Interventions targeted at women to encourage the uptake of cervical screening (Review)

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ABSTRACT

Background

Cervical cancer is the third most common cancer world-wide. Increasing the uptake of screening, alongside increasing informed choice is of great importance in controlling this disease through prevention and early detection.

Objectives

To assess the effectiveness of interventions aimed at increasing uptake, and informed uptake of cervical cancer screening.

Search strategy

Twenty-three electronic databases (to March 2000) were searched with no language restrictions.

Selection criteria

Randomised controlled trials (RCTs), or quasi-RCTs of interventions to increase uptake/informed uptake of cervical cancer screening.

Data collection and analysis

Data on study characteristics and quality were extracted independently by two reviewers. Where data were available, relative risks and 95% CI were calculated and a chi-squared test for heterogeneity was performed.

Main results

Thirty-five studies were included (27 RCTs and eight quasi-RCTs). Heterogeneity between studies limited statistical pooling of data. Overall, however, invitations appear to be effective methods of increasing uptake. In addition, there is limited evidence to support the use of educational materials. The number and quality of included studies limited evidence regarding effectiveness of other interventions. Informed uptake of cervical screening was not considered by any studies.

Authors' conclusions

There was some evidence to support the use of invitation letters to increase the uptake of cervical screening. There was limited evidence to support educational interventions but it was unclear what format was most effective. The majority of the studies were from developed countries and so the relevance to developing countries is unclear.

PLAIN LANGUAGE SUMMARY

Invitations and probably educational interventions increase the uptake of Pap smears.

Methods of encouraging women to undergo cervical screening - invitations, reminders, education, message framing, counselling, risk factor assessment, procedures and economic interventions were looked at in this review. Evidence supports the use of invitations, and to a lesser extent, educational materials. It is likely other methods are advantageous, but the evidence is not as strong. Further research is required.

BACKGROUND

Cervical cancer is the third most common cancer world-wide, with at least 400,000 new cases identified throughout the world each year. Eighty per cent (80%) of these cases occur in developing countries where some 200,000 women die as a result of cervical cancer every year (Parkin 1999). Figures for developed nations are lower, but nevertheless cervical cancer remains a major cause of morbidity and mortality amongst women. In the UK for instance, cervical cancer affects just over 4,000 women each year and is responsible for 1400 deaths (ICRF 1999), and in the USA during 2000 it is estimated that 12,800 new cases of invasive cervical cancer will be diagnosed and 4600 deaths will occur (Greenlee 2000).

Human papillomavirus (HPV) infection is believed to be a significant primary cause of cancer of the cervix, with a recent study estimating the world-wide HPV prevalence in cervical cancers to be 99.7% (Walboomers 1999). In particular, two subtypes of the virus HPV (16 and 18) are present in over 80% of invasive cervical cancers. Other known risk factors for cervical cancer include smoking (Brinton 1986), the early onset of sexual activity, multiple sexual partners and the presence of other sexually transmitted diseases (STDs) (La Vecchia 1986). In addition, the immunological status of the woman plays a significant role in the development and progression of cervical cancer (Schneider 1983). Individuals who receive immunosuppressive therapy for organ transplants and those infected with human immunodeficiency virus (HIV) are therefore particularly at risk of developing pre-invasive disease. Primary strategies to prevent the development of cervical cancer focus on reducing these known risk factors by encouraging a healthy lifestyle, smoking cessation and the adoption of 'safer' sexual behaviours aimed at reducing the risk of HPV infection (Shepherd 1999). However world-wide many countries rely on secondary prevention methods to control incidences of cervical cancer, through screening for the detection of abnormal or precancerous cell changes (i.e. any changes which 'may' proceed, be associated with or carry a significant risk of developing cancer).

The Papanicolau, or Pap smear, screening test is used world-wide and is primarily aimed at detecting pre-cancerous changes within the cervix (i.e. abnormalities in the cells of the cervix known as dysplasia) before they have an opportunity to progress to invasive carcinoma. More than 90% of cervical cancers develop within a small area of the cervix known as the transformation zone and disease progression from dysplasia to invasive cancer is usually slow, therefore providing the opportunity to detect and treat pre-cancerous disease. During a smear test cells within the external and internal layers of the transformation zone (i.e. ecto- and endocervical cells) are collected and subsequently examined for abnormal cytological changes. The reliability of the technique is however dependent both on the expertise of the health professional taking the smear and the individual examining the smear. Falsenegative smear rates vary but are usually in the region of 20-60%,

depending on the quality control measures in force within individual screening laboratories (Peters 1988). Even in the best laboratories 5-15% of abnormal smears may be reported as normal (Nottingham 1998). Where comprehensive screening programmes exist however, studies have shown that Pap smear screening can be linked to trends in cervical cancer survival, by identifying precancerous lesions, reducing their incidence and selectively preventing more aggressive cancers (Gatta 1999).

World-wide great variation exists between countries in terms of the coverage and uptake of cervical cancer screening. In a number of countries including the UK, Finland, Australia, Sweden and Spain, national cervical cancer screening programmes have been introduced. Such screening programmes are usually aimed at those women most at risk of developing cervical cancer (i.e. usually women aged between 20 and 65 years). Recommendations vary between countries, but women are usually screened every one to five years. In many other countries Pap smear services are provided on a much more local basis, if at all. For instance in the majority of developing countries the lack of funds and qualified personnel limit the development of widespread screening initiatives. Recent figures for England where a national screening programme has existed since 1964, showed that 84% of women aged 25 to 64 years had been screened at least once in the previous five years (Dept of Health 1999). However, in comparison it has been estimated that only about 5% of women in developing countries have been screened for cervical cancer in the past five years (Koroltchouk

The World Health Organisation have calculated the level of protection women gain as a population by regular screening and the number of tests they will need in a lifetime (IARC 1986). Annual screening smears provide a 93.5% reduction in the incidence of cervical cancer and will mean a woman has 50 smear tests in her lifetime. A smear every 2 years porvides a 92.5% reduction with a woman having 25 screening smears in total. Three yearly smears mean women will have a total of 16 screening smears to achieve a 90.8% reduction. Five yearly smears will mean a total of 10 screening smears with an 83.6% reduction in the incidence of cervical cancer. Even a smear every 10 years has a benefit with a 64.1% reduction in incidence.

Pap smear uptake and coverage not only varies between countries, but differences also exist within countries between different sociodemographic groups, according to factors including ethnic origin, age, education and socio-economic status. For instance low uptake rates have been found to occur in those women who are older, less well-educated, from lower socio-economic groups or who reside in rural locations (Brinton 1994; Ries 1999). Certain ethnic groups have also been identified as having lower rates of Pap smear uptake, such as African-American, Hispanic and Native American in the USA and Asian women in the UK (Luke 1996; Miller 1994). In many cases therefore interventions have been aimed at trying to increase screening amongst these groups of women. There are

therefore a number of factors to consider when developing interventions to increase the uptake of Pap smear screening. These factors are likely to differ between developing and developed countries. Improving population coverage requires to some extent an understanding of the reasons why women do or do not attend for cervical screening. Women may not attend due to reasons such as their perceptions of vulnerability, the costs involved, the perceived benefits of screening, anxiety, embarrassment, fear of cancer or because of family difficulties/personal circumstances (Austoker 1994; Jepson 2000). The possible future use of accompanying tests for HPV for instance may discourage women from attending for screening. The connotation of sexual pomiscuity associated with this viral infection may discourage women from participating in cervcial screening programmes. Given the complex nature of the factors involved a number of interventions have therefore been based on theoretical models of health behaviour, such as the Health Belief Model (Kreuter 1996; Marcus 1992) and the Transtheoretical Model (Rimer 1999). It is important to realise that because of varying populations, interventions that are effective in one setting may not be as effective in another. This is particularly relevant with regard to differences between developing and developed nations.

Up until relatively recently the main focus of attention has been solely to increase the uptake of cervical screening. However, in many countries such as the UK the issue of informed consent and informed uptake has arisen through the recognition that screening can have associated harms as well as benefits for participants. Individuals may experience such detrimental side effects as anxiety, false alarms, false reassurance, unnecessary colposcopies and biopsies, over-diagnosis, and over-treatment (Austoker 1999). In particular important issues for Pap smear screening includes the rate of false negatives and the possibility that lower grade cervical abnormalities will never progress to invasive cancer. In many cases the lower grades of cervical dysplasia will spontaneously regress or never develop into cancer. However, women with such grades of dysplasia may suffer adversely through receiving an abnormal smear test result and perhaps undergoing unnecessary treatment. A report on cervical screening from the UK (Bristol) showed that abnormalities were found in 15,551 of 225, 974 women tested and 6000 were referred for colposcopy (Raffle 1995). The numbers were excessively high compared with the incidence of cancer that could possibly be prevented. The study concluded that despite being well organised, much of the effort was devoted to limiting the harm done to healthy women. These issues have now led to a debate about 'informed uptake' and whether increasing uptake at all costs is justified if it is at the expense of the individual's well-being. Informed uptake dictates that before women agree to screening they should be made fully aware of all of the issues involved in participating in a population screening programme, both positive and negative, and how these may personally affect them. Historically informed consent has not been sought for screening tests and the potential harms/risks of screening have been played down so as not to discourage individuals from participating. Tensions can arise between the need to inform each woman about the benefits/risks of screening, and the need for policy makers to achieve significant levels of uptake in order to maintain the viability of screening programmes (Jepson 2001). However, informed uptake is currently a major issue in screening and so it is not only important to determine which interventions are successful at increasing cervical screening uptake, but also which interventions are successful at promoting the informed uptake of screening (Nottingham 1999). This review will consider both of these issues.

OBJECTIVES

To assess the effectiveness of interventions targeted at women and aimed at increasing the uptake, and/or informed uptake of cervical cancer screening.

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

Types of studies

Randomised controlled trials (RCTs), cluster RCTs or quasi-RCTs (e.g. using pseudo-randomisation such as alternation or date of birth) of universal, selective or opportunistic cervical cancer screening.

Types of participants

All women eligible to participate in a cervical cancer screening programme as defined by the entry criteria for that programme. Women due, overdue, or returning for repeat smears plus those returning for abnormal smear follow-up were all considered for inclusion.

Types of intervention

All interventions targeted at women who are eligible for screening. Interventions aimed at communities such as mass media campaigns (Grilli 2000) and those aimed at health professionals were excluded as they are considered in other Cochrane reviews. Interventions targeted at health professionals that are covered in other Cochrane reviews include: audit and feedback (Jamtvedt 2006), educational outreach visits (O'Brien 1997), printed educational materials (Freemantle 1997), computer-generated paper reminders (Gorman 1998), manual paper reminders (Romero 2004), on-screen computer reminders (Gordon 1998), and other interventions (Hulscher 2006). For the sub-group analyses the interventions were categorised as in the HTA review investigating interventions to increase the uptake of screening (Jepson 2000):

• Invitations

Invitations to women due for screening (either first round or second round). Does not include women who are overdue for screening. Includes fixed or open appointments, letters, telephone calls, verbal recommendations, prompts and follow-up letters.

• Reminders

Reminders to women who are overdue for screening and have not responded to the first round of screening. Includes fixed or open appointments, letters, telephone calls, verbal recommendations, prompts and follow-up letters.

Education

Educational interventions aiming to increase knowledge of the screening programme or the disease being screened for, that do not contain a counselling component. Includes printed educational materials, audio-visual materials, group and individual teaching and home visits.

• Message Framing

Messages about screening (either verbal or written) that are framed either positively or negatively.

• Counselling

Counselling either face-to-face or on the telephone. Must involve a discussion of barriers to screening as well as an educational component.

• Risk Factor Assessment

Risk factor questionnaires and computer programmes assessing a person's risk status.

• Procedures

Interventions to increase screening uptake by making the screening procedure easier or more acceptable to individuals undergoing screening. Includes different screening tests for the same disease, varying diets, or length of time that screening test takes, and opportunistic testing and notification of results.

• Economic

Removal of financial barriers or economic incentives. Includes reduced cost or free screening tests, transport costs, free postage for returning tests and 'rewards' for completion of a screening test.

Types of outcome measures

Primary outcomes:

- Uptake or non-uptake of cervical screening as recorded by health service records (such as screening administration system, hospital or primary care physician records)
- Uptake or non-uptake of cervicalscreening as collected via selfreport (i.e. directly reported by the participant in a telephone interview or questionnaire)
- Informed uptake of cervical screening as defined by the following criteria:

Three or more of the criteria had to be met in order for uptake to be classified as informed uptake of screening. These criteria are based on those used in a systematic review of informed decision making (Bekker 1999) and from personal communication with the author of the review.

