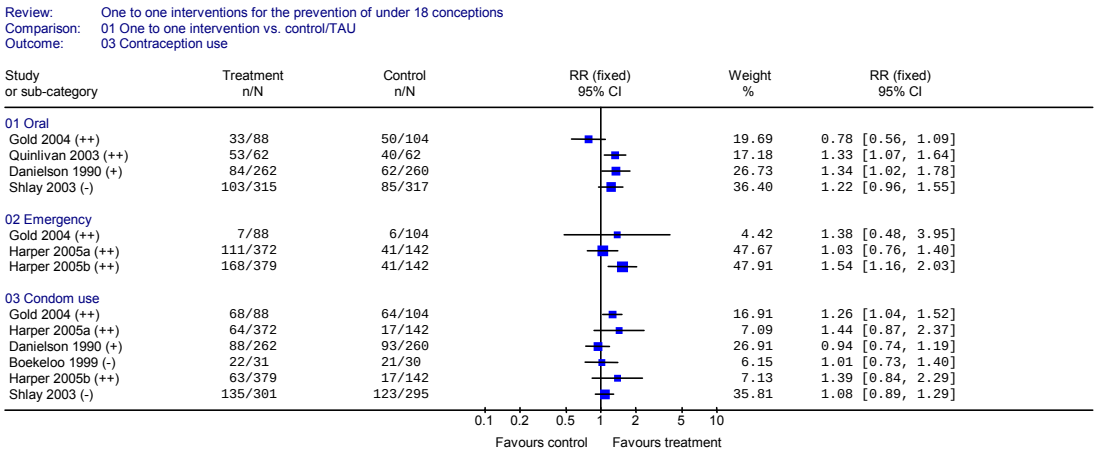
Longer term

Six studies measured contraception use at long term follow up. At six months one (++) Australian RCT (Quinlivan 2003) of post-natal visiting for low income teenage mothers found a significant difference in reliable contraception use (RR 1.33; 95% CI 1.07,1.64). Of the two clinic based studies one (+) controlled trial (Winter 1991) found a significant difference in numbers using original contraception method (92.4%

vs. 84.9%) and in those using any method of contraception (97.4% vs. 92.1%) and the other (-) RCT (Shlay 2003) found an increase in effective contraceptive use (RR 1.49; 95% CI 1.09, 2.05) but no significant difference in effective condom use (RR 1.10; 95% CI 0.83, 1.46). Of the two (++) RCTs evaluating the provision of emergency contraception one (Harper 2005) found that the group allocated to advance provision of EC were significantly more likely to use it than those who had clinic or pharmacy access (44.3% vs. 28.9%) and the other (++) (Gold 2004) found no statistically significant difference in use of the oral contraceptive pill (RR 0.78; 95% CI 0.56, 1.09), or in the use of emergency contraception (RR 1.38; 95% CI 0.48, 3.95), but found a statistically significant increase in those using condoms (RR 1.26; 95% CI 1.04, 1.52). The (-) RCT of counselling by a paediatrician found no significant difference in condom use (RR 1.01; 95% CI 0.73, 1.40)

Very long term

Three studies measured contraception use at 12 months. One RCT (+), of a reproductive health consultation in adolescent males (Danielson 1990), found a significant difference in the number of partners using the contraceptive pill (RR 1.34; 95% CI 1.02, 1.78), although no significant difference in condom use at most recent intercourse (RR 0.94; 95% CI 0.74, 1.19). The other two studies of clinic care found that there was no longer a statistically significant difference in contraception use. One (Winter 1991) found no significant effect on use of contraception (95.8% vs. 92.4%), and the other found no significant difference in effective contraceptive use (RR 1.22; 95% CI 0.96, 1.55) or effective condom use (RR 1.08; 95% CI 0.89, 1.29).



++ = low risk of bias, + = moderate risk of bias, - = high risk of bias

Figure 13: Effect of one to one interventions on contraception use (by type of contraceptive)

Table 14: Effect of one to one interventions on contraceptive use

Study ID	Quality	Outcome	Long term	Very long term
Boekeloo 1999	-	Condom use at last vaginal intercourse	0: RR 1.01 (95% CI 0.73, 1.40)	
Danielson 1990	+	Partner used contraceptive pill Condom use at most recent intercourse		+: RR 1.34 (1.02, 1.78) 0:RR 0.94 (0.74, 1.19)
Gold 2004	++	Used oral contraceptive pill Used EC Used condoms	0: RR 0.78 (0.56, 1.09) 0: RR 1.38 (0.48, 3.95) +: RR 1.26 (1.04, 1.52)	
Harper 2005	++	Used EC	Advanced provision +: RR 1.54 (1.16, 2.03) Pharmacy access 0: RR 1.03 (0.76, 1.40)	
Quinlivan 2003	++	Reliable contraception use	+: RR 1.33 (1.07, 1.64)	
Shlay 2003	-	Effective contraceptive use Effective condom use	+: RR 1.49 (95% CI 1.09, 2.05) 0: RR 1.10 (95% CI 0.83, 1.46)	0: RR 1.22 (95% CI 0.96, 1.55) 0: RR 1.08 (95% CI 0.89, 1.29)
Winter 1991	2+	Using any method of contraception	+: p<.01; ES: h=0.34	0: p<.05; ES: h = 0.22

Quality score: ++ = low risk of bias, + = moderate risk of bias, - = high risk of bias.
Effect score: (+) = positive effect, (0) = no statistically significant effect, (-) = negative effect. Blank column = data not reported for this time period

Qualitative results

The use of emergency contraception was also explored in an in-depth (+) UK based interview study (Free 2005). This study found that despite an increase in availability obtaining emergency contraception was still a difficult task for young women, particularly for young women from disadvantaged backgrounds. Women with the strongest desire not to become pregnant and those with strong personal aspirations in terms of lifestyle, educational achievement, careers or travel, were most likely to use contraception and if necessary emergency contraception. Barriers to the use of emergency contraception included stigma, guilt, feelings they would be judged, denial of risk, and lack of knowledge of emergency contraception and how to access it.

Table 15: Evidence Summary Prevention of under 18 conceptions

Under 18 conceptions (Adolescents)					
Study ID	**Definition of one to one intervention**	**Intermediate outcomes**	**Long term outcomes**	**Quality grading**	**Comment (evidence statement)**
Boekeloo 1999	Skills based safe sex education (theory based) (STI)	Pregnancy 0 Sexual intercourse - Condom use +	Pregnancy 0 Sexual intercourse 0 Condom use 0	-	Evidence that skills based safe sex education has no effect on long term outcomes. Impact on sexual activity and condom use is short lived
Danielson 1990	Reproductive health consultation	Not reported	Sexual activity 0 Condom use 0 Contraceptive pill used by partner + Knowledge about fertility +	+	Evidence that reproductive health consultation has no effect on sexual activity or condom use. There is evidence of positive effect on contraceptive pill use by partner and enhancing knowledge about fertility at 12 months
Gold 2004	Emergency (EC) contraception education	Pregnancy 0 STI 0 Unprotected Intercourse 0 Condom use + Contraceptive pill use in past month 0 EC use in past month 0		++	Evidence of no effect of EC provision on pregnancy, unprotected sexual intercourse and use of contraceptive pill. There is evidence of some effect of EC on condom use, but the intervention was not designed to promote condom use or prevent STI
Harper 2005	Direct advanced access to EC	Pregnancy 0 Used EC 0 Any STI 0 Unprotected intercourse 0		++	Evidence that EC is not effective on use of EC, pregnancy, unprotected intercourse or STI, although the study was not designed to increase condom use or prevent STI. Evidence of some effect of advanced provision on use of EC
Norr 2003	Nurse health advocate home visiting programme for pregnant women		Repeat pregnancy 0	-	No evidence that home visiting for pregnant women reduces repeat pregnancies in either African Americans or Mexican Americans.
Olds 1997	Nurse home visiting programme for pregnant women		Repeat pregnancy 0 Subsequent births 0	-	Although there were no statistically significant differences in the overall sample there was evidence that home visiting can reduce the number of subsequent pregnancies in low income unmarried mothers for up to 15 years after the birth of their first child.

Under 18 conceptions (Adolescents)					
Study ID	**Definition of one to one intervention**	**Intermediate outcomes**	**Long term outcomes**	**Quality grading**	**Comment (evidence statement)**
Olds 2002	Home visiting by nurses and paraprofessionals for pregnant women		Repeat pregnancy Nurses + Paraprofessionals 0 Subsequent birth Nurses + Paraprofessionals 0 Time to next conception Nurses + Paraprofessionals 0	+	Home visiting by nurses can prevent repeat pregnancies and subsequent births and delay time to next conception, in pregnant women with no previous live births, and is more effective than home visiting by paraprofessionals.
Olds 2004	Home visiting programme for pregnant women		Repeat pregnancy + No of subsequent children + Time to next conception +	+	There is evidence that nurse home visiting can reduce repeat pregnancies and births and increase intervals between the birth of first and second children in low income ethnic minority women.
O'Sullivan 1992	Skills based counselling support for mothers		Repeat pregnancy + Return to school 0	-	Strong evidence that individual counselling is effective on preventing repeat pregnancy but study quality is low. No effect on improving mother's outcomes
Quinlivan 2003	Home based education and training support for mothers	Reliable contraception use + Contraception knowledge +		++	Strong evidence that home based support for adolescent mothers increases contraception knowledge and use
Shlay 2003	Contraceptive care in STI clinic	Effective contraceptive use + Effective condom use 0 Duel protection +	Effective contraceptive use 0 Effective condom use 0 Dual protection 0 Pregnancy 0	-	There is evidence that contraceptive counselling in an STI clinic can improve contraceptive use in the short term but the effect was not maintained at 12 months.
Winter 1991	Protocols for care, education, counselling, medical examination	 Continued contraceptive use using original method + Using any method of contraception + Patient satisfaction 0	Pregnancy 0 Continued contraceptive use using original method + Using any method of contraception 0 Patient satisfaction 0	2+	There is evidence that family planning protocols of care in the long-term are ineffective in reducing pregnancy but have some effect in improving continued use of contraception using original method. Insufficient evidence to draw conclusions on patient satisfaction, and the effect on using any method of contraception is short lived.

Effect score (+) = positive effect, (-) = negative effect, (0) = no effect shown

Condom use

Only 12 quantitative studies met the inclusion criteria for the question relating to the prevention of under 18 conceptions. However, a number of the studies that aimed to prevent STIs/HIV in adolescents, and that are reported in the previous section on the prevention of STIs/HIV, promoted the use of condoms. Therefore, those studies, although not directly aiming to prevent conceptions, are also relevant to this outcome. The full results for condom use in adolescents for the prevention of STIs/HIV are presented in full in section 6.1 and are summarised here in table 16.

In summary of the ten RCTs, two (++), three (+), five (-), only three found a significant increase in condom use in the intervention group compared to control. However, in only one study was there a no treatment control. In the others the intervention was compared to TAU or to another intervention and two RCTs reported a significant increase in condom use in both groups pre to post intervention.

Table 16: Effect on one to one interventions on condom use in adolescent populations

Study ID	Quality score	Target Group	Effect Very short	Effect Short	Effect Long	Effect Very long
Adolescents						
Boekeloo 1999	-	Adolescents		+	0	
Danielson 1990	+	Adolescents				0
DeLamater 2000	-	Adolescent males			0	
Downs 2004	+	Female adolescents		0	0	
Gold 2004	++	Female adolescents			+ condom use 0 unprotected sex	
Harper 2005	++	Female adolescents			0	
Mansfield 1993	-	Adolescents		0		
Metzler 2000	-	Adolescents			0	
Orr 1996	-	Adolescent females			+	
Shrier 2001	-	Adolescents			0	0

Effect score (+) = positive effect, (-) = negative effect, (0) = no effect shown

Blank columns = data not reported for this time period

6.4 OTHER RESEARCH QUESTIONS

6.4.1 How does the content of the intervention (what?) influence effectiveness?

Evidence Statement 1.20

There are few studies evaluating interventions to prevent under 18 conceptions and in general there is insufficient evidence to say whether or not the content of one to one interventions influences effectiveness. However, there is good evidence that multi-session support and home visiting for disadvantaged low-income pregnant women or mothers can prevent repeat pregnancies with two (+) (Olds 2002, Olds 2004) and two (-) (Olds 1997, O'Sullivan 1992) studies showing a significant reduction in repeat pregnancies in the intervention group compared to control.

Previous research has demonstrated that sexual health interventions are more likely to be effective if they use theoretical models and use behavioural, communication and social skills training (Ellis & Grey 2004). Six studies (Boekeloo 1999, Norr 2003, Olds 1997, Olds 2002, Olds 2004, Winter 1991) reported that the intervention used some form of model to inform the development or delivery of the intervention. In one a primary care intervention based on a social cognitive theory of reasoned action was used to reduce sexual risk behaviours in young adolescents in comparison to a TAU educational control (Boekeloo 1999). They found no statistically significant difference in pregnancies at nine months although there was a statistically significant increase in condom use at last vaginal intercourse at three months. However, this was no longer significant at nine months. Another study which reported using a theory based intervention was a controlled study of family planning protocols (Winter 1991). The intervention was developed with a focus on the psychosocial model. They found a significant effect on contraception use at six months but not at 12 months. In the other four studies, which all looked at home visiting for pregnant women, one (Norr 2003) used an ecological model and the other three (Olds 1997, Olds 2002, Olds 2004) used bandura's theory of self-efficacy. Of these studies of home visiting two (Olds 2002, Olds 2004) found a significant reduction in repeat pregnancies and one (Olds 1997) found a reduction in a sub group of low income unmarried women.

Six studies evaluated support for mothers or pregnant women. In general this included long term follow up and support with contraception advice and education provided by health care professionals. Of these three (Olds 2002, Olds 2004,

O'Sullivan 1991) found a statistically significant reduction in repeat pregnancies and one (Quinlivan 2003), which didn't measure pregnancies, found an increase in reliable contraception use. There is, therefore, good evidence that multi-session support for mothers is effective in preventing repeat pregnancies and that this appears to be particularly effective for low income women.

6.4.2 Does the way that the intervention is carried out e.g. Type/mode of communication, influence effectiveness?

Evidence Statement 1.21

There is insufficient evidence to say whether or not the type/mode of communication of one to one interventions to prevent under 18 conceptions influence effectiveness.

All of the interventions included face to face communication compared with face to face communication. In one the participants also watched a half hour video (Danielson 1990).

6.4.3 Does the effectiveness depend on the job title/position or other factors such as age, gender, sexuality, ethnicity, of the deliverer (leader)? What are the significant features of an effective deliverer (leader)?

Evidence Statement 1.22

In general there is insufficient evidence to say whether or not the type of leader influences the effectiveness of one to one interventions for preventing under 18 conceptions. However, one (+) US study of home visiting for mothers (Olds 2002) found that nurses were more effective than paraprofessionals in reducing repeat pregnancies.

In two of the studies the deliverer was not specified (Gold 2004, Harper 2005). In the other studies the intervention was delivered by a health care professional; most commonly nurses. This included; paediatricians (Boekeloo 1999), nurse-midwives (Quinlivan 2003), nurses or physicians assistants (Danielson 1990), nurses (Norr 2003, Olds 1997, Olds 2002, Olds 2004, Shlay 2003), paraprofessionals (Olds 2002), a multi-disciplinary health care team (O'Sullivan 1992), and clinic staff (role not specified) (Winter 1991). One study compared nurses and paraprofessionals with usual care (Olds 2002) and found that home visiting by nurses was more effective than that by paraprofessionals on a range of maternal and child outcomes. From the

qualitative studies it emerged that peer delivered interventions may be preferred (Salyers 2005) and that where interventions are delivered by trained health care professionals/providers a non-judgemental approach is considered by participants to be very important (Free 2005).

6.4.4 Setting (where?). Does the site/setting of delivery of the intervention influence effectiveness?

Evidence Statement 1.23

Most intervention were delivered in clinics or via home visiting. There is good evidence that multi-session support and home visiting for disadvantaged low-income pregnant women or mothers can prevent repeat pregnancies with two (+) (Olds 2002, Olds 2004) and one (-) (O'Sullivan 1992) studies showing a significant reduction in repeat pregnancies in the intervention group compared to control, and one (++) study an increase in reliable contraception use (Quinlivan 2003). In addition one (-) study (Olds 1997) found a reduction in repeat pregnancies in poor unmarried women, although not in the sample as a whole.

A number of the interventions were delivered in clinics. This included hospital clinics (Gold 2004, O'Sullivan 1992), family planning clinics (Harper 2005, Winter 1991), an STI clinic (Shlay 2003) and a primary care clinic (Boekeloo 1999). Of the other studies five involved home visiting (Quinlivan 2003, Norr 2003, Olds 1997, Olds 2002, Olds 2004) and one took place at the offices of a health maintenance organisation (Danielson 1990).

Unsurprisingly settings appeared to be chosen because they provided the opportunity to access the relevant populations. Only one study compared one site/setting with another. This was a study of the provision of advanced emergency contraception (EC) (Harper 2005). They compared advanced provision of EC to pharmacy or clinic access. They found a statistically significant increase in the use of EC in the advance provision group compared to clinic access but no significant difference in pregnancy. Of the five studies evaluating home visiting interventions three found a decrease in repeat pregnancies in either the whole sample (Olds 2002, Olds 2004), or in a subgroup of low income women (Olds 1997), and one found an increase in reliable contraception use (Quinlivan 2003).

6.4.5 Does the intensity (or length) of the intervention influence effectiveness/duration of effect?

Evidence Statement 1.24

There is insufficient evidence that the length of clinic based one to one interventions, for the prevention of under 18 conceptions, influences the effectiveness/duration of effect. There is good evidence from one (++) study (Quinlivan 2003) two (+) (Olds 2002, Olds 2004) and two (-) studies (Olds 1997, O'Sullivan 1992) that multi-session one to one interventions may increase effective contraception use and prevent repeat pregnancies.

In two studies the length and duration of the intervention was not specified (Gold 2004, Harper 2005). Two studies involved a single session; in one the length of the session was not specified (Boekeloo 1999) and in the other it involved a 30 minute face to face consultation and a 30 minute video (Danielson 1990). Of those single session interventions one (Boekeloo 1999) found a significant increase in condom use at three months but not at nine months; and the other (Danielson 1990) found a significant effect on fertility knowledge and use of the contraceptive pill by partners at 12 months. One study included a three-session intervention (Winter 1991). The length of the sessions was not specified but the authors say they added an extra 15-20 minutes to the normal counselling and education session, and 10 minutes to the medical examination. They found a significant effect on contraception use at six months but not at 12 months.

The interventions to provide support and education to mothers or pregnant women tended to be multi-session interventions. These included five sessions (Norr 2003, Quinlivan 2003), five to ten sessions (Olds 1997, O'Sullivan 1991) over 20 sessions (Olds 2002) or over thirty visits (Olds 2004). Of the shorter, five session, interventions one (Norr 2003) found no significant differences between intervention and control groups and one (Quinlivan 2003) found a statistically significant effect on reliable contraception use. A study, which included eight clinic visits over 18 months, (O'Sullivan 1991) had a statistically significant effect on repeat pregnancies although there was a high attrition rate from clinic attendance. This highlights the potential problems of getting high-risk groups to participate in long-term interventions. Three studies, of intensive home visiting support, by the same authors (Olds 1997, Olds 2002, Olds 2004) found a statistically significant reduction in repeat pregnancies, although in one (Olds 1997) this was in a subgroup of low-income women only. Two

of these interventions (Olds 2002, Olds 2004) involved regular visits through pregnancy and for the first two years of the child's life.

6.4.6 Does the effectiveness vary with age, gender, sexuality, socio-economic status, ethnicity?

Age

Although our review question was about the prevention of unwanted conceptions in the under 18s we also included several studies whose populations were not restricted to adolescents (Norr 2003, Olds 1997, Olds 2002, Olds 2004, Shlay 2003). This was because research in this area was limited and in all the studies at least 40% of participants were under 20.

In one study (Harper 2005), a subgroup analysis of a larger study involving all age groups (Raine 2005), they found that adolescents were far more likely than adults to rely on the condom as their contraceptive method. The youngest adolescents (<16 yrs) were also more likely to report consistent condom use than older adolescents. Increased access to emergency contraception (EC) for adolescents may be controversial due to fears of an increase in unsafe sexual behaviour. However, both studies of provision of EC to adolescents found no increase in STIs or risky sexual behaviour in the intervention group compared to the control.

Gender

Evidence Statement 1.25

In summary, there is insufficient evidence to say whether or not gender influences the effectiveness of one to one interventions to prevent under 18 conceptions. Most studies included in the review were aimed at females and there would appear to be a need for further research.

One study involved males only (Danielson 1990), in nine the intervention was targeted at women (Gold 2004, Harper 2005, Norr 2003, Olds 1997, Olds 2002, Olds 2004, O'Sullivan 1992, Quinlivan 2003, Shlay 2003), and in one a mixture of males and females were included (Boekeloo 1999). In the other study (Winter 1991) the sex of the population was not specified although it can be assumed that they were female as the study took place in family planning clinics. The majority of interventions were, therefore, aimed at females.

Socio-economic status

Evidence Statement 1.26

There is good evidence from one (++) study (Quinlivan 2003) two (+) (Olds 2002, Olds 2004) and two (-) studies (Olds 1997, O'Sullivan 1992) that multi-session home visiting or support can be effective in increasing effective contraception use and preventing pregnancies in low-income disadvantaged women.

Those from unskilled manual backgrounds are more than 10 times as likely to become teenage mothers as those from professional backgrounds (Kiernan 1995). Six studies specifically stated that the majority of the population had a low socio-economic status (Norr 2003, Olds 1997, Olds 2002, Olds 2004, O'Sullivan 1992, Quinlivan 2003) and in one of the others (Gold 2004), nearly 50% of the sample used public medical assistance for health care insurance coverage, which would indicate a population with high levels of economic disadvantage.

The link between adolescent childbearing and poverty becomes stronger if there are rapid repeat pregnancies (O'Sullivan 1992, Furstenberg 1989). One (++) (Quinlivan 2003), two (+) (Olds 2002, Olds 2004) and two (-) studies (Olds 1997, O'Sullivan 1992) found that multi-session home visiting or support can be effective in increasing effective contraception use and preventing pregnancies in low-income disadvantaged women.

Ethnicity

In four studies the participants were multiethnic (Harper 2005, Olds 2002, Quinlivan 2003, Shlay 2003), in six all or the majority were black (Boekeloo 1999, Gold 2004, Norr 2003, Olds 1997, Olds 2004, O'Sullivan 1992) and in two studies all or the majority were white (Danielson 1990, White 1991). There is insufficient evidence to say whether the effectiveness of one to one interventions for the prevention of under 18 conceptions varies with ethnicity.

6.4.7 Implementation. What are the barriers to implementing effective interventions?

There are a number of potential barriers to implementation. One of these is the problem of recruiting and retaining participants. For example in a study with young adolescents (aged 12-15) 58% of those who were eligible refused to participate in the study (Boekeloo 1999). Of those 43% did not participate because of parental refusal.

Interventions therefore need to be relevant and appealing to both adolescents and their parents. Another difficulty may be in maintaining participation in interventions that involve several sessions over a number of months. In a study of a clinic based intervention for teenage mothers there was a drop out rate of 60% in the intervention group (O'Sullivan 1992). In the other study of home visiting (Quinlivan 2003), which also included multiple sessions, there was no indication of how many of the participants received the visits. Their loss to follow up however was relatively low at 11%. High initial refusal rates and loss to follow up reduce the applicability of studies.

One of the barriers to implementing effective interventions is the lack of previous UK based research to inform the development and delivery of sexual health promotion interventions. Nearly all of the relevant interventions had been developed and evaluated in the US and further research is needed to establish applicability for the UK.

7. DISCUSSION

This review included 62 studies, 56 quantitative and six qualitative, of one to one interventions to prevent STIs in the whole population and conceptions in the under 18s. The scope of the review was broad, involving a diverse range of populations, settings and interventions. The quality of the quantitative studies varied considerably, with only nine studies graded as having a low risk of bias (++) and 16 a medium risk of bias(+). The remaining 31 studies were judged to be of poorer quality and to have a high risk of bias (-).

What works to reduce the rate of STIs (including HIV)?

Most studies involved face to face safer sex counselling and education delivered by a health care professional or a trained health educator or counsellor in a clinic setting (e.g. STI, public health or family planning clinic). Many interventions were theory based and/or included skills development. The strongest evidence found in the review was based on work done in the USA. This included two large good quality RCTs, one with heterosexuals attending a public health clinic (Kamb 1998), and one an intervention with MSM (EXPLORE 2004). Both found one to one counselling could reduce STIs and increase safer sexual practices. One involved two or four sessions (Kamb 1998) and the other 10 sessions with boosters (EXPLORE 2004).

What works to reduce the rate of under 18 conceptions?

We found only 12 studies evaluating one to one interventions to prevent conceptions in the under 18s. This included a variety of interventions including: the provision of emergency contraception, support for pregnant women or mothers, clinic based contraceptive care and advice and sexual/reproductive health education. The strongest evidence found was around multi-session interventions to support low income pregnant women or mothers with four studies finding a reduction in repeat pregnancies in this group (Olds 2002, Olds 2004, Olds 1997, O'Sullivan 1992). There was also evidence from two good quality studies (Gold 2004, Harper 2005) that adolescents given easier access to emergency contraception were more likely to use it than those who were not, and that the provision of advanced emergency contraception did not lead to an increase in unprotected sex.

Limitations of the review

Overall we found few evaluations of one to one interventions; in particular few studies evaluated interventions to prevent under 18 conceptions. This may be because the majority of work with this age group is in a school setting and group based. In addition, as previously noted, there did not seem to be a coherent idea about what is meant by one to one interventions. This was highlighted by the fact that most systematic reviews did not make the distinction between group based or one to one interventions when presenting their results and where, therefore, excluded from our review.

Of those studies that we did find, few reported our primary outcomes of STIs or pregnancy, and only one reported new cases of HIV. Using self-reported sexual outcomes such as condom use or unprotected sex as the primary outcome affects study validity and applicability because of the issues surrounding recall bias. In addition, many of the studies in the review had small sample sizes and were not powered to detect an effect on STIs or pregnancy. In many cases confidence intervals were wide and did not rule out either a beneficial or a harmful treatment effect.

In many studies the intervention was compared with TAU, which was often one to one counselling. This makes assessing the real effect of the interventions difficult. In addition in many US studies treatment as usual or control groups received interventions which are more structured and detailed than usual care currently provided in GUM clinics in the UK. This makes generalisability to the UK difficult Additionally in some studies the intervention and control treatments were delivered by the same counsellors, which may have led to contamination (e.g Kalichman 2005).

This review includes studies with a variety of interventions, populations, settings and outcomes. Therefore, we did not think it was appropriate to perform an overall meta-analysis but have presented the data in a narrative and tabular format. This can make presentation and interpretation of the findings difficult. Therefore, to give a more visual representation of the results we have, where possible, used forest plots, but without a summary statistic. We were not able to present data for all studies in forest plots and, as the use of forest plots in this way is not well established, they need to be considered in conjunction with the narrative and tabular summaries of the data.

A significant weakness of this review is the lack of evaluations of interventions in the UK. We found only two studies that had been done in the UK, the rest were mostly conducted in the USA. Differences in settings, populations and health care systems may, therefore, limit applicability.