1) Was the intervention described in sufficient detail to make an assessment of the information provided to the person undergoing screening?

- 2) Was information provided on the benefits and risks of screening?
- 3) Was the level of participant knowledge about screening assessed?
- 4) Was the level of informed decision-making assessed?

Studies including the following intermediate and other outcomes were included if they also reported a primary outcome measure.

Intermediate measures of uptake (included in those studies reporting primary outcome measures):

- Booking of appointments;
- Reported intentions to attend screening;
- Attitudes to screening;
- Knowledge of screening;
- Satisfaction with screening service.

Other outcomes (included in studies reporting primary outcome measures):

• Costs of the interventions

SEARCH METHODS FOR IDENTIFICATION OF STUDIES

See: methods used in reviews.

This Cochrane review was based on the comprehensive search strategy developed for the HTA review investigating interventions to increase the uptake of screening (Jepson 2000). The following search terms were used to identify relevant studies:

vaginal smears/

vagina\$ smear\$.tw.

pap test\$.tw.

(papanicolaou adj2 (smear or test\$)).tw.

(cervical adj2 (smear or screen\$)).tw.

cytology.tw.

pap smear.tw.

pap smear.tw.

combined with:

(satisf* or dropout* or drop out)@TKA(compliance or complie* or comply*)@TKA(encourage* or improve* or improving or increas* or promor*)@TKA(uptake or particip* or nonattend*)@TKA(accept* or attend* or attitude* or utilisation or utilization)@TKA

(refus* or respon* or reluctan* or nonrespon*)@TKA

Electronic databases which were searched included: MEDLINE (1966 to March 2000), BIDS Science Citation Index (1981-March 2000), BIDS Social Science Index (1981-March 2000), Econlit (1969-March 2000), EMBASE (1985-March 2000), Cancerlit (1985-March 2000), DHSS data (1985-March 2000), Dissertation Abstracts (1985-March 2000), ERIC (1985-March 2000), HealthStar (1985-March 2000), ASSIA (1985-1997), Pascal (1985-March 2000), SIGLE (1980-March 2000), Cinahl (1982-March 2000), Sociofile (1974- March 2000), Psycinfo (1985-March 2000), SHARE (Kings Fund), Library of Congress

database, NHS CRD DARE, Cochrane Database of Systematic Reviews, Cochrane Controlled Trials Register, and the National Research Register

The Specialised Trials Register of the Cochrane Gynaecological Cancer Review Group was also searched according the search strategy developed for the Review Group as a whole.

Additional references were located through searching the bibliographies of related papers and contacting specialists in the subject area of the review. The Journal of Medical Screening was handsearched for all relevant reports, from Issue 1 (1994) until December 1999. There were no language restrictions, and both published and unpublished studies were included, if they met the inclusion criteria for the review.

Future versions and updates of the review will also search the LILACS database.

METHODS OF THE REVIEW

There were five stages to the review process:

Stage 1: Two reviewers (CF, RJ) screened electronic versions of articles (titles and abstracts). Any disagreements were resolved through discussion. Where there was insufficient information to determine relevance full paper copies of articles were examined.

Stage 2: Two reviewers (CF, RJ) independently examined full paper copies of articles to determine whether they fulfilled the inclusion criteria. One reviewer assessed all of the papers and the second reviewer assessed a random sample of the papers in order to check agreement. Any disagreements were resolved through discussion.

Stage 3: The following data were extracted from relevant studies by one reviewer and checked by a second reviewer: study population, study methods, follow-up and dropout, assessment of outcomes, results, authors' conclusions and limitations. Authors were contacted for additional information. Any disagreements were resolved through discussion with a third reviewer (PMH).

Stage 4: Both reviewers independently assessed and recorded information regarding the methodological quality of each study. Validity checklists in CRD Report Number 4 (CRD Report 1996) were modified and the validity items (see below) were assessed for each study design. Each item was graded as 'adequate', 'inadequate' or 'unclear'. The quality criteria were not used to obtain an overall quality score. Instead, the information was compiled into tables and the results reported descriptively in the text.

The criteria for assessing the quality of included studies were as follows:

- 1. Was the assignment to the intervention groups really random?
- 2. Was there allocation concealment (a central randomisation procedure is ideal, sealed envelopes and an internal randomisation log on the same site are less secure but acceptable. Methods such as

month of birth or odd/even hospital numbers are less secure and such trials will be described as quasi-randomised. Studies will be graded according to the Cochrane system i.e. awarded a grading A-D)?

- 3. Were those assessing outcomes blinded to the intervention allocation?
- 4. Was relatively complete follow-up achieved (the numbers of participants entering the trial, the number randomised, those excluded (with reasons), and the number included in the final evaluation should all be clearly stated)?
- 5. Were the outcomes of people who withdrew described and included in the analysis (intention to intervene)?
- 6. Were the control and intervention groups comparable at entry?
- 7. Was there adequate outcome measurement (verifiable data vs. self report)?
- 8. Was the analysis appropriate (e.g. cluster randomisation taken into account in the analysis)?

Stage 5: Where the data was available, relative risks (RR) and 95% confidence intervals (CI) were calculated for dichotomous outcomes (e.g. uptake) using a random effects model. Numerical scale data of suitable quality were combined using the standardised mean difference statistic where possible, otherwise the data were reported in the text of the review. Subgroup analyses were performed according to the different categories of intervention type. To determine if differences among the results of the studies were greater than could be expected by chance, a chi-squared test for heterogeneity was performed for all comparisons. Pooled RR were not calculated if the heterogeneity between studies was significant. Where interventions differed to any degree or there was other significant heterogeneity the results were reported in a narrative. A random effects model was used for all comparisons. The analyses were repeated under the following conditions in order to determine the sensitivity of the results: unpublished studies were removed; those studies of the lowest quality were removed; and any very large studies were examined separately to determine their overall influence.

Where trials randomised participants in clusters (e.g. streets, GP practices), the author's relative risks and 95% CI were reported in the text if the data were correctly analysed using the same unit of allocation and analysis (e.g. the GP practice was both the unit of allocation and analysis) or if appropriate statistical analyses which take into account the effects of clustering were performed. Suitable analyses include adjusted individual level analysis, which adjusts for the design effect and logistic regression analysis which allows for cluster level and individual variation. For all remaining trials where the unit of allocation (e.g. streets) was different from the unit of analysis (e.g. individuals), only relative risks and not confidence intervals have been calculated. In such trials confidence intervals would be spuriously narrow.

DESCRIPTION OF STUDIES

Over 46,000 titles and abstracts (where available) were screened for the original HTA review covering all screening tests, of which 440 full paper copies were then further assessed for inclusion in the review. Forty-two of these studies specifically focussed on cervical cancer screening and appeared to fulfil the inclusion criteria. In order to confirm that studies met the inclusion criteria and to enable further analysis, additional information was requested from the authors of all 42 studies (37 authors). Replies were received for 20 of the studies (17 authors). In total 35 studies met all of the inclusion criteria and were included in this review.

Excluded studies

The majority of excluded studies were excluded during the first round of the selection process where articles were assessed on the basis of their titles and abstracts. These studies obviously did not fulfil one or more of the inclusion criteria. However, a further seven studies were excluded after assessing full paper copies of the articles. These studies and the reasons for their exclusion are listed in the characteristics of excluded studies table. Two of the studies included participants that may have been screened before receiving the intervention (Dignan 1996, Dignan 1998), one study used an intervention aimed at both the physician and patient (Campbell 1997), a further study used an intervention not strictly concerned with increasing uptake (Del Mar 1995), one study did not separate attendance for cervical cancer screening from other screening tests (Mitchell 1991, Powers 1992) and the final study upon further investigation was found not to use a randomised or quasirandomised design (German 1995).

Included studies

Of the 35 studies included in the review 27 were RCTs, including seven cluster RCTs (Byles 1994, Byles 1995, Byles 1996, Navarro 1995, Ornstein 1991, Peters 1999) and eight were quasi-RCTs (Baele 1998, Hicks 1997, Lantz 1995, Margolis 1998, Paskett 1990, Ward 1999, Yancey 1995), including one was a cluster quasi-RCT (Marcus 1992). Fifteen of the studies were performed in the USA (Binstock 1997, Burack 1998, Clementz 1990, Greene 1999, Kreuter 1996, Lantz 1995, Marcus 1992, Margolis 1998, Navarro 1995, Ornstein 1991, Paskett 1990, Rimer 1999, Somkin 1997, Sung 1997, Yancey 1995), nine in Australia (Bowman 1995, Byles 1994, Byles 1995, Byles 1996, Del Mar 1998, Hunt 1998, Pritchard 1995, Ward 1991, Ward 1999), seven in the UK (Hicks 1997, Lancaster 1992, McAvoy 1991, Peters 1999, Pierce 1989, Robson 1989, Wilson 1987), two in Canada (Buehler 1997, Mc-Dowell 1989), one in Italy (Segnan 1998) and one in Belgium (Baele 1998). The majority of the studies were set in community clinics and primary care practices. However, three of the studies based in the USA were set in Health Maintainance Organisations (HMOs) (Binstock 1997, Burack 1998, Somkin 1997), and two of the UK studies were based around the UK national cervical screening programme (McAvoy 1991, Wilson 1987). The study set in Italy was also based around a national cervical screening program (Segnan 1998). In addition three studies were aimed at specific ethnic populations including Asian women (McAvoy 1991), Moroccan/Spanish immigrants (Baele 1998) and Latinas (Navarro 1995).

METHODOLOGICAL QUALITY

The quality of the 35 studies was assessed according to seven criteria (Table 01):

1. Was the assignment to the intervention groups really random? Eight of the studies used quasi methods of randomisation including alternate numbers (Baele 1998), patient record numbers (Hicks 1997, Lantz 1995, Margolis 1998, Paskett 1990) and periods of clinic time (Marcus 1992, Ward 1999, Yancey 1995). The remaining 27 studies were designated as truly randomised controlled trials. However, nine studies failed to state the method of the randomisation used and so this could not be confirmed (Bowman 1995, Buehler 1997, Greene 1999, Kreuter 1996, Lancaster 1992, McAvoy 1991, Navarro 1995, Rimer 1999, Sung 1997). Of those studies (n=18) that did state the method of randomisation used 12 used computer-generated random numbers (Binstock 1997, Burack 1998, Clementz 1990, Del Mar 1995, Hunt 1998, McDowell 1989, Peters 1999, Pierce 1989, Pritchard 1995, Segnan 1998, Somkin 1997, Wilson 1987), four used coin tossing (Byles 1994, Byles 1995, Byles 1996, Ornstein 1991) and two used random number tables (Robson 1989, Ward 1991). Overall, only these 18 studies were described as using an adequate method of randomisation.

2. Was there allocation concealment?

Only nine of the 35 studies adequately concealed of the allocation of participants to treatment groups (Binstock 1997, Burack 1998, Clementz 1990, Del Mar 1998, Hicks 1997, Peters 1999, Segnan 1998, Somkin 1997, Wilson 1987). These studies used a centralised independent randomisation and allocation service which was protected from any potential tampering by those involved in the study. Seven studies used inadequate methods of allocation concealment (Baele 1998, Lantz 1995, Marcus 1992, Margolis 1998, Pritchard 1995, Ward 1999, Yancey 1995), i.e. sealed envelopes or the use of quasi random methods of allocation (medical record number, periods of clinic time etc.). In a further 13 studies the adequacy of concealment was unclear (Bowman 1995, Buehler 1997, Greene 1999, Hunt 1998, Kreuter 1996, Lancaster 1992, McAvoy 1991, McDowell 1989, Navarro 1995, Pierce 1989, Rimer 1999, Sung 1997, Ward 1991) and in the remaining six studies no attempt had been made to conceal the allocation process (Byles 1994, Byles 1995, Byles 1996, Ornstein 1991, Paskett 1990, Robson 1989).

3. Were those assessing outcomes blinded to the intervention allocation?

In only eight out of the 35 studies the individual responsible for assessing the outcomes of the study was blinded to the treatment

allocation (Bowman 1995, Burack 1998, Byles 1994, Del Mar 1998, Hunt 1998, Margolis 1998, Pierce 1989, Robson 1989). In contrast the assessor was not blinded in 14 studies (Baele 1998, Binstock 1997, Byles 1995, Byles 1996, Hicks 1997, Lantz 1995, McDowell 1989, Ornstein 1991, Paskett 1990, Segnan 1998, Somkin 1997, Ward 1991, Ward 1999, Wilson 1987) and in 13 studies the status of the assessor with regards to blinding was unclear (Buehler 1997, Clementz 1990, Greene 1999, Kreuter 1996, Lancaster 1992, Marcus 1992, McAvoy 1991, Navarro 1995, Peters 1999, Pritchard 1995, Rimer 1999, Sung 1997, Yancey 1995).

4. Was relatively complete follow-up achieved?

Thirteen of the 35 studies included all of the participants originally included in the randomisation process in the final follow up analysis (Binstock 1997, Byles 1995, Del Mar 1998, Hicks 1997, Lantz 1995, McDowell 1989, Ornstein 1991, Pierce 1989, Pritchard 1995, Robson 1989, Segnan 1998, Somkin 1997, Yancey 1995). A further five studies achieved greater than 90% follow-up (Ward 1991, Lancaster 1992, Paskett 1990, Wilson 1987, Hunt 1998), whilst five studies achieved 80-90% follow-up (Clementz 1990, Margolis 1998, Baele 1998, Buehler 1997, Peters 1999). The number of participants followed up in the final analysis of the study was unclear in four cases (Byles 1994, Byles 1996, Greene 1999, Marcus 1992) and the remaining studies achieved 14% (Ward 1999), 15.6% (Kreuter 1996), 66% (Burack 1998), 61% (Sung 1997), 70.5% (Navarro 1995), and 72% (Bowman 1995) respectively. In total if an arbitrary cutoff point of 80% is considered as an adequate level of follow-up 23 studies could be considered as adequately fulfilling this criterion (Baele 1998, Binstock 1997, Buehler 1997, Byles 1995, Clementz 1990, Del Mar 1998, Hicks 1997, Hunt 1998, Lantz 1995, Lancaster 1992, Margolis 1998, McDowell 1989, Ornstein 1991, Paskett 1990, Peters 1999, Pierce 1989, Pritchard 1995, Robson 1989, Segnan 1998, Somkin 1997, Ward 1991, Wilson 1987, Yancey 1995).

5. Were the outcomes of people who withdrew described and included in the analysis (intention to intervene)?

Only seven studies analysed the data on an intention to treat basis, i.e. all of those participants originally included in the randomisation procedure were accounted for in the final analysis (Byles 1995, Lantz 1995, McDowell 1989, Ornstein 1991, Pierce 1989, Pritchard 1995, Robson 1989). A further six studies did not lose any participants during the course of the trial and so did not need to use an intention to treat analysis (Binstock 1997, Del Mar 1998, Hicks 1997, Segnan 1998, Somkin 1997, Yancey 1995). However, 18 studies failed to include all of the randomised participants in the final analysis (Baele 1998, Bowman 1995, Buehler 1997, Burack 1998, Clementz 1990, Hunt 1998, Kreuter 1996, Lancaster 1992, Margolis 1998, McAvoy 1991, Navarro 1995, Paskett 1990, Peters 1999, Rimer 1999, Sung 1997, Ward 1991, Ward 1999, Wilson 1987). In addition eight of these studies failed to report clearly why participants were missing from the final analysis (Baele 1998, Bowman 1995, Hunt 1998, Kreuter 1996, Lancaster 1992, Margolis 1998, Ward 1991, Ward 1999). In four studies the numbers of participants included in the final analysis was unclear so it was not possible to determine if an intention to treat analysis was required or if one had been performed (Byles 1994, Byles 1996, Greene 1999, Marcus 1992).

6. Were the control and intervention groups comparable at entry? The baseline comparability of the control and intervention groups was examined in all but six studies (Baele 1998, Greene 1999, Marcus 1992, McAvoy 1991, Rimer 1999, Ward 1999). Of those that examined baseline comparability 27 studies showed no statistically significant differences between the study groups with regards to any of the variables examined (Binstock 1997, Bowman 1995, Buehler 1997, Burack 1998, Byles 1994, Byles 1995, Byles 1996, Clementz 1990, Del Mar 1998, Hicks 1997, Hunt 1998, Kreuter 1996, Lancaster 1992, Lantz 1995, McDowell 1989, Navarro 1995, Paskett 1990, Peters 1999, Pierce 1989, Pritchard 1995, Robson 1989, Segnan 1998, Somkin 1997, Sung 1997, Ward 1991, Wilson 1987, Yancey 1995). However, two studies did identify one or more statistically significant differences (Margolis 1998, Ornstein 1991), but failed to consider how the differences may influence their findings. A further two studies also identified baseline differences between the study groups, but these differences were not thought to threaten the internal validity of the study (Navarro 1995, Peters 1999).

7. Was there adequate outcome measurement (verifiable data vs. self report)?

Twenty-seven studies used verifiable data from either medical or administrative records (Baele 1998, Binstock 1997, Buehler 1997, Bowman 1995, Burack 1998, Byles 1994, Byles 1995, Byles 1996, Clementz 1990, Del Mar 1998, Greene 1999, Hicks 1997, Hunt 1998, Lancaster 1992, Lantz 1995, Marcus 1992, McAvoy 1991, McDowell 1989, Ornstein 1991, Pierce 1989, Pritchard 1995, Robson 1989, Segnan 1998, Somkin 1997, Ward 1991, Wilson 1987, Yancey 1995). Six studies used self-reported data from the participants (Kreuter 1996, Navarro 1995, Peters 1999, Rimer 1999, Sung 1997, Ward 1999). Two studies used both verifiable data and self-reported data, although the analyses were based on the verifiable data (Margolis 1998, Paskett 1990).

8. Was the analysis appropriate?

Ideally studies should follow-up all of the study participants or if not use an intention to treat analysis. Therefore those studies which 1. failed to use such an analysis; 2. did not state clearly whether all participants had been followed up; or 3. where it was not clear whether an intention to treat analysis was performed, were deemed not to have fulfilled this criterion adequately (Baele 1998, Bowman 1995, Buehler 1997, Burack 1998, Byles 1994, Byles 1996, Clementz 1990, Greene 1999, Hunt 1998, Kreuter 1996, Lancaster 1992, Margolis 1998, Marcus 1992, McAvoy 1991, Navarro 1995, Paskett 1990, Rimer 1999, Sung 1997, Ward 1991, Ward 1999, Wilson 1987). Similarly, those studies that used a different unit of allocation from the unit of analysis (i.e. cluster trials) were also considered as inadequate if they did not appropriately

account for the effects of this difference in their analysis (Byles 1994, Byles 1995, Byles 1996, Marcus 1992, Navarro 1995, Ornstein 1991). Consequently, 23 studies in total were considered not to have adequately fulfilled this criterion (Baele 1998, Bowman 1995, Buehler 1997, Burack 1998, Byles 1994, Byles 1995, Byles 1996, Clementz 1990, Greene 1999, Hunt 1998, Kreuter 1996, Lancaster 1992, Marcus 1992, Margolis 1998, McAvoy 1991, Navarro 1995, Ornstein 1991, Paskett 1990, Rimer 1999, Sung 1997, Ward 1991, Ward 1999, Wilson 1987).

Overall, only one of the studies fulfilled all eight criteria satisfactorily (Del Mar 1998). However, eight studies adequately fulfilled six or seven of the criteria (Binstock 1997, Hunt 1998, McDowell 1989, Pierce 1989, Pritchard 1995, Robson 1989, Segnan 1998, Somkin 1997). Two studies failed to fulfil any of the criteria adequately and were of very poor quality (Rimer 1999, Ward 1999). One of these studies may have been of reasonable quality, but the reporting of the study was poor and so it was not possible to clearly assess four of the quality criteria (Rimer 1999).

Of the remaining studies a further six studies only adequately fulfilled one or two of the criteria (Greene 1999, Kreuter 1996, Marcus 1992, McAvoy 1991, Navarro 1995, Sung 1997). Data from two of these studies were not included in the meta-analysis for this review as the studies were cluster trials that had not conducted appropriate analyses (Marcus 1992, Navarro 1995). However, the poor performance of all of these studies in the quality assessment may have been due to poor reporting as all of the studies were graded as unclear on at least three of the criteria. One of the studies was only available in the form of an abstract and the authors were unable to provide any further details until full publication of the study results (Greene 1999).

RESULTS

Where possible relative risks were calculated using a random effects model. The data were also analysed using a fixed effects model, which produced similar findings. Only data from the random effects analyses are presented below. Using the random effects model with the exception of counselling vs control, printed materials vs control, letter with fixed appointment vs letter with open invitation, and telephone vs invitation letter, all of the comparisons displayed significant heterogeneity (as demonstrated using a chisquared test). Consequently, pooled relative risk values are only presented for those groups of studies that were not found to have statistically significant heterogeneity.

1. Uptake of screening

a) Invitations

Nineteen studies evaluated the effectiveness of invitation letters (Binstock 1997, Byles 1994, Byles 1995, Byles 1996, Bowman 1995, Buehler 1997, Burack 1998, Clementz 1990, Del Mar 1995, Hunt 1998, Lancaster 1992, Marcus 1992, McDowell

1989, Ornstein 1991, Pierce 1989, Pritchard 1995, Segnan 1998, Ward 1999, Wilson 1987). The studies were subdivided according to the invitation type (i.e. GP letter, letter from another authority source, face-to-face invitation, open invitation and invitation with fixed appointment). Comparison groups included different types of invitation or a control group (usually consisting of usual care or no intervention).

Overall, relative risk values could be calculated for nine studies (n= 9400 participants in total) that compared invitation letters with a control (usual care or no invitation) (Binstock 1997, Bowman 1995, Buehler 1997, Burack 1998, Del Mar 1998, Hunt 1998, Lancaster 1992, McDowell 1989, Pierce 1989). All but one of the studies favoured invitation letters with five studies (Binstock 1997, Bowman 1995, Lancaster 1992, McDowell 1989, Pierce 1989) finding statistically significant improvements in screening uptake in the intervention group compared with the control group. The one study that favoured the control over the intervention group was not statistically significant (Del Mar 1998). Due to statistical heterogeneity between the studies a pooled relative risk value was not calculated. Five of the studies (all but one favouring the intervention) were of good quality, fulfilling six to eight of the quality criteria (Binstock 1997, Del Mar 1998, Hunt 1998, Mc-Dowell 1989, Pierce 1989). One study was of reasonable quality (five out of eight quality criteria were adequately fulfilled), though only 66% of participants were followed up in the final analysis (Burack 1998). The quality of the remaining three studies was poor or difficult to assess due to missing information (Bowman 1995, Buehler 1997, Hunt 1998).

Two studies (n=4370 participants in total) looked at invitations from different authority sources (Bowman 1995, Segnan 1998). Both reported a significant increase in uptake for GP invitation letters versus invitation letters from health clinics (RR=1.84, 95% CI: 1.21, 2.81) (Bowman 1995) and invitation letters from screening programme co-ordinators (RR=1.13, 95% CI: 1.05, 1.21) (Segnan 1998). The latter study was of good quality, whilst the study of GP letters versus health clinic invitations was of poorer quality, failing to adequately fulfil five of the quality criteria and only including 72% of the trial participants in the final analysis.

Four studies examined the use of letters with appointments to attend for screening (Bowman 1995, Segnan 1998, Pritchard 1995, Wilson 1987). Three studies (n=3086 participants in total) examined the use of letter with open invitations to make appointments versus control (usual care) (Bowman 1995, Pritchard 1995, Somkin 1997). Two good quality studies (adequately fulfilled 6-7 of the eight quality criteria) reported statistically significant differences in screening uptake favouring the intervention (RR=1.54, 95% CI: 1.03, 2.28) (Pritchard 1995) and (RR=2.13, 95% CI: 1.72, 2.64) (Somkin 1997). The third study slightly favoured the control, but the finding was not statistically significant (RR=0.95, 95% CI: 0.57, 1.55) (Bowman 1995). The studies were not pooled because of significant heterogeneity. One of the studies also com-

pared letters with appointments to invitation letters and found that screening uptake was significantly greater in the invitation letter group (RR=0.54, 95% CI: 0.36, 0.83) (Bowman 1995). It was difficult to assess the quality of this study due to missing information and only 72% of the original study participants were included in the final analysis. Three of the appointment studies (n=4807 participants in total) reported differences in uptake favouring fixed appointments versus letters with open appointments (RR=1.18, 95% CI: 0.85, 1.63) (Pritchard 1995) (RR=1.60, 95% CI: 1.45, 1.76) (Segnan 1998) and (RR=1.48, 95% CI: 1.08, 2.05) (Wilson 1987). Two of the findings were statistically significant and all of the studies were of reasonable quality, one of the studies fulfilling all but one of the quality criteria (Segnan 1998). The combined relative risk for the three studies was 1.55 (95% CI: 1.42, 1.70), chi-squared=3.10, df=2 in favour of fixed appointments. One of the studies (n=353) compared fixed appointments versus control (not stated) and again produced a significant increase in screening uptake favouring the intervention (RR=1.81, 95% CI: 1.22, 2.69) (Pritchard 1995).