8. CONCLUSIONS

There is evidence that one to one interventions can reduce STIs and may increase condom use and prevent unsafe sexual behaviours. However, effectiveness decreases over time. A brief US STI prevention intervention, Project RESPECT, delivered in the context of routine health services with existing staff has been shown to be effective (Kamb 1998) in reducing STIs and increasing condom use. Components of Project RESPECT included:

- Client centred intervention tailored to individual's personal risk
- Behavioural goal setting and risk reduction strategies
- Standardised training and structured protocols for clinic staff
- Quality control through observation and feedback

For MSM a multi-session intervention was shown to be more effective than the brief Project RESPECT model (EXPLORE 2004). However, this involved over 10 sessions.

One to one interventions can also improve contraception use and prevent pregnancies in the under 18's. Multi-session interventions involving home visiting appear to be particularly effective in preventing repeat pregnancies in high-risk groups.

Recommendations for future research

There were a number of gaps in the evidence base identified by this review, in particular for the prevention of under 18 conceptions. Many of these gaps have been identified by previous work (Swann 2003). Overall the effectiveness of many STI and under 18 conception prevention programmes remains in doubt. For this reason further high-quality large scale research is needed with evaluation an integral part of programmes. Areas for future research identified by the review include the following:

Prevention of STIs (including HIV)

- Evaluations aimed specifically at vulnerable groups – e.g. young people in or leaving care, young people from some ethnic backgrounds, sex workers, refugees and asylum seekers

- Evaluations of interventions in the UK as most of the included studies were from the USA
- Replication, and evaluation, in the UK of successful US interventions (e.g. Project RESPECT) to evaluate applicability in the UK setting
- Studies large enough to detect a reduction in STIs/HIV infections
- Evaluations of peer-led interventions

Prevention of under 18 conceptions

- Evaluations aimed specifically at vulnerable groups – e.g. young people in or leaving care, young people from some ethnic backgrounds, refugees and asylum seekers
- Evaluations of interventions in the UK as most of the included studies were from the USA
- Studies large enough to detect a reduction in conceptions
- The development and evaluation of one to one interventions in different settings (e.g school based, clinic based)

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Appendix one: Search strategy

Contraceptive Advice and Provision for the Prevention of Under-18 Conceptions and STIs

This is a very comprehensive subject and we initially decided to search separately for three aspects of this review, starting with PubMed.

1. Teenage pregnancy prevention
2. Sexually Transmitted Diseases
3. Contraceptive awareness / compliance etc.

These 'scoping searches' were followed by a 'unified' very sensitive search on PubMed and more specific 'unified' searches (i.e. searches covering all three aspects on a range of databases).

We started by looking at some 20 references which are part of all the three initial sets of references, and then worked in an iterative way through a range of different, similar articles, using the 'related article' algorithm on PubMed, added focused sample searches, review articles and similar.

A set of some 180 references was created and we then developed a unified search strategy (covering all aspects) which retrieved a substantial percentage of the control set, trying not to focus on specific interventions, and applying no regional or 'social class' restrictions.

Particular care was taken to incorporate search terms which might include one-to-one, clinic-based interventions. No age limit was applied to the STI or contraceptive awareness etc. aspects of this review.

In addition we checked reference lists of included studies and of relevant systematic reviews.

Searches were restricted to studies published after 1990
Databases and Search Formulations Checklist

Database	Interface	Date	Search Formulation	Records
AMED	WinSpirs	18.11.05	E	14
CINAHL	WinSpirs	18.11.05	E	1300
Cochrane SR	Wiley Cochrane	27.11.05	G	37
Cochrane Centr Reg	Wiley Cochrane	27.11.05	G	712
Cochrane Meth Reviews	Wiley Cochrane	27.11.05	G	
DARE	Wiley Cochrane	27.11.05	G	33
EMBASE	OVID Web	21.11.05	F	2513
HMIC	WinSpirs	18.11.05	E	150
HTA	Cochrane Wiley	27.11.05	G	8
IBSS	WinSpirs	18.11.2005	E	75
NHS EED	Cochrane Wiley	27.11.05	G	80
PsycInfo	WinSpirs	18.11.05	E	1149
PubMed	WWW	14.11.05	A Pregnancy	1948
			B STI	1371

			C Contraception	1512
PubMed	WWW	17.11.05	D Unified search	8087
SIGLE	WinSpirs	18.11.05	E	27

Search Strategy A

Pregnancy Prevention
PubMed

Pregnancy:

1. "Pregnancy in Adolescence"[MeSH]
2. "Pregnancy"[MAJR] Field: All Fields, Limits: Adolescent: 13-18 years
3. "Pregnancy"[MAJR] AND (teen* or adolescence or adolescen*)
4. (teenag* or adolec*) AND pregnan*
5."teen* mother*" OR teen* father* OR teen* parent*
6. 1 or 2 or 3 or 4 or 5
7. prevent* or prevention or reduce* or reduction or avoid*
8. 6 and 7
9. Counselling or guidance OR brief advice[tw] or opportunistic advice[tw] OR motivational OR support or Advice OR directive counselling or behavior therapy or cognitive therapy OR patient leaflet OR patient flyer OR one-to-one or individual
10. randomi* OR randomised controlled trial OR trial OR review OR cohort studies OR case-control studies OR qualitative OR follow-up OR interrupted time series OR validated or evidence OR guidelines OR consensus
11. 8 AND (9 OR 10) 1948 hits (14.11.2005)

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Search **#39 AND ((Counselling or guidance OR brief advice[tw] or opportunistic advice[tw] OR motivational OR support or Advice OR directive counselling or behavior therapy or cognitive therapy OR patient leaflet OR patient flyer OR one-to-one or individual) OR (randomi* OR randomised controlled trial OR trial OR review OR cohort studies OR case-control studies OR qualitative OR follow-up OR interrupted time series OR validated or evidence OR guidelines OR consensus))** Limits: **Publication Date from 1990 to 2005**	17:22:26 1949
Search **#37 AND #38** Limits: **Publication Date from 1990 to 2005**	17:21:01 2807
Search **prevent* or prevention or reduce* or reduction or avoid*** Limits: **Publication Date from 1990 to 2005**	17:20:41 1441983
Search **#35 OR #36** Limits: **Publication Date from 1990 to 2005**	17:20:11 8451
Search **teen* mother* OR teen* father* OR teen* parent*** Limits: **Publication Date from 1990 to 2005**	17:19:43 1682
Search **#32 OR #34** Limits: **Publication Date from 1990 to 2005**	17:19:20 7439
Search **(teenag* AND pregnan*)** Limits: **Publication Date from 1990 to 2005**	17:18:35 1919
Search **(teenag* AND pregnan*** Limits: **Publication Date from 1990 to 2005**	17:18:24 1919
Search **#31 OR #19 OR #23** Limits: **Publication Date from 1990 to 2005**	17:17:29 6685
Search **#30 AND #22** Limits: **Publication Date from 1990 to 2005**	17:16:50 5969
Search **teen* OR adolescence OR adolescen*** Limits: **Publication Date from 1990 to 2005**	17:16:25 550268

Search **teen* or adolscence OR adolescen*** Limits: **Publication Date from 1990 to 2005** 17:16:19 550268

Search **#19 OR #23 OR #26** Field: **All Fields,** Limits: **Publication Date from 1990 to 2005** 17:15:57 6534

Search **#19 OR #23 OR #26** Limits: **Adolescent: 13-18 years, Publication Date from 1990 to 2005** 17:15:31 6426

Search **#22 AND #25** Limits: **Adolescent: 13-18 years, Publication Date from 1990 to 2005** 17:14:56 5711

Search **teen* OR adolescence OR adolescen*** Limits: **Adolescent: 13-18 years, Publication Date from 1990 to 2005** 17:14:34 535237

Search **teen* or adolscence OR adolescen*** Limits: **Adolescent: 13-18 years, Publication Date from 1990 to 2005** 17:14:24 535237

Search **"Pregnancy"[MAJR]** Field: **All Fields,** Limits: **Adolescent: 13-18 years, Publication Date from 1990 to 2005** 17:13:47 5711

Search **"Pregnancy"[MAJR]** Limits: **Publication Date from 1990 to 2005** 17:13:36 42624

Search **"Pregnancy in Adolescence"[MeSH]** Limits: **Publication Date from 1990 to 2005** 17:12:19 3177

Search Strategy B

STI

sexually transmitted diseases OR sexually transmitted infections OR chlamydia OR HIV infections
Counselling or guidance OR brief advice[tw] or (concise[ti] AND advice[ti]) or opportunistic advice[tw] OR motivational OR support or Advice OR directive counselling or behavior therapy or cognitive therapy OR patient leaflet OR patient flyer OR one-to-one or individual
1 and 2
socioeconomic factors OR socioeconomic status or social class OR social exclusion or socially excluded or social isolation OR poverty areas or poverty OR social gradients or inequalit* or inequity or inequitable OR ((deprivation or deprived) AND (people or person* or families)) OR vulnerable populations OR occupations or manual work* OR working class OR public housing or unemployment or unemployed OR blue collar OR vulnerable people
3 and 4
randomi* OR randomised controlled trial OR trial OR review OR cohort studies OR case-control studies OR qualitative OR follow-up OR interrupted time series OR validated or evidence OR guidelines OR consensus
5 and 6 imited to 1990-2005 1371 hits

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Search **(sexually transmitted diseases OR sexually transmitted infections OR chlamydia OR HIV infections OR genital warts OR gonorrhoea OR syphilis) AND (Counselling or guidance OR brief advice[tw] or (concise[ti] AND advice[ti]) or opportunistic advice[tw] OR motivational OR support or Advice OR directive counselling or behavior therapy or cognitive therapy OR patient leaflet OR patient flyer OR one-to-one or individual) AND (randomi* OR randomised controlled trial OR trial OR review OR cohort studies OR case-control studies OR qualitative OR follow-up OR interrupted time series OR validated or evidence OR guidelines OR consensus) AND (socioeconomic factors OR socioeconomic status or social class OR social exclusion or socially excluded or social isolation OR poverty areas or poverty OR social gradients or inequalit* or inequity or inequitable OR ((deprivation or deprived) AND (people or person* or families)) OR vulnerable populations OR occupations or manual work* OR working class OR** 17:05:55 1372

public housing or unemployment or unemployed OR blue collar OR vulnerable people) Field: **All Fields,** Limits: **Publication Date from 1990 to 2005**

Search C
Contraception Advice etc.

Contraception

contraception OR barrier contraception OR family planning services OR family planning policy OR contraceptive agents OR contraceptive devices OR (contracep* AND (method* OR devic*)) OR sex education OR patient education OR condoms OR emergency contraception OR family planning methods OR contraception behavior or contraceptive behaviour OR pregnancy OR "unwanted pregnancy" OR "unplanned pregnancy"
Counselling or guidance OR brief advice[tw] or (concise[ti] AND advice[ti]) or opportunistic advice[tw] OR motivational OR support or Advice OR directive counselling or behavior therapy or cognitive therapy OR patient leaflet OR patient flyer OR one-to-one or individual
1 and 2
socioeconomic factors OR socioeconomic status or social class OR social exclusion or socially excluded or social isolation OR poverty areas or poverty OR social gradients or inequalit* or inequity or inequitable OR ((deprivation or deprived) AND (people or person* or families)) OR vulnerable populations OR occupations or manual work* OR working class OR public housing or unemployment or unemployed OR blue collar OR vulnerable people
3 and 4
randomi* OR randomised controlled trial OR trial OR review OR cohort studies OR case-control studies OR qualitative OR follow-up OR interrupted time series OR validated or evidence OR guidelines OR consensus
5 and 6
7 AND (Europe or North America) limited to 1990 – 2005 1512 hits

=

Search **(contraception OR barrier contraception OR family planning services OR family planning policy OR contraceptive agents OR contraceptive devices OR (contracep* AND (method* OR devic*)) OR sex education OR condoms OR emergency contraception OR family planning methods OR contraception behavior or contraceptive behaviour OR pregnancy OR "unwanted pregnancy" OR "unplanned pregnancy") AND (Counselling or guidance OR brief advice[tw] or (concise[ti] AND advice[ti]) or opportunistic advice[tw] OR motivational OR support or Advice OR directive counselling or behavior therapy or cognitive therapy OR patient leaflet OR patient flyer OR one-to-one or individual) AND (randomi* OR randomised controlled trial OR trial OR review OR cohort studies OR case-control studies OR qualitative OR follow-up OR interrupted time series OR validated or evidence OR guidelines OR consensus) AND (socioeconomic factors OR socioeconomic status or social class OR social exclusion or socially excluded or social isolation OR poverty areas or poverty OR social gradients or inequalit* or inequity or inequitable OR ((deprivation or deprived) AND (people or person* or families)) OR vulnerable populations OR occupations or manual work* OR working class OR public housing or unemployment or unemployed OR blue collar OR vulnerable people) AND (europe or North America)** Limits: **Publication Date from 1990 to 2005** 17:10:40 1512

Search D

'Unified' search on PubMed

("Sexually Transmitted Diseases"[MAJR] OR "HIV Infections"[MAJR] OR "Chlamydia Infections"[MAJR] OR "Condylomata Acuminata"[MAJR] OR "Herpes Genitalis"[MAJR] OR "Gonorrhea"[MAJR] OR "Gonorrhea"[MAJR] OR "Syphilis"[MAJr] OR "Pregnancy in Adolescence"[MAJR] OR "Contraception"[MAJR] OR "Contraceptive Agents"[MAJR] OR "Contraceptive Devices"[MAJR] OR sexually transmitted[ti] OR hiv[ti] or chlamydia[ti] OR acuminata[ti] or syphilis[ti] or herpes genitalis[ti] or gonorrhea[ti] OR ((sexual health[ti] OR pregnan*[ti]) AND (teen* or adolescen*[ti])) OR contracept*[ti])
AND (prevention or prevent*[ti] OR control*[ti] or reduc*[ti] or promot*[ti])
AND (Counselling or guidance OR brief advice[tw] or opportunistic advice[tw] OR motivational OR support or Advice OR directive counselling or behavior therapy or cognitive therapy OR patient leaflet OR patient flyer OR one-to-one or individual OR patient-centred OR patient centered OR patient-oriented OR improve*[ti] or policy[ti] or policies[ti] OR program*[ti]) AND (randomi* OR randomised controlled trial OR trial OR review OR cohort studies OR case-control studies OR qualitative OR follow-up OR interrupted time series OR validated or evidence OR evaluation or validation or appraisal OR guidelines OR process evaluation OR consensus OR intervention or intervene OR challeng*[ti] OR outcome*[ti] OR opportunit*[ti] OR strateg*[ti] OR servic*[ti] or uptake[ti] OR use[ti])

=
("Sexually Transmitted Diseases"[MAJR] OR "HIV Infections"[MAJR] OR "Chlamydia Infections"[MAJR] OR "Condylomata Acuminata"[MAJR] OR "Herpes Genitalis"[MAJR] OR "Gonorrhea"[MAJR] OR "Gonorrhea"[MAJR] OR "Syphilis"[MAJr] OR "Pregnancy in Adolescence"[MAJR] OR "Contraception"[MAJR] OR "Contraceptive Agents"[MAJR] OR "Contraceptive Devices"[MAJR] OR sexually transmitted[ti] OR hiv[ti] or chlamydia[ti] OR acuminata[ti] or syphilis[ti] or herpes genitalis[ti] or gonorrhea[ti] OR ((sexual health[ti] OR pregnan*[ti]) AND (teen* or adolescen*[ti])) OR contracept*[ti]) AND (prevention or prevent*[ti] OR control*[ti] or reduc*[ti] or promot*[ti]) (Counselling or guidance OR brief advice[tw] or opportunistic advice[tw] OR motivational OR support or Advice OR directive counselling or behavior therapy or cognitive therapy OR patient leaflet OR patient flyer OR one-to-one or individual OR patient-centred OR patient centered OR patient-oriented OR improve*[ti] or policy[ti] or policies[ti] OR program*[ti]) (randomi* OR randomised controlled trial OR trial OR review OR cohort studies OR case-control studies OR qualitative OR follow-up OR interrupted time series OR validated or evidence OR evaluation or validation or appraisal OR guidelines OR process evaluation OR consensus OR intervention or intervene OR challeng*[ti] OR outcome*[ti] OR opportunit*[ti] OR strateg*[ti] OR servic*[ti] or uptake[ti] OR use[ti])

Search E

CINAHL, HMIC, IBBS, PsycInfo, Sigle, AMED

((((teen* or adolescen*) and pregnan*) or sexual* transmi* or HIV or acquired immun* or CHLAMYDIA* or Gonorrhea or syphilis or condylomata or herpes genitalis or genital wart* or contracepti* or contraception or condom* or morning after or venereal) in TI)and((prevention or prevent* or control or reduce or reduct* or promot* or educat*) in TI)and(randomised or randomized or trial or trials or review or cohort or case-control or qualitative or follow-up or evidence or evaluation or validation or appraisal or guidelines or process evaluation or consensus or intervention or intervene or systematic)

Search F

EMBASE

((teen$ or adolescen$) and pregnan$) or sexual$ transmi$ or HIV or acquired immun$ or CHLAMYDIA$ or Gonorrhea or syphilis or condylomata or herpes genitalis or genital wart$ or contracepti$ or contraception or condom$ or morning after or venereal)).ti. and (prevention or prevent$ or control or reduce or reduct$ or promot$ or educat$).ti. and (randomised or randomized or trial or trials or review or cohort or case-control or qualitative or follow-up or

evidence or evaluation or validation or appraisal or guidelines or process evaluation or consensus or intervention or intervene or systematic).mp.

1. ((teen$ or adolescen$) and pregnan$).ti.

2. (sexual$ transmi$ or HIV or acquired immun$ or CHLAMYDIA$ or Gonorrhea or syphilis or condylomata or herpes genitalis or genital wart$ or contracepti$ or contraception or condom$ or morning after or venereal).ti.

3. (prevention or prevent$ or control or reduce or reduct$ or promot$ or educat$).ti.

4. (randomised or randomized or trial or trials or review or cohort or case-control or qualitative or follow-up or evidence or evaluation or validation or appraisal or guidelines or process evaluation or consensus or intervention or intervene or systematic).mp.

5. (1 OR 2) and 3 and 4 2,513

Search G

Cochrane etc.

((teen* or adolescen*) and pregnan*) or sexual* transmi* or HIV or acquired immun* or CHLAMYDIA* or Gonorrhea or syphilis or condylomata or herpes genitalis or genital wart* or contracepti* or contraception or condom* or morning after or venereal in ti

AND

(prevention or prevent* or control or reduce or reduct* or promot* or educat*) in ti

No further study type, intervention, or geographical restriction

#5	**((teen* or adolescen*) and pregnan*) or sexual* transmi* or HIV or acquired immun* or CHLAMYDIA* or Gonorrhea or syphilis or condylomata or herpes genitalis or genital wart* or contracepti* or contraception or condom* or morning after or venereal** in **Record Title** and **(prevention or prevent* or control or reduce or reduct* or promot* or educat*)** in **Record Title** in **all products**	**892**	edit	delete

Show Results in:
Cochrane Reviews [37] | DARE [33] | CENTRAL [712] | Methodology Reviews [0] | CMR [22] | HTA [8] | NHS EED [80] | About [0]

Appendix Two

Data Extraction Tool – Controlled Studies

A. Study Identification

A.1 Ref ID (number assigned by Access database)	
A.2 Citation	
A.3 Associated citations (ref IDs)	A.4 Is this the primary reference? ☐ Yes ☐ No
A. 4 Data extracted by:	A.5 Date of extraction:
A.6 Funding of the study	☐ Government (including university) ☐ Voluntary sector ☐ Industry ☐ Unclear/not reported

B. Overview

B.1 Describe the study type:	
Systematic review (including at least one RCT)	☐
Systematic review of experimental studies	☐
Systematic review of observational studies	☐
Randomised controlled trial: Individual	☐
Randomised controlled trial: cluster	☐
Controlled before and after	☐
Interrupted time series	☐
Before and after study	☐
Cross sectional (survey)	☐
Audit/Evaluation	☐
Economic analysis	☐
Case study	☐
Local practice report	☐
Qualitative study Focus group(s) Brief interview Extended interview Semi-structured interview Document analysis Observation (passive/participant)	☐ ☐ ☐ ☐ ☐ ☐

B.2 What was the research question/aim?	
B.3 Objectives clearly stated?	Yes ☐ No ☐
B.4 Inclusion and exclusion criteria documented?	Yes ☐ No ☐
B. 5 Intervention described?	Yes ☐ No ☐
B. 6 Comparison described?	Yes ☐ No ☐
B. 7 Outcome described?	Yes ☐ No ☐
B. 8 Methodology checklist question 1.1 (study addresses an appropriate and clearly focused question?)	
B.9 Topic(s) covered HIV STIs Teenage conceptions/pregnancies Relevant to teenage pregnancy prevention (e.g condom promotion in teenagers)	 ☐ ☐ ☐ ☐

C. Setting and participants

C.1 Geographical location (City/Country): **Country specify**	☐ UK ☐ North American (USA, Canada) ☐ Europe ☐ Australia/New Zealand ☐ Other
C.2 Date of study (to/from):	
C.3 Setting	☐ Genitourinary medicine/STD clinic ☐ General practice/primary care clinic ☐ Community outreach ☐ School ☐ Workplace ☐ Hospital ☐ Other
C.4 Describe the setting:	
C.5 Participants Number of participants/organisations enrolled:	
C.6 Types of participants	☐ Adolescents/teenagers ☐ women only ☐ MSM ☐ Heterosexuals only ☐ Drug users ☐ People with mental health problems ☐ People with HIV ☐ commercial sex workers ☐ Refugee or asylum seekers ☐ People in prison ☐ People in or leaving care ☐ Homeless people ☐ other (please specify)

C.7 Ethnic Group	☐ White ☐ Black (including Caribbean) ☐ Asian ☐ Hispanic ☐ Other ☐ Not reported/not clear
C.8 Socio-economic data (if presented):	
C.9 Age (range or mean):	
C. 10 Sex (%)	
C.11 Method of recruitment/enrolment and response rate:	
C.12 Inclusion criteria	
C.13 Exclusion criteria	

D. Intervention

D.1 How many groups?	
D.2 Comparisons	☐ Comparison with other intervention ☐ Comparison with TAU ☐ Comparison with no intervention ☐ No control/comparison
D.3 Timing of control	☐ Concurrent control group ☐ Historical control group ☐ Not reported/unclear
D.4 Describe intervention 1	
D.5 Describe intervention 2	
D.6 Describe intervention 3	
D.7 Describe control arm	
D.8 Is the intervention well described?	
D.9 Were the individuals in the different groups otherwise treated the same?	☐ Yes ☐ No ☐ Unclear
D.10 Methodology checklist question 1.6 (the only difference between the groups is the treatment under investigation)	
D.11 Method/mode of delivery (e.g. peer education):	
D.12 Providers/deliverers of the intervention:	

D.13 Is intervention based on any model/theory? **If yes please specify:**	☐ Yes ☐ No
D.14 Did intervention address socio-economic/cultural factors? (if so please specify)	
D. 15 Length, duration and intensity of intervention:	
D.16 Time to follow up (average/median)	
D.17 How many participants completed the intervention?	☐ 80% or more followed up ☐ 60-80% followed up ☐ less than 60% followed up
D.18 Were there differences in numbers lost to follow up between different arms of the trial?	
D.19 Methodology checklist question 1.8	
D. 20 For non-completers, were the reasons for non-completion described?	

E. Randomisation and allocation

E.1 Level of randomisation	☐ Individual ☐Group/clusters If clusters specify
E.2 Description of generation of randomisation sequence?	☐ Computer generated ☐ Other (if so specify)
E.3 Methodology checklist question 1.2 (assignment of subjects to treatment groups is randomised	
E.4 Description of concealment of allocation (e.g central telephone randomisation, sealed opaque envelopes)	
E.5 Method of allocation to intervention	☐ Central telephone randomisation ☐ Central pharmacy randomisation ☐ Sealed opaque sequentially numbered envelopes ☐ Other adequate method of concealment
E.6 Method of allocation concealment	☐ Sealed opaque envelopes ☐ Sealed envelopes
E.7 Method of allocation concealment	☐ Alternation ☐ Allocation by day of week, case record number
E.8 Method of allocation concealment	☐ Not described ☐ Not clear
E. 9 Methodology checklist question 1.3 (an adequate allocation method is used)	

F. Blinding

F.1Type of blinding described?	☐ Yes ☐ No ☐ Unclear/not stated
F.2 Stated that patients blinded?	☐ Yes ☐ No ☐ Unclear/not stated
F.3 Stated that intervention provider blinded?	☐ Yes ☐ No ☐ Unclear/not stated
F.4 Stated that outcome assessor blinded?	☐ Yes ☐ No ☐ Unclear/not stated
F.5 Stated that analyst blinded?	☐ Yes ☐ No ☐ Unclear/not stated
F.6 Methodology checklist question 1.4 (subjects and investigators are kept blind about treatment allocation)	

G. Methods (other)

G.1 Were treatment groups balanced at baseline? Comments:	☐ Yes ☐ No ☐ Unclear/not stated
G.2 Methodology checklist question 1.5 (the treatment and control groups are similar at the start of the trial)	
G.3 Was a power calculation presented? **Was the study powered to detect an effect if one exists?**	☐ Yes ☐ No ☐ Yes ☐ No ☐ Unclear/not stated
G.4 Give details of numbers needed for power calculation	
G.5 Describe data collection methods used	

H. Analyses

H.1 If cluster –randomised trial is clustering factored for in the analysis?	☐ Yes ☐ No ☐ Unclear/not stated ☐ N/A
H.2 Intention to treat analysis done **Comments:**	☐ Yes ☐ No ☐ Unclear/not stated
H.3 Methodology checklist question 1.9 (are all the subjects analysed in the groups to which they were randomly allocated)	
H.4 Multivariate analyses performed?	☐ Yes ☐ No
H.5 Any comments on analyses	
H.6 Multi-centre study?	☐ Yes ☐ No
H.7 Analysis on centres taken into account in interpretation	☐ Yes ☐ No ☐ Unclear/Not stated ☐ N/A
H.8 Methodology checklist question 1.10 (where the study is carried out at more than one site, results are comparable for all sites?)	

I Outcomes measured

Primary outcomes	Measured at follow up	Measured at baseline
Pregnancy	☐	☐
Conceptions	☐	☐
Sexually acquired infection	☐	☐
HIV	☐	☐
Secondary outcomes		
Contraception use	☐	☐
Condom use	☐	☐
Knowledge of contraception	☐	☐
Intention to use condoms	☐	☐
Delay in initiation of sexual intercourse	☐	☐
Reduction in number of partners	☐	☐
Participants experiences	☐	☐
Other relevant outcome (please specify):	☐	☐
Were the outcome measures validated? If so, how?		