Two studies looked at telephone invitations (n=5652 participants in total) (Binstock 1997, McDowell 1989). Both trials were of good quality, adequately fulfilling seven or eight of the quality criteria respectively. In each case the intervention was compared to a no invitation control and to invitation letters. Both studies significantly favoured the intervention over no intervention (RR=2.15, 95% CI: 1.89, 2.46) (Binstock 1997) and (RR=1.50, 95% CI: 1.02, 2.22) (McDowell 1989). The studies showed no significant heterogeneity and the combined relative risk was 1.89 (95% CI: 1.34, 2.65), chi-squared=2.95, df=1. When telephone invitations were compared to invitation letters (n=3759 participants in total) one study showed a statistically significant difference in screening uptake favouring invitation letters (RR=0.75, 95% CI: 0.67, 0.84) (Binstock 1997), whilst the other favoured telephone invitations (RR=1.30, 95% CI: 0.96, 1.77) (McDowell 1989). However, the latter finding was not statistically significant. The studies were not pooled due to the presence of significant heterogeneity.

Two studies (n=412 participants in total) looked at face-to-face invitations from a health worker or GP (Hunt 1998, Ward 1999 respectively). Both of the studies were of reasonable quality, but the numbers of participants were low as were the levels of screening uptake in both studies (range 0-4%). In one small study (n= 53) uptake was higher in the control group (no invitation) than the invitation group (RR=0.22, 95% CI: 0.01, 4.04) (Ward 1999) and in the other uptake was higher in the invitation group than the control group (usual care) (RR=17.43, 95% CI: 01.02, 298.57) (Hunt 1998). Neither of the findings were statistically significant. and the findings were not pooled due to the presence of significant heterogeneity. The latter study was set in an Aboriginal community in Australia with women being invited by Aboriginal health workers to attend for screening. This study also favoured face-toface invitations over invitation letters, although the finding was not statistically significant (RR=2.80, 95% CI: 0.76, 10.31).

Relative risks were not calculated for six of the studies (5 RCTs and 1 quasi-RCT). Four were cluster RCTs where the unit of allocation was different from the unit of analysis (Byles 1994, Byles 1995, Byles 1996, Ornstein 1991). The authors had not adequately accounted for this is their analysis and actual numbers of participants were not reported, therefore relative risks could not be calculated. Three of the studies were undertaken in Australia by the same author and evaluated interventions at the community or regional level (Byles 1994, Byles 1995, Byles 1996).

Two of these were RCTs of mass letter campaigns and found the intervention to have some effect, but results were reported as change from baseline in intervention groups, rather than the differences between intervention and control (Byles 1995, Byles 1996). Thus their results and conclusions should be interpreted with some caution. The third RCT found that a GP letter combined with a mass media campaign was more effective than a mass media campaign alone, but the effect varied by community (Byles 1994). Data could not be extracted from one RCT, which evaluated the effectiveness of letters for multiple tests, including Pap smear (Clementz 1990). The study did not report how many women were eligible for Pap smears, but looked at a number of tests combined together. The study reported an adverse effect of the intervention (Clementz 1990). A quasi-RCT of women with abnormal smears found no effect of a pamphlet (with prompt) plus a notification letter, compared to a letter alone (64.2% vs. 51.3%; p=0.097) (Paskett 1990). Lastly, a cluster quasi-RCT inviting women to return after an abnormal smear result found that the letter intervention was no more effective than control (Marcus 1992).

b) Reminders

No studies examining the effects of reminders on cervical screening uptake were identified.

c) Education

Six studies and four different categories of educational interventions were identified - printed material (Bowman 1995, McAvoy 1991, Paskett 1990), video/slide presentations (Yancey 1995), and face-to-face visits (McAvoy 1991, Navarro 1995, Sung 1997). The format of the educational intervention was not reported in one study (Greene 1999). One cluster randomised study adequately accounted for the clustering in its analyses, but the data reported was not suitable for calculating relative risks (Navarro 1995). This study compared two different community group sessions by lay community workers in a US population of Latinas. When analysed at lay community worker level there was no statistical difference in uptake between the group receiving cancer screening information and those receiving just general community living skills information (22.1% vs 16.2%). However, the quality of this study was difficult to assess. Only 70.5% of the original participants were included in the final analysis and data regarding screening uptake was verified by self-report and not administrative records. One quasi-RCT of women with abnormal smears found no effect of an educational pamphlet (with prompt) plus a notification letter,

compared to a letter alone (64.2% vs. 51.3%; p=0.097) (Paskett 1990). However, the majority of women (70%) were self-referred and may therefore may be self-motivated to attend without the need for any intervention.

There were three printed material studies, none of the findings were statistically significant. One (n=255 participants) favoured printed material versus control (RR=2.21, 95% CI: 0.88, 5.57) (McAvoy 1991), and the other two (n=725 participants in total) favoured the control over the intervention group (RR=0.96, 95% CI: 0.58, 1.57 (Bowman 1995) and RR=0.87, 95% CI: 0.59, 1.29 (Rimer 1999). The pooled relative risk favoured printed materials (RR=1.03, 95% CI: 0.75, 1.43), chi-squared=3.29, df=2.

It was not appropriate to pool the relative risk data from the remaining studies examining educational interventions due to problems with heterogeneity, both within the individual subgroups of educational interventions and across the group as a whole. The one study (n=1744 participants) that examined video/slide presentations versus control reported a statistically significant increase in screening uptake in the intervention group (RR=4.58, 95% CI: 3.78, 5.53) (Yancey 1995). In addition both of the studies (n= 1184 participants in total) that examined face-to-face home visits favoured the intervention over the control (McAvoy 1991, Sung 1997), but only one of the findings was statistically significant (RR=5.83, 95% CI: 2.65, 12.81) (McAvoy 1991). Both of the studies focused on minority ethnic groups and used lay members of the communities concerned to present culturally tailored materials presented. The one study (n=176 participants) that failed to identify the type of educational intervention used, also reported a statistically significant increase in the uptake of screening in the intervention group versus control (RR=2.31, 95% CI: 1.51, 3.56) (Greene 1999).

Across all of the different educational formats, five of the studies favoured the educational intervention (Greene 1999, McAvoy 1991, Sung 1997, Yancey 1995) and only one study favoured the control group (Bowman 1995). This study only followed up 72% of the original participants in the trial and adequately fulfilled just three of the eight quality criteria. Three of the five studies favouring the intervention group were statistically significant (Greene 1999, McAvoy 1991, Yancey 1995). The quality of two of these studies was difficult to assess due to a lack of information (Greene 1999, McAvoy 1991), but the other study was of reasonable quality adequately fulfilled four of the eight quality criteria (Yancey 1995).

d) Message Framing

No studies examining the effects of message framing on Pap smear uptake were identified.

e) Counselling

Two studies examined the use of counselling (n=599 participants in total). One looked at face-to-face counselling by a GP versus no counselling (Ward 1991). The second study looked at tele-

phone counselling and patient prompts, versus patient prompts alone (control group) and provider prompts alone (Rimer 1999). Both studies demonstrated an increased uptake of screening in the counselling group as compared to the control group. The relative risk for the two studies combined was 1.23 (95% CI: 1.07, 1.41), chi-squared=0.00, df=1.

The study that examined telephone counselling and patient prompts also reported that the intervention produced a greater increase in Pap smear uptake as compared to using prompts aimed at the provider (i.e. GP) (RR=1.14, 95% CI: 0.97, 1.34) (Rimer 1999). However, this difference in uptake was not statistically significant. In addition, a number of quality issues associated with the study were either not clear or inadequately fulfilled. Only 47% of the original study randomised participants were included in the final analysis. The face-to-face counselling study also only fulfilled half of the eight quality criteria adequately and failed to follow-up 9% of the participants originally included in the trial (Ward 1991).

f) Risk Factor Assessment

Two studies (n=256 in total) looked at risk factor assessment (Greene 1999, Kreuter 1996). Both used an enhanced risk factor assessment that involved a personally tailored assessment and discussion with the health care provider about the individuals personal risk factors for developing cervical cancer. Both interventions were based on theoretical models of behaviour, the Social Cognitive Theory and Motivational Interviewing Methods (Greene 1999) and the Health Belief Model (Kreuter 1996), with a view to changing behaviour to increase the uptake of Pap smears. One study (n=176 participants) compared the intervention to usual care and showed a significant increase in uptake for the intervention group (2.66, 95% CI: 1.75, 4.04) (Greene 1999). The other study (n=80 participants) compared the intervention to a no intervention control group and showed no statistically significant difference between the two groups (RR=0.95, 95% CI: 0.68, 1.33) (Kreuter 1996). Similarly, this study also compared enhanced risk factor assessment with a less intense 'typical' risk factor assessment (n=94 participants), and found no statistically significant difference between the two groups (RR=1.20, 95% CI: 0.84, 1.70) (Kreuter 1996). The typical risk factor assessment involved supplying the participant with their personal risk factor information but not discussing the information provided. The first study compared enhanced risk factor assessment to education and found that there was no statistically significant difference between the two (RR=0.71, 95% CI: 0.40, 1.26) (Greene 1999). Both studies used only small sample sizes and it was difficult to assess their validity without further information. Statistical pooling was not appropriate due to heterogeneity between the studies.

g) Procedures

Three different procedures were identified: revealing the gender of the smear taker in the letter of invitation (Hicks 1997); access to a health prevention nurse (Robson 1989, Peters 1999); and

access to a lay health worker who offered women screening with a female nurse practitioner (Margolis 1998). Relative risks were not calculated for the latter study as differences were identified between the intervention and control group participants. In order to correct for this the authors used a multiple regression analysis. The study found that Pap smear uptake rates were improved in the lay health worker intervention group when compared to usual care, and that this effect was strongest in women in greatest need of screening (Margolis 1998).

Both studies that used an organised programme of prevention that included the use of a health-promotion nurse found that the intervention was more effective at increasing uptake than usual care (RR=1.56,95% CI: 1.44, 1.69) (Robson 1989) and (RR=1.03 (95% CI: 0.92, 1.15) (Peters 1999). However, this finding was only statistically significant in one of the studies (Robson 1989). This good quality study (n=1407) fulfilled seven out of the eight quality criteria and was based in a UK GP practice. The second study (n=235 participants) was of reasonable quality fulfilling four of the eight quality criteria (Peters 1999).

Where the gender of the smear taker was revealed as opposed to not in the letter of invitation, the uptake rates were not significantly different (RR=1.00, 95% CI: 0.65, 1.53) (Hicks 1997). However, when the offer of screening with a male smear taker was compared with a female smear taker significantly more women in the female group attended for screening (RR=2.50, 95% CI: 1.37, 4.57) (Hicks 1997). This quasi-RCT (n=75 participants in total) was only designed as a pilot study and therefore used a small sample size (25 women per group).

h) Economic

One US study (n=1791) of follow-up visits for abnormal Pap smears, examined the effects of supplying transportation incentives in the form of bus tickets or supplying parking permits (Marcus 1992). This intervention was compared with sending a follow-up letter notifying women of their first Pap smear result and playing an educational slide-tape programme in the clinic waiting room. However, this study was a cluster quasi-RCT that did not adequately consider the effects of cluster randomisation or present sufficient information in order to calculate relative risks. However, the authors reported that transport incentives emerged as the dominant intervention among population subgroups that were characterised as more disadvantaged socioeconomically and at higher risk of developing cervical cancer, including women receiving care from the county health department (P<0.05), women without health insurance (P<0.01), and women with more severe Pap smear results (P<0.05). A number of details about this study were unclear from the published report and so it was difficult to adequately assess the quality of the study.

2. Informed uptake of cervical screening

None of the studies identified in this review measured the informed uptake of cervical screening.

3. Secondary outcomes

A summary of the data relating to secondary outcomes is presented in Table 02.

a) Booking of appointments

One study (n=273) used the booking of appointments for screening as an outcome measure (Greene 1999). The study population was randomly divided into three groups: usual care (women received general dietary and health information), cancer education (women received general information about cervical cancer risk factors and screening recommendations), and cognitive behavioural intervention (women received feedback about personal risk for cancer and engaged in a clinical interview to enhance self-efficacy for preventative behaviour). Women in the usual care group were more likely to schedule an appointment for a Pap smear than those who received the cognitive behavioural intervention. (usual care = 79.4% vs. cognitive behavioural intervention = 36.7%, p</=0.0001). Women in the usual care group were also more likely to attend without rescheduling the appointment (usual care = 63.9% vs. cognitive behavioural intervention = 35.4%, p</= 0.001). The booking of appointments did not differ significantly between the women who received cancer education and those who received the cognitive behavioural intervention. It was difficult to assess the quality of this study as it was only published as an abstract and not further details were available.

b) Attitudes to screening

One study (n=3094) examined participants attitudes to Pap smear screening (Byles 1995) The following number (%) of responding women reported receiving the intervention: invitation letter 154 (72%), invitation letter and behavioural prompts (e.g. prompt cards) designed to address aspects believed to be associated with poor screening rates 134 (78%) letter, 100 (58%) card, and 109 (64%) pamphlet; control (not applicable). The following number (%) of women responders said they had read the material sent: 1. 147 (69%); 2. 128 (75%) letter, 7 (4%) card, 101 (59%) pamphlet; control (not applicable). In terms of those women who received the invitation letter 118/151 (78%) of the women said that they were pleased to have the intervention personally addressed to them, only 1/151 (1%) said they were displeased and the remainder were not sure. In comparison, of those women who received the invitation letter and behavioural prompts 89/132 (68%) were pleased, 3/132 (2%) were displeased and the remainder were unsure. 152/155 (98%) of the women who received the invitation letter thought that the intervention should be sent to all women, 2/155 (1.3%) did not and the remainder were unsure. 124/130 (95%) of women who received the invitation letter and behavioural prompts thought the intervention should be sent to all women, 1/130 (1%) did not and the remainder were unsure.

c) Costs of the interventions

Two studies (n=4578 participants in total) presented cost data (Binstock 1997, McDowell 1989). The first study used five different intervention groups (Binstock 1997). However only those groups that used an intervention aimed at women (and not health-

care providers) were included in this review: telephone invitation, invitation letter, and a control group. The total estimated costs (\$US) per intervention group were as follows: telephone invitation \$4,282, invitation letter \$1,918, memo to primary provider \$8,933, medical record reminder \$1,0.90 and control group (not stated). In terms of the uptake of screening tests invitation letters produced a greater increase compared with invitation letters or the control group.

The second study used four different intervention groups, but again not all of the interventions were aimed solely at women, some were aimed at healthcare providers (McDowell 1989). The following groups were considered in this review: GP letter invitation, telephone invitation, and control (usual care). The estimated costs (\$US) per additional Pap smear performed as compared with usual care were: GP invitation letter \$14.23, telephone intervention \$11.75 (assuming a salary of \$60) or \$5.88 (assuming a salary of \$30 per hour).

DISCUSSION

Summary of main findings

Overall, invitations and educational interventions appeared to be the most effective methods of increasing the absolute uptake of cervical screening. However, heterogeneity between the studies limited the statistical pooling of data. Evidence regarding the effectiveness of other interventions such as economic incentives, procedural interventions (i.e. revealing the gender of the smear taker and using a health promotion nurse), counselling and risk factor assessment was limited by the number and quality of included studies. In addition statistical pooling of the data was limited by the presence of heterogeneity between the studies. No studies examined the effectiveness of interventions at increasing the informed uptake of cervical screening.

Invitations

In general invitation letters were effective at encouraging women to attend for Pap smear. Cervical cancer screening programmes in the UK, Italy, Sweden and other countries already invite women to attend via a letter - with or without appointments - as part of their national call/recall system. However, the use of such systems in developing countries may be difficult to implement where issues of migration, literacy and access to remote ares may be of concern.

There was also some limited evidence that telephone invitations increased uptake, but it was unclear whether this practice was more effective than invitation letters. Telephone invitations are not routinely used in organised screening programmes such as that in the UK and would be even more difficult to implement in developing countries where access to telephones may be an issue. It was also unclear as to whether sending invitation letters with appointments was any more effective than sending invitation letters alone. However, there was some evidence to suggest that

invitation letters with fixed appointments were more effective than invitations with open appointments.

Current practice in the UK, Italy and a number of other countries involves sending invitation letters both from GPs and/or Health Authorities (Dept of Health 1998a, Segnan 1998). The effectiveness of sending letters from different authority sources was evaluated in two studies. Both studies favoured GP letters over other sources, but it was not possible to say definitively which approach was more effective, due to the limited evidence from good quality studies. A recent survey of general practices in the UK found that 52% of responders reported that women received written invitations from both their health authority and from their GP (Dept of Health 1998a). Not only may this process cause duplication or unnecessary effort, it does not appear to be supported by current research evidence.

A key issue influencing uptake of screening programmes, is the accuracy of population registers. This is borne out in the studies included in this review, with study participants being lost to follow-up or not receiving the intervention due to incorrect contact details. Other studies of invitations for cervical screening, for example, have found that between 30% and 60% of invitations were sent to the wrong address in London and Manchester, UK (Austoker 1994). Furthermore, at the present time, only 60% of UK Health Authorities attempt to locate women due for Pap smear no longer living at the address held by the Health Authority (Dept of Health 1998a). Although no evidence was available it is likely that potential screening programmes in developing countries may encounter even greater problems with maintaining registers of women eligible for screening. Whilst it is appropriate to continue using existing invitation approaches - which may also be worth considering for newer screening programmes - the issue of inaccurate registers needs to be addressed.

Education

There was insufficient evidence in the form of statistically significant findings from good quality trials to support any particular educational intervention, but overall the consensus from the studies examining educational interventions was in favour of the intervention over the no intervention/usual care control. However, heterogeneity between the studies limited the statistical pooling of data. Amongst ethnic minority groups there appeared to be some limited evidence to support the use of lay members of the community in presenting culturally-tailored information. This may be particularly relevant to developing countries where many areas may be geographically remote and literacy may be an issue. However, the findings may vary according to ethnic group and further research is required. The only study which examined the use of video/slide presentations was of reasonable quality and showed a statistically significant increase in Pap smear uptake in favour of the intervention as compared with control.

Educational materials are likely to be important in increasing informed uptake, providing they cover all aspects of the screening process. For example, the Cervical Screening Action Team in the UK has recommended that a leaflet emphasising the risks and benefits should be included with every invitation for screening (Dept of Health 1998b). However, no studies have attempted to measure the effectiveness of interventions at increasing the informed uptake of Pap smears. The issue of informed uptake is not likely to be a consideration for screening programmes in developing countries, which are likely to suffer from economic and possibly administrative constraints. Such programmes are more likely to be concerned purely with increasing the overall uptake of screening.

Informed uptake

The purpose of any screening test needs to be adequately explained to potential participants, and given alongside information about what the results of the screening test actually mean and the risks and benefits of screening (Austoker 1999). However, in this review none of the studies reported giving information on the risks and benefits of screening, and none of them included informed uptake or knowledge as an outcome measures. Whether informed uptake affects actual levels of uptake, therefore, has yet to be fully evaluated. All of the trials included in this review were undertaken on the premise that screening was beneficial and high uptake should be achieved at all costs.

Any future intervention studies should aim to minimise barriers to uptake amongst those who chose screening, based on a full understanding of the likely benefits, limitations and potential harm. Studies should include a measure of knowledge and whether the information provided is used in the decision making process. Just as an intervention to increase uptake may be ineffective, an intervention to increase informed uptake might also be ineffective. For example, it should not be assumed that giving a leaflet on the risks and benefits of screening will necessarily increase informed uptake. It may be that some interventions, which are effective for increasing uptake (such as appointments), are not effective at increasing informed uptake, and the opposite may also be true. Similarly interventions which are effective in developed countries may not be as effective in developing countries or may present problems in terms of their implementation. At present the evidence regarding the effectiveness of interventions is dominated by studies set in developed countries and there is a need for research which which is likely to be which is more applicable to developing nations. Future studies should also consider ongoing changes in screening technology. As new screening tests become available there potential effects on participation levels in cervical screening programmes should be considered. At present randomised controlled trials are underway to assess the effectiveness of HPV testing and its likely role in the UK cervical screening programme. However, it has been suggested that the introduction of this test may adversely effect the screening uptake rates because of the connotation of sexual promiscuity attached to a positive HPV test/abnormal Pap smear.

Limitations of the review

The comprehensive search strategy used in the review is likely to have located most of the published and unpublished studies. Decisions on the relevance of the majority of the studies were made by one reviewer who pre-screened titles and abstracts of the search results. Another reviewer checked a random sample. In cases of disagreement, the full article was ordered. However, it is acknowledged that although some abstracts and unpublished reports were found (through contacting experts in the field and searching the grey literature and reference lists), some may have been missed, but this risk of publication bias is likely to be minimal.

The review and the findings of the review are very much dependent on the validity and quality of the studies reported. The quality of the individual studies included in the review was assessed independently by two reviewers using pre-defined checklists. Although a number of the studies were of good or reasonable quality, a number of remaining studies suffered from methodological problems and inadequate reporting. With regards to the latter attempts were made to contact authors to clarify various points, but replies were not received in a number of studies. In particular the following issues were either not adequately accounted for or not clearly reported in the study: adequate randomisation and concealment of allocation, blinding of those assessing the study outcomes, adequate follow-up and inclusion of all participants originally randomised to take part in the trial. A number of studies randomised women without first assessing their eligibility so leading to the exclusion of large numbers of women post-randomisation. A number of studies also failed to use appropriate analyses such as intention to intervene analyses and the appropriate consideration of the effects of clustering in cluster randomised studies. By not adequately accounting for the potential effects of clustering data from a number of studies was not available for inclusion in the summary of relative risk values.

Even though relative risks were calculated in most of the RCTs included in this review, the pooling of data was limited because of statistical heterogeneity. Thus the conclusions are based on a narrative synthesis of the studies taking into account individual study quality. Consequently, the conclusions and implications for practice are based on those interventions for which there was evidence from several RCTs, i.e. invitations and educational materials. However, issues of heterogeneity and study quality should be borne in mind when interpreting these findings. A number of studies looked at other interventions but these were often either limited in number, were of questionable validity or both. In all cases the studies focussed on the actual uptake of Pap smears and not informed uptake. To increase informed uptake, future interventions should include information on the likely harms and risks, as well as the benefits of screening. These studies should include a measure of knowledge and whether this knowledge was used in the decision to undergo screening. Furthermore, more studies are needed which target ethnic minority groups and other groups where uptake is low. Only a very limited number of studies among minority groups were identified in this review.

Research into screening uptake including the uptake of Pap smears is still expanding with new studies being published each year. However, at present there is very little research relevant to developing countries and it is difficult to state with any degree of certainty how effective the interventions discussed in this review will be in such settings. In contrast the focus of future research in developed countries is likely to change through the issue of informed uptake, and this may result in an increase in the number of publications.

AUTHORS' CONCLUSIONS

Implications for practice

There was sufficient evidence from good quality RCTs to support the use of invitation letters in increasing the uptake of Pap smears. There was also some evidence to suggest that educational materials may increase Pap smear uptake. Overall, educational materials appeared promising, but it is unclear without evidence from additional good quality RCTs which methods (i.e. printed, video/slide or face to face presentations) are most effective. A number of other interventions including revealing the gender of the smear taker and using a health promotion nurse appeared to be promising approaches, but their effectiveness was only examined in a limited number of studies. In addition, there was no evidence on which to base implications for practice regarding the informed uptake of cervical screening. Through informed uptake it is hoped that there will be a greater satisfaction and better understanding of the purpose of national screening programmes. Thus attempts to increase the informed uptake of screening should be pursued alongside initiatives to increase actual uptake, but until such evidence becomes available no implications for how this should be implemented can be given. Overall, these findings relate to screening in developed countries and their relevance to developing countries is unclear.

Implications for research

The following implications are likely to be relevant to screening in developed countries:

1. Invitations and educational materials appear to be effective at increasing uptake of cervical cancer screening. Further research into the relative effectiveness and cost effectiveness of these interventions would help to inform decision-making. In particular it is unclear which types of educational materials (i.e. printed, video/ slides and face-to-face presentations) are the most effective and whether invitation letters with appointments were more or less effective than invitation letters alone.

- 2. Further research is required to determine the effectiveness of promising interventions such as revealing in an invitation letter the gender of the smear taker and using a health promotion nurse. In addition the effectiveness of a number of other interventions remains unclear, including the use of risk factor assessment.
- 3. In view of the increasing interest in informed uptake and the current lack of studies which consider this outcome, all future studies should consider and where possible measure informed uptake as well as actual uptake.
- 4. When designing and reporting future studies researchers should pay particular attention to the following issues: the use of an adequate method of randomisation, the blinding of those assessing study outcome measures, adequate concealment of treatment allocation, adequate follow-up of all participants included in the initial randomisation process, and the use of appropriate analyses, particularly in the case of cluster RCTs. Researchers should also try to ensure the enrolment of adequate numbers of eligible participants and interventions should be reported in sufficient detail.