J. Results

Outcome 1:

Describe the outcome				
How is outcome defined?				
How was outcome measured?				
Outcome measured in a standard, valid and reliable way?				
Type of data (e.g. continuous. Dichotomous)				
	Intervention 1	Intervention 2	Intervention 3	Control group
Number of participants randomised				
Number of participants in analysis				
Number of events **before** intervention (if data available)				
Number of events **after** (specify time point)				
Mean (SD)				
Risk ratio (95% CI)				
Odds ratios (95% CI)				

Mean difference between groups	
Any comments	

Results:
Any other information

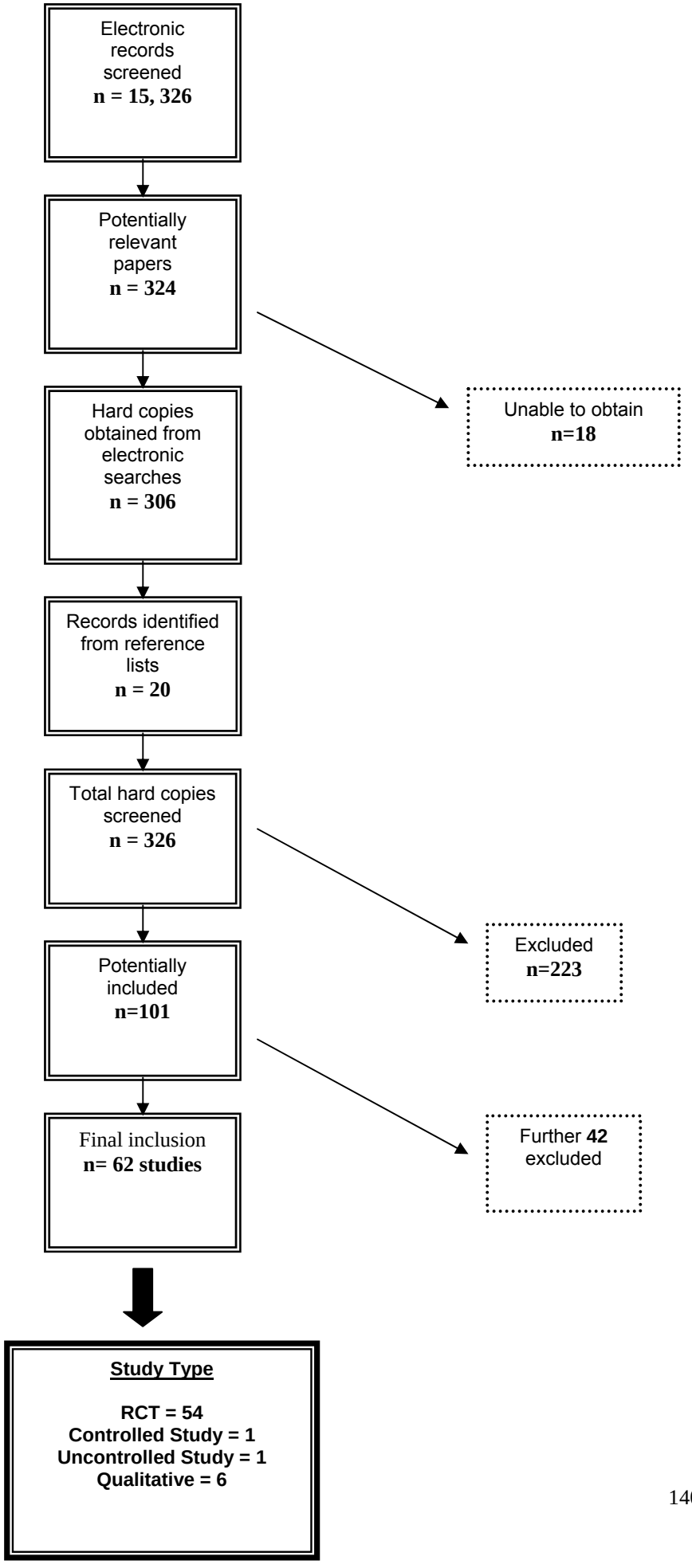
K Applicability

K.1 Does the paper address of offer any evidence of effect in the following groups: If so please ensure that evidence is presented in results above? Young people (e.g. under the age of 18) ☐ Older people ☐ Gender ☐ Black and minority ethnic groups ☐ Lower socio-economic groups ☐ MSM ☐ Sex workers ☐ Refugees and asylum seekers ☐ Other (please specify): ☐	
K.2 Does the paper demonstrate any evidence of harms or adverse effects associated with the intervention?	
K.3 Do the authors identify any strengths and/or weaknesses of the evidence presented?	
K.4 In your opinion are the results generalisable to the UK? Why?	☐ Yes ☐ No ☐ Unclear
K.5 Are the results likely to be: 1.Applicable across a broad range of populations and settings 2.Applicable across a broad range of populations and settings assuming appropriately adapted 3.Applicable only to populations or settings included in the studies, and broader applicability is uncertain 4.Applicable only to settings or populations included in the studies Please specify number (1-4)	
K.6 Do the authors identify any evidence gaps or make any recommendations for further research?	
K.7 Is there any data on cost-effectiveness presented?	
K.8 Are there any policy implications for the work?	
K.9 Are there effective practice implications for the work?	

Notes

APPENDIX THREE: Identification of studies

Figure 14: Identification of Studies



Appendix Four: References to included studies

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APPENDIX FIVE: Evidence Tables

Table 17: Evidence for the effectiveness of one to one interventions for the prevention of STIs including HIV – presented by population

Adolescents

First Author	Study design	Research quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention I = intervention C = control	Outcome variable(s)	Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect		Applicability to the UK populations and settings Score 1-4	Notes
								3 months	9 months		
Boekeloo 1999	RCT	-	Does primary care based STI prevention education reduce risky sexual behaviours in young adolescents?	**Population** Adolescents aged 12-15 attending for general health examination (majority African American, 50% female). **Setting** 5 primary care HMO practices (3 suburban, 2 inner-city). **Country** Washington, USA	215 (8% lost to follow up) No PC reported.	**I)** Pre-visit audiotaped STI risk assessment by researchers. Then Program ASSESS (awareness, skills, self-efficacy/self-esteem and social support). Involved education (tailored to individual) & brochures. Based on social cognitive, theory of reasoned action. **Providers** Paediatricians with 45 minute STI prevention training. **Duration & intensity** 1 session (length not specified) **C)** Usual care - regular health examination (18% received non study-specific HIV/STI educational materials).	Vaginal intercourse in last 3 months: Vaginal, oral or anal intercourse in last 3 months Condom use at last vaginal intercourse among those sexually active in last 3 months Unprotected sex Been treated for an STI	- adjusted OR 2.46 (1.04-5.84) 0 unadjusted RR 1.37 (0.82, 2.28) 0 adjusted OR 1.55 (0.73 – 3.32); 0 unadjusted RR 1.04 (0.67, 1.61) + (adjusted) OR 18.05 (1.27-256.03) + (unadjusted) RR 1.61 (1.09, 2.37) + (adjusted) OR 8.63 (1.60-46.45) + unadjusted RR 0.19 (0.05, 0.77) 0 2.2% vs. 4.7% ES: h=0.05	0 adjusted OR 1.64 (0.81 -3.34); 0 Unadjusted RR 1.13 (0.75, 1.72) 0 (adjusted) OR 1.56 (0.79-3.08); 0 unadjusted RR 1.16 (0.80, 1.67) 0 (adjusted) OR 1.00 (0.31-3.24) (unadjusted) RR 1.01 (0.73, 1.40) 0 1.1% vs. 5.8% ES:h=0.09 RR 0.18 (0.02, 1.49)	3	Theory based

Table 17 continued - Adolescents

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention I = intervention C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect**	**Applicability to the UK populations and settings** Score 1-4	**Notes**
Bolu 2004 (sub group analyses from Kamb 1998) Project RESPECT	RCT	++	Do two face-to - face didactic interactive counselling interventions - for vulnerable populations - prevent high risk sexual behaviours and new STIs and is one more effective than the other?	**Population** Looks at subgroup analyses for adolescents under the age of 20 (n= 764). Multiethnic	764 PC done for full trial (Kamb 1998) – not powered for this subgroup analysis.	(Ia)**Enhanced counselling (EC).** based on theory of reasoned action and social cognitive theory. Sought to change key elements underlying condom use (e.g. self efficacy, attitudes and perceived norms). Included behavioural goal setting and risk-reduction plan. (Ib) **Brief counselling (BC)** modelled after CDC's recommended HIV counselling. Addressed barriers to risk reduction and negotiated risk-reduction plan. **Duration & Intensity** Ia) enhanced 4 sessions (1x 20 mins, 3x 60 mins) Ib) brief – 2 x 20-mins C) 2x 5 min sessions. **Provider** Ia & Ib) Counsellors with standard training; used structured intervention protocols. C) Clinician **C) Didactic messages** - informational intervention – designed to approximate TAU in most clinics.	**STI** (by subgroup) EC vs. control BC vs. control EC vs. BC	12 months + RR 0.65 (0.49, 0.86) + RR 0.66 (0.47, 0.92) 0 OR 1.1 (95% CI 0.63-1.78	2	9.4 STIs prevented per 100 people counselled.

Table 17 continued - Adolescents

First Author	Study design	Research quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention I = intervention C = control	Outcome variable(s)	Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect	Applicability to the UK populations and settings Score 1-4	Notes
Danielson 1990	RCT	+	Does a reproductive health consultation affect male sexual activity behaviour?	**Population** Adolescent males (aged 15-18) **Setting** Kaiser Permanente (a health maintenance organisation) offices. **Country** Northwest, USA	1449 (18% lost to follow up). PC not reported.	**I)** Medical appointment which included slide-tape programme (seen privately) covering general reproductive health concerns. Then visit with health care practitioner that focused on contraception & was guided by patients' interests (included info on STIs). **Duration and intensity** 30 min tape show + 30 min consultation **Providers** Nurse practitioners, physicians' assistants, registered nurses. **C)** Delayed intervention	Became sexually active following intervention Condom used at most recent intercourse. Partner used contraceptive pill Knowledge about preventing STIs Knowledge about AIDS	12 months 0 30% vs. 34% ; ES: h=0.08 0 33.6% vs. 35.8%; ES: h=0.05 RR 0.94 (0.74, 1.19) + 32.4% vs. 23.9%; ES: h=0.18 RR 1.34 (1.02, 1.78) + OR 1.98 (p<0.001) (% change not reported) + OR 1.28 (p<0.05)	3	Money given for travel
Deas 2000	RCT	-	Does a brief educational motivation intervention reduce HIV/AIDS risk behaviours in treatment seeking substance-abusing adolescents?	**Population** Adolescents seeking substance abuse treatment (mean age 15, 56.5% males, majority white). **Setting** In-patients in Institute of Psychiatry **Country** South Carolina, USA	60 (17% lost to follow up) PC not reported	**I)** Educational motivation intervention. General discussion of psychiatric and substance abuse assessment + one to one intervention. Designed to educate about HIV/AIDS, correct misconceptions, and motivate to avoid or reduce risk behaviours. **Duration and intensity** One x 15-minute session. **Provider** Child/adolescent psychiatrist **C)** TAU discussion of psychiatric and substance abuse assessment only	Knowledge on HIV/AIDS Total risk behaviour (included sexual and drug related behaviours)	6 months 0 p=0.440 (change scores not given) ES: d=0.24 0 p=0.840 (change scores not given) ES: d=0.06 Both groups showed a reduction in risky behaviours over time (p=0.047)	3	

Table 17 continued - Adolescents

First Author	Study design	Research quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention I = intervention C = control	Outcome variable(s)	Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect		Applicability to the UK populations and settings Score 1-4	Notes
DeLamater 2000	RCT	-	Do videotape or health educator interventions affect sexual risk behaviour among black adolescent males?	**Population** Male African American adolescents 15-19 yrs old (mean age 18.3, 28% 1 year or more below expected grade level). **Setting** Community health agencies **Country** USA	562 (lost to follow up not specified) No PC reported	**Ia) (health educator)** Face to face individually tailored information session. **Provider** Trained female African American health educator. **Ib) (video)** Individually attended video health education session. **Duration and intensity** Both interventions lasted 14 minutes. Both covered same information, were culturally specific and based on self-regulation model of illness behaviour, self-efficacy theory. **C)** Standard care and education programme.		30 days	6 months	3	Theory based
							Condom use with casual partner (last 30 days)	0 Ia 0 Ib	0 Ia 0 Ib		
							Condom use with steady partner (last 30 days)	0 Ia 0 Ib	0 Ia 0 Ib		
							Number of partners (last 30 days)	0 Ia 0 Ib	0 Ia 0 Ib		
							Consistent condom use with casual partners (pre to post, all groups combined)	+ 14% increase	+ 24% increase		
							Consistent condom use with steady partners (pre to post, all groups combined)	+ 35% increase	+ 33% increase		
							Number of partners (last 30 days) Pre to post, all groups combined	Both groups combined ($p<0.05$)			

Table 17 continued - Adolescents

First Author	Study design	Research quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention I = intervention C = control	Outcome variable(s)	Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect	Applicability to the UK populations and settings Score 1-4	Notes
Di Noia 2004	Cluster RCT	-	Does a brief computer-mediated intervention alter HIV/AIDS related knowledge, protective attitudes and self-efficacy for risk reduction?	**Population** Adolescent females aged 11-14 (mean age 13, 43% black, 46% Hispanic, 11% white, 9% sexually active). **Setting** Social service agencies. **Country** New York, USA	205 (loss to follow up not reported) Post hoc PC calculation – 80% power to detect .20 effect size	**I)** 'Keeping it safe' computer assisted intervention. Didactic instruction about HIV risk, interactive game with feedback. Scenarios to help participants learn assertive responding to manage interpersonal situations and reduce risk behaviour. **Duration and intensity** One x 30-mins. **C)** Waiting list control who did not receive the intervention.	HIV/AIDS related knowledge Self-efficacy for HIV risk reduction	2 weeks + p<.001 (no change scores given) (ES: d=0.12) + p<.05 (ES: d=0 .02)		

Table 17 continued - Adolescents

First Author	Study design	Research quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention I = intervention C = control	Outcome variable(s)	Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect		Applicability to the UK populations and settings Score 1-4	Notes
Downs 2004	RCT	+	Does a theoretically based, interactive video intervention affect adolescent girls STI knowledge, risk behaviour and STI acquisition?	**Population** Sexually active female adolescents aged 14-18 (75% African American) **Setting** 4 Urban healthcare sites. **Country** Pittsburg, USA	300 (14% lost to F.U) Not clear how many participants were in each group. PC not reported	**I)** Interactive hour long video looking at sexual health decisions, addressing gaps and misconceptions identified from previous qualitative interviews. Included negotiation behaviours, condom efficacy & information about STIs. Based on mental models approach. Participants watched video at baseline (30 mins) and 3 further visits (1,3,6 months) for about 15 mins each time. **Provider** Interactive video developed by research team. **Ca)** Same content as video but in book form **Cb)** Commercially available brochures (similar length and content).	STI acquisition Condom use STI knowledge (intervention versus either control) STI knowledge (pre to post both intervention and control) Abstinent (defined as no sexual partners since baseline)	3 months Not measured 0 (p=0.57) ES: d=0.07 0 (data not reported) + OR 2.50 (p=0.027)	6 months Adjusted + OR 2.79 (p=0.05) unadjusted 0 RR 0.53 (0.28, 1.02) 0 p=0.15 ES:d=0.17 0 (data not reported) + p<0.001 ES: d=0.96 0 OR 1.45 (p=0.344)	3	Theory based Monetary incentive to take part in follow up. Not powered to detect STIs except Chlamydia (p=0.05)

Table 17 continued - Adolescents

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention** **I = intervention** **C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified)** **(+) = positive effect, (-) = negative effect, (0) = no effect**	**Applicability to the UK populations and settings** Score 1-4	**Notes**
Mansfield 1993	RCT	-	Does HIV education and counselling reduce risk behaviours in adolescents?	**Population** Adolescents who have had at least one sexually transmitted disease (majority black & female, mean age 17.6,) **Setting** Adolescent clinic of urban children's hospital **Country** USA	90 (7.8% lost to follow up) PC not reported	**I)** Same as control + counselling session to discuss HIV risk & prevention, efficacy of condoms, drug use and HIV testing **C)** TAU- individualised risk assessment for HIV, counselling on condom use, HIV pamphlet, free condoms **Duration and intensity** Intervention – 1 20 minute session Control – 1 10-minute session. **Provider** Physicians	Always use condoms Average number of partners a month Reduction in mean number of partners (both groups combined)	2 months Intervention versus control 0 34.4% vs. 26.7% (p=0.16) RR 1.50 (0.67, 3.38) + Both groups combined (pre to post) 13% to 19% increase (p=0.001) 0 0.9 vs. 0.7 (MD 0.20 (-0.05, 0.45); ES: d=0.29 + 0.4 (± 0.9) p = 0.0001 (t-test)	3	Both groups had a significant increase in condom use but no difference between intervention and control.

Table 17 continued - Adolescents

First Author	Study design	Research quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention I = intervention C = control	Outcome variable(s)	Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect		Applicability to the UK populations and settings Score 1-4	Notes
Metzler 2000	RCT	-	Do behavioural interventions with adolescents attending an STD clinic reduce unsafe sexual practices?	**Population** Adolescents aged 15-19 engaged in high risk sexual behaviour (average age 17, 68% female, 68% white) **Setting** Public STI clinics **Country** USA	339 (53% lost to follow up) PC not reported.	**I)** Individual counselling sessions addressing decision making about safer sex, setting safer sex goals, increasing social skills, and acceptance of negative thoughts associated with change. Based on social cognitive theory, information motivational-behavioural skills model. **Duration and intensity** 5 x 60-90 mins. **Provider** General public health clinic staff with 2 days training. **C)** Usual care which generally involved a clinic examination and a brief interaction with the nurse (may have included discussion about condoms and safer sex)	New self-reported STIs (covariate adjusted means) Condom use in past 3 months (covariate adjusted means) Number of partners in past 3 months (covariate adjusted means)	3 months 0 p=0.76 (effect size .00) 0 p=0.94 (effect size .00) 0 p=0.55 (effect size .00)	6 months 0 p=0.24 (ES d=0.01) 0 p=0.96 (ES d=0.00) + (all) p=0.0001 (effect size .11) + Men (p = 0.02) 0 Women (p = 0.08) 0 Minority males (p=0.56) Minority females (p=0.55)	3	Theory based

Table 17 continued - Adolescents

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention I = intervention C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect**	**Applicability to the UK populations and settings** Score 1-4	**Notes**
Orr 1996	RCT	-	Does a behavioural intervention increase condom use and reduce STIs among high-risk female adolescents?	**Population** Sexually active female adolescents with C. trachomatis infection (55% black, mean age 17.9, predominantly lower class, 49% previous pregnancy) **Setting** Two family planning clinics and a county STD clinic. **Country** Indianapolis, USA	209 (46% lost to follow up) PC not reported	**I)** STI education, condom negotiation skills, condom skills training and promoting positive attitudes about condoms (included role-playing). Based on health belief model. **Provider** Trained, adult research assistant. **C)** Standard treatment – individual discussion with clinic nurse about STIs (including partner notification and condom use) & printed information about c.trachomatis. **Duration and intensity** Both intervention and control one session, 10-20 mins long.	Reinfection rates (c. trachomatis) Frequency of condom use (adjusted) Always use condom Sometimes use condom	5-7 months 0: RR 1.50 (0.73, 3.10) 26% vs. 17% (p=0.3) ES: h=0.18 + OR 2.8 (1.1,7.1) (p = 0.03) 0 RR 0.90 (95% CI 0.29, 2.76) + RR 1.90 (95% CI 1.19, 3.02)	3	Theory based

Table 17 continued - Adolescents

First Author	Study design	Research quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention I = intervention C = control	Outcome variable(s)	Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect		Applicability to the UK populations and settings Score 1-4	Notes
Shrier 2001	RCT	-	Does an individualised safer sex intervention affect condom use and recurrent STIs among female adolescents diagnosed with an STI?	**Population** Multiethnic female adolescents with cervicitis or PID (median age 17.2, 49% black, 18% Hispanic, 14% white) **Setting** Hospital-based adolescent clinic **Country** Boston, USA	123 (lost to follow up – 6 months 27%, 12 months 48%) No PC reported (but not powered to detect STI)	**I)** Individualised education session which included 7 minute video, self assessment exercises, male and female condom demonstration, educational sessions based on stages of change (looked at risk, consequences of unprotected sex, preventing pregnancy and STI and condom use). Based on social cognitive theory, transtheoretical model of behaviour change & motivational enhancement interviewing. **Duration and intensity** One session (video + 30 minute discussion) and booster at 1,3 & 6 months. **Delivered by** Female health educators trained by principal investigator. **C)** STI education at the discretion of the physician (including discussion of STI transmission and importance of consistent condom use).	STI Condom use with last sexual encounter Consistent (every time) condom use with main partner (data only for those reporting current partner) Consistent (every time) condom use with other partner (data only for those reporting another partner)	6 months Not reported 0 RR 1.10 (0.77, 1.58) 0 50% vs. 32% RR 1.62 (0.88, 2.99) 0 60% vs. 68% ES: h=0.21	12 months 0 RR 0.52 (0.20, 1.31) ES: h = 0.31 0 RR 1.13 (0.74, 1.74) 0 52% vs. 36% RR 1.31 (0.68, 2.53) 0 71% vs. 42% ES: h=0.71	3	Theory based

Table 17 continued - Adolescents

First Author	Study design	Research quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention I = intervention C = control	Outcome variable(s)	Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect	Applicability to the UK populations and settings Score 1-4	Notes
Winter 1993	RCT	-	Do two educational interventions in a family planning clinic improve condom acceptance, attitudes and knowledge in adolescents already using oral contraceptives?	**Population** Sexually active white female adolescents, 13-19. already using oral contraceptives (mean age 17.6) **Setting** Two family planning clinics **Country** Pennsylvania, USA	291 (none lost to follow up) No PC reported.	**Ia)** Direct-experience intervention. Same information as in control but educator had client handle condom and practice use. Client asked to give opinion about condoms. **Ib)** Contingency-planning condition. Same as direct-experience intervention but also explored barriers & facilitators to condom use Interventions based on models of mental representations and behaviour. **Duration & intensity** 1 session, length not specified. **Provider** Health educator C) Standard condom education including information about condom use and effectiveness and demonstration.	Mean number of condoms accepted (used as a measure of condom acceptance) Attitude towards condoms Condom knowledge (one way analysis of variance)	Follow up immediately post intervention 0 Ia vs. control (p value not reported) ES: d=0.02 + Ib vs. control (p<.005) ES: d=0.45 + Ib vs. Ia (p<.001) ES: d=0.44 0 Ia) vs. control (p value not reported) ES: d=0.04 + Ib vs. control (p<.011) ES: d=0.39 ES: d=0.39 + Ib vs. Ia (p=.006) ES d=0.35 0 P = 0.69) For all comparisons. ES: d= 0.10		

Table 17: Evidence for the effectiveness of one to one interventions for the prevention of STIs including HIV – presented by population

General population

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention** **I = intervention** **C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified)** **(+) = positive effect, (-) = negative effect, (0) = no effect**		**Applicability to the UK populations and settings** Score 1-4	**Notes**
Artz 2000	Uncontrolled before/after study	2-	Does promotion of the female condom to a high-risk population increase use of barrier methods during intercourse?	**Population** Female; median age 23; 87% single; median number of years in school=12; median per capita household income=$200/ month; 84% African American **Setting** 2 STD clinics. **Country** Alabama, USA	1159 (55% lost to follow-up overall but 88% attended at least one assessment) No PC reported	I) Video**:** to familiarise participants with FC and correct usage Counselling session with nurse clinician: Individual, skills-orientated, 30-45 mins. Covered STD prevention, FC promotion, FC demonstration and practice, partner communication, safe sex info, method selection, condom availability, problem solving, promise to use condom, insertion practice and check, free supplies of male and female condoms, handouts **Provider** Nurse clinicians, trained to deliver the intervention. **Intensity/duration** Single session, with follow-up interviews once/ month for 6 months **C)** No Control	Male or female condom used during 100% of intercourse Male or female condoms never used during intercourse	1 month 28% (of 955 participants at baseline) vs. 55% (of 806 participants). + among women who were sexually active (p<.001) 0 34% (baseline) vs. 6% (follow up) ES: h=0.43	6 months 28% vs. 56% (of 407 participants) + among women who were sexually active (p<.001) 0 34% vs. 17% ES: h=0.35	3	

Table 17 continued: General population

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention I = intervention C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect**	**Applicability to the UK populations and settings** Score 1-4	**Notes**
Ashworth 1994	RCT	-	Do two educational approaches effect knowledge and attitudes towards HIV and reduce HIV risk-taking behaviour?	**Population** Low income mothers aged 15-24 (average age 25.8 yrs, 94.5% Black) **Setting** Children and youth programme for dietary supplementation **Country** Georgia, USA	217 (lost to follow up not specified) No PC done	**Ia)** Nurse education **-** One to one standardised presentation on AIDS/HIV transmission and prevention **Ib)** Video-tape instruction called 'The Subject is AIDS'. **Duration and Intensity** Nurse education –1 session of 15-18 mins Video- 1 session of 18 mins. **Provider** Black community health nurse **C)** No educational programme except for opportunity to read pamphlets for 15 mins and ask questions.	AIDS/HIV knowledge Decreased intention to engage in risk taking behaviour	2 months 0 Nurse education MD 0.60 (-0.28, 1.48) ES: d=0.20 0 Video MD 0.70 (-0.13, 1.53) ES: d=0.25 0 Nurse education MD 0.10 (-0.31, 0.51) ES: d=0.08 0 Video 0.0 (-0.42, 0.42) 1.0 ES: d=0.00	3	

Table 17 continued: General population

First Author	Study design	Research quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention I = intervention C = control	Outcome variable(s)	Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect		Applicability to the UK populations and settings Score 1-4	Notes
								1 month	3 months		
Belcher 1998	RCT	+	Does a single-session skills based HIV prevention intervention reduce sexual risk behaviour among women?	**Population** Economically disadvantaged females aged 18-56 (mean age 34.9, 95% African-American) **Setting** Community based organisation providing services to men and women in transition **Country** Atlanta, USA	74; 36 intervention, 38 control. 92% completed final follow-up No PC reported	**I)** Single session, skills-building HIV risk-reduction intervention, based on social-cognitive principles and the Information-Motivation-Behaviour Skills Model. Intervention included informational, motivational and behavioural skills components, leading to an individualized personal action plan to reduce risk of HIV. **Provider** Female African American graduate students, trained in HIV and AIDS counselling, and in using the intervention protocol **Duration & intensity** Single 2-hr session. Follow-up at 1 and 3 months **C)** HIV education session, time matched for counsellor contact and time of exposure. No skills training or motivation enhancing elements included.	HIV/ AIDS knowledge Intention to use condom Condom use Unprotected sex % vaginal sex occasions in which condoms used	0 ES: d=0.00 0 ES: d=0.32 Not reported Not reported Not reported	0 ES d=0.20 0 ES: d=0.25 + (p<0.05) ES d=2.26 0 (p<0.06) ES d=0.48 + 66% vs. 43% (p<0.02) ES: h=0.55	3	Theory Based Monetary incentive to take part.

Table 17 continued: General population

First Author	Study design	Research quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention I = intervention C = control	Outcome variable(s)	Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect		Applicability to the UK populations and settings Score 1-4	Notes
Boyer 1997	RCT	+	Does a cognitive behavioural skills building intervention prevent STD in high-risk heterosexual adults.	**Population** High risk heterosexual adults 18-35 (46% black, 29% white,15% Hispanic) **Setting** Public health STD clinic **Country** California, USA	399 randomised (65% followed up at 3 months, 60% at 5 months, 52% followed up at both). PC – 200 subjects in each arm to detect a difference in STI acquisition.	**I)** Individual, multi-component sessions designed to increase knowledge about prevention of STD/HIV, build effective decision making & communication skills, and identify and modify STD/HIV related risk factors. Based on AIDS risk reduction model (ARRM) **Duration & intensity** Four 60-minute sessions over 4 weeks. **Provided by** Trained intervention counsellor. **C)** Standard 15-minute risk-reduction counselling session offered to all patients.	STI (diagnosed or suspected) Sexual intercourse without condoms (in 2 months prior to assessment) – change from baseline Mean number of sexual partners without a condom	3 months Not reported + Reduction in intervention and control group ($p<0.001$), ES: c=0.11 greater in intervention group ($p<0.05$) ES: c=0.02 Data not reported	5/ 6 months 0 (all) 13% vs. 11% RR 1.17 (95% CI 0.68, 2.02) 0 Men 7% vs. 8% ($p>0.20$) ES: h=0.02 0 Women 22% vs. 22% ($p>0.20$) ES h=0.00 0 (data not reported_ + 0.6 vs. 0.9 ($p<0.01$)	3	Theory Based Financial incentive for participation in follow up.