POTENTIAL CONFLICT OF INTEREST

No known conflict of interest.

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TABLES

Characteristics of included studies

Study	Baele 1998
Methods	Design - Quasi-RCT Randomisation - alternate numbers (quasi) Concealment of allocation - inadequate Assessor blinding - not blinded Sample size - sample size and power calculations not performed Baseline comparability - not reported Follow-up - 6mths Outcome measure - administrative records Losses to follow-up - no intention to intervene analysis; incomplete data available; post-randomisation 5 women refused to take part and 2 were incapable; 4 women who were not originally randomised were contacted and included by mistake. % analysed - 260/313 (83%)
Participants	Country - Belgium Setting - Community (Moroccan/Spanish migrants) Initial screening status - unknown Inclusion criteria - Moroccan/Spanish origin; aged 40-64yrs; resident is Vilvoorde; not screened in previous 3yrs Exclusion criteria - none
Interventions	 Standard procedure consisting of invitation letter, screening voucher, information leaflets and media advertising (control) n=156 (135 analysed) Standard procedure and home visit from member of migrant organisation n= 157 (125 analysed)

^{*}Indicates the major publication for the study

Outcomes	Pap smear uptake
Notes	Published in Dutch. Invitation letters were sent in Dutch therefore as the target population were women of Moroccan and Spanish origin they may not have been able to understand the letter. Those in the intervention group though received information during the migrant workers visit in their own language. The intervention was aimed at underscreened women but the screening status of those included in the study was unknown.
Allocation concealment	C – Inadequate
Study	Binstock 1997
Methods	Design - RCT Randomisation - computer-generated Concealment of allocation - adequate Assessor blinding - not blinded Sample size - sample size and power calculations not performed Baseline comparability - no significant differences between study groups
	Follow-up - 1yr Outcome measure - administrative records Losses to follow-up - none % analysed - 100%
Participants	Country - USA Setting - HMO Initial screening status - overdue Eligible participants were identified from the medical records of the Kaiser Permanente Health Plan, South California Region (HMO). Half of those eligible (n=7630) were included in the final analysis Inclusion criteria - aged 25-49yrs; enrolled in HMO for at least 3yrs; likely to seek outpatient care at one of the three medical centres Exclusion criteria - Pap smear within the last 3yrs
Interventions	1. Telephone call n=1,526 (1,526 analysed) 2. Letter n=1,526 (1,526 analysed) 3. Memo to woman's primary provider n=1,526 (1,526 analysed) 4. Chart reminder affixed to outside of woman's medical record n=1,526 (1,526 analysed) 5. Control group n=1,526 (1,526)
Outcomes	Pap smear uptake Costs
Notes	No details were provided as to the selection criteria for half of the women who were entered into the study.
Allocation concealment	A – Adequate
Study	Bowman 1995
Methods	Design - RCT Randomisation - method not stated Concealment of allocation - unclear Assessor blinding - blinded Sample size - sample size and power calculations not performed Baseline comparability - no significant differences between study groups Follow-up - 6mths Outcome measure - administrative records Losses to follow-up - no intention to intervene analysis; 35 women excluded from GP letter group post randomisation. Follow-up data was available for 659 women.

Participants Country - Australia	
Setting - General practice	
Initial screening status - overdue	
Over 7,000 potentially eligible women in an Australian community were identifie	ed by a random household
survey (developed by the Australian Bureau of Statistics)	
Inclusion criteria - aged 18-70yrs	
Exclusion criteria - not sexually active; could not speak English; infirm; not a	it home when contacted;
hysterectomy	
Interventions 1. GP reminder letter n=255 (178 analysed)	
2. Women's health clinic invitation n=220 (164 analysed)	
3. Pamphlet n=219 (162 analysed)	
4. Control group (not stated) n=219 (155 analysed)	
Outcomes Pap smear uptake	
Notes Comparison of self-reported uptake and administrative records of uptake indicate	ed that women were very
accurate in their self-report of screening when it had actually taken place, but inac	curate in almost a quarter
of instances when they stated that it had occurred	
Allocation concealment B – Unclear	
Study Buehler 1997	
Methods Design - RCT	
Randomisation - method not stated	
Concealment of allocation - unclear	
Assessor blinding - unclear	
Sample size - 159 women were required in the intervention group to detect an in	ncrease to 15% at the 5%
level of significance and 80% power	
Baseline comparability - no significant differences between study groups	
Follow-up - 2mths and 6mths	
Outcome measure - administrative records	
Losses to follow-up - no intention to intervene analysis; analysis excluded 32 wor	
who had moved and 23 women who had a Pap smear before the intervention was	as performed (n=11 inter-
vention, n=12 control)	
% analysed - 87.5% (386/441)	
Participants Country - Canada	
Setting - Family medicine clinic	
Initial screening status - due	
Random sample of 441 women listed as patients of two clinics (one urban and on	ie rural) affiliated with the
Memorial University of Newfoundland	
Inclusion criteria - 18-69yrs	
Exclusion criteria - Pap smear in past 3yrs; hysterectomy; moved or had records w	ith clerical errors
Interventions 1. Personal letter and reminder letter 4wks later n=221 (178 analysed)	
2. Control group received no letter n=220 (208 analysed)	
Outcomes Pap smear uptake	
Notes Sample size calculations did not take into account the lag time between taking	tests and registering tests,
which could and did cause the loss of participants	
Allocation concealment B – Unclear	
0. 1	
Study Burack 1998	
Methods Design - RCT Randomisation - computer-generated random numbers	

Characteristics of included studies	(Continued)
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Characteristics of inc	cluded studies (Continued)
	Concealment of allocation - adequate Assessor blinding - blinded Sample size - assuming baseline uptake of 25-60%, sample sizes (n=160) were designed to provide at least 80% power (significance level 0.05) to detect a difference of 15% in uptake between at least two of the intervention groups Baseline comparability - no significant differences between study groups Follow-up - 1yr Outcome measure - administrative records Losses to follow-up - no intention to intervene analysis performed; women were excluded if their last smear was abnormal/insufficient for cytology (n=4708); 140 were excluded from the patient reminder intervention as they discontinued HMO membership; 2055 were excluded from the physician reminder intervention as they did not attend their physician % analysed - 66% (3848/5801)
Participants	Country - USA Setting - HMO Initial screening status - due Women were recruited from five HMO sites enrolled in year 1. Only three of these sites enrolled in year 2. 5801 women were randomised to physician reminder/no reminder. During a second later round of randomisation (patient reminder vs no reminder) further women were excluded Inclusion criteria - at least 40yrs old; HMO member; visited one of the primary care study sites in Detroit, Michigan, USA Exclusion criteria - previous abnormal or insufficient Pap smear
Interventions	 An invitation letter reminding women that they were due for a Pap smear n=? (964 analysed) Reminders for both physician and participants n=? (960 analysed) Reminders for the physicians n=? (960 analysed) Control (no reminder to either physicians or participants n=? (964 analysed)
Outcomes	Pap smear uptake
Notes	Unclear methodology. Two stage randomisation and large numbers of exclusions after first randomisation. Not clear how many women were originally randomised to each of the four study groups.
Allocation concealment	A – Adequate
Study	Byles 1994
Methods	Design - RCT (cluster) Randomisation - coin tossing Concealment of allocation - not concealed Assessor blinding - blinded Sample size - sample size and power calculations not performed Baseline comparability - study regions matched on census data Follow-up - 3mths (TV media and letter), 6mths (GP intervention) Outcome measure - administrative records Losses to follow-up - unclear if intention to intervene analysis performed; up to 24% of the letter group may potentially have not received the intervention and no intention to intervene analysis % analysed - unclear
Participants	Country - Australia Setting - Community Initial screening status - due and overdue Nine geographically discrete, regions were selected within three adjacent TV broadcasting areas. The regions were randomly assigned to the study groups and data gathered on eligible women through administrative records pre-and post-intervention Inclusion criteria - aged 18-70yrs; English-speaking

	Exclusion criteria - physically/intellectually impaired
Interventions	1. TV media campaign n=n/a 2. TV media combined with invitation letter n=n/a 3. TV media combined with GP based recruitment through workshops n=n/a n/a not applicable as data was gathered from administrative records for the regions giving overall Pap smear attendences during the pre- and post- intervention periods In the letter intervention group using information gathered from electoral registers (registration was mandatory) all eligible women were sent a letter
Outcomes	Pap smear uptake
Notes	Analysis limited by the 3 and 6mth post-intervention follow-up periods, a longer period was prevented by contamination by a state-wide media campaign. Differential effects of interventions on outcome for the different regions may reflect different baseline screening rates that could not be assessed during matching. Unit of allocation different from unit of analysis and no appropriate account was taken of this is the analysis
Allocation concealment	D – Not used
Study	Byles 1995
Methods	Design - RCT (cluster) Randomisation - coin tossing Concealment of allocation - not concealed Assessor blinding - not blinded Sample size - sample size calculations performed not performed Baseline comparability - study regions were matched as closely as possible using census data Follow-up - 3mths Outcome measure - administrative records Losses to follow-up - intention to intervene analysis performed; 28% of the letter intervention group did not recall ever receiving the intervention; not clear how many women were followed-up % analysed - 100% (3094/3094)
Participants	Country - Australia Setting - Community Initial screening status - due Three geographically separate postal regions were randomly allocated to different interventions. Data on eligible women within the regions was gathered via administrative records pre- and post-intervention Inclusion criteria - aged 18-70yrs; no Pap smear in previous 3yrs; Australian or British citizenship Exclusion criteria - not stated
Interventions	1. Personally addressed letter with simple information about Pap smears n=? (959 analysed) 2. Personally addressed letter combined with a series of targeted behavioural prompts (e.g. prompt cards) designed to address aspects believed to be associated with poor screening rates n=?(933 analysed) 3. Control n=? (1,202 analysed)
Outcomes	Pap smear uptake
Notes	Timescale of the intervention was not stated and the 3mth follow-up period was short and may have limited the results. Unit of allocation different from unit of analysis and no appropriate account was taken of this in the analysis. Unclear how many women were followed-up.
Allocation concealment	D – Not used
Study	Byles 1996
Methods	Design - RCT (cluster) Randomisation - coin tossing Concealment of allocation - not concealed Assessor blinding - not blinded