Table 17 continued: General population

First Author	Study design	Research quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention I = intervention C = control	Outcome variable(s)	Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect		Applicability to the UK populations and settings Score 1-4	Notes
El-Bassel 2003	RCT	+	Does a relationship based HIV/STI program for heterosexual couples promote safe sex behaviour and is it most effective when delivered to the couple or the women alone	**Participants** Couples in long-term relationship known, or suspected, to have at least one HIV/STD risk criteria. Mainly low income, ethnic minorities **Setting** Hospital outpatient clinics **Country** USA	217 couples (20% intervention grp, 33% control grp lost to follow up) No PC reported	**Ia (couples - C)** Relationship-based counselling to couple together **Ib (women only - WA)** Relationship-based counselling to woman alone Both based on AIDS risk reduction model and ecological perspective, emphasised importance of relationship communication, negotiation & problem solving skills, gender roles & expectations and HIV/STI prevention. **Duration & intensity** Both interventions 6x 2-hour sessions. Control 1x1 hr. **Provider** Facilitators **C)** 1 HIV/STD information session for women alone	Number of unprotected sexual acts Percentage of protected sexual acts Number of STD symptom Number of sexual partners	3 months + WA vs. control, C vs. control 0 WA vs. couples + WA vs. control, ES h=0.37 C vs. control, ES:h=0.24 0 WA vs. couples ES h=0.14 0 Intervention vs. control (p=0.72), WA vs. C (p=0.52) ES: d=0.03 0 Intervention vs. control (p = 0.36), WA vs. C (p= 0.15) ES: d=0.14	12 months + WA vs. control, C vs. control 0 WA vs. couples 0 (data not reported)	2	Theory Based Authors report regression analysis demonstrated that either intervention was associated with safer sexual behaviour (particularly condom use) but that there was no significant difference between the intervention groups.

Table 17 continued: General population

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention** **I = intervention** **C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified)** **(+) = positive effect, (-) = negative effect, (0) = no effect**	**Applicability to the UK populations and settings** Score 1-4	**Notes**
Evans 2000	RCT	-	Does a theoretically based, interactive video intervention affect college students' self-efficacy for HIV preventive behaviours, and intentions to practice such behaviours with current and future partners?	**Population** College students aged 19-23 (69% white) **Setting** University of Texas. **Country** Texas, USA	162 (152 (94%) completed study) 51 completed intervention 1 51 completed intervention 2 50 completed control	**Ia:** Interactive computer assisted instruction (CAI) intended to reduce risk of contracting HIV. Uses stories, role modelling and demonstrations (application of Social Cognitive Theory) to provide information about HIV prevention. **Provider 1** Interactive video. **Intensity/duration 1** Group 1 watched 1x1 hr video and completed post-test immediately after. **Ib:** Lecture, designed to be as similar as possible to the CAI programme in content, objectives, and SCT constructs. Students given opportunity to interact and share experiences. **Provider 2** Health education professional **Intensity/duration 1** Group 2 attended 1x1 hr lecture and completed post-test immediately after. **C)** No intervention; students completed measures after a routine class lecture (not on AIDS or HIV).	Condom intention with current partner Condom intention with future partner(s) (post hoc analysis) Knowledge	Immediately post intervention + Ia vs. Ib (p=0.03) ES f=0.35, d=0.17 0 Ia vs. control ES d=0.06 0 Ia vs. 1b (p= 0.54) ES f=0.13, d=0.09 0 Ia vs. control ES d=0.07 + Ia vs. Ib (p<0.01) ES f=0.72, d=0.25 + Ia vs. control (p <0.01) ES d=0.86 + Ib vs. control (p<0.01) ES d=0.60	2	Theory based

Table 17 continued: General population

First Author	Study design	Research quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention I = intervention C = control	Outcome variable(s)	Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect		Applicability to the UK populations and settings Score 1-4	Notes
James 1998	RCT	+	Does sexual health promotion prevent transmission of HIV and STI?	**Participants** Men and women aged 16 and over (51% men, 93% heterosexual) **Setting** Urban genitourinary medicine clinic **Country:** Nottingham, UK	492 (49% lost to follow up) PC – 101 participants per group to detect an increase in condom use of 25%	**I)** Individually tailored skill training counselling session that aimed to reduce risk-taking behaviours, promote use of condoms & encourage development of interpersonal skills. Included demonstration of condom use & role-play. Based on social learning theory. **Duration & Intensity** One 20-minute session. **Provided by** Health advisors **Ca)** Standard clinic session with health advisor **Cb)** Same as control a + leaflet and condom pack		4 months	18 months	2	Theory based
							RE-attendance at clinic with new STI	Not reported	0 p=0.26 ES c=0.03		
							Always or almost always use condom	RR 0.99 (95% CI 0.61, 1.60)			
							Frequency of condom use with regular partner	0 p=0.39 (no change between groups or between pre and post test) ES c=0.10	Not reported		
							Frequency of condom use with non-regular partner	0 p=0.25 (no change between groups or between pre and post test) Esc=0.09	Not reported		
							Perception of risk (believed themselves to be 'not at all at risk)	+ RR 0.21 (95% CI 0.08, 0.51) (reduction in intervention group compared to either control)			

Table 17 continued: General population

First Author	Study design	Research quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention I = intervention C = control	Outcome variable(s)	Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect			Applicability to the UK populations and settings Score 1-4	Notes
Kalichman 2005	RCT	+	Does a brief risk-reduction counselling intervention reduce unsafe sexual behaviour and prevent HIV/STIs?	**Population** People attending STI clinic (mean age 35.3 yrs, 69% men, 85% African American, 88% annual income less than $20,000) **Setting** Large urban public STI clinic **Country** Wisconsin, USA	612 (22% lost to follow up overall – 21% lost at 3 months, 26% lost at 6 months, 27% lost at 9 months) PC not reported	**Ia) Full Information-motivation-behavioural skills model (IMB).** Included: 1. **Information** on HIV transmission, risk behaviours, prevalence, clarification of myths and misconceptions & information about HIV testing. 2. **Motivational enhancement** - giving participants feedback of own personal risk and using motivational strategies to mobilise individuals own change resources. 3) **Behavioural self-management and sexual communication skills** – looked at risk behaviour and how to manage it, learnt safe-sex strategies. Included role-play & condom use instruction with anatomical models. **Ib)** Information + Motivational enhancement (IM) **Ic)** Information + Behavioural skills (IB) **C)** Information only – delivered by counsellors in didactic style (I) **Provided by:** Counsellors (male and female) with no previous counselling experience.	Unprotected intercourse (results are for each intervention compared against all other interventions) Newly diagnosed STI (intervention	3 months **IMB** 0 Men ES d=.06 - Women ES d=.33 **IM** 0 men ES d=.11 + women ES d=.46 **IB** 0 men ES d=.04 0 women ES d= .06 Not reported	6 months **IMB** + men ES d=.29 0 women ES d= .15 **IM** 0 men ES d=.20 + women ES d=.54 **IB** 0 men ES d= .01 + women ES d=.38 Not reported	9 months **IMB** 0 men ES d=.13 0 women ES. D=.27 **IM** 0 men ES d=.12 + women ES d=.65 **IB** 0 men ES d= .01 + women ES d=.28 IMB 0 RR 0.60 (0.25,	3	Monetary incentive to participate in follow up Full intervention reduced unprotected intercourse in men at 6 months (but not other time points) and reduced STIs. Had no positive effect on women. Most effects for men lost by 9 months. Data only reported for IMB men – not

						Similar qualifications to those typically employed in public health clinics. Were extensively trained in the intervention and basic counselling skills. **Duration and intensity** All groups (including control) received one 90 minute session	versus control) Number of sexual partners	No significant between group differences.		1.46) + men adjusted OR = 7.3 0 women IM 0 RR 1.19 (0.59, 2.40) IB 0 RR 1.16 (0.57, 2.39)		enough data to calculate effect sizes for women or other conditions

Table 17 continued: General population

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention** **I = intervention** **C = control**	**Outcome variable(s)**	**Main results at follow up** **(Reported as intervention vs. control unless otherwise specified)** **(+) = positive effect, (-) = negative effect, (0) = no effect**	**Applicability to the UK populations and settings** Score 1-4	**Notes**

Kamb 1998 Project RESPECT	RCT	++	Do two face-to-face didactic interactive counselling interventions prevent high-risk sexual behaviours and new STIs and is one more effective than the other?	**Population** HIV negative heterosexuals aged 14 and over (median age 25, 57% male, 59% black, 54% unemployed). **Setting** Five public health clinics in different cities. **Country** USA	5758 (66% follow up at final assessment) PC – 1500 per arm for 80% power to detect a 25% reduction in STIs	(Ia)**Enhanced counselling (EC).** based on theory of reasoned action and social cognitive theory. Sought to change key elements underlying condom use (e.g. self efficacy, attitudes and perceived norms). Included behavioural goal setting and risk-reduction plan. (Ib) **Brief counselling (BC)** Brief counselling intervention modelled after CDC's recommended HIV counselling. Addressed barriers to risk reduction and negotiated risk-reduction plan. **Duration & Intensity** Ia) enhanced 4 sessions (1 20 mins, 3 60 mins) Ib) brief – Two 20-minute sessions. C) Two 5 minute sessions. **Provider** Ia & Ib) Counsellors who received standard training and used structured intervention protocols. C) Clinician doing examination **C) Didactic messages** - informational intervention – designed to approximate what was TAU in most clinics.	New STI EC vs. control BC vs. control Condom use (100% self-reported condom use with all partners). EC vs. control BC vs. control EC vs. BC	3 months + 46% vs. 38%,RR 1.21 95% CI 1.09-1.35 + 44% vs. 38%;RR 1.15, 95% CI 1.03-1.27 0 46% vs. 44% RR 1.06, 95% CI 0.96-1.17	6 months + 10.4% vs. 7.2%; RR 0.69 (0.54-0.88) + 10.4% vs. 7.3%; RR 0.71 (0.58-0.89) + 39% vs. 34%;RR 1.15 (1.04-1.26) 0 39% vs. 34%;RR 1.15 (1.04-1.26)	12 months + 14.6% vs. 11.5%; RR 0.78 (0.64-0.94) + 14.6% vs. 12% RR 0.81 (0.67-0.98) 0 data not reported 0 data not reported	2	Monetary incentive to attend sessions, and for follow up (+ free condoms) 82% completed all assigned intervention sessions. Lower in 4-session intervention (72%) than in either of others (85%) Theory based

Table 17 continued: General population

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention** **I = intervention** **C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified)** **(+) = positive effect, (-) = negative effect, (0) = no effect**	**Applicability to the UK populations and settings** Score 1-4	**Notes**
Maher 2003	RCT	++	Does a community-based, intensive counselling intervention reduce STIs among high-risk STI clinic patients?	**Population** Black males aged 16-29 who had had at least one STI **Setting** 2 community STI clinics **Country** Florida, USA	581; 288 intervention and 293 control Numbers lost to follow up not clear.	**I)** Intensive STI counselling. Sessions covered: condom knowledge and correct use, male & female anatomy, personalising risk for HIV and STIs, future educational & job plans. Encouraged screening for STIs, use of condoms, development of condom negotiation skills, & alternatives to intercourse. Culturally sensitive. **Provider** STI counsellors **Intensity/duration** 3 x 40-60 mins. **C)** TAU	Definite STI (clinical test) Possible STI More than 1 STD	12 months 0 16% (intervention) vs. 12% (control) RR 1.31 (0.87, 1.97) 0 31% vs. 27% RR 1.1 (0.9-1.5) 0 3% vs. 4% ES: h=0.02	3	No scheduled follow up – computerised records used to determine new STIs 63% attended at least one session, 38% completed all three.

Table 17 continued: General population

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention I = intervention C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect**		**Applicability to the UK populations and settings** Score 1-4	**Notes**
Metcalf 2005 Project RESPECT-2	RCT	++	Does a booster counselling session 6 months after HIV testing and counselling prevent STDs?	**Population** Sexually active HIV negative people (including MSM) aged 15-39 (mean age 25.6, 46% women, 50% black 22% white 18% Hispanic) **Setting** 3 public health STD clinics in Denver, Long Beach and Newark. **Country** USA	3297 (12% lost to follow up) PC – sample size of 4100 for 80% power to detect a 33% difference in STIs – would be underpowered to detect a smaller reduction.	Both groups received HIV testing (rapid or standard) and given prevention counselling based on a brief 2-session model used in Project RESPECT. Then randomised to: **I)** Additional booster counselling session –based on Project RESPECT (integrates theoretical principles from several models of behaviour change but is not based on a single theoretical model). **Intensity and duration** 1 x 20-minute session 6 months after enrolment. **Provider** Clinic staff **C)** No booster counselling session		9 months	12 months	2	Theory based Monetary incentive for assessment but not to complete intervention.
							STI (defined as one or more STI during follow up – yes/no)	0 RR 1.06 (0.78-1.44) 0 Women RR 1.05 (0.72 – 1.52) 0 Men RR 1.07 (0.64-1.82)	0 RR 0.97 (0.78-1.25) 0 Women RR 1.03 (0.77-1.36) 0 Men RR 0.90 (0.63-1.28)		
							Unprotected sex (all)	0 RR 0.96 (0.90-1.02) 0 Women RR 1.01 (0.92-1.10) 0 Men RR 0.90 (0.46-1.78)	0 data not reported		
							Unprotected sex MSM	0 RR 0.91 (0.83-1.00)	0 data not reported		

Table 17 continued: General population

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention** **I = intervention** **C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified)** **(+) = positive effect, (-) = negative effect, (0) = no effect**	**Applicability to the UK populations and settings** Score 1-4	**Notes**
Oakeshott 2000	Cluster RCT	-	Does a practice based sexual health intervention encourage GPs and practice nurses to offer advice and does this increase condom use?	**Population** **Women 16-34 yrs, attending for smears (mean age 27, 80% white, mean Jarman score of practices 23)** **Setting** General Practice **Country** London, UK	1382 (24% lost to follow up)	**I)** Condom promotion. Backed up with regular supplies of condoms and patient leaflets. When appropriate gave advice about safer sex and condoms to women having smears. **Provider** Practice nurses and GPs **C)** No teaching received	Condom use	1-3 months 0 8% vs. 6% (differences 2% (-1 to 6%) ES h = .04	2	

Table 17 continued: General population

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention** **I = intervention** **C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified)** **(+) = positive effect, (-) = negative effect, (0) = no effect**	**Applicability to the UK populations and settings** Score 1-4	**Notes**
Oliva 2005	Cluster RCT	-	Is a bio-psycho-behavioural HIV prevention intervention superior to standard HIV counselling and testing in reducing HIV risk behaviour and promoting the use of condoms?	**Population** Low-income high-risk sexually active men and women aged 18-55 (88% African American, high levels of drug use, 29% traded sex for money, drugs or shelter, 40% been homeless in past year). **Setting** Mobile health clinic in areas with high rates of Chlamydia and AIDS **Country** USA	667 (lost to follow up not clear) No PC reported	**I)** Bio-psycho-behavioural intervention that targets factors in each domain. Includes HIV testing & counselling, physical examination for STIs, targets risk perceptions, knowledge, motivations & efficacy. Used role-model stories, teaches condom use and negotiations for condom use. **Duration & Intensity** 1 session + follow up for test results. **Provider** Test counsellors at non profit organisation (not medically trained & many former drug addicts or sex workers). Doctors did physical exams. **C)** Standard HIV counselling and testing.	Attitudes towards condoms	1 week + More positive attitudes towards condoms on all 6 of the items on the scale.	3	Poor quality follow up data but study included for process information.

Table 17 continued: General population

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention** **I = intervention** **C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified)** **(+) = positive effect, (-) = negative effect, (0) = no effect**	**Applicability to the UK populations and settings** Score 1-4	**Notes**
Proude 2004	RCT	-	Does brief advice in routine family practice consultations modify HIV/STI risk perception and risk behaviour?	**Population** Young people aged 18-25 (89% heterosexual, 71% female, 47% 18-21) **Setting** Family practice **Country** Australia	312 (32% lost to follow up) PC – 100 in each arm to detect a between group difference of 15-20% on risk behaviours with 80% power.	**I)** Patients asked about perception of risk and then given brief behavioural advice and a set of complementary resources (including condoms & pamphlets about safe sex, HIV, STI) **Duration & Intensity** 1 session **Provider** Family practitioner during usual consultation. **C)** TAU + asked about smoking as a health risk factor.	Perception of risk for HIV Condom used on first occasion when had sex with new partner	3 months 0 OR 1.3 (0.72-2.4) 0 RR 0.95 (0.59, 1.51 73% vs. 77% (p=0.813) ES h=0.12	3	

Table 17 continued: General population

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention I = intervention C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect**	**Applicability to the UK populations and settings** Score 1-4	**Notes**
Scholes 2003	RCT	+	Does a theory based tailored minimal self-help intervention increase condom use among young women at risk of HIV/STI?	**Population** Non-monogamous sexually active women aged 18-24 at risk for heterosexual HIV/STD. (69% white, 19% black. 70% educated beyond high school, mean age 21). **Setting** Community **Country** USA	1210 (14% lost to follow up) No PC reported	**I)** 2 Individually tailored materials – 1) after randomisation a 12 page magazine style booklet, a safe sex kit (including male and female condoms + instructions on how to use) 2) at 3 months – tailored booster feedback newsletter and condom packet (focused on removing barriers to condom use). Intervention based in social science theory. **C)** TAU (not described)	Any use of condoms in prior 3 months (%) Average % of total episodes of intercourse during which condoms used in previous 3 months Consistent condom use with all partners STI diagnosis	6 months + Unadjusted OR 1.57 (1.18 – 2.10), adjusted 1.86 (1.32-2.65) P=0.0005 + Unadjusted OR 4.8 (-1.2 – 10.7), adjusted 5.2 (0.4-10.4) p=0.05 0 Unadjusted RR 1.10 (0.91, 1.32), adjusted OR 1.24 (0.89-1.73) p=0.21 0 Unadjusted RR 0.95 (0.51, 1.79), adjusted 0.97 (0.48-1.96) P=0.93	2	Theory based High use of condoms prior to intervention.

Table 17: Evidence for the effectiveness of one to one interventions for the prevention of STIs including HIV – presented by population

MSM

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention** **I = intervention** **C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified)** **(+) = positive effect, (-) = negative effect, (0) = no effect**		**Applicability to the UK populations and settings** Score 1-4	**Notes**
Dilley 2002	RCT	**++**	Does one counselling session focusing on self-justifications reduce future high-risk behaviour among HIV negative men?	**Population** High risk MSM 18-49 with a history of repeat testing for HIV (median age 33 yrs, 92% white) **Setting** Anonymous HIV testing clinic **Country** California, USA	248 (17% lost to follow up) PC – 456 participants for 80% power to detect a 25% decrease in unprotected anal intercourse at significance level of p= .0125	**Ia)** Standard HIV test counselling + asked to keep sexual diary for 90 days (diary based on that used by Gold 1995) **Ib)** Standard HIV test counselling + self-justification questionnaire & individual counselling. Counselling involved 4 parts; introduction, recent story, critical examination & closure. **Ic)** Standard HIV test counselling + self-justification questionnaire & individual counselling session + asked to keep 90 day sexual diary. **Duration and intensity** B1 & B2 – 1x 60 mins **Provider** Mental health professional **C)** Standard HIV test counselling according to US federal guidelines.	Any unprotected anal intercourse (in preceding 90 days) - Mean change from baseline Any unprotected anal intercourse (in preceding 90 days) Ia vs. control Ib vs. control Ic vs. control	6 months Ia + Mean change -0.50 Ib + Mean change -3.20 (p<.001) Ic + Mean change -2.50 (p<.05) C 0 Mean change -0.50 (p=.086) 0 (p value not reported) + p=.008 0 (p value not reported)	12 months Ia + Mean change -1.50 (p<.001) Ib + Mean change -2.90 (p<.001) Ic + Mean change -2.90 (p<.05) C 0 Mean change -0.15 (P=.856) + p=.006 + p=.001 + p=.047	2	Monetary incentive to take part in follow up. Not enough data provided to calculate effect sizes.

Table 17 continued: MSM

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention** **I = intervention** **C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified)** **(+) = positive effect, (-) = negative effect, (0) = no effect**	**Applicability to the UK populations and settings** Score 1-4	**Notes**
The EXPLORE study team 2004 (baseline data from Chesney 2003) EXPLORE	RCT	**++**	Do 10 sessions of one on one counselling prevent HIV infection, and is it better than twice yearly counselling?	**Population** Sexually active, high risk urban HIV negative MSM (mean age 34, 72.5% white, 40% annual income of less than $30,000) **Setting** 6 cities **Country** USA	**4295 (15% lost to follow up)** PC 4350 – to detect HIV acquisition.	**I)** Same as control arm + additional counselling in form of multiple intensive behavioural counselling sessions (with motivational interviewing and cognitive behaviour theory as key components). Also received booster sessions (n=2144) **Duration and intensity** 10 core-counselling modules delivered over 10 sessions within 4-6 month period. Then booster sessions every 3 months (up to on average 3.25 yrs) **Provider** Counsellors with 40hrs training delivered both intervention and control **C)** Twice yearly counselling on risk reduction based on the CDC Project RESPECT model (n=2151)	HIV acquisition Unprotected anal intercourse	48 months 0 Reduction but not statistically significant RR 0.80 (0.63, 1.02) 18.2% reduction (95% CI –4.7% to 36%). Difference greatest in first 12-18 months of study. + RR 0.92 (0.87, 0.97), difference of 13.9% (5.6 to 21.5)	2	75% of intervention group completed all ten sessions. Theory based

Table 17 continued: MSM

First Author	Study design	Research quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention I = intervention C = control	Outcome variable(s)	Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect	Applicability to the UK populations and settings Score 1-4	Notes
Gold 1995	RCT	-	Does examining self-justification prevent unprotected anal intercourse in gay men?	**Population** MSM who would like to maintain safe sex but fail to do so, aged 17-61 (mean age 27.9 yrs) **Setting** Community **Country** Australia	138 (21% lost to follow up) PC not reported	All participants kept sexual diaries for 4 weeks. Then randomised to: **Ia)** Self-justification group. – asked to recall recent occasion when had unprotected anal sex and asked to think about the self-justifications used. **Ib)** Sent 10 posters that had been used in AIDS education programmes directed at gay men. Were asked to rate each poster. **Provider** Researchers **C) No intervention**	Unprotected anal intercourse (at least one incidence) More than one incidence of unprotected anal intercourse	8 weeks +: Ia) vs. control RR 0.90 (0.60, 1.37) 0: Ib) vs. control RR 1.07 (0.73, 1.55) Ia) 17%, 1b) 41%, c) 42% + Ia vs control (p<.05) ES h=.53 0 Ib vs control, ES h=.02	3	Monetary incentive to take part
Gold 1998	RCT	-	Does a technique of examining self-justifications for unsafe sex reduce risk behaviour in gay men?	**Population** MSM aged 17-47 who had had unprotected anal intercourse at least once (average age 29) **Setting** Community **Country** Australia	92 (16% lost to follow up) PC not reported	All participants kept sexual diaries for 4 weeks. Then randomised to: **Ia)** Specific encounter group – asked to reconstruct a recent instance of unprotected sex, but without questions about self-justification. Ib) Examination of posters focusing on self-justification. Sent 10 posters and asked to rate each one. **C)** No intervention	At least one incidence of unprotected anal intercourse More than one incidence of unprotected anal intercourse	12 weeks Ia) 58%, Ib) 66%, C) 56% 0: Ia) vs. control ES h=.05 RR 1.03 (0.67, 1.58) 0: Ib vs. control, ES h=.25 RR 1.16 (0.78, 1.74) Ia) 45%, Ib) 48%, C) 44% 0: Ia) vs. control, ES H=.02 RR 1.03 (0.59, 1.79) 0: Ib) vs control, ES h=.09 RR 1.10 (0.64, 1.90)	3	Monetary incentive to take part

Table 17 continued: MSM

First Author	Study design	Research quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention I = intervention C = control	Outcome variable(s)	Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect	Applicability to the UK populations and settings Score 1-4	Notes
Picciano 2001	RCT	-	Does brief telephone based counselling reduce sexual risk taking among MSM	**Population** MSM – those currently engaged in unsafe sexual practices (76% white, mean age 36.6) **Setting** Community **Country** Seattle, USA	103 (54 intervention, 49 control, 14% lost to follow up) No PC reported	**I)** Personal feedback report (PFR) prepared. Then counselling sessions (using PFR). Used a motivational interviewing style, which included role-plays and reinforcement of safe sex practices. **Duration & Intensity** Baseline assessment then 2x 90-minute sessions 6 weeks apart. **Provided by:** Trained counsellors by telephone. C) Delayed intervention control (got intervention 7 weeks later)	Unprotected anal sex Unprotected oral sex Number of partners Protected anal sex Potected oral sex	6 weeks 0 RR 1.38; p= 0.60 ES d=.02 0 RR 0.66; p=0.19 ES d=.07 0 RR 0.97; p=0.92 ES d=.29 0 RR 0.76; p=0.59 ES d=.07 0 RR 1.23; p=0.88 D=.06 No differences between groups but both showed significant overall reduction in unprotected anal intercourse (3.4-2.0, p=.02), unprotected oral sex (declined from mean of 22.6 to 13.3 p<.01) and number of sexual partners (mean of 6.5 to 3.4 p<.01)	2	Incentive payment Data was highly skewed

Table 17 continued: MSM

First Author	Study design	Research quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention I = intervention C = control	Outcome variable(s)	Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect	Applicability to the UK populations and settings Score 1-4	Notes
Robert 1990	RCT	-	Do AIDS education interventions affect condom use and sexual risk behaviour?	**Population** Sexually active MSM **Setting** Community **Country** Auckland, New Zealand	159 (23% lost to follow up or excluded from analysis) Ia) n=30 Ib) n=32 C) n=36 No PC reported	**Ia)** Individual counselling (modelled on HIV re-test counselling using behaviourally orientated HIV risk assessment system BOHRAS. Uses open ended questions to assess risk, & provides info on AIDS and safer sex. **Ib)** Video called 'Do the right thing' – portrays two gay men participating in variety of safe sex practices. **Providers** Not specified **Duration and Intensity** Individual counselling 1 x 20-30 mins Video x 15 mins C) No intervention.	Condom use Overall measure of safer sex behaviour (includes consistent condom use)	6 months 0 Increased across all groups but no difference between groups. 0 post intervention; Individual counselling 71%, video 78%, control 76%. Ia) vs. control RR 1.00 (0.83, 1.19) Ib) vs. control RR 0.88 (0.70, 1.10) Change pre to post; Individual counselling +18% ES h=.62 video 0% ES h=.00 Control +13%. ES h=.47	3	Theory based High levels of safer sex practices at baseline.

Table 17: Evidence for the effectiveness of one to one interventions for the prevention of STIs including HIV – presented by population

Drug-substance users

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention** **I = intervention** **C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified)** **(+) = positive effect, (-) = negative effect, (0) = no effect**		**Applicability to the UK populations and settings** Score 1-4	**Notes**
Baker 1994	RCT	-	Does a brief cognitive behavioural motivational intervention reduce HIV risk taking behaviours among injecting drug users.	**Population** Injecting drug users (35% homeless, 83% unemployed, 3% HIV +ve, 66% sexually active, mean age 29, 80% male). English literate and no known diagnosis of mental illness **Setting** Inner city general medical clinic for homeless people and pharmacy **Country** Sydney, Australia	200 (39.5% lost to follow up at 3 months, 56% at 6 months) No PC reported	**I)** Motivational interviewing strategies used according to participant's stage of change. Looks at risk behaviour and attempts to move to more advanced stage of change. Involves interactive and objective feedback regarding health and risk taking behaviour. **Duration and Intensity** One 30-minute session. **Provider** Therapist (nurse, or psychologist) **C)** No intervention control	Overall sexual risk score for past month (includes unprotected sex) Highest HIV risk taking behaviour score (HHRBS)	3 months 0 MD 0.11 (0.17, 0.39) ES d=.05 MD 0.04 (-0.32, 0.39)	6 months 0 MD 0.24 (-1.14,1.62) ES d=.08 MD 0.07 (0.35, 0.49)	**3**	Theory based (Prochaska's stage of change model)

Table 17 continued: Drug-substance users

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention** **I = intervention** **C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified)** **(+) = positive effect, (-) = negative effect, (0) = no effect**	**Applicability to the UK populations and settings** Score 1-4	**Notes**
Bolu 2004 (sub group analyses from Kamb 1998) Project RESPECT	RCT	++	Do two face-to - face didactic interactive counselling interventions - for vulnerable populations - prevent new STIs and is one more effective than the other?	**Population** Looks at subgroup analyses for injecting drug use	109 PC done for full trial (Kamb 1998) – not powered for subgroup analysis.	**(Ia)Enhanced counselling (EC).** based on theory of reasoned action and social cognitive theory. Sought to change key elements underlying condom use (e.g. self efficacy, attitudes and perceived norms). Included behavioural goal setting and risk-reduction plan. **(Ib) Brief counselling (BC)** counselling intervention modelled after CDC's recommended HIV counselling. Addressed barriers to risk reduction and negotiated risk-reduction plan. Both sessions 20 mins. **Duration & intensity** Ia) EC = 4 (1x20 mins, 3 x 60 mins) Ib) BC = 2 x 20 mins C) 2 x 5 mins **Provider** Counsellors with standard training using structured protocols. **C) Didactic messages** - 2 session informational intervention – designed to approximate what was TAU in most clinics. Both sessions 5 mins each and conducted by clinician doing examination.	**STI** EC vs. control BC v control EC vs. BC	12 months 0 OR 1.4 (0.50-3.87) + OR 0.50 (0.29-0.85) 0 OR 1.45 (0.83-2.52)	2	Theory based

Table 17 continued: Drug-substance users

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention I = intervention C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect**	**Applicability to the UK populations and settings** Score 1-4	**Notes**
Deas 2000	RCT	-	Does a brief educational motivation intervention reduce HIV/AIDS risk behaviours in treatment seeking substance-abusing adolescents?	**Population** Adolescents seeking substance abuse treatment (mean age 15, 56.5% males). **Setting** In-patients in Institute of Psychiatry **Country** South Carolina, USA	60 (17% lost to follow up) No PC reported	**I)** Educational motivation intervention. Discussion of psychiatric and substance abuse assessment + intervention to educate about HIV/AIDS, correct misconceptions, and motivate to avoid or reduce risk behaviours. **Duration and intensity** One x 15-mins. **Provider** Child/adolescent psychiatrist **C)** General discussion of psychiatric and substance abuse assessment only (TAU)	Knowledge on HIV/AIDS Total risky behaviour (included sexual and drug related behaviours)	6 months 0 p=0.440, ES d=.13 0 p=0.840 ES d=.04	3	Both groups showed a reduction in risky behaviours over time (p=0.047)
Kwiatkowski (1998, 1999)	RCT	+	Does a community based AIDS intervention increase condom use	**Population** Injection drug users not currently in treatment (average age 38.6 yrs) **Setting** Office setting (9 cities) **Country** USA	5372 (38% lost to follow up) No PC reported	**I)** SI + site specific enhanced intervention: including AIDS education, risk reduction information, skills demonstration & rehearsal (e.g. condom use). Including audio & visual information. **Duration and intensity** 1-3 personalised sessions **C)** NIDA/CA standard manual driven intervention (SI). Included HIV pre & posttest counselling, optional HIV testing, written material.	Increase in condom use (Enhanced versus standard) Increase in condom use both groups combined	6 months **+** 31% versus 27% (p=0.04) ES h=.08 + 15% to 22% (p=<0.001) ES h=.14	**3**	Statistically significant results (due to very large sample) but small effect size and not clinically significant.

Table 17 continued: Drug-substance users

First Author	Study design	Research quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention I = intervention C = control	Outcome variable(s)	Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect			Applicability to the UK populations and settings Score 1-4	Notes
								3 months (mth)	12 months	Overall pretest/post test for both groups		
Gibson 1999 Study one (Gibson 1999a) Study two (Gibson 1999b)	Two RCTs	-	**Study 1** Does brief counselling reduce HIV risk behaviour in injecting drug users? **Study 2** Does brief counselling with HIV testing reduce HIV risk behaviour in injecting drug users?	**Study 1 Population** Injecting drug users entering heroin detoxification treatment, men aged 30-49 years, mixed racial/ethnic background, 66% with no previous history of methadone treatment **Study 2** Similar to study 1but were seronegative **Setting** Hospital based detoxification centre **Country** USA	**Study 1** N=295 Overall follow-up: 3 months 75% 12 months 56% Lost to follow-up reduced power to detect statistically significant results **Study 2** N=109 **Follow-up** 6 months 70% 12 months 60% PC not reported	**Study 1** **I)** Counselling sessions involving individualised problem solving exploring high risk practices, such as sharing needles, sexual practices, preventative strategies and participant's interest in entering drug treatment. Also included 'hands on' demonstration of proper use of condoms and syringes **C)** Educational brochures All subjects had baseline and follow-up assessment interviews **Duration and intensity** 50 minutes counselling **Provider** Health educator **Study 2** **I)** Participants received pre test HIV counselling followed by enhanced 50 minute post test counselling as Study 1, but modified to discuss their risk of HIV infection involving detailed and systematic problem solving. **C)** Pre test counselling plus standard 15 minute post test counselling (based on	**Study 1** Follow-up at 3 months and 12 months for behaviours in the past month More than one sexual partner Condom use all the time Condom use some of the time At sexual risk	0 I 16% C 22% RR 0.74(0.38-1.46) 0 I 24% C 22% RR 1.10(0.59-2.02) 0 I 48% C 37% RR1.27(0.78-2.07) 0 I 51% C 56% 0.92(0.59-1.45)	0 I 13% C 16% RR 0.81(0.34-1.92) 0 I 24% C 19% RR 1.20 (0.66, 2.15) 0 I 33% C 39% RR 0.83 (0.46-1.51) 0 I 45% C 55% RR 0.82 (0.48-1.40)	+ Baseline 25% 3 mth 19% p 0.05 12 mth 15% p0.05 Baseline 12% + 3 mth 24% p 0.05 0 12 mth 21% 0 Baseline 32% 3 mth 42% 12 mth 37% + Baseline 66% 3 mth 54% p 0.001	4	Data from two studies presented in one paper.

						guidelines on AIDS Health Project) All subjects had baseline and follow-up assessment interviews				12 month 50% p 0.001		
							Study 2 Follow-up at 6 & 12 mths (assumed from paper, data presentation unclear)	6 months	12 months	Overall pretest/post test for both groups		
							More than one sexual partner	0 I 8% C 8% RR 1.00 (0.19-5.27)	0 I 4% C 15% RR 0.23 (0.03-2.05)	0 Baseline 24% 6 mth 8% 12 mth 9%		
							Condom use all the time	0 I 22% C 21% RR 1.00 (0.34-2.94)	0 I 31% C 13% RR 2.55 (0.87, 7.44)	0 Baseline 13% 6 month 21% 12 month 21%		
							Condom use some of the time	0 I 41% C 38% RR 1.14 (0.49-2.66)	0 I 38% C 38% RR 0.96 (0.37-2.46)	0 Baseline 32% 6 mth 38% 12 mth 37%		
							At sexual risk	0 I 5% C3% RR 2.00 (0.17-23.00)	0 I 3% C 9% RR 0.38 (0.04-3.83)	0 Baseline 24% 6 mth 4% 12 mth 8%		

Table 17 continued: Drug-substance users

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention I = intervention C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect**	**Applicability to the UK populations and settings** Score 1-4	**Notes**
Kotranski 1998 One site of a multi –site project	RCT	-	Does an HIV risk reduction counselling intervention reduce HIV risk taking behaviours in out of treatment drug users?	**Population** High risk group of participants (mean age 39 years, 85% African American, 63% male, 55% high school education, 72% low income, 77% stable housing, 72% with arrest history, 94% heterosexual) **Setting** Community based clinic **Country** USA	N=684 No completed study 595, 87% 417 (61%) completed 6 month follow-up; 70% retention I 69% C 71% PC not reported	**EI)** Standard intervention plus additional information on STD risk reduction. Affective strategy based on emotional experiences was used. **SI)** Two individual level education sessions on HIV infection and transmission, HIV testing with pre and post test counselling and training in condom use and drug related practices. Cognitive, and behavioural strategies were used. All participants received financial remuneration according to completion of follow-up **Duration and intensity** EI Not given. SI included two sessions three weeks apart **Provider** Trained health educator	**Sexual risk behaviour in past 30 days** Unsafe vaginal sex (%) Number of sexual partners Drug-injecting sex partner % Used drug during sex	6 month follow-up + RR 1.24 (1.01, 1.53) Within group differences between baseline and followup 0 MD -0.17 (-0.36, 0.02) 0 RR 1.11(0.93-2.50) 0 RR 1.52 (0.93-2.50) The paper shows difference between follow-up values for SI and EI, but ES is not significant	3	Cognitive and behavioural strategies suggest theory based

Table 17 continued: Drug-substance users

First Author	Study design	Research quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention I = intervention C = control	Outcome variable(s)	Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect			Applicability to the UK populations and settings Score 1-4	Notes
								Pre Mean (sd)	**Post Mean(sd)**	**9 months Mean(sd)**		
O'Neill 1996	RCT	_	Does a cognitive behavioural relapse prevention programme reduce HIV risk behaviour in pregnant injecting drug users?	**Population** Pregnant women, injecting drug users (IDU), mean age 26.2 years, mean 22 weeks pregnant, HIV negative, mean years of education 10.2, 76% IDU male partner, 41% with no children, 53% had ever engaged in sex work, mean duration on methadone programme 23 months **Setting** Drug treatment and antenatal clinics **Country** Australia	N=92 Follow-up 79.3% I 78.7% C 80.0% PC not reported	**I)** Usual counselling and advice on HIV risk-taking behaviours plus a cognitive-behavioural relapse prevention intervention. This included motivational interview, identifying high risk situations, problem solving strategies, coping with cravings and lapses, relaxation, decision making and lifestyle balance. **C)** Usual counselling and advice on HIV risk-taking behaviours **Duration and intensity** Five individual sessions of about 60-90 minutes each **Provider** Psychology therapists	**HIV Risk taking behaviour score (HRBS)** Sexual risk (includes use of condoms) Previous month Between subjects ES **Highest HIV Risk taking behaviour score (HHRBS)** Sexual risk Highest risk month (in last 6 months) The scores are derived from multiitem instrument, the authors discuss sexual risk in the context of condom use	0 I 5.12 (3.49) C 5.60(3.0) MD -0.15 (-0.59,0.29) 0 I 7.60 (2.57) C 6.67(2.37) MD 0.38 (-0.07,0.82)	0 I 3.70 (3.17) C 4.92(2.69) MD -0.41 (-0.86,0.03) No data Both groups reduced risk score from pre to post	0 I 4.32 (3.47) C 4.08(2.94) MD 0.07 (-0.38,0.53) 0 I 5.46 (2.76) C 5.06(2.86) MD 0.14 (-0.32,0.60) Both groups reduced risk score from pre to post	3	Self determination theory is proposed for Motivational interviewing

Table 17 continued: Drug-substance users

First Author	Study design	Research quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention I = intervention C = control	Outcome variable(s)	Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect	Applicability to the UK populations and settings Score 1-4	Notes
Sterk 2003	RCT	+	Do two culturally specific counselling interventions reduce the risk of HIV infection in women who use crack cocaine?	**Population** Sexually active low-income African American women who use crack cocaine (aged 18-59). **Setting** Project office Inner city neighbourhoods **Country** Atlanta, USA	**265 (4% lost to follow up)** No PC reported	**Ia)** Enhanced motivation intervention (MI). Included HIV risk & risk reduction information, goal setting for behavioural change, control and risk reduction messages tailored to participant's level of readiness for change. **Ib)** Enhanced negotiation intervention (NI). Similar to MI but looked at negotiation, skills training & development of tailored negotiation and conflict resolution styles. Both interventions gender and culturally specific. Based on social cognitive theory, theory of reasoned action, theory of planned behaviour. Social context of women's daily lives central. **Duration & Intensity** Intervention: 4 sessions Control: 2 sessions **Provider** Trained female health interventionist (mainly African American) **C)** NIDA standard intervention (SI) Information on HIV risk & risk reduction strategies.	Frequency of condom use with steady partners Vaginal sex Frequency of condom use with steady partners (all groups pre to post) Number of paying partners (vaginal, oral or anal sex) Number of paying partners (vaginal, oral or anal sex - all groups pre to post)	6 months 0 **MI vs. SI ES d=.0** + NI vs. SI (p<.01) ES d=.017 0 NI vs. MI (p<.10) ES d=.18 + (p<.05) Vaginal sex, ES d= 0.12 Oral sex, ES d=0.11 0 MI vs. SI (p<.10), ES d=.08 + NI vs. SI (p<.001), ES d=.33 + NI vs. MI (p<.001), ES d=.26 + (p<.001) 41% reduction vaginal sex, 50% reduction oral sex ES d= 0.48	**3**	Theory based Monetary incentive to take part. Standard intervention appears as effective as enhanced interventions for many of sexual risk behaviours.

Table 17: Evidence for the effectiveness of one to one interventions for the prevention of STIs including HIV – presented by population

Prisoners/Probationers

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention** **I = intervention** **C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified)** **(+) = positive effect, (-) = negative effect, (0) = no effect**	**Applicability to the UK populations and settings** Score 1-4	**Notes**
Grinstead 2001	RCT	-	Does a one to one peer-led pre-release HIV prevention intervention reduce HIV risk behaviour?	**Population** Male prison inmates (mean age 35, > 50% African American, average 12 yrs education) **Setting** Large state prison (within 14 days of release) **Country** California, USA	414 (57.5% lost to follow up) No PC reported	**I)** Individualised one to one risk assessment and risk reduction plan + provision of appropriate referrals for after release. **Duration and intensity** One x 30 mins **Provider** HIV +ve inmate peer educator (trained in conducting HIV prevention programs in prison) **C)** No intervention.	Used a condom first time has sex since release	17 days after release + 37.5% vs. 19.6% (p = 0.05) ES h=.37	4	Financial incentive for follow up.

Table 17 continued: Prisoners/Probationers

First Author	Study design	Research quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention I = intervention C = control	Outcome variable(s)	Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect	Applicability to the UK populations and settings Score 1-4	Notes
Martin 2003	RCT	-	Does a focused intervention based on a cognitive thought mapping model reduce HIV/AIDS risk behaviour in comparison to the NIDA standard intervention?	**Population** Drug involved male and female probationers 18 and over (mean age 34.5, 70% black, 24% white, mean of 5 previous prison incarcerations). **Setting** Community **Country** Delaware, USA	706 (40 % lost to follow up). No PC reported.	**I)** Probation focused intervention (PFI) Information provided similar to control (ESI) group. Also aims to use thought mapping to develop personalised strategies to promote safer behaviour (based on idea that knowledge alone is a poor predictor of behaviour). **Duration & Intensity** Baseline session with HIV test + posttest session. **C)** Enhanced version of NIDA (ESI). Modified version of standard NIDA intervention. Included pre + post-test HIV counselling, education on HIV risk related behaviours, condom demonstration and advice on safe sex.	Had some unprotected sex PFI Had some unprotected sex ESI Had some unprotected sex PFI vs. ESI Mean number of unprotected sex acts PFI Mean number of unprotected sex acts ESI Mean number of unprotected sex acts PFI vs. ESI Had multiple partners PFI Had multiple partners ESI Had multiple partners PFI vs. ESI	6 months Pre to post change + Men, ES h = .83 0 women, ES h=.00 Pre to post change + men, ES h=.58 + women, ES h=.00 0 (not enough data to calculate ES) Pre to post change + Men + women Not enough data to calculate ES Pre to post change + Men + Women Not enough data to calculate ES 0 Not enough data to calculate ES Pre to post change + ES h=.34 Pre to post change + ES h=.24 0 ES h=.10	3	Similar to intervention used by Kwaitowski Reduction in high-risk sexual behaviours in both groups but no difference between two groups.

Table 17: Evidence for the effectiveness of one to one interventions for the prevention of STIs including HIV – presented by population

People with HIV

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention** **I = intervention** **C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified)** **(+) = positive effect, (-) = negative effect, (0) = no effect**	**Applicability to the UK populations and settings** Score 1-4	**Notes**
Patterson 2003	RCT	-	Does a behavioural intervention based on Social Cognitive Theory increase safer sex practices in HIV positive individuals?	**Population** HIV positive; 91% male; 22-62 years (M=37.4 years); 85% gay or bisexual, 65% white; 15% African American; 12% Hispanic; 64% had some college education **Setting** Off-campus project office. **Country** San Diego, USA	387 (not reported by study arm) 54.8% completed baseline and all 3 follow up visits. No PC reported.	**Ia) Brief targeted intervention**: Tailored to individual by addressing only those behaviours that the participant indicated were problematic. **Ib) Comprehensive intervention**: addressing condom use, negotiation of safer sex practices, and disclosure of HIV+ serostatus to sex partners. Social Cognitive Theory (SCT) techniques were used to increase knowledge, self-efficacy, and positive outcome expectancies in relation to those three areas. **Ic) Comprehensive + booster:** as above, + booster sessions to reinforce positive behavioural change **Provider** Trained project staff **Intensity/duration** Ia: 1x 90 mins Ib: 1x 90 mins Ic: 3x90 mins (monthly) C: 3x90 minutes **C)** Addressed diet and exercise as related to HIV.	STIs Unprotected sexual acts (only included participants who completed all 4 assessments in analysis, n=212).	8 months 0 Comprehensive with boosters vs. diet & exercise control RR 0.92 (0.44, 1.90) Comprehensive with no boosters vs. control RR 1.01 (0.48, 2.13) Brief targeted vs. control RR 0.75 (0.34, 1.64) Boosters vs. no boosters RR 0.91 (0.42, 1.95) ANOVA showed a significant main effect of trials ($F(3, 624)=35.39$, $p<.05$) and trials x group interaction ($F(9, 624)=1.86$, $p<.05$), indicating that comprehensive + booster group reported more unprotected sex acts than other groups at 8 months. + all groups pre compared to post - Comprehensive + booster vs other groups.	3	Theory based Monetary incentive for taking part All interventions included role-play and problem solving 'real-life' situations.

Table 17 continued: People with HIV

First Author	Study design	Research quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention I = intervention C = control	Outcome variable(s)	Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect	Applicability to the UK populations and settings Score 1-4	Notes
Richardson 2004	Cluster RCT (randomised by clinic)	-	Does brief safer-sex counselling reduce unprotected sex in HIV + ve patients.	Population **HIV positive patients (mean age 38, 86% male)** Setting **HIV clinics.** Country California, USA	886 (44% lost to follow up) No PC reported	**Ia) (GF)** Partnership for health. Clinic staff had 4-hr training session on behaviour change theory, communications skills building, role-playing etc. Then gave brief counselling session using message framing that emphasizes the enefits of protective behaviour (gain frame) **Ib) (LF)** (IB)Same as above but used messages emphasizing negative consequences of risky behaviour (loss-frame) **Duration and intensity** 1 x 3-5 mins **Provided by:** Clinic staff **C)** Focused on medication adherence. Used counselling and tailored medication schedule.	**Unprotected anal or vaginal intercourse (adjusted):** People who had had only one partner at baseline People who had had two or more partners at baseline Overall sample (adjusted) Overall sample (unadjusted)	Follow up – not specified 0 Ia vs. control OR 1.18 (0.65-2.17 p= 0.59) Ib vs. control OR 1.20 (95% CI 0.65-2.22 p = 0.56) 0 Ia vs. control OR 0.81 (0.36-1.82 p=0.61) + Ib vs. control OR 0.42 (0.19-0.91 p=0.03) 0 Ia vs. control OR 0.96 I(0.60-1.54 p=0.88) Ib vs. control OR 0.78 (0.50-1.22 p=0.28) 0 Ia vs. control RR 0.96 (0.70, 1.30) Ib vs. control RR 0.95 (0.71, 1.27) Both groups combined vs. control RR 0.93 (0.72, 1.21)	3	Theory based

Table 17 continued: People with HIV

First Author	Study design	Research quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention I = intervention C = control	Outcome variable(s)	Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect	Applicability to the UK populations and settings Score 1-4	Notes
Rotheram-Borus 2004	RCT	+	Does face to face or telephone HIV prevention counselling intervention reduce risk behaviour and transmission acts among drug using HIV positive young people?	Population **Substance using, HIV positive people aged 16-29 (median age 29, 78% male, 42% Latino, 26% black, 23% white, 76% gay or bisexual)** Setting **Community** Country **Los Angeles, New York, San Francisco, USA**	175 (18% lost to follow up 15 months) No PC reported	Ia) In-person 1 0n 1 sessions. Ib) Telephone 1 on 1 sessions. Both interventions had similar format: Module 1 : focused on improving physical health Module 2: aimed to reduce unprotected sexual acts and substance use Module 3: aimed to reduce emotional distress and improve quality of life. Each session started with recognising personal successes in meeting goals, then introduced new material and used rehearsal, planning, & further goal setting. **Duration and intensity** 18 x 2 hours **Provider** Masters level licensed therapists or social workers or those working towards licensure. Received intensive 3-day training for each module. **C)** Delayed intervention control.	Percent of protected acts (all partners) Cost	15 months In – person vs. control + (13% increase vs. 8% decrease, p= <0.01) Es h=.79 In-person vs. telephone 0 (13% increase vs. 0% change) ES h=.02 Telephone vs. control 0 (o% change vs. 8% decrease) ES h=.82 In person - $3500 per participant Telephone -$2692 per participant	2	Monetary incentive for attending assessments and sessions. 78% attended at least one session 35% attended all sessions Authors highlight issue that many participants were not engaged in risky behaviour at baseline – therefore harder to detect an effect.

Table 18: Evidence Table type of intervention: theory/model based vs. didactic control

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention** **I = intervention** **C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified)** **(+) = positive effect, (-) = negative effect, (0) = no effect**		**Applicability to the UK populations and settings** Score 1-4	**Notes**
Boekeloo 1999	RCT	-	Does primary care based STI prevention education reduce risky sexual behaviours in young adolescents?	**Population** Adolescents aged 12-15 attending for general health examination (majority African American, 50% female). **Setting** 5 primary care HMO practices (3 suburban, 2 inner-city). **Country** Washington, USA	215 (8% lost to follow up) No PC reported.	**I)** Pre-visit audiotaped STI risk assessment by researchers. Then Program ASSESS (awareness, skills, self-efficacy/self-esteem and social support). Involved education (tailored to individual) & brochures. Based on social cognitive, theory of reasoned action. **Providers** Paediatricians with 45 minute STI prevention training. **Duration & intensity** 1 session (length not specified) **C)** Usual care - regular health examination (18% received non study-specific HIV/STI educational materials).		3 months	9 months	3	Theory based
							Vaginal intercourse in last 3 months:	- adjusted OR 2.46 (1.04-5.84) 0 unadjusted RR 1.37 (0.82, 2.28)	0 adjusted OR 1.64 (0.81 -3.34); 0 Unadjusted RR 1.13 (0.75, 1.72)		
							Vaginal, oral or anal intercourse in last 3 months	0 adjusted OR 1.55 (0.73 – 3.32); 0 unadjusted RR 1.04 (0.67, 1.61)	0 (adjusted) OR 1.56 (0.79-3.08); 0 unadjusted RR 1.16 (0.80, 1.67)		
							Condom use at last vaginal intercourse among those sexually active in last 3 months	+ (adjusted) OR 18.05 (1.27-256.03) + (unadjusted) RR 1.61 (1.09, 2.37)	0 (adjusted) OR 1.00 (0.31-3.24) (unadjusted) RR 1.01 (0.73, 1.40)		
							Unprotected sex	+ (adjusted) OR 8.63 (1.60-46.45) + unadjusted RR 0.19 (0.05, 0.77)			
							Been treated for an STI	0 2.2% vs. 4.7% ES: h=0.05	0 1.1% vs. 5.8% ES:h=0.09 RR 0.18 (0.02, 1.49)		

Table 18 continued: Evidence Table type of intervention: theory/model based vs. didactic control

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention** **I = intervention** **C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified)** **(+) = positive effect, (-) = negative effect, (0) = no effect**		**Applicability to the UK populations and settings** Score 1-4	**Notes**
Belcher 1998	RCT	+	Does a single-session skills based HIV prevention intervention reduce sexual risk behaviour among women?	**Population** Economically disadvantaged females aged 18-56 (mean age 34.9, 95% African-American) **Setting** Community based organisation providing services to men and women in transition **Country** Atlanta, USA	74; 36 intervention, 38 control. 92% completed final follow-up No PC reported	**I)** Single session, skills-building HIV risk-reduction intervention, based on social-cognitive principles and the Information-Motivation-Behaviour Skills Model. Intervention included informational, motivational and behavioural skills components, leading to an individualized personal action plan to reduce risk of HIV. **Provider** Female African American graduate students, trained in HIV and AIDS counselling, and in using the intervention protocol **Duration & intensity** Single 2-hr session. Follow-up at 1 and 3 months **C)** HIV education session, time matched for counsellor contact and time of exposure. No skills training or motivation enhancing elements included.		1 month	3 months	3	Theory based Monetary incentive to take part.
							HIV/ AIDS knowledge	0 ES: d=0.00	0 ES d=0.20		
							Intention to use condom	0 ES: d=0.32	0 ES: d=0.25		
							Condom use	Not reported	+ (p<0.05) ES d=2.26		
							Unprotected sex	Not reported	0 (p<0.06) ES d=0.48		
							% vaginal sex occasions in which condoms used	Not reported	+ 66% vs. 43% (p<0.02) ES: h=0.55		

Table 18 continued: Evidence Table type of intervention: theory/model based vs. didactic control