Characteristics of included studies (Continued)	Characteristics	of included	studies ((Continued)
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	Baseline comparability - regions were matched as closely as possible using census data
	Sample size - sample size and power calculations not performed
	Follow-up - 3mths
	Outcome measure - administrative records
	Losses to follow-up - unclear if intention to intervenen analysis performed; losses not stated, a 15% adjustment
	of the denominator was made to account for the estimated hysterectomy rate
	% analysed - unclear
Participants	Country - Australia
	Setting - Community
	Initial screening status - due and overdue
	Nine geographically distinct postal regions were randomly allocated to one of the intervention groups. Data
	about the women within the regions were gathered pre- and post- intervention using administrative record
	Inclusion criteria - aged 18-70yrs; no Pap smear in the previous 3yrs
	Exclusion criteria - not stated
Interventions	1. Personalised letter advising women to attend screening and providing simple information Followed up by
	a second mailing campaign 3yrs later n=? (? analysed)
	2. No letter in the first mailing but letter sent during second mailing 3yrs later n=? (? analysed)
	3. Control, no letter on either occasion n=? (? analysed)
Outcomes	Pap smear uptake
Notes	Previous campaigns may have had an unknown influence on the current campaign. The iterative process used
	to provide estimates of expected and observed may be affected by the limited follow-up period, questioning
	the reliability of the analysis. Participants were only partially randomised (to initial letter). Unit of allocation
	different from unit of analysis and no appropriate account taken of this in the analysis
Allocation concealment	D – Not used
Study	Clementz 1990
Methods	Design - RCT
	Randomisation - computer-generated random numbers
	Concealment of allocation - adequate
	Concealment of allocation - adequate
	Concealment of allocation - adequate Assessor blinding - unclear, physicians blinded
	Concealment of allocation - adequate Assessor blinding - unclear, physicians blinded Sample size - 0.90 with an alpha of 0.05, assuming 50% compliance for the intervention group and 30%
	Concealment of allocation - adequate Assessor blinding - unclear, physicians blinded Sample size - 0.90 with an alpha of 0.05, assuming 50% compliance for the intervention group and 30% for the control group
	Concealment of allocation - adequate Assessor blinding - unclear, physicians blinded Sample size - 0.90 with an alpha of 0.05, assuming 50% compliance for the intervention group and 30% for the control group Baseline comparability - no differences in any of the variables examined Follow-up - 4mths Outcome measure - administrative records
	Concealment of allocation - adequate Assessor blinding - unclear, physicians blinded Sample size - 0.90 with an alpha of 0.05, assuming 50% compliance for the intervention group and 30% for the control group Baseline comparability - no differences in any of the variables examined Follow-up - 4mths
	Concealment of allocation - adequate Assessor blinding - unclear, physicians blinded Sample size - 0.90 with an alpha of 0.05, assuming 50% compliance for the intervention group and 30% for the control group Baseline comparability - no differences in any of the variables examined Follow-up - 4mths Outcome measure - administrative records Losses to follow-up - no intention to intervene analysis performed; 42 patients were excluded post-randomisation
	Concealment of allocation - adequate Assessor blinding - unclear, physicians blinded Sample size - 0.90 with an alpha of 0.05, assuming 50% compliance for the intervention group and 30% for the control group Baseline comparability - no differences in any of the variables examined Follow-up - 4mths Outcome measure - administrative records Losses to follow-up - no intention to intervene analysis performed; 42 patients were excluded post-randomic
Participants	Concealment of allocation - adequate Assessor blinding - unclear, physicians blinded Sample size - 0.90 with an alpha of 0.05, assuming 50% compliance for the intervention group and 30% for the control group Baseline comparability - no differences in any of the variables examined Follow-up - 4mths Outcome measure - administrative records Losses to follow-up - no intention to intervene analysis performed; 42 patients were excluded post-randomisation
Participants	Concealment of allocation - adequate Assessor blinding - unclear, physicians blinded Sample size - 0.90 with an alpha of 0.05, assuming 50% compliance for the intervention group and 30% for the control group Baseline comparability - no differences in any of the variables examined Follow-up - 4mths Outcome measure - administrative records Losses to follow-up - no intention to intervene analysis performed; 42 patients were excluded post- randomisation % analysed - 81% (178/220)
Participants	Concealment of allocation - adequate Assessor blinding - unclear, physicians blinded Sample size - 0.90 with an alpha of 0.05, assuming 50% compliance for the intervention group and 30% for the control group Baseline comparability - no differences in any of the variables examined Follow-up - 4mths Outcome measure - administrative records Losses to follow-up - no intention to intervene analysis performed; 42 patients were excluded post-randomisation % analysed - 81% (178/220) Country - USA Setting - University family medicine clinic Initial screening status - due
Participants	Concealment of allocation - adequate Assessor blinding - unclear, physicians blinded Sample size - 0.90 with an alpha of 0.05, assuming 50% compliance for the intervention group and 30% for the control group Baseline comparability - no differences in any of the variables examined Follow-up - 4mths Outcome measure - administrative records Losses to follow-up - no intention to intervene analysis performed; 42 patients were excluded post-randomisation % analysed - 81% (178/220) Country - USA Setting - University family medicine clinic
Participants	Concealment of allocation - adequate Assessor blinding - unclear, physicians blinded Sample size - 0.90 with an alpha of 0.05, assuming 50% compliance for the intervention group and 30% for the control group Baseline comparability - no differences in any of the variables examined Follow-up - 4mths Outcome measure - administrative records Losses to follow-up - no intention to intervene analysis performed; 42 patients were excluded post-randomisation % analysed - 81% (178/220) Country - USA Setting - University family medicine clinic Initial screening status - due
Participants	Concealment of allocation - adequate Assessor blinding - unclear, physicians blinded Sample size - 0.90 with an alpha of 0.05, assuming 50% compliance for the intervention group and 30% for the control group Baseline comparability - no differences in any of the variables examined Follow-up - 4mths Outcome measure - administrative records Losses to follow-up - no intention to intervene analysis performed; 42 patients were excluded post-randomisation % analysed - 81% (178/220) Country - USA Setting - University family medicine clinic Initial screening status - due 220 female patients attending ambulatory clinic
	Concealment of allocation - adequate Assessor blinding - unclear, physicians blinded Sample size - 0.90 with an alpha of 0.05, assuming 50% compliance for the intervention group and 30% for the control group Baseline comparability - no differences in any of the variables examined Follow-up - 4mths Outcome measure - administrative records Losses to follow-up - no intention to intervene analysis performed; 42 patients were excluded post- randomisation % analysed - 81% (178/220) Country - USA Setting - University family medicine clinic Initial screening status - due 220 female patients attending ambulatory clinic Inclusion criteria - aged 50-69yrs
Participants Interventions	Concealment of allocation - adequate Assessor blinding - unclear, physicians blinded Sample size - 0.90 with an alpha of 0.05, assuming 50% compliance for the intervention group and 30% for the control group Baseline comparability - no differences in any of the variables examined Follow-up - 4mths Outcome measure - administrative records Losses to follow-up - no intention to intervene analysis performed; 42 patients were excluded post- randomisation % analysed - 81% (178/220) Country - USA Setting - University family medicine clinic Initial screening status - due 220 female patients attending ambulatory clinic Inclusion criteria - aged 50-69yrs Exclusion criteria - symptomatic for cervical cancer; previously had cancer
	Concealment of allocation - adequate Assessor blinding - unclear, physicians blinded Sample size - 0.90 with an alpha of 0.05, assuming 50% compliance for the intervention group and 30% for the control group Baseline comparability - no differences in any of the variables examined Follow-up - 4mths Outcome measure - administrative records Losses to follow-up - no intention to intervene analysis performed; 42 patients were excluded post- randomisation % analysed - 81% (178/220) Country - USA Setting - University family medicine clinic Initial screening status - due 220 female patients attending ambulatory clinic Inclusion criteria - aged 50-69yrs Exclusion criteria - symptomatic for cervical cancer; previously had cancer
	Concealment of allocation - adequate Assessor blinding - unclear, physicians blinded Sample size - 0.90 with an alpha of 0.05, assuming 50% compliance for the intervention group and 30% for the control group Baseline comparability - no differences in any of the variables examined Follow-up - 4mths Outcome measure - administrative records Losses to follow-up - no intention to intervene analysis performed; 42 patients were excluded post- randomisation % analysed - 81% (178/220) Country - USA Setting - University family medicine clinic Initial screening status - due 220 female patients attending ambulatory clinic Inclusion criteria - aged 50-69yrs Exclusion criteria - symptomatic for cervical cancer; previously had cancer 1. Personalised GPs letter, one month before due date of tests with an educational component n=116 (102 analysed)
Interventions	Concealment of allocation - adequate Assessor blinding - unclear, physicians blinded Sample size - 0.90 with an alpha of 0.05, assuming 50% compliance for the intervention group and 30% for the control group Baseline comparability - no differences in any of the variables examined Follow-up - 4mths Outcome measure - administrative records Losses to follow-up - no intention to intervene analysis performed; 42 patients were excluded post- randomisation % analysed - 81% (178/220) Country - USA Setting - University family medicine clinic Initial screening status - due 220 female patients attending ambulatory clinic Inclusion criteria - aged 50-69yrs Exclusion criteria - symptomatic for cervical cancer; previously had cancer 1. Personalised GPs letter, one month before due date of tests with an educational component n=116 (102 analysed) 2. Control group received usual care (not described) n=104 (76 analysed) Pap smear uptake
Interventions Outcomes	Concealment of allocation - adequate Assessor blinding - unclear, physicians blinded Sample size - 0.90 with an alpha of 0.05, assuming 50% compliance for the intervention group and 30% for the control group Baseline comparability - no differences in any of the variables examined Follow-up - 4mths Outcome measure - administrative records Losses to follow-up - no intention to intervene analysis performed; 42 patients were excluded post- randomisation % analysed - 81% (178/220) Country - USA Setting - University family medicine clinic Initial screening status - due 220 female patients attending ambulatory clinic Inclusion criteria - aged 50-69yrs Exclusion criteria - symptomatic for cervical cancer; previously had cancer 1. Personalised GPs letter, one month before due date of tests with an educational component n=116 (102 analysed) 2. Control group received usual care (not described) n=104 (76 analysed)

the study was attributed to imbalances between the intervention and control groups. There was an additional
imbalance as a result of excluding patients post-randomisation

Allocation concealment A – Adequate

Study	Del Mar 1998
Methods	Design - RCT
	Randomisation - computer-generated random numbers
	Concealment of allocation - adequate
	Assessor blinding - blinded
	Baseline comparability - no differences in age and postcode area
	Sample size - authors' state they had 'sufficient numbers to detect any meaningful change'
	Follow-up - 1yr
	Outcome measure - administrative records
	Losses to follow-up - none reported
	% analysed - 100%
Participants	Country - Australia
	Setting - Community
	Initial screening status - due and overdue
	689 women on the electoral roll in South Brisbane
	Inclusion criteria - aged 18-67yrs; Vietnamese
	Exclusion criteria - not stated
Interventions	Media campaign on cervical screening introduced for whole region 2mths before letters sent
	1. Personal letter (in Vietnamese) informing them about screening and its benefits n=359 (359 analysed)
	2. Control group did not receive a letter n=330 (330 analysed)
Outcomes	Pap smear uptake
Notes	Women in both groups were drawn from the Vietnamese community resident in one area, so there is a
	possibility of contamination.
Allocation concealment	A – Adequate

Study	Greene 1999
Methods	Design - RCT
	Randomisation - method not stated
	Concealment of allocation - unclear
	Assessor blinding - unclear
	Baseline comparability - not stated
	Sample size - sample size and power calculations not performed
	Follow-up - 6mths
	Outcome measure - administrative records
	Losses to follow-up - not stated
	% analysed - unclear
Participants	Country - USA
-	Setting - Rural primary care in low income, minority population
	Initial screening status - due
	273 women presenting for outpatient care who did not have a Pap test during the preceding year
	Inclusion criteria - not stated
	Exclusion criteria - not stated
Interventions	Based on Social Cognitive Theory and Motivational Interviewing Methods
	1. Usual care n=79 (? analysed) received general dietary and health information

Characteristics	of included	studies ((Continued))

	screening recommedations 3. Cognitive behavioral intervention n=97 (? analysed) received feedback about personal risk for cancer and engaged in a clinical interview to enhance self-efficacy for preventative behaviour
Outcomes	Pap smear uptake Booking of appointments
Notes	Standard clinical procedures to advocate for and provide Pap tests were not withheld from any of the participants; all study participants received attention in addition to usual preventative care.
Allocation concealment	B – Unclear

2. Cancer education n=97 (? analysed) received general information about cervical cancer risk factors and

Study **Hicks 1997** Methods Design - Quasi-RCT Randomisation - medical record number (quasi) Concealment of allocation - adequate, centralised blinded allocation, participants and physicians blinded Assessor blinding - not blinded Baseline comparability - no significant differences were found in terms of the variables examined Sample size - sample size and power calculations not performed Follow-up - not stated Outcome measure - administrative records Losses to follow-up - no drop-outs % analysed - 100% Country - UK Participants Setting - Community Initial screening status - due (first time) 75 women from an urban area Inclusion criteria - first time attenders for screening

	3. Sex of smear-taker not stated - control n=25 (25 analysed)
Outcomes	Pap smear uptake
Notes	This was a pilot study and therefore only used a small study sample
Allocation concealment	C – Inadequate

1. Invitation card stating that the smear-taker will be male n=25 (25 analysed) 2. Invitation card stating the smear-taker will be female n=25 (25 analysed)

Study	Hunt 1998
Methods	Design - RCT
	Randomisation - computer-generated random numbers
	Concealment of allocation - unclear
	Assessor blinding - blinded
	Baseline comparability - no significant differences between the study groups in terms the factors investigated
	Sample size - sample size and power calculations not performed
	Follow-up - 3mths
	Outcome measure - administrative records
	Losses to follow-up - no intention to intervene analysis performed; 97/119 (81.5%) of women in the personal approach group and 37/125 (30%) of in the letter group were not contacted. These women were included
	in the final analysis, however 6 women who had Pap smears prior to the intervention were not included (not
	stated which group these belonged to)
	% analysed - 98% (366/372)
Participants	Country - Australia

Exclusion criteria - not stated

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Interventions

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Characteristics	of in	cluded	studies (Continued)