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention** **I = intervention** **C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified)** **(+) = positive effect, (-) = negative effect, (0) = no effect**		**Applicability to the UK populations and settings** Score 1-4	**Notes**
Boyer 1997	RCT	+	Does a cognitive behavioural skills building intervention prevent STD in high-risk heterosexual adults.	**Population** High risk heterosexual adults 18-35 (46% black, 29% white,15% Hispanic) **Setting** Public health STD clinic **Country** California, USA	399 randomised (65% followed up at 3 months, 60% at 5 months, 52% followed up at both). PC – 200 subjects in each arm to detect a difference in STI acquisition.	**I)** Individual, multi-component sessions designed to increase knowledge about prevention of STD/HIV, build effective decision making & communication skills, and identify and modify STD/HIV related risk factors. Based on AIDS risk reduction model (ARRM) **Duration & intensity** Four 60-minute sessions over 4 weeks. **Provided by** Trained intervention counsellor. **C)** Standard 15-minute risk-reduction counselling session offered to all patients.		3 months	5/ 6 months	3	Theory based Financial incentive for participation in follow up.
							STI (diagnosed or suspected)	Not reported	0 (all) 13% vs. 11% RR 1.17 (95% CI 0.68, 2.02) 0 Men 7% vs. 8% (p>0.20) ES: h=0.02 0 Women 22% vs. 22% (p>0.20) ES h=0.00		
							Sexual intercourse without condoms (in 2 months prior to assessment) – change from baseline	+ Reduction in intervention and control group (p<0.001), ES: c=0.11 greater in intervention group (p<0.05) ES: c=0.02	0		
							Mean number of sexual partners without a condom	Data not reported	+ 0.6 vs. 0.9 (p<0.01)		

Table 18 continued: Evidence Table type of intervention: theory/model based vs. didactic control

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention** **I = intervention** **C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified)** **(+) = positive effect, (-) = negative effect, (0) = no effect**	**Applicability to the UK populations and settings** Score 1-4	**Notes**
Deas 2000	RCT	-	Does a brief educational motivation intervention reduce HIV/AIDS risky behaviours in treatment seeking substance-abusing adolescents?	**Population** Adolescents seeking substance abuse treatment (mean age 15, 56.5% males, majority white). **Setting** In-patients in Institute of Psychiatry **Country** South Carolina, USA	60 (17% lost to follow up) PC not reported	**I)** Educational motivation intervention. General discussion of psychiatric and substance abuse assessment + one to one intervention. Designed to educate about HIV/AIDS, correct misconceptions, and motivate to avoid or reduce risk behaviours. **Duration and intensity** One 15-minute session. **Provider** Child/adolescent psychiatrist **C)** General discussion of psychiatric and substance abuse assessment only (TAU)	Knowledge on HIV/AIDS Total risky behaviour (included sexual and drug related behaviours)	6 months 0 p=0.440 (change scores not given) ES: d=0.24 0 p=0.840 (change scores not given) ES: d=0.06	3	Theory based Both groups showed a reduction in risky behaviours over time (p=0.047)

Table 18 continued: Evidence Table type of intervention: theory/model based vs. didactic control

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention** **I = intervention** **C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified)** **(+) = positive effect, (-) = negative effect, (0) = no effect**		**Applicability to the UK populations and settings** Score 1-4	**Notes**
El-Bassel 2003	RCT	+	Does a relationship based HIV/STI program for heterosexual couples promote safe sex behaviour and is it most effective when delivered to the couple or the women alone	**Participants** Couples in long-term relationship known, or suspected, to have at least one HIV/STD risk criteria. Mainly low income, ethnic minorities **Setting** Hospital outpatient clinics **Country** USA	217 couples (20% intervention grp, 33% control grp lost to follow up) No PC reported	**Ia (couples - C)** Relationship-based counselling to couple together **Ib (women only - WA)** Relationship-based counselling to woman alone Both based on AIDS risk reduction model and ecological perspective Emphasised importance of relationship communication, negotiation & problem solving skills, gender roles & expectations and HIV/STI prevention. **Duration & intensity** Both interventions 6 2-hour sessions. Control one, one hour, session. **Provider** Facilitators **C)** 1 HIV/STD information session for women alone	Number of unprotected sexual acts Percentage of protected sexual acts Number of STD symptom Number of sexual partners	3 months + WA vs. control, C vs. control 0 WA vs. couples + WA vs. control, ES h=0.37 C vs. control, ES,h=0.24 0 WA vs. couples ES h=0.14 0 Intervention vs. control (p=0.72), WA vs. C (p=0.52) ES d=0.03 0 Intervention vs. control (p = 0.36), WA vs. C (p= 0.15) ES d=0.14	12 months + WA vs. control, C vs. control 0 WA vs. couples 0 (data not reported)	2	Regression analysis demonstrated that either intervention was associated with safer sexual behaviour (particularly condom use) but that there was no significant difference between the intervention groups. Theory based

Table 18 continued: Evidence Table type of intervention: theory/model based vs. didactic control

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention** **I = intervention** **C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified)** **(+) = positive effect, (-) = negative effect, (0) = no effect**		**Applicability to the UK populations and settings** Score 1-4	**Notes**
James 1998	RCT	+	Does sexual health promotion prevent transmission of HIV and STI?	**Participants** Men and women aged 16 and over (51% men, 93% heterosexual) **Setting** Urban genitourinary medicine clinic **Country:** Nottingham, UK	492 (49% lost to follow up) PC – 101 participants per group to detect an increase in condom use of 25%	**I)** Individually tailored skill training counselling session that aimed to reduce risk-taking behaviours, promote use of condoms & encourage development of interpersonal skills. Included demonstration of condom use & role-play. Based on social learning theory. **Duration & Intensity** One 20-minute session. **Provided by** Health advisors **Ca)** Standard clinic session with health advisor **Cb)** Same as control a + leaflet and condom pack		4 months	18 months	2	Theory based
							RE-attendance at clinic with new STI	Not reported	0 p=0.26 ES c=0.03		
							Always or almost always use condom	RR 0.99 (95% CI 0.61, 1.60)			
							Frequency of condom use with regular partner	0 p=0.39 (no change between groups or between pre and post test) ES c=0.10	Not reported		
							Frequency of condom use with non-regular partner	0 p=0.25 (no change between groups or between pre and post test) Esc=0.09	Not reported		
							Perception of risk (believed themselves to be 'not at all at risk)	+ RR 0.21 (95% CI 0.08, 0.51) (reduction in intervention group compared to either control)			

Table 18 continued: Evidence Table type of intervention: theory/model based vs. didactic control

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention** **I = intervention** **C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified)** **(+) = positive effect, (-) = negative effect, (0) = no effect**			**Applicability to the UK populations and settings** Score 1-4	**Notes**
Kalichman 2005	RCT	+	Does a brief risk-reduction counselling intervention reduce unsafe sexual behaviour and prevent HIV/STIs?	**Population** People attending STI clinic (mean age 35.3 yrs, 69% men, 85% African American, 88% annual income less than $20,000) **Setting** Large urban public STI clinic **Country** Wisconsin, USA	612 (22% lost to follow up overall – 21% lost at 3 months, 26% lost at 6 months, 27% lost at 9 months) PC not reported	**Ia) Full Information-motivation-behavioural skills model (IMB).** Included: 1. **Information** on HIV transmission, risk behaviours, prevalence, clarification of myths and misconceptions & information about HIV testing. 2. **Motivational enhancement** - giving participants feedback of own personal risk and using motivational strategies to mobilise individuals own change resources. 3) **Behavioural self-management and sexual communication skills** – looked at risk behaviour and how to manage it, learnt safe-sex strategies. Included role-play & condom use instruction with anatomical models. **Ib)** Information + Motivational enhancement (IM) **Ic)** Information + Behavioural skills (IB) **C)** Information only – delivered by counsellors in didactic style (I) **Provided by:** Counsellors (male and female) with no previous counselling experience.	Unprotected intercourse (results are for each intervention compared against all other interventions) Newly diagnosed STI (intervention	3 months **IMB** 0 Men ES d=.06 - Women ES d=.33 **IM** 0 men ES d=.11 + women ES d=.46 **IB** 0 men ES d=.04 0 women ES d=.06 Not reported	6 months **IMB** + men ES d=.29 0 women ES d=.15 **IM** 0 men ES d=.20 + women ES d=.54 **IB** 0 men ES d=.01 + women ES d=.38 Not reported	9 months **IMB** 0 men ES d=.13 0 women ES. D=.27 **IM** 0 men ES d=.12 + women ES d=.65 **IB** 0 men ES d=.01 + women ES d=.28 IMB 0 RR 0.60 (0.25,	3	Monetary incentive to participate in follow up Full intervention reduced unprotected intercourse in men at 6 months (but not other time points) and reduced STIs. Had no positive effect on women. Most effects for men lost by 9 months.

						Similar qualifications to those typically employed in public health clinics. Were extensively trained in the intervention and basic counselling skills. **Duration and intensity** All groups (including control) received one 90 minute session	versus control) Number of sexual partners	No significant between group differences.		1.46) + men adjusted OR = 7.3 0 women IM 0 RR 1.19 (0.59, 2.40) IB 0 RR 1.16 (0.57, 2.39)		

Table 18 continued: Evidence Table type of intervention: theory/model based vs. didactic control

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention** **I = intervention** **C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified)** **(+) = positive effect, (-) = negative effect, (0) = no effect**			**Applicability to the UK populations and settings** Score 1-4	**Notes**
								3 months	6 months	12 months		
Kamb 1998 Project RESPECT	RCT	++	Do two face-to - face didactic interactive counselling interventions prevent high-risk sexual behaviours and new STIs and is one more effective than the other?	**Population** HIV negative heterosexuals aged 14 and over (median age 25, 57% male, 59% black, 54% unemployed). **Setting** Five public health clinics in different cities. **Country** USA	5758 (66% follow up at final assessment) PC – 1500 per arm for 80% power to detect a 25% reduction in STIs	(Ia)**Enhanced counselling (EC).** based on theory of reasoned action and social cognitive theory. Sought to change key elements underlying condom use (e.g. self efficacy, attitudes and perceived norms). Included behavioural goal setting and risk-reduction plan. (Ib) **Brief counselling (BC)** Brief counselling intervention modelled after CDC's recommended HIV counselling. Addressed barriers to risk reduction and negotiated risk-reduction plan. **Duration & Intensity** Ia) enhanced 4 sessions (1 20 mins, 3 60 mins) Ib) brief – Two 20-minute sessions. C) Two 5 minute sessions. **Provider** Ia & Ib) Counsellors who received standard training and used structured intervention protocols. C) Clinician doing examination **C) Didactic messages** - informational intervention – designed to approximate what was TAU in most clinics.	New STI EC vs. control BC vs. control Condom use (100% self-reported condom use with all partners). EC vs. control BC vs. control EC vs. BC	+ 46% vs. 38%,RR 1.21 95% CI 1.09-1.35 + 44% vs. 38%;RR 1.15, 95% CI 1.03-1.27 0 46% vs. 44% RR	+ 10.4% vs. 7.2%; RR 0.69 (0.54-0.88) + 10.4% vs. 7.3%; RR 0.71 (0.58-0.89) + 39% vs. 34%;RR 1.15 (1.04-1.26) 0 39% vs. 34%;RR 1.15 (1.04-1.26)	+ 14.6% vs. 11.5%; RR 0.78 (0.64-0.94) + 14.6% vs. 12% RR 0.81 (0.67-0.98) 0 data not reported 0 data not reported	2	Monetary incentive to attend sessions, and for follow up (+ free condoms) 82% completed all assigned intervention sessions. Lower in 4-session intervention (72%) than in either of others (85%) Theory based

								1.06, 95% CI 0.96-1.17				

Table 18 continued: Evidence Table type of intervention: theory/model based vs. didactic control

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention I = intervention C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect**	**Applicability to the UK populations and settings** Score 1-4	**Notes**
Kwiatkowski (1998, 1999)	RCT	+	Does a community based AIDS intervention increase condom use	**Population** Injection drug users not currently in treatment (average age 38.6 yrs) **Setting** Office setting (9 cities) **Country** USA	5372 (38% lost to follow up) No PC reported	**I)** SI + site specific enhanced intervention: including AIDS education, risk reduction information, skills demonstration & rehearsal (e.g. condom use). Including use of audio & visual information. **Duration and intensity** Usually consisting of 1-3 personalised sessions **C)** NIDA/CA standard manual driven intervention (SI). Included HIV pre & posttest counselling, optional HIV testing, written material.	Increase in condom use (Enhanced versus standard) Increase in condom use both groups combined	6 months **+** 31% versus 27% (p=0.04) ES h=.08 + 15% to 22% (p=<0.001) ES h=.14	**3**	Statistically significant results (due to very large sample) but small effect size and not clinically significant. Theory based

Table 18 continued: Evidence Table type of intervention: theory/model based vs. didactic control

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention** **I = intervention** **C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified)** **(+) = positive effect, (-) = negative effect, (0) = no effect**	**Applicability to the UK populations and settings** Score 1-4	**Notes**
Maher 2003	RCT	++	Does a community-based, intensive counselling intervention reduce STIs among high-risk STI clinic patients?	**Population** Black males aged 16-29 who had had at least one STI **Setting** 2 community STI clinics **Country** Florida, USA	581; 288 intervention and 293 control Numbers lost to follow up not clear.	**I)** Intensive STI counselling. Sessions covered: condom knowledge and correct use, male & female anatomy, personalising risk for HIV and STIs, future educational & job plans. Encouraged screening for STIs, use of condoms, development of condom negotiation skills, & alternatives to intercourse. Culturally sensitive. **Provider** STI counsellors **Intensity/duration** 3 x 40-60 mins. **C)** TAU	Definite STI (clinical test) Possible STI More than 1 STD	12 months 0 16% (intervention) vs. 12% (control) RR 1.31 (0.87, 1.97) 0 31% vs. 27% RR 1.1 (0.9-1.5) 0 3% vs. 4% ES: h=0.02	3	No scheduled follow up – computerised records used to determine new STIs 63% attended at least one session, 38% completed all three.

Table 18 continued: Evidence Table type of intervention: theory/model based vs. didactic control

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention I = intervention C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect**	**Applicability to the UK populations and settings** Score 1-4	**Notes**
Martin 2003	RCT	-	Does a focused intervention based on a cognitive thought mapping model reduce HIV/AIDS risk behaviour in comparison to the NIDA standard intervention?	**Population** Drug involved male and female probationers 18 and over (mean age 34.5, 70% black, 24% white, mean of 5 previous prison incarcerations). **Setting** Community **Country** Delaware, USA	706 (40 % lost to follow up). No PC reported.	**I)** Probation focused intervention (PFI) Information provided similar to control (ESI) group. Also aims to use thought mapping to develop personalised strategies to promote safer behaviour (based on idea that knowledge alone is a poor predictor of behaviour). **Duration & Intensity** Baseline session with HIV test + posttest session. **C)** Enhanced version of NIDA (ESI). Modified version of standard NIDA intervention. Included pre + post-test HIV counselling, education on HIV risk related behaviours, condom demonstration and advice on safe sex.	Had some unprotected sex PFI Had some unprotected sex ESI Had some unprotected sex PFI vs. ESI Mean number of unprotected sex acts PFI Mean number of unprotected sex acts ESI Mean number of unprotected sex acts PFI vs. ESI Had multiple partners PFI Had multiple partners ESI Had multiple partners PFI vs. ESI	6 months Pre to post change + Men, ES h = .83 0 women, ES h=.00 Pre to post change + men, ES h=.58 + women, ES h=.00 0 (not enough data to calculate ES) Pre to post change + Men , + women Not enough data to calculate ES Pre to post change + Men , + Women Not enough data to calculate ES 0 Not enough data to calculate ES Pre to post change + ES h=.34 Pre to post change + ES h=.24 0 ES h-.10	3	Similar to intervention used by Kwaitowski Reduction in high-risk sexual behaviours in both groups but no difference between two groups. Theory based

Table 18 continued: Evidence Table type of intervention: theory/model based vs. didactic control

First Author	Study design	Research quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention I = intervention C = control	Outcome variable(s)	Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect		Applicability to the UK populations and settings Score 1-4	Notes
Metzler 2000	RCT	-	Do behavioural interventions with adolescents attending an STD clinic reduce unsafe sexual practices?	**Population** Adolescents aged 15-19 engaged in high risk sexual behaviour (average age 17, 68% female, 68% white) **Setting** Public STI clinics **Country** USA	339 (53% lost to follow up) PC not reported.	**I)** Individual counselling sessions addressing decision making about safer sex, setting safer sex goals, increasing social skills, and acceptance of negative thoughts associated with change. Based on social cognitive theory, information motivational-behavioural skills model. **Duration and intensity** 5 sessions 60-90 minutes long. **Provider** General public health clinic staff with 2 days training. **C)** Usual care which generally involved a clinic examination and a brief interaction with the nurse (may have included discussion about condoms and safer sex)	New self-reported STIs (covariate adjusted means) Condom use in past 3 months (covariate adjusted means) Number of partners in past 3 months (covariate adjusted means)	3 months 0 p=0.76 (effect size .00) 0 p=0.94 (effect size .00) 0 p=0.55 (effect size .00)	6 months 0 p=0.24 (ES d=0.01) 0 p=0.96 (ES d=0.00) + (all) p=0.0001 (effect size .11) + Men (p = 0.02) 0 Women (p = 0.08) 0 Minority males (p=0.56) Minority females (p=0.55)	3	Theory based

Table 18 continued: Evidence Table type of intervention: theory/model based vs. didactic control

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention I = intervention C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect**	**Applicability to the UK populations and settings** Score 1-4	**Notes**
Oliva 2005	Cluster RCT	-	Is a bio-psycho-behavioural HIV prevention intervention superior to standard HIV counselling and testing in reducing HIV risk behaviour and promoting the use of condoms?	**Population** Low income high-risk sexually active men and women aged 18-55 (88% African American, high levels of drug use, 29% traded sex for money, drugs or shelter, 40% been homeless in past year). **Setting** Mobile health clinic in areas with high rates of Chlamydia and AIDS for African Americans **Country** USA	667 (lost to follow up not clear) No PC reported	**I)** Bio-psycho-behavioural intervention that targets factors in each domain. Includes HIV testing & counselling, physical examination for STIs, targets risk perceptions, knowledge, motivations & efficacy. Used role-model stories, teaches condom use and negotiations for condom use. **Duration & Intensity** 1 session then follow up to receive test results. **Provider** Test counsellors at non profit organisation (not medically trained & many former drug addicts or sex workers). Doctors did physical exams. **C)** Standard HIV counselling and testing.	Attitudes towards condoms	1 week + More positive attitudes towards condoms on all 6 of the items on the scale.	3	Theory based

Table 18 continued: Evidence Table type of intervention: theory/model based vs. didactic control

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention I = intervention C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect**	**Applicability to the UK populations and settings** Score 1-4	**Notes**
Orr 1996	RCT	-	Does a behavioural intervention increase condom use and reduce STIs among high-risk female adolescents?	**Population** Sexually active female adolescents with C. trachomatis infection (55% black, mean age 17.9, predominantly lower class, 49% previous pregnancy) **Setting** Two family planning clinics and a county STD clinic. **Country** Indianapolis, USA	209 (46% lost to follow up) PC not reported	**I)** STI education, condom negotiation skills, condom skills training and promoting positive attitudes about condoms (included role-playing). Based on health belief model. **Provider** Trained, adult research assistant. **C)** Standard treatment – individual discussion with clinic nurse about STIs (including partner notification and condom use) & printed information about c.trachomatis. **Duration and intensity** Both intervention and control one session, 10-20 mins long.	Reinfection rates (c. trachomatis) Frequency of condom use (adjusted) Always use condom Sometimes use condom	5-7 months 0: RR 1.50 (0.73, 3.10) 26% vs. 17% (p=0.3) ES: h=0.18 + OR 2.8 (1.1,7.1) (p = 0.03) 0 RR 0.90 (95% CI 0.29, 2.76) + RR 1.90 (95% CI 1.19, 3.02)	3	Theory based

Table 18 continued: Evidence Table type of intervention: theory/model based vs. didactic control

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention I = intervention C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect**	**Applicability to the UK populations and settings** Score 1-4	**Notes**
Robert 1990	RCT	-	Do AIDS education interventions affect condom use and sexual risk behaviour?	**Population** Sexually active MSM **Setting** Community **Country** Auckland, New Zealand	159 (23% lost to follow up or excluded from analysis) Ia) n=30 Ib) n=32 C) n=36 No PC reported	**Ia)** Individual counselling (modelled on HIV re-test counselling using behaviourally orientated HIV risk assessment system BOHRAS. Uses open ended questions to assess risk, & provides info on AIDS and safer sex. **Ib)** Video called 'Do the right thing' – portrays two gay men participating in variety of safe sex practices. **Providers** Not specified **Duration and Intensity** Individual counselling 1 x 20-30 mins Video x 15 mins C) No intervention.	Condom use Overall measure of safer sex behaviour (includes consistent condom use)	6 months 0 Increased across all groups but no difference between groups. 0 post intervention; Individual counselling 71%, video 78%, control 76%. Ia) vs. control RR 1.00 (0.83, 1.19) Ib) vs. control RR 0.88 (0.70, 1.10) Change pre to post; Individual counselling +18% ES h=.62 video 0% ES h=.00 Control +13%. ES h=.47	3	Theory based High levels of safer sex practices at baseline.

Table 18 continued: Evidence Table type of intervention: theory/model based vs. didactic control

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention I = intervention C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect**	**Applicability to the UK populations and settings** Score 1-4	**Notes**
Scholes 2003	RCT	+	Does a theory based tailored minimal self-help intervention increase condom use among young women at risk of HIV/STI?	**Population** Non-monogamous sexually active women aged 18-24 at risk for heterosexual HIV/STD. (69% white, 19% black. 70% educated beyond high school, mean age 21). **Setting** Community **Country** USA	1210 (14% lost to follow up) No PC reported	**I)** 2 Individually tailored materials – 1) after randomisation a 12 page magazine style booklet, a safe sex kit (including male and female condoms + instructions on how to use) 2) at 3 months – tailored booster feedback newsletter and condom packet (focused on removing barriers to condom use). Intervention based in social science theory. **C)** TAU (not described)	Any use of condoms in prior 3 months (%) Average % of total episodes of intercourse during which condoms used in previous 3 months Consistent condom use with all partners STI diagnosis	6 months + Unadjusted OR 1.57 (1.18 – 2.10), adjusted 1.86 (1.32-2.65) P=0.0005 + Unadjusted OR 4.8 (-1.2 – 10.7), adjusted 5.2 (0.4-10.4) p=0.05 0 Unadjusted RR 1.10 (0.91, 1.32), adjusted OR 1.24 (0.89-1.73) p=0.21 0 Unadjusted RR 0.95 (0.51, 1.79), adjusted 0.97 (0.48-1.96) P=0.93	2	Theory based High use of condoms prior to intervention.

Table 18 continued: Evidence Table type of intervention: theory/model based vs. didactic control

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention** **I = intervention** **C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified)** **(+) = positive effect, (-) = negative effect, (0) = no effect**		**Applicability to the UK populations and settings** Score 1-4	**Notes**
Shrier 2001	RCT	-	Does an individualised safer sex intervention affect condom use and recurrent STIs among female adolescents diagnosed with an STI?	**Population** Multiethnic female adolescents with cervicitis or PID (median age 17.2, 49% black, 18% Hispanic, 14% white) **Setting** Hospital-based adolescent clinic **Country** Boston, USA	123 (lost to follow up – 6 months 27%, 12 months 48%) No PC reported (but not powered to detect STI)	**I)** Individualised education session which included 7 minute video, self assessment exercises, male and female condom demonstration, educational sessions based on stages of change (looked at risk, consequences of unprotected sex, preventing pregnancy and STI and condom use). Based on social cognitive theory, transtheoretical model of behaviour change & motivational enhancement interviewing. **Duration and intensity** One session (video + 30 minute discussion) and booster at 1,3 & 6 months. **Delivered by** Female health educators trained by principal investigator. **C)** STI education at the discretion of the physician (including discussion of STI transmission and importance of consistent condom use).		6 months	12 months	3	Theory based
							STI	Not reported	0 Intervention 17%, control 32% RR 0.52 (0.20, 1.31)		
							Condom use with last sexual encounter	0 RR 0.91 (0.63, 1.30)	0 RR 0.88 (0.57, 1.36)		
							Consistent (every time) condom use with main partner (data only for those reporting current partner)	0 50% vs. 32% RR 1.62 (0.88, 2.99)	0 52% vs. 36% RR 1.31 (0.68, 2.53)		
							Consistent (every time) condom use with other partner (data only for those reporting another partner)	0 60% vs. 68% ES: h=0.21	0 71% vs. 42% ES: h=0.71		

Table 18 continued: Evidence Table type of intervention: theory/model based vs. didactic control

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention** **I = intervention** **C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified)** **(+) = positive effect, (-) = negative effect, (0) = no effect**	**Applicability to the UK populations and settings** Score 1-4	**Notes**
Sterk 2003	RCT	**+**	Do two culturally specific counselling interventions reduce the risk of HIV infection in women who use crack cocaine?	**Population** Sexually active low-income African American women who use crack cocaine (aged 18-59). **Setting** Project office Inner city neighbourhoods **Country** Atlanta, USA	**265 (4% lost to follow up)** No PC reported	**Ia)** Enhanced motivation intervention (MI). Included HIV risk & risk reduction information, goal setting for behavioural change, control and risk reduction messages tailored to participant's level of readiness for change. **Ib)** Enhanced negotiation intervention (NI). Similar to MI but looked at negotiation, skills training & development of tailored negotiation and conflict resolution styles. Both interventions gender and culturally specific. Based on social cognitive theory, theory of reasoned action, theory of planned behaviour. Social context of women's daily lives central. **Duration & Intensity** Intervention: 4 sessions Control: 2 sessions **Provider** Trained female health interventionist (mainly African American) **C)** NIDA standard intervention (SI) Information on HIV risk & risk reduction strategies.	Frequency of condom use with steady partners Vaginal sex Frequency of condom use with steady partners (all groups pre to post) Number of paying partners (vaginal, oral or anal sex) Number of paying partners (vaginal, oral or anal sex - all groups pre to post)	6 months 0 **MI vs. SI ES d=.0** + NI vs. SI (p<.01) ES d=.017 0 NI vs. MI (p<.10) ES d=.18 + (p<.05) Vaginal sex, ES d= 0.12 Oral sex, ES d=0.11 0 MI vs. SI (p<.10), ES d=.08 + NI vs. SI (p<.001), ES d=.33 + NI vs. MI (p<.001), ES d=.26 + (p<.001) 41% reduction vaginal sex, 50% reduction oral sex ES d= 0.48	**3**	Monetary incentive to take part. Standard intervention appears as effective as enhanced interventions for many of sexual risk behaviours. Theory based

Table 18 continued: Evidence Table type of intervention: theory/model based vs. didactic control

First Author	Study design	Research quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention I = intervention C = control	Outcome variable(s)	Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect	Applicability to the UK populations and settings Score 1-4	Notes
Winter 1993	RCT	-	Do two educational interventions in a family planning clinic improve condom acceptance, attitudes and knowledge in adolescents already using oral contraceptives?	**Population** Sexually active white female adolescents, 13-19. already using oral contraceptives (mean age 17.6) **Setting** Two family planning clinics **Country** Pennsylvania, USA	291 (none lost to follow up) No PC reported.	**Ia)** Direct-experience intervention. Same information as in control but educator had client handle condom and practice use. Client asked to give opinion about condoms. **Ib)** Contingency-planning condition. Same as direct-experience intervention but also explored barriers & facilitators to condom use Interventions based on models of mental representations and behaviour. **Duration & intensity** 1 session, length not specified. **Provider** Health educator C) Standard condom education including information about condom use and effectiveness and demonstration.	Mean number of condoms accepted (used as a measure of condom acceptance) Attitude towards condoms Condom knowledge (one way analysis of variance)	Follow up immediately post intervention 0 Ia vs. control (p value not reported) ES: d=0.02 + Ib vs. control (p<.005) ES: d=0.45 + Ib vs. Ia (p<.001) ES: d=0.44 0 Ia) vs. control (p value not reported) ES: d=0.04 + Ib vs. control (p<.011) ES: d=0.39 ES: d=0.39 + Ib vs. !a (p=.006) ES d=0.35 0 P = 0.69) For all comparisons. ES: d= 0.10		Theory based

Table 19: Evidence Table Duration/Intensity of intervention (studies that compared different numbers of sessions)

First Author	Study design	Research quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention I = intervention C = control	Outcome variable(s)	Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect		Applicability to the UK populations and settings Score 1-4	Notes
Boyer 1997	RCT	+	Does a cognitive behavioural skills building intervention prevent STD in high-risk heterosexual adults.	**Population** High risk heterosexual adults 18-35 (46% black, 29% white,15% Hispanic) **Setting** Public health STD clinic **Country** California, USA	399 randomised (65% followed up at 3 months, 60% at 5 months, 52% followed up at both). PC – 200 subjects in each arm to detect a difference in STI acquisition.	**I)** Individual, multi-component sessions designed to increase knowledge about prevention of STD/HIV, build effective decision making & communication skills, and identify and modify STD/HIV related risk factors. Based on AIDS risk reduction model (ARRM) **Duration & intensity** Four 60-minute sessions over 4 weeks. **Provided by** Trained intervention counsellor. **C)** Standard 15-minute risk-reduction counselling session offered to all patients.	STI (diagnosed or suspected) sexual intercourse without condoms (in 2 months prior to assessment) – change from baseline Mean number of sexual partners without a condom	3 months Not reported + Reduction in intervention and control group ($p<0.001$), ES: c=0.11 greater in intervention group ($p<0.05$) ES: c=0.02 Data not reported	5/ 6 months 0 (all) 13% vs. 11% RR 1.17 (95% CI 0.68, 2.02) 0 Men 7% vs. 8% ($p>0.20$) ES: h=0.02 0 Women 22% vs. 22% ($p>0.20$) ES h=0.00 0 + 0.6 vs. 0.9 ($p<0.01$)	3	Financial incentive for participation in follow up.

Table 19 continued: Evidence Table Duration/Intensity of intervention (studies that compared different numbers of sessions)

First Author	Study design	Research quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention I = intervention C = control	Outcome variable(s)	Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect		Applicability to the UK populations and settings Score 1-4	Notes
Downs 2004	RCT	+	Does a theoretically based, interactive video intervention affect adolescent girls STI knowledge, risk behaviour and STI acquisition?	**Population** Sexually active female adolescents aged 14-18 (75% African American) **Setting** 4 Urban healthcare sites. **Country** Pittsburg, USA	300 (14% lost to F.U) Not clear how many participants were in each group. PC not reported	**I)** Interactive hour long video looking at sexual health decisions, addressing gaps and misconceptions identified from previous qualitative interviews. Included negotiation behaviours, condom efficacy & information about STIs. Based on mental models approach. Participants watched video at baseline (30 mins) and 3 further visits (1,3,6 months) for about 15 mins each time. **Provider** Interactive video developed by research team. **Ca)** Same content as video but in book form **Cb)** Commercially available brochures (similar length and content).	STI acquisition Condom use STI knowledge (intervention versus either control) STI knowledge (pre to post both intervention and control) Abstinent (defined as no sexual partners since baseline)	3 months Not measured 0 (p=0.57) ES: d=0.07 0 (data not reported) + OR 2.50 (p=0.027)	6 months Adjusted + OR 2.79 (p=0.05) unadjusted 0 RR 0.53 (0.28, 1.02) 0 p=0.15 ES:d=0.17 0 (data not reported) + p<0.001 ES: d=0.96 0 OR 1.45 (p=0.344)	3	Theory based Monetary incentive to take part in follow up. Not powered to detect STIs except Chlamydia (p=0.05)

Table 19 continued: Evidence Table Duration/Intensity of intervention (studies that compared different numbers of sessions)

First Author	Study design	Research quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention I = intervention C = control	Outcome variable(s)	Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect		Applicability to the UK populations and settings Score 1-4	Notes
El-Bassel 2003	RCT	+	Does a relationship based HIV/STI program for heterosexual couples promote safe sex behaviour and is it most effective when delivered to the couple or the women alone	**Participants** Couples in long-term relationship known, or suspected, to have at least one HIV/STD risk criteria. Mainly low income, ethnic minorities **Setting** Hospital outpatient clinics **Country** USA	217 couples (20% intervention grp, 33% control grp lost to follow up) No PC reported	**Ia (couples - C)** Relationship-based counselling to couple together **Ib (women only - WA)** Relationship-based counselling to woman alone Both based on AIDS risk reduction model and ecological perspective Emphasised importance of relationship communication, negotiation & problem solving skills, gender roles & expectations and HIV/STI prevention. **Duration & intensity** Both interventions 6 2-hour sessions. Control one, one hour, session. **Provider** Facilitators **C)** 1 HIV/STD information session for women alone	Number of unprotected sexual acts Percentage of protected sexual acts Number of STD symptom Number of sexual partners	3 months + WA vs. control, C vs. control 0 WA vs. couples + WA vs. control, ES h=0.37 C vs. control, ES,h=0.24 0 WA vs. couples ES h=0.14 0 Intervention vs. control (p=0.72), WA vs. C (p=0.52) ES d=0.03 0 Intervention vs. control (p = 0.36), WA vs. C (p= 0.15) ES d=0.14	12 months + WA vs. control, C vs. control 0 WA vs. couples 0 (data not reported)	2	Regression analysis demonstrated that either intervention was associated with safer sexual behaviour (particularly condom use) but that there was no significant difference between the intervention groups.

Table 19 continued: Evidence Table Duration/Intensity of intervention (studies that compared different numbers of sessions)

First Author	**Study design**	**Research quality Internal validity score ++/+/_**	**Research Question**	**Study population, setting and country of study**	Sample size Include power calculation if available	**Description of intervention I = intervention C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect**	**Applicability to the UK populations and settings Score 1-4**	**Notes**
The EXPLORE study team 2004 (baseline data from Chesney 2003) EXPLORE	RCT	++	Do 10 sessions of one on one counselling prevent HIV infection, and is it better than twice yearly counselling?	**Population** Sexually active, high risk urban HIV negative MSM (mean age 34, 72.5% white, 40% annual income of less than $30,000) **Setting** 6 cities **Country** USA	**4295 (15% lost to follow up)** PC 4350 – to detect HIV acquisition.	**I)** Same as control arm + additional counselling in form of multiple intensive behavioural counselling sessions (with motivational interviewing and cognitive behaviour theory as key components). Also received booster sessions (n=2144) **Duration and intensity** 10 core-counselling modules delivered over 10 sessions within 4-6 month period. Then booster sessions every 3 months (up to on average 3.25 yrs) **Provider** Counsellors with 40hrs training delivered both intervention and control **C)** Twice yearly counselling on risk reduction based on the CDC Project RESPECT model (n=2151)	HIV acquisition Unprotected anal intercourse	48 months 0 Reduction but not statistically significant RR 0.80 (0.63, 1.02) 18.2% reduction (95% CI –4.7% to 36%). Difference greatest in first 12-18 months of study. + RR 0.92 (0.87, 0.97), difference of 13.9% (5.6 to 21.5)	2	75% of intervention group completed all ten sessions. Theory based

Table 19 continued: Evidence Table Duration/Intensity of intervention (studies that compared different numbers of sessions)

First Author	Study design	Research quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention I = intervention C = control	Outcome variable(s)	Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect			Applicability to the UK populations and settings Score 1-4	Notes
								3 months	6 months	12 months		
Kamb 1998 Project RESPECT	RCT	++	Do two face-to - face didactic interactive counselling interventions prevent high-risk sexual behaviours and new STIs and is one more effective than the other?	**Population** HIV negative heterosexuals aged 14 and over (median age 25, 57% male, 59% black, 54% unemployed). **Setting** Five public health clinics in different cities. **Country** USA	5758 (66% follow up at final assessment) PC – 1500 per arm for 80% power to detect a 25% reduction in STIs	(Ia)**Enhanced counselling (EC).** based on theory of reasoned action and social cognitive theory. Sought to change key elements underlying condom use (e.g. self efficacy, attitudes and perceived norms). Included behavioural goal setting and risk-reduction plan. (Ib) **Brief counselling (BC)** Brief counselling intervention modelled after CDC's recommended HIV counselling. Addressed barriers to risk reduction and negotiated risk-reduction plan. **Duration & Intensity** Ia) enhanced 4 sessions (1 20 mins, 3 60 mins) Ib) brief – Two 20-minute sessions. C) Two 5 minute sessions. **Provider** Ia & Ib) Counsellors who received standard training and used structured intervention protocols. C) Clinician doing examination **C) Didactic messages** - informational intervention – designed to approximate what was TAU in most clinics.	New STI EC vs. control BC vs. control Condom use (100% self-reported condom use with all partners). EC vs. control BC vs. control EC vs. BC	+ 46% vs. 38%,RR 1.21 95% CI 1.09-1.35 + 44% vs. 38%;RR 1.15, 95% CI 1.03-1.27 0 46% vs. 44% RR	+ 10.4% vs. 7.2%; RR 0.69 (0.54-0.88) + 10.4% vs. 7.3%; RR 0.71 (0.58-0.89) + 39% vs. 34%;RR 1.15 (1.04-1.26) 0 39% vs. 34%;RR 1.15 (1.04-1.26)	+ 14.6% vs. 11.5%; RR 0.78 (0.64-0.94) + 14.6% vs. 12% RR 0.81 (0.67-0.98) 0 data not reported 0 data not reported	2	Monetary incentive to attend sessions, and for follow up (+ free condoms) 82% completed all assigned intervention sessions. Lower in 4-session intervention (72%) than in either of others (85%) Theory based

								1.06, 95% CI 0.96-1.17				

Table 19 continued: Evidence Table Duration/Intensity of intervention (studies that compared different numbers of sessions)

First Author	Study design	Research quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention I = intervention C = control	Outcome variable(s)	Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect	Applicability to the UK populations and settings Score 1-4	Notes
Kwiatkowski (1998, 1999)	RCT	+	Does a community based AIDS intervention increase condom use	**Population** Injection drug users not currently in treatment (average age 38.6 yrs) **Setting** Office setting (9 cities) **Country** USA	5372 (38% lost to follow up) No PC reported	**I)** SI + site specific enhanced intervention: including AIDS education, risk reduction information, skills demonstration & rehearsal (e.g. condom use). Including use of audio & visual information. **Duration and intensity** Usually consisting of 1-3 personalised sessions **C)** NIDA/CA standard manual driven intervention (SI). Included HIV pre & posttest counselling, optional HIV testing, written material.	Increase in condom use (Enhanced versus standard) Increase in condom use both groups combined	6 months **+** 31% versus 27% (p=0.04) ES h=.08 + 15% to 22% (p=<0.001) ES h=.14	**3**	Statistically significant results (due to very large sample) but small effect size and not clinically significant.
Maher 2003	RCT	++	Does a community-based, intensive counselling intervention reduce STIs among high-risk STI clinic patients?	**Population** Black males aged 16-29 who had had at least one STI **Setting** 2 community STI clinics **Country** Florida, USA	581; 288 intervention and 293 control Numbers lost to follow up not clear.	**I)** Intensive STI counselling. Sessions covered: condom knowledge and correct use, male & female anatomy, personalising risk for HIV and STIs, future educational & job plans. Encouraged screening for STIs, use of condoms, development of condom negotiation skills, & alternatives to intercourse. Culturally sensitive. **Provider** STI counsellors **Intensity/duration** 3 x 40-60 mins. **C)** TAU	Definite STI (clinical test) Possible STI More than 1 STD	12 months 0 16% (intervention) vs. 12% (control) RR 1.31 (0.87, 1.97) 0 31% vs. 27% RR 1.1 (0.9-1.5) 0 3% vs. 4% ES: h=0.02	3	No scheduled follow up – computerised records used to determine new STIs 63% attended at least one session, 38% completed all three.

Table 19 continued: Evidence Table Duration/Intensity of intervention (studies that compared different numbers of sessions)

First Author	Study design	Research quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention I = intervention C = control	Outcome variable(s)	Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect		Applicability to the UK populations and settings Score 1-4	Notes
Metcalf 2005 Project RESPECT-2	RCT	++	Does a booster counselling session 6 months after HIV testing and counselling prevent STDs?	**Population** Sexually active HIV negative people (including MSM) aged 15-39 (mean age 25.6, 46% women, 50% black 22% white 18% Hispanic) **Setting** 3 public health STD clinics in Denver, Long Beach and Newark. **Country** USA	3297 (12% lost to follow up) PC – sample size of 4100 for 80% power to detect a 33% difference in STIs – would be underpowered to detect a smaller reduction.	Both groups received HIV testing (rapid or standard) and given prevention counselling based on a brief 2-session model used in Project RESPECT. Then randomised to: **I)** Additional booster counselling session –based on Project RESPECT (integrates theoretical principles from several models of behaviour change but is not based on a single theoretical model). **Intensity and duration** Single 20-minute session 6 months after enrolment. **Provider** Clinic staff **C)** No booster counselling session		9 months	12 months	2	Monetary incentive for assessment but not to complete intervention.
							STI (defined as one or more STI during follow up – yes/no)	0 RR 1.06 (0.78, 1.44) 0 Women RR 1.05 (0.72 – 1.52) 0 Men RR 1.07 (0.64, 1.82)	0 RR 0.97 (0.76, 1.25) 0 Women RR 1.03 (0.77, 1.36) 0 Men RR 0.90 (0.63, 1.28)		
							Unprotected sex (all)	0 RR 0.96 (0.90-1.02) 0 Women RR 1.01 (0.92, 1.10) 0 Men RR 0.90 (0.46, 1.78)	0 data not reported		
							Unprotected sex MSM	0 RR 0.91 (0.83-1.00)	0 data not reported		

Table 19 continued: Evidence Table Duration/Intensity of intervention (studies that compared different numbers of sessions)

First Author	Study design	Research quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention I = intervention C = control	Outcome variable(s)	Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect		Applicability to the UK populations and settings Score 1-4	Notes
Metzler 2000	RCT	-	Do behavioural interventions with adolescents attending an STD clinic reduce unsafe sexual practices?	**Population** Adolescents aged 15-19 engaged in high risk sexual behaviour (average age 17, 68% female, 68% white) **Setting** Public STI clinics **Country** USA	339 (53% lost to follow up) PC not reported.	**I)** Individual counselling sessions addressing decision making about safer sex, setting safer sex goals, increasing social skills, and acceptance of negative thoughts associated with change. Based on social cognitive theory, information motivational-behavioural skills model. **Duration and intensity** 5 sessions 60-90 minutes long. **Provider** General public health clinic staff with 2 days training. **C)** Usual care which generally involved a clinic examination and a brief interaction with the nurse (may have included discussion about condoms and safer sex)	New self-reported STIs (covariate adjusted means) Condom use in past 3 months (covariate adjusted means) Number of partners in past 3 months (covariate adjusted means)	3 months 0 p=0.76 (effect size .00) 0 p=0.94 (effect size .00) 0 p=0.55 (effect size .00)	6 months 0 p=0.24 (ES d=0.01) 0 p=0.96 (ES d=0.00) + (all) p=0.0001 (effect size .11) + Men (p = 0.02) 0 Women (p = 0.08) 0 Minority males (p=0.56) Minority females (p=0.55)	3	Theory based

Table 19 continued: Evidence Table Duration/Intensity of intervention (studies that compared different numbers of sessions)

First Author	Study design	Research quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention I = intervention C = control	Outcome variable(s)	Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect	Applicability to the UK populations and settings Score 1-4	Notes
Patterson 2003	RCT	-	Does a behavioural intervention based on Social Cognitive Theory increase safer sex practices in HIV positive individuals?	**Population** HIV positive; 91% male; 22-62 years (M=37.4 years); 85% gay or bisexual, 65% white; 15% African American; 12% Hispanic; 64% had some college education **Setting** Off-campus project office. **Country** San Diego, USA	387 (not reported by study arm) 54.8% completed baseline and all 3 follow up visits. No PC reported.	**Ia) Brief targeted intervention**: Tailored to individual by addressing only those behaviours that the participant indicated were problematic. **Ib) Comprehensive intervention**: addressing condom use, negotiation of safer sex practices, and disclosure of HIV+ serostatus to sex partners. Social Cognitive Theory (SCT) techniques were used to increase knowledge, self-efficacy, and positive outcome expectancies in relation to those three areas. **Ic) Comprehensive + booster:** as above, + booster sessions to reinforce positive behavioural change **Provider** Trained project staff **Intensity/duration** Ia: 1x 90 mins Ib: 1x 90 mins Ic: 3x90 mins (monthly) C: 3x90 minutes **C)** Addressed diet and exercise as related to HIV.	STIs Unprotected sexual acts (only included participants who completed all 4 assessments in analysis, n=212).	8 months 0 Comprehensive with boosters vs. diet & exercise control RR 0.92 (0.44, 1.90) Comprehensive with no boosters vs. control RR 1.01 (0.48, 2.13) Brief targeted vs. control RR 0.75 (0.34, 1.64) Boosters vs. no boosters RR 0.91 (0.42, 1.95) ANOVA showed a significant main effect of trials ($F(3, 624)=35.39$, $p<.05$) and trials x group interaction ($F(9, 624)=1.86$, $p<.05$), indicating that comprehensive + booster group reported more unprotected sex acts than other groups at 8 months. + all groups pre compared to post - Comprehensive + booster vs other groups.	3	Theory based Monetary incentive for taking part All interventions included role-play and problem solving 'real-life' situations.

Table 19 continued: Evidence Table Duration/Intensity of intervention (studies that compared different numbers of sessions)

First Author	Study design	Research quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention I = intervention C = control	Outcome variable(s)	Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect	Applicability to the UK populations and settings Score 1-4	Notes
Picciano 2001	RCT	-	Does brief telephone based counselling reduce sexual risk taking among MSM	**Population** MSM – those currently engaged in unsafe sexual practices (76% white, mean age 36.6) **Setting** Community **Country** Seattle, USA	103 (54 intervention, 49 control, 14% lost to follow up) No PC reported	**I)** Personal feedback report (PFR) prepared. Then counselling sessions (using PFR). Used a motivational interviewing style, which included role-plays and reinforcement of safe sex practices. **Duration & Intensity** Baseline assessment then 2x 90-minute sessions 6 weeks apart. **Provided by:** Trained counsellors by telephone. C) Delayed intervention control (got intervention 7 weeks later)	Unprotected anal sex Unprotected oral sex Number of partners Protected anal sex Potected oral sex	6 weeks 0 RR 1.38; p= 0.60 ES d=.02 0 RR 0.66; p=0.19 ES d=.07 0 RR 0.97; p=0.92 ES d=.29 0 RR 0.76; p=0.59 ES d=.07 0 RR 1.23; p=0.88 D=.06 No differences between groups but both showed significant overall reduction in unprotected anal intercourse (3.4-2.0, p=.02), unprotected oral sex (declined from mean of 22.6 to 13.3 p<.01) and number of sexual partners (mean of 6.5 to 3.4 p<.01)	2	Incentive payment Data was highly skewed

Table 19 continued: Evidence Table Duration/Intensity of intervention (studies that compared different numbers of sessions)

First Author	Study design	Research quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention I = intervention C = control	Outcome variable(s)	Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect	Applicability to the UK populations and settings Score 1-4	Notes
Scholes 2003	RCT	+	Does a theory based tailored minimal self-help intervention increase condom use among young women at risk of HIV/STI?	**Population** Non-monogamous sexually active women aged 18-24 at risk for heterosexual HIV/STD. (69% white, 19% black. 70% educated beyond high school, mean age 21). **Setting** Community **Country** USA	1210 (14% lost to follow up) No PC reported	**I)** 2 Individually tailored materials – 1) after randomisation a 12 page magazine style booklet, a safe sex kit (including male and female condoms + instructions on how to use) 2) at 3 months – tailored booster feedback newsletter and condom packet (focused on removing barriers to condom use). Intervention based in social science theory. **C)** TAU (not described)	Any use of condoms in prior 3 months (%) Average % of total episodes of intercourse during which condoms used in previous 3 months Consistent condom use with all partners STI diagnosis	6 months + Unadjusted OR 1.57 (1.18 – 2.10), adjusted 1.86 (1.32-2.65) P=0.0005 + Unadjusted OR 4.8 (-1.2 – 10.7), adjusted 5.2 (0.4-10.4) p=0.05 0 Unadjusted RR 1.10 (0.91, 1.32), adjusted OR 1.24 (0.89-1.73) p=0.21 0 Unadjusted RR 0.95 (0.51, 1.79), adjusted 0.97 (0.48-1.96) P=0.93	2	Theory based High use of condoms prior to intervention.

Table 19 continued: Evidence Table Duration/Intensity of intervention (studies that compared different numbers of sessions)

First Author	Study design	Research quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention I = intervention C = control	Outcome variable(s)	Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect		Applicability to the UK populations and settings Score 1-4	Notes
Shrier 2001	RCT	-	Does an individualised safer sex intervention affect condom use and recurrent STIs among female adolescents diagnosed with an STI?	**Population** Multiethnic female adolescents with cervicitis or PID (median age 17.2, 49% black, 18% Hispanic, 14% white) **Setting** Hospital-based adolescent clinic **Country** Boston, USA	123 (lost to follow up – 6 months 27%, 12 months 48%) No PC reported (but not powered to detect STI)	**I)** Individualised education session which included 7 minute video, self assessment exercises, male and female condom demonstration, educational sessions based on stages of change (looked at risk, consequences of unprotected sex, preventing pregnancy and STI and condom use). Based on social cognitive theory, transtheoretical model of behaviour change & motivational enhancement interviewing. **Duration and intensity** One session (video + 30 minute discussion) and booster at 1,3 & 6 months. **Delivered by** Female health educators trained by principal investigator. **C)** STI education at the discretion of the physician (including discussion of STI transmission and importance of consistent condom use).	STI Condom use with last sexual encounter Consistent (every time) condom use with main partner (data only for those reporting current partner) Consistent (every time) condom use with other partner (data only for those reporting another partner)	6 months Not reported 0 RR 1.10 (0.77, 1.58) 0 50% vs. 32% RR 1.62 (0.88, 2.99) 0 60% vs. 68% ES: h=0.21	12 months 0 RR 0.52 (0.20, 1.31) ES: h = 0.31 0 RR 1.13 (0.74, 1.74) 0 52% vs. 36% RR 1.31 (0.68, 2.53) 0 71% vs. 42% ES: h=0.71	3	Theory based

Table 19 continued: Evidence Table Duration/Intensity of intervention (studies that compared different numbers of sessions)

First Author	Study design	Research quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention I = intervention C = control	Outcome variable(s)	Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect	Applicability to the UK populations and settings Score 1-4	Notes
Sterk 2003	RCT	+	Do two culturally specific counselling interventions reduce the risk of HIV infection in women who use crack cocaine?	**Population** Sexually active low-income African American women who use crack cocaine (aged 18-59). **Setting** Project office Inner city neighbourhoods **Country** Atlanta, USA	265 (4% lost to follow up) No PC reported	**Ia)** Enhanced motivation intervention (MI). Included HIV risk & risk reduction information, goal setting for behavioural change, control and risk reduction messages tailored to participant's level of readiness for change. **Ib)** Enhanced negotiation intervention (NI). Similar to MI but looked at negotiation, skills training & development of tailored negotiation and conflict resolution styles. Both interventions gender and culturally specific. Based on social cognitive theory, theory of reasoned action, theory of planned behaviour. Social context of women's daily lives central. **Duration & Intensity** Intervention: 4 sessions Control: 2 sessions **Provider** Trained female health interventionist (mainly African American) **C)** NIDA standard intervention (SI) Information on HIV risk & risk reduction strategies.	Frequency of condom use with steady partners Vaginal sex Frequency of condom use with steady partners (all groups pre to post) Number of paying partners (vaginal, oral or anal sex) Number of paying partners (vaginal, oral or anal sex - all groups pre to post)	6 months 0 MI vs. SI ES d=.0 + NI vs. SI (p<.01) ES d=.017 0 NI vs. MI (p<.10) ES d=.18 + (p<.05) Vaginal sex, ES d= 0.12 Oral sex, ES d=0.11 0 MI vs. SI (p<.10), ES d=.08 + NI vs. SI (p<.001), ES d=.33 + NI vs. MI (p<.001), ES d=.26 + (p<.001) 41% reduction vaginal sex, 50% reduction oral sex ES d= 0.48	3	Monetary incentive to take part. Standard intervention appears as effective as enhanced interventions for many of sexual risk behaviours.

Table 20: Evidence for the effectiveness of one to one interventions to prevent under 18 conceptions

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention** **I = intervention** **C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified)** **(+) = positive effect, (-) = negative effect, (0) = no effect**		**Applicability to the UK populations and settings** Score 1-4	**Notes**
Boekeloo 1999	RCT	-	Does primary care based STI prevention education reduce risky sexual behaviours in young adolescents?	**Population** Adolescents aged 12-15 attending for general health examination (majority African American, 50% female). **Setting** 5 primary care HMO practices (3 suburban, 2 inner-city). **Country** Washington, USA	215 (8% lost to follow up) No PC reported.	**I)** Pre-visit audiotaped STI risk assessment by researchers. Then Program ASSESS (awareness, skills, self-efficacy/self-esteem and social support). Involved education (tailored to individual) & brochures. Based on social cognitive, theory of reasoned action. **Providers** Paediatricians with 45 minute STI prevention training. **Duration & intensity** 1 session (length not specified) **C)** Usual care - regular health examination (18% received non study-specific HIV/STI educational materials).	Got someone pregnant or been pregnant Vaginal intercourse in last 3 months: Vaginal, oral or anal intercourse in last 3 months Condom use at last vaginal intercourse among those sexually active in last 3 months Unprotected sex	3 months 0 RR 0.23 (0.01, 4.73) - adjusted OR 2.46 (1.04-5.84) 0 unadjusted RR 1.37 (0.82, 2.28) 0 adjusted OR 1.55 (0.73 – 3.32); 0 unadjusted RR 1.04 (0.67, 1.61) + (adjusted) OR 18.05 (1.27-256.03) + (unadjusted) RR 1.61 (1.09, 2.37) + (adjusted) OR 8.63 (1.60-46.45) + unadjusted RR 0.19 (0.05, 0.77)	9 months 0 RR 0.18 (0.02, 1.49 0 adjusted OR 1.64 (0.81 -3.34); 0 Unadjusted RR 1.13 (0.75, 1.72) 0 (adjusted) OR 1.56 (0.79-3.08); 0 unadjusted RR 1.16 (0.80, 1.67) 0 (adjusted) OR 1.00 (0.31-3.24) (unadjusted) RR 1.01 (0.73, 1.40)	3	Theory based

Table 20 continued: Evidence for the effectiveness of one to one interventions to prevent under 18 conceptions

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention** **I = intervention** **C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified)** **(+) = positive effect, (-) = negative effect, (0) = no effect**	**Applicability to the UK populations and settings** Score 1-4	**Notes**
Danielson 1990	RCT	+	Does a reproductive health consultation affect male sexual activity behaviour?	**Population** Adolescent males (aged 15-18) **Setting** Kaiser Permanente (a health maintenance organisation) offices. **Country** Northwest, USA	1449 (18% lost to follow up). PC not reported.	**I)** Medical appointment which included slide-tape programme (seen privately) covering general reproductive health concerns. Then visit with health care practitioner that focused on contraception & was guided by patients' interests (included info on STIs). **Duration and intensity** 30 min tape show + 30 min consultation **Providers** Nurse practitioners, physicians' assistants, registered nurses. **C)** Delayed intervention	Became sexually active following intervention Condom used at most recent intercourse. Partner used contraceptive pill Knowledge about preventing STIs Knowledge about fertility	12 months 0 30% vs. 34% ; ES: h=0.08 0 33.6% vs. 35.8%; ES: h=0.05 RR 0.94 (0.74, 1.19) + 32.4% vs. 23.9%; ES: h=0.18 RR 1.34 (1.02, 1.78) + OR 1.98 (p<0.001) (% change not reported) + OR 1.37 (p<0.01) No change scores given.	3	Money given for travel

Table 20 continued: Evidence for the effectiveness of one to one interventions to prevent under 18 conceptions

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention** **I = intervention** **C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified)** **(+) = positive effect, (-) = negative effect, (0) = no effect**	**Applicability to the UK populations and settings** Score 1-4	**Notes**
Gold 2004	RCT	++	Do adolescents given advance emergency contraception have higher sexual and contraceptive risk-taking behaviour?	**Population** **Sexually active female adolescents aged 15-20 (mean age 17.1 yrs, predominantly African American)** **Setting** **Adolescent medicine department of children's hospital** **Country** USA	301 (36% lost to follow up) PC - assuming 40% loss to follow up needed 150 in each group for unprotected intercourse and use of EC. Not powered for pregnancies or STIs	**I)** Emergency contraception (EC) education + one complete AEC course + informed could get further 2 courses during 6 month study (whether or not had had unprotected intercourse). **C)** EC education only + could only access EC if they had had unprotected intercourse	Pregnancies STIs Unprotected intercourse over past month Condom use in past month Used oral contraceptive pill in last month Used EC in past month	6 months 0 RR 0.85 (0.44, 1.64) 0 RR 1.21 (0.51, 2.85) 0 p = 0.68 + 77% vs. 62% RR 1.26 (1.04, 1.52) 0 36% vs. 48% RR 0.78 (0.56, 1.09) 0 8% vs. 6% (p=0.54) RR 1.38 (0.48, 3.95)	3	Monetary incentive for follow up N.B intervention not designed to promote condom use or prevent STIs. Providing advanced EC did not increase unprotected sex.

Table 20 continued: Evidence for the effectiveness of one to one interventions to prevent under 18 conceptions

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention I = intervention C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect**	**Applicability to the UK populations and settings** Score 1-4	**Notes**
Harper 2005	RCT	++	Does direct access to emergency contraception (EC) prevent unintended pregnancies?	**Population** Multiethnic women aged 15-19 (mean age 17.4) **Setting** Family planning clinics **Country** California, USA	964 (7% lost to follow up) This was a subgroup analysis of a larger study (Raine 2005). PC done for larger study but not for subgroup. 620 women needed in each group to detect pregnancies. They calculated subgroup study had 86% power to detect difference in EC use.	**Ia)** Pharmacy access (PA) to EC **Ib)** Advance provision (AP) of EC **C)** Clinic access (CA) to EC (this group eliminated before end of trial as new legislation meant pharmacy access available to all.	Pregnancy Used emergency contraception Any STI Unprotected intercourse	6 months 0 PA 7.8% versus 9.9% RR 0.79 (0.43, 1.45) AP 12.4% versus 9.9% RR 1.26 (0.72, 2.21) 0 PA 29.8% versus 28.9% RR 1.03 (0.76, 1.40) + AP 44.3% versus 28.9% RR 1.54 (1.16, 2.03) 0 PA 14.2% versus 13.4% (p=0.808) ES: h=0.02 AP 12.1% versus 13.2% (p=0.702) ES: h=0.03 0 PA 39.5% versus 47.2% (p=0.115) ES h = 0.17 AP 45.8% versus 43.4% (p=0.773) ES h=0.05	3	Monetary incentive to participate N.B subgroup analysis of larger study (Raine 2005) which included women aged 15-24 Study not designed to increase condom use or prevent STIs Providing advanced EC did not increase unprotected sex.

Table 20 continued: Evidence for the effectiveness of one to one interventions to prevent under 18 conceptions

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention I = intervention C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect**	**Applicability to the UK populations and settings** Score 1-4	**Notes**
Norr 2003	RCT	-	Does a nurse health advocate home visiting programme improve maternal and infant outcomes at one year in African Americans and Mexican Americans?	**Population** Pregnant women (69% African Americans AA, 31% Mexican Americans MA), all low income from high infant mortality Inner-city neighbourhood, 40% under 20 years age, 50% high school graduates, 39% employed or in school. **Setting** Prenatal clinics **Country** USA	N=588 Follow-up 477 (81%) AA I 182 C 142 MA I 76 C 78 PC not reported	**I)** REACH-Futures (Resources, Education and Care in the Home) involved home visits by trained community residents offering culturally sensitive program. The nurse-advocate combines health knowledge and the advocate's understanding of social realities of communities. Education and counselling is needs based, focusing on developmental changes, preventive care needed, health status, appropriate parenting and positive discipline strategies. Nurse conducts health screen at 1, 6 and 12 months and facilitates health clinic appointments. **C)** Routine well-child visits at the clinic or provider of their choice (standard care) **Duration and intensity** Each family contacted once a month and more often if necessary. Average of five home visits and seven contacts during 12 months **Provider** A team of one nurse and two health advocates (bilingual)	Repeat pregnancy	Follow-up 12 months; No differences observed in either ethnic group 0 All RR 0.95 (0.58-1.56) African Americans 0 I 13.2% C 12.8% t value -0.11 RR 1.03 (0.54-1.98) Mexican Americans 0 I 6.7% C 10.3% t value 0.80 RR 0.64 (0.25-1.63)	4	Theory- based on ecological model of child development (used in Olds' studies) & WHO primary health care model.

Table 20 continued: Evidence for the effectiveness of one to one interventions to prevent under 18 conceptions

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention I = intervention C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect**	**Applicability to the UK populations and settings** Score 1-4	**Notes**
Olds 1997 Elmira, New York	RCT	-	Does a nurse home visiting programme have a long term effect on improving outcomes for mothers and their children?	**Population** Pregnant women with no previous live births, <26 weeks gestation, 48% were < 19 years age, (mean age 19 years), 62%unmarried, 59% with low socioeconomic status, majority African American **Setting** Home visits (and screening at clinic) **Country** USA	Eligible N=500 Enrolled N=400 Response rate 80% Completed N=324 (81%) N=300 (for groups included in analysis) I 76% C 2 84% C 3 79% I 4 84% I Intervention vs. Control for two groups 83.6 vs. 80.4% PC reported on all outcomes. Assuming α 0.05 and β 0.20, detect differences of 0.36 and 0.57 in total and high risk groups. Actual analyses sufficiently powered N=245 for analysis (Excludes	Assessments based intervention to families: Skills based activities/education that 1) promoted improvements in women's (and other family members') behavior the health and development of the children, and parents' life course; 2) helped women build supportive relationships with family members and friends; and (3) they linked women and their family members with other needed health and human services. **Control Group 1** Screening and referral for children at 12 and 24 months **Control Group 2** Screening and referral for children at 12 and 24 months Free transportation for prenatal and well-child care through 24 months **(Intervention) Group 3** Screening and referral for children at 12 and 24 months Free transportation for prenatal and well-child care through 24 months Home visits by nurse during pregnancy	**Elmira Maternal Life** 15 year follow-up Subsequent pregnancies Subsequent births Time between first and second children	Group 4 (intervention) versus Groups 1 and 2 combined (Control) No differences observed for the whole sample. + For poor unmarried mothers, groups visited by nurses during pregnancy and infancy, averaged fewer subsequent pregnancies (1.5 versus 2.2; p=0.03) + fewer subsequent births (1.1 versus 1.6); p=0.02, + a longer time between first and second children (65 versus 37 months p=0.001)	**3**	Theory-based (Bandura self efficacy, human ecology and human attachment)

					Group3) And N=100 for sub group analysis low SES unmarried	**(Intervention) Group 4** Screening and referral for children at 12 and 24 months Free transportation for prenatal and well-child care through 24 months Home visits by nurse during pregnancy and until child's second birthday **Duration and intensity** 75-90 minutes per home visit, every week to two weeks average of 9 visits completed **Provider** Nurses				

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First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention I = intervention C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect**	**Applicability to the UK populations and settings** Score 1-4	**Notes**
Olds 2002 Denver	RCT	+	Does a home visiting by para professionals and by nurses improve outcomes for mothers and their children?	**Population** Pregnant women with no previous live births, qualified for Medicaid or had no private health insurance, (low SES) 92% unmarried, mixed ethnic background,95% <28 weeks gestation, mean age approx 19 years,40% low psychological resource (function) **Setting** Home visits (and screening at clinic) **Country** USA	Eligible N=1178 Enrolled N=735 Response rate 62.4% Follow-up Completed N=630 (85.7%) Intervention 1 Paraprofessional 87% Intervention 2 Nurses 83% Control 87% PC: Assuming α 0.05 and 80% power, assume effects in range of 0.3 sd and for high risk group had power to detect differences in 0.42 SD range. Actual analyses sufficiently powered	Assessments based interventions to families: Skills based activities/education that aimed to improve 1) maternal and fetal health during pregnancy 2) health and development of child by helping parents provide more competent care giving and 3) to enhance parents' personal development by planning future pregnancies, education and employment **Control** Developmental screening and referral services for children at 6,12, 15, 21 and 24 months **Intervention 1** Screening and referral plus paraprofessional home visitation during pregnancy and infancy (first two years of child's life) **Intervention 2** Screening and referral plus paraprofessional home visitation during pregnancy and infancy (first two years of child's life) **Duration and intensity** Paraprofessional completed average of 6.3 visits during pregnancy and 16 visits	24 months postpartum follow-up **Subsequent fertility** Subsequent pregnancy Subsequent birth Time to next conception	24 months Least squares means 0 Paraprofessional 33 Control 41 Mean difference 0.70 (0.46-1.06), p<0.10 RR 0.81(0.63, 1.03) + Nurse 29% Control 41% Mean difference 0.60 (0.39-0.93), p<=0.05 RR 0.71 (0.54, 0.93) 0 Paraprofessional 13% Control 19% Mean difference 0.63 (0.37-1.07), p<0.10 RR 0.75 (0.45-1.24) + (borderline) Nurse 12% Control 19% Mean difference 0.58 (0.33-1.01), p<=0.05 RR 0.63 (0.37-1.08) + Nurse visited group had longer intervals compared with control	**3**	Theory-based (Bandura self efficacy, human ecology and human attachment)

						during infancy Nurses completed average of 6.5 visits during pregnancy and 21 visits during infancy **Provider** Paraprofessionals and nurses		(Proportional hazards analysis p=0.02) 0 Trend to delay subsequent pregnancy was non significant in paraprofessional group		

Table 20 continued: Evidence for the effectiveness of one to one interventions to prevent under 18 conceptions

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention I = intervention C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect**	**Applicability to the UK populations and settings** Score 1-4	**Notes**
Olds 2004 Memphis	RCT	+	Does a nurse-home visiting programme improve outcomes for mothers and their children at age 6?	**Population** Pregnant women with no previous live births, 85% low SES, 98% unmarried, 92% black, <29 weeks gestation, 64% <=18 years age mean age approx 18 years, **Setting** Home visits (and screening at clinic) **Country** USA	Eligible N=1290 Enrolled N=1139 Response rate 88.3% Follow-up Completed for all groups 615 (54%) For groups 2 and 4 86% Group 1 N/A Group 2 86.2% Group 3 N/A Group 4 86.4% PC: Assuming α 0.05 and 80% power, assume effects in range of 1.38-1.16 pregnancies PC were based on Elmira findings	Assessments based interventions to families: Skills based activities/education that aimed to improve 1) maternal and fetal health during pregnancy 2) health and development of child by helping parents provide more competent care giving and 3) to enhance parents' personal development by planning future pregnancies, education and employment **Group 1** Free transportation for schedules prenatal appointments **Group 2 (served as comparison)** As Group 1 plus screening and referral for child at 6, 12, 24 months **Group 3 (Intervention)** As group 1 plus intensive home visiting during pregnancy **Group 4 (Intervention)** As Group 3 plus nurse visitation though the child's second birthday **Duration and intensity**	Follow-up at 6 years (age 6) Group2 versus Group 4 No of subsequent pregnancy No of subsequent children Months between births of first and second children	+ RR 0.43 (0.24, 0.77) ES (Cohen's d) -0.22,p<0.01 + Least squares mean, mean differences (se) Nurse 1.08 (0.07) Comparison 1.28 (0.04) ES (Cohen's d) -0.22,p<0.01 + Least squares mean, mean differences (se) Nurse 34.38 (1.33) Comparison 30.23 (0.85) ES (Cohen's d) -0.23,p<0.01	**3**	Theory-based (Bandura self efficacy, human ecology and human attachment)

						Nurses completed average of 7 visits during pregnancy and 26 visits post natally **Provider** Nurses				

Table 20 continued: Evidence for the effectiveness of one to one interventions to prevent under 18 conceptions

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention** **I = intervention** **C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified)** **(+) = positive effect, (-) = negative effect, (0) = no effect**	**Applicability to the UK populations and settings** Score 1-4	**Notes**
O'Sullivan 1992	RCT	-	Does a special health care programme for adolescent mothers prevent repeat pregnancies and improve outcomes for mother and infant?	**Population** Economically disadvantaged black teenage mothers, (M=16.5 years). **Setting** Large teaching hospital. **Country** Eastern USA	243 (120 intervention, 123 control) High drop out from attending clinic (60% intervention, 82% control), but only 9% lost to follow up. No PC reported.	**I)** Counselling abut family planning methods, infant care, role modelling for parenting behaviours; discussion of plans of returning to school and referral to birth control clinic if appropriate. Reminders if missed appointments. **Provider** Social worker, nurse practitioners, paediatrician **Duration & intensity** Clinic appointments at 2 weeks, 2, 4, 6, 9, 12, 15, & 18 months. **C)** Routine care - well baby visits, including appropriate immunizations; physical examinations. No reminder phone calls or letters.	Repeat pregnancy Return to school	18 months + RR 0.43 (0.24,0.77) (p=.003) 0 RR 1.01 (0.80, 1.28)	3	Mothers in intervention were given infant immunization records free of charge if forgetting or losing those during study; mothers in control had to pay a nominal fee every time a record card was lost or forgotten
Quinlivan 2003	RCT	++	Does post-natal home visiting reduce adverse neonatal outcomes and improve knowledge of contraception?	**Population** Teenage first time mothers, mean age 16, overall low socio-economic status. 25%indigenous Australian. **Setting** Antenatal clinic **Country** Australia	139 (11% lost to follow up). PC -assuming 10% drop out rate calculated needed 134 participants to detect 0.05 improvement in knowledge and 5% reduction in adverse neonatal outcomes.	**I)** Education, advice and training; including education on parenting, breastfeeding, immunization and contraception. **Duration & Intensity** Five sessions over 6 month postnatal period. **Provided by:** Certified nurse-midwife **C)** Usual care	Reliable contraception use Contraception knowledge (maximum score 9)	6 months + RR 1.33 (1.07, 1.64) p=0.007 + Mean difference 0.92 points (95% CI 0.32 – 1.52; p=0.0056)	2	

Table 20 continued: Evidence for the effectiveness of one to one interventions to prevent under 18 conceptions

First Author	Study design	Research quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention I = intervention C = control	Outcome variable(s)	Main results at follow up (Reported as intervention vs. control unless otherwise specified) (+) = positive effect, (-) = negative effect, (0) = no effect			Applicability to the UK populations and settings Score 1-4	Notes
								4months	8 months	12 months		
Shlay 2003	RCT	-	Does the provision of contraceptive care initiated in an STD clinic increase contraceptive use and reduce pregnancy rates?	**Population** Premenopausal women using no or less effective contraceptives, not currently pregnant or intending to become pregnant, 40% age 19 or under, mixed ethnic background, majority non-white, 85% never married, 74% high school diploma, 35% full time employment, 55% had previous pregnancy,27% had current primary care provider, 61% did not have health insurance **Setting** STD health clinic **Country** USA	Screened N=7305, 1909 (26%), eligible 877 enrolled (45.9%) I 437 C 440 Follow-up 72% overall I 72.1% C 72.0% PC: 325 women were considered sufficient to show decrease in annual proportion of women who would have an unintended pregnancy with α 0.05 and power >=0.80. Recruitment goal of 866, assuming 25% lost to follow-up	**I**) Medical screening and enhanced individual counselling about contraception methods, initial provision of contraception and facilitating referral to a primary care provider (PCP) of their choice **C)** Education/information about contraceptive options without counselling. Both group were counselled about use of condoms at initial visits as per routine protocol **Duration and intensity** Thirty minutes counselling **Provider** Family planning nurse	Effective contraceptive use	+ I 49.7% C 22.3% p<0.0001 RR 2.23 (1.60-3.10)	+ I 44.0% C 25.8% p<0.0001 RR 1.71 (1.23-2.37)	0 I 32.7% C 26.8 p=0.11 RR 1.22 (0.96, 1.55)	2	
							Effective condom use	0 I 52.8% C 51.9% p=0.83 RR 1.02 (0.77-1.35)	0 I 50.9% C 44.3% P=0.13 RR 1.15 (0.85-1.55)	0 I 44.9% C 41.7% P=0.44 RR 1.08 (0.89, 1.29)		
							Dual protection	+ I 28.7% C 14.1% p<0.0001 RR 2.04 (1.37-3.04)	+ I 23.0% C 14.3% p=0.007 RR 1.61 (1.06-2.45)	0 I 14.3% C 13.3% p=0.71 RR 1.08 (0.69-1.69)		
							Pregnancy rate (during follow-up period)			0 I 24.0% C 28.2% p=0.16 RR 0.85 (0.68, 1.07)		
							Unintended pregnancy rate			0 I 21.9% C 26.5% p=0.17		

										RR 0.86 (0.61, 1.21)		
							Therapeutic abortion rate			0 I 5.4% C 4.7% p=0.73 RR 1.14 (0.56-2.32)		
							Time to pregnancy for <=19 years	+	+	0 Cox proportional hazard ratio 1.18 (0.83-1.67		
							Transition to PCP	I 50.6% C 42.6% p<0.02 RR 1.19 (0.93-1.52)	I 64.5% C 44.1% p<0.0001 RR 1.46 (1.15-1.85)	0 I 71.5% C 69.5% p=0.53 RR 1.03 (0.83-1.28)		

Table 20 continued: Evidence for the effectiveness of one to one interventions to prevent under 18 conceptions

First Author	**Study design**	**Research quality** Internal validity score ++/+/_	**Research Question**	**Study population, setting and country of study**	**Sample size** Include power calculation if available	**Description of intervention** **I = intervention** **C = control**	**Outcome variable(s)**	**Main results at follow up (Reported as intervention vs. control unless otherwise specified)** **(+) = positive effect, (-) = negative effect, (0) = no effect**		**Applicability to the UK populations and settings** Score 1-4	**Notes**
Winter 1991	Controlled trial (3 clinics in each arm)	2+	Do tailored teenage family planning protocols, including counselling and education, affect contraception use?	**Population** Family planning patients under 18 yrs old (98% white). **Setting** Non-metropolitan family planning clinics **Country** Pennsylvania, USA	1,256 (518 intervention, 738 control). About 27% lost to follow up) PC not reported	**I)** Family planning protocols developed with focus on psychosocial model. Education and counselling provided in a one-to-one sessions with the use of visual aids. Intervention also included medical examination and the provision of contraception. **Intensity & duration** Two initial sessions, and one follow up session. Length not specified but they added 15-20 mins to normal counselling and education session and 10 mins to medical examination. **Provided by** Clinic staff members who had received two-days training on adolescent psychosocial and cognitive development and how to administer protocols. **C)** Family planning clinics giving usual care without special training or the protocols.	Pregnancy Continued contraceptive use using original method Using any method of contraception Patient satisfaction	6 months Not reported + 92.4% vs. 84.9% (p<.01) ES: h=0.33 + 97.4% vs. 92.1% (p<.01) ES: h=0.34 0 (data not reported)	12 months 0 3.1% vs. 5.5% RR 0.51 (0.27, 0.96) + 89.8% vs. 81% (p<.05) ES: h=0.34 0 95.8% vs. 92.4% ES:h=0.22 0 (data not reported)	3	

Abbreviations used in tables:
CDC - Centre for Disease Control and Prevention (US government funded organisation)
NIDA – National Institute for Drug Abuse (US government funded organisation)

Table 21: Evidence Tables –Qualitative Studies

First Author	Study design	Quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention	Outcome variable(s)	Main results	Applicability to the UK populations and settings Score 1-4	Notes
Beck	Qualitative	++	To explore barriers to accessing sexual health care among the Bangladeshi community of East London To develop a model of community participation in service development	Bangladeshi community of East London UK	58 total interviews. Interviewees were attendees at local sexual health clinic 12 individual 7 male 5 female Interviews Rest interviewed in 6 focus groups	N/A	N/A	Community values were an important underlying feature of Older (more senior??) Women stated – sex did not occur outside marriage and therefore sexual health services not relevant for the community. Women especially only supposed to learn about sex after marriage. For younger people they acknowledged sex outside of marriage did happen – but accessing services very stigmatising and concerns over confidentiality very high. How health promotion approached very difficult e.g. Could be stopped going to youth clubs etc if they do sexual health promotion. Younger or different gender practitioners are very problematic Main themes: Confidentiality concerns, Relevance of services to the community Problems discussing sexual issues Problems with previous experiences of health promotion	4 (relevant for Bangladeshi community)	Not stated/

Table 21 continued: Evidence Tables –Qualitative Studies

First Author	Study design	Quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention	Outcome variable(s)	Main results	Applicability to the UK populations and settings Score 1-4	Notes
Free (22)	Qualitative interview study	+	**To explore young women's use and non-use of emergency contraception**	Young women who were sexually active (aged 16-25). Living in deprived inner city areas	41 women (11 were virgins and excluded)	N/A	N/A	Obtaining emergency contraception is a task of great enormity for young women. Resulting from: • Access • Stigma - e.g. Good girls don't need emergency contraception (guilt a key feature • Psychological denial or sense of personal invulnerability • Limited knowledge of availability or even that it existed Professionals were felt to be most helpful when matter of fact and non-judgemental. Consultations that focused on risks made women feel as if they had been 'told off'	4 (relevant to young women across the UK)	Not stated
Choi (57)	Qualitative Structured Questionnaire & Intervention	+	To explore how women in an intervention negotiated use of the female condom with their partners	Female attendees at local family planning clinic Sanfrancisco US	Number of participants: 92 women Types of participants: aged 18-39 years any ethnic background and multiple sexual partners.	Initial structured questionnaire semi-structured interviewer three months after intervention = female condom provision and training session on use provided.	Use of female condom	62 women in study 49 introduced idea to partners of the female condom – 30 successfully negotiated using it 13 did not attempt to introduce idea Gender based power relationships determine women's ability to negotiate use	2	Not stated

Table 21 continued: Evidence Tables –Qualitative Studies

First Author	Study design	Quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention	Outcome variable(s)	Main results	Applicability to the UK populations and settings Score 1-4	Notes
Dorfman	Process and outcome evaluation Qualitative Interview and field notes on observation of outreach activities	+	1. Enrolment to the project by sex workers 2. Nature of the interaction between project staff & participants? 3. Risk perceptions and risk behaviours 4 What enables sex workers to changer their sexual risk behaviour.	Female Sex workers who were participants in an AIDS prevention programme. US.	Process evaluation and outcome –and observation data collected on 182 women and 42 non-commercial male partners Interview data on 58 participants	Outreach work with individual sex workers - Appropriate insider language. - Offer of condoms - Information and or educational session. - Field staff sensitivity to context – non judgemental	Use of condoms social norm among female sex workers. Decrease of other sexual risk behaviours.	Sex workers (working on the street) not a hard to reach populations if targeted appropriately. Field staff (as ex sex workers) from same community act as positive role models and gain access. Qualitative report on reduced risk behaviours with commercial partners. More difficult with personal partners.	4	Not stated

Table 21 continued: Evidence Tables –Qualitative Studies

First Author	Study design	Quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention	Outcome variable(s)	Main results	Applicability to the UK populations and settings Score 1-4	Notes
Seal	Qualitative interview study	++	What was the research question/aim? Primary Aim. To solicit input and recommendations from YMSM themselves concerning the kinds of HIV prevention programmes that would best meet their needs and would address risk issues they believed are critical. Secondary Aim. To gain information on the HIV risk experiences of the young men.	YMSM between the ages of 16-25 years (M=20.9 years).	72 interviewees 41 Milwaukee and 31 in Detroit. 44% White, 32% black/African-American, 10% Latino, 8% Biracial, 4% Asian American and 1% Middle Eastern. 69% of the men interviewed self-identified as gay, 14% bisexual, 6% gay/Bisexual, 6% as ambivalent or exploring, 3% transgender and 1% heterosexual.	N/A	N/A	1) Recommendations concerning the content of HIV prevention interventions. The importance of programmes addressing the social, psychological, interpersonal and cultural contexts of high-risk behaviour, rarely was the need for basic HIV education mentioned. 2) Recommendations for the delivery of HIV prevention interventions. Need for multiple approaches to HIV prevention with YMSM were often emphasized. HIV risk was not perceived to be equal across different YMSM segments. Participants stressed the importance of addressing sub-cultural and behavioural differences between various risk segments when developing HIV prevention programmes. 3) Recommendations for HIV prevention community resources. YMSM identified several community resources including Aids service organisations, community-based organisations, university or high-school based organisations, GLBT groups, HIV testing sites and outreach, AIDS hotlines, bars, churches, mass media and special events (e.g. Pride-Fest). 4) Barriers to participation. Participants strongly felt that programmes that overtly targeted gay men or were marked as HIV prevention would result in decreased participation, especially among non-gay identified or closeted YMSM. Few systematic differences in key	3/4	$40 incentive payment

								themes emerged from respondents of different backgrounds in the study. “The most dominant theme among participants was that their status as YMSM served as a common bond that superseded other differences		

Table 21 continued: Evidence Tables –Qualitative Studies

First Author	Study design	Quality Internal validity score ++/+/_	Research Question	Study population, setting and country of study	Sample size Include power calculation if available	Description of intervention	Outcome variable(s)	Main results	Applicability to the UK populations and settings Score 1-4	Notes
Salyers	Qualitative interview study	++	Using a bioecological model to consider the multiple levels of influence on 'dual protection' for un-wanted conception prevention and STI's prevention for women	Women aged 13 + - 35+ enrolled in a RCT family planning study undertaken with clients of an STD clinic who had completed the final follow up interview. Setting Denver, US.	48 women (65 women approached, 53 interviews scheduled)	N/A not described in this paper	N/A not described in this paper	Structural: US health care system, policy on condom provision and cost determined access. Social: Social exclusion and family life key factors, abusive, violent relationships in childhood strong features of the women's lives. Partners – women did not aspire to long term monogamous relationships. Peers most significant source of support Psychological: low self esteem dominant among the women (25% had positive self esteem) Factors determining acceptability of dual protection: 1. Practitioners to obtain detailed sexual history to enable determination of acceptability and need for dual protection. 2. Peer led interventions of possible value. 3. Increased promotion/knowledge of dual protection methods among practitioners. 4. Interventions (counselling) to increase self-efficacy for dual protection methods and method sampling.		$30