Characteristics of file	citated stadies (Commuea)
	Setting - Community
	Initial screening status - overdue
	372 women identified from files at a women's clinic staffed by Aboriginal health workers in Danila Bilba
	Inclusion criteria - resident in the Darwin area; overdue for screening
	Exclusion criteria - not stated
Interventions	1. Personal approach. Women approached by Aboriginal health workers and invited for screening n=? (119
	analysed)
	2. Letter. Designed by Aboriginal workers stating individual overdue for smear and inviting them to attend
	n=? (125 analysed)
	3. Control. Usual care with reminder tags for clinic staff attached to medical records n=? (122 analysed)
0	
Outcomes	Pap smear uptake
Notes	Women were included in the final analysis even though in many cases, particularly in the personal approach
	group, they had not received the intervention. The 3mth follow-up period is relatively short
Allocation concealment	B – Unclear
0.1	VI 1006
Study	Kreuter 1996
Methods	Design - RCT
	Randomisation - method not stated, randomised within practices
	Concealment of allocation - unclear
	Assessor blinding - unclear
	Baseline comparability - no significant differences between the study groups in terms of demographic variables
	Sample size - sample size and power calculations not performed
	Follow-up - 6mths
	Outcome measure - self-report via questionnaire
	Losses to follow-up - no intention to intervene analysis performed; 186/1317 failed to complete the 6mth
	follow-up questionnaire; 457/1131 were not considered to be at risk or did not want to change and so were
	not included in the final analysis
	% analysed - 15.6% (206/1317)
Participants	Country - USA
1 articipants	Setting - Family medical practice
	Initial screening status - unclear
	1,317 adult patients from eight family medical practices in North Carolina, USA
	Inclusion criteria - aged 18-75yrs; completed baseline survey
	Exclusion criteria - not stated
Interventions	Based on Health Belief Model
	1. Typical HRA-computerised assessment of participants' health risks and provision of individualised feedback
	as to their calculated mortality risks n=427 (67 analysed)
	2. Enhanced HRA-as previous but also assesses benefits, barriers and other psychosocial factors influencing
	the individuals' health related behaviour in order to provide individualised feedback designed to facilitate
	self change in health behaviours n=427 (70 analysed)
	3. Control-no feedback given to participants n=463 (69 analysed)
Outcomes	Pap smear uptake
Notes	Also mentions the Precaution Adaption Model. Absolute values for the original number of individuals eligible
	to receive the tests at baseline not stated
Allocation concealment	B – Unclear
Study	Lancaster 1992
Methods	Design - RCT
	Randomisation - method not stated

Characteristics	of included	studies	(Continued)
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Characteristics of inc	cluded studies (Continuea)
	Concealment of allocation - unclear Assessor blinding - unclear Baseline comparability - no significant differences between study groups in terms of mean age Follow-up - not stated Sample size - sample size and power calculations not performed Losses to follow-up - no intention to intervene analysis performed; 118 women were excluded from the final analysis but not clear why Outcome measure - administrative records % analysed - 94% (1794/1912)
Participants	Country - UK Setting - General practice Initial screening status - due 2131 women registered with general practices in North Manchester Inclusion criteria - aged 50-64yrs; resident in study area Exclusion criteria - hysterectomy
Interventions	 Cervical screening invitation sent with breast screening invitation n=965 (908 analysed) Breast screening invitation only sent (control) n=947 (886 analysed)
Outcomes	Pap smear uptake
Notes	Eligibility criteria for participation in the study and for breast and cervical screening were not explicit. Ineligible women were included in the initial randomisation
Allocation concealment	B – Unclear
Study	Lantz 1995
Methods	Design - Quasi-RCT Randomisation - patient record number (quasi) Concealment of allocation - inadequate Assessor blinding - not blinded Baseline comparability - no significant differences between study groups for any of the variables examined Sample size - sample size and power calculations not performed Follow-up - 6mths Outcome measure - administrative records Losses to follow-up - intention to intervene analysis performed; 33 (10%) of women assigned to intervention group did not receive the intervention, but were included in the analysis; 13 women in the intervention group did not receive a reminder by phone % analysed - 100%
Participants	Country - USA Setting - Community health centre Initial screening status - due 659 women from a community health centre providing an insurance-like package for people with low incomes Inclusion criteria - aged 40-79 years; enrolled in benefit scheme; no claim for mammogram in past 18mths (if aged 50+) or 2yrs (if aged 40-49); no claim for Pap smear in past 3yrs Exclusion criteria - not stated
Interventions	1. Reminder letter from primary care physician for test(s) required. Follow-up phone call/letter from a health educator (nurse or social work intern) 7-10 days later, to offer barrier counselling and/or assistance with appointment making n=337 (337 analysed) 2. Control group received 'usual care' (not described) n=332 (332 analysed)
Outcomes	Pap smear uptake
Notes	Study design did not allow evaluation of the relative impact of the physician reminder letter vs counselling (as received in follow-up phone call)

Study	Marcus 1992
Methods	Design - Quasi-RCT (cluster) with factorial design Randomisation - month of initial Pap smear (quasi) Concealment of allocation - inadequate Assessor blinding - unclear Baseline comparability - not stated Sample size - sample size and power calculations not performed Follow-up - 4mths Outcome measure - administrative records Losses to follow-up - unclear if intention to intervene analysis performed; 3% of the each of the personalised follow-up (n=16) and transportation incentives (n=22) groups did not receive the interventions; data also suggests that not all of the slide-tape program study group may have received the intervention (figures not stated) % analysed - unclear
Participants	Country - USA Setting - Primary health care clinic Initial screening status - abnormal smear result 2,044 women from 12 Los Angeles area primary health care clinics Inclusion criteria - abnormal Pap smear result; registered at a participating site; signed a consent form Exclusion criteria - not stated
Interventions	Based on Health Belief Model 1. Personalised follow-up (letter notifying women of abnormal pap smear results) n=533 (? analysed) 2. Transportation incentives. Bus tickets to allow two one- way fares. One site also gave a parking permit n=724 (? analysed) 3. Educational slide-tape programme (12min) played in clinic waiting rooms about pap smear etc Produced in English and Spanish n=534 (? analysed) A 2x2x2 factorial design was used and so there were 8 different intervention groups but the above numbers of participants were not broken down into the 8 groups
Outcomes	Pap smear uptake
Notes	Implementation of the intervention protocols was less than perfect, and thus likely to introduce a conservative bias into the outcome evaluation. Complex study design including unit of randomisation (months of the year); combinations of interventions due to the 2x2x2 factorial design. Unit of allocation different from unit of analysis and no appropriate consideration was given to this in the final analysis
Allocation concealment	C – Inadequate
Study	Margolis 1998
Methods	Design - Quasi-RCT Randomisation - medical record number (quasi) Concealment of allocation - inadequate Assessor blinding - blinded Baseline comparability - differences in age, screening status and insurance status Sample size - sample size and power calculations not performed Follow-up - 1yr after women due for screening Outcome measure - administrative records and self-report via interview /questionnaire Losses to follow-up -no intention to intervene analysis performed; n=99 women were lost to follow-up in the control group and n=96 in the intervention group % analysed - 82% (907/1102)

Participants	Country - USA
1	Setting - Community health centre
	Initial screening status - due
	1,908/4,247 women recruited from non-primary-care outpatient clinics (mainly surgery and orthopaedic)
	at Hennepin Country Medical Center
	Inclusion criteria - aged 40yrs and over
	Exclusion criteria - hysterectomy; history of cervical cancer; too disoriented to give their address; acutely ill;
	refused to participate
Interventions	1. Lay health workers assessed screening status and offered women screening with a female nurse practitioner n=566 (437 analysed)
	2. Usual care group n=536 (470 analysed)
Outcomes	Pap smear uptake
Notes	The method of allocation (odd/even medical record numbers) did not result in an equal distribution of patients on several potentially important confounders. However the multivariate analyses suggested that the overall study results were not due to baseline differences between the groups
Allocation concealment	C – Inadequate
Study	McAvoy 1991
Methods	Design - RCT
	Randomisation - method not stated
	Concealment of allocation - unclear
	Assessor blinding - unclear
	Baseline comparability - not stated
	Sample size - the numbers in each group were chosen to be of sufficient size to allow detection of an increase in untake of 10% with a probability of 0.8
	in uptake of 10% with a probablility of 0.8 Follow-up - 2mths and 4mths
	Outcome measure - administrative records
	Losses to follow-up - intention to intervene analysis performed; the overall response and consent rate was
	73%
	% analysed - 100%
Participants	Country - UK
	Setting - National screening programme
	Initial screening status - overdue
	737 randomly selected women from the Asian community in Leicester
	Inclusion criteria - resident of Leicester; aged 18-52yrs; not recorded as having had a smear test
	Exclusion criteria - not stated
Interventions	1. Home visit and a multilingual video n=263 (263 analysed)
	2. Home visit, multilingual leaflet and fact sheet n=219 (219 analysed)
	3. Posted multilingual leaflet and fact sheet n=131(131 analysed)
	4. Control group received no intervention n=124 (124 analysed)
Outcomes	Pap smear uptake
Notes	Sample may not be representative of the general population as it uses only Asian participants and originates
Allocation concealment	from a previous study on use of health services. The sample had an over- representation of Moslems B – Unclear
Anocation conceannent	D – Unciear
Study	McDowell 1989
Methods	Design - RCT
	Randomisation - computer-generated random numbers
	Concealment of allocation - unclear

Characteristics of inc	cluded studies (Continued)
	Assessor blinding - not blinded Baseline comparability - no significant differences between study groups in terms of marital status and age Sample size - sample and power calculations not performed Follow-up - 1yr Outcome measure - administrative records Losses to follow-up - intention to intervene analysis performed; 447/2034 women who were not due for screening were excluded pre-randomisation % analysed - 100% (1406/1406)
Participants	Country - Canada Setting - Hospital Initial screening status - due and overdue 2034 female patients attending a hospital-based family medical center in Ottawa Inclusion criteria - aged 18-35yrs; no previous smear in past year Exclusion criteria - not stated
Interventions	1. GP letter and reminder letter after 21 days n=367 (367 analysed) 2. Physician reminder n=332 (332 analysed) 3. Telephone call n=377 (377 analysed) 4. Control group n=330 (330 analysed)
Outcomes	Pap smear uptake Costs
Notes	Study also incorporated 628/2034 women who were assigned to a practice control group, but these women were not randomly assigned. By not assessing the eligibility of women (ie whether they had had a smear in the preceding year) a number of women were excluded from the study post- randomisation
Allocation concealment	B – Unclear
Study	Navarro 1995
Methods	Design - RCT (cluster) Randomisation - method not stated Concealment of allocation - unclear Assessor blinding - unclear Baseline comparability - only one statistically significant difference found, the proportion of women who were employed (17.5% control vs. 8.9% intervention), but not regarded as a threat to internal validity Sample size - sample size or power calculations not performed Follow-up - 6mths

Follow-up - 6mths Outcome measure - self-report via interview

	Losses to follow-up - no intention to intervene analysis performed; 151/512 women failed to complete the follow-up survey and were excluded from the final analysis (76 in control, 75 in intervention) % analysed - 70.5% (361/512)
Participants	Country - USA
	Setting - Community
	Initial screening status - unclear
	500 Latinas in groups of 10-15 were recruited through 'consejeras' (traditional lay health workers in the
	Latino community) and randomly assigned according to their consejeras to either the intervention or control
	Inclusion criteria - not stated
	Exclusion criteria - not stated
Interventions	Based on Cognitive Social Learning Theory
	1. Por La Vida (PLV) programme with consejeras (n=18) taking 12 weekly educational sessions with the
	groups of women n=274 (199 analysed)
	2. Control, no PLV programme instead consejeras (n=18) participated in a 'Community Living Skills' program n=238 (162 analysed)
	1 0 ' ' '

Outcomes	Pap smear uptake
Notes	The generalisability may be limited as the study focuses on US Latinas of low socio-economic status who have a low level of acculturation. The differences between the control (Community Living Skills) and intervention (PLV) programmes were not very clear. Unit of allocation different from unit of analysis but appropriate analysis using clusters not individuals was performed. The results were presented using both the women and the Consejera as the units of analysis. The authors state that the results were limited as the test completion rates for both the pre- and post-test are lower than desired
Allocation concealment	B – Unclear
Study	Ornstein 1991
Methods	Design - RCT (cluster) Randomisation - coin tossing Concealment of allocation - not concealed Assessor blinding - not blinded Baseline comparability - study groups differed significantly (p=0.0001) in terms of race, type of insurance and visit frequency Sample size - sample size and power calculations not performed Follow-up - 1yr Outcome measure - administrative records Losses to follow-up - intention to intervene analysis performed; 818/3833 in the letter intervention groups (letter only; letter + physician reminder) did not receive the letters % analysed - 100% (7397/7397)
Participants	Country - USA Setting - Family medicine clinic Initial screening status - due 7,397 participants and 49 physicians from a university-based medical center participated in the study Inclusion criteria - aged 18yrs and over; not screened in previous 2yrs; 'active' patient of the family medicine center (ie had visited clinic in previous 2yrs) Exclusion criteria - not stated
Interventions	1. Physicians received computerised reminders n=1988 participants, 14 physicians (n=1988 analysed) 2. Participants were sent an invitation to attend followed by another personalised reminder letter (6mths later) n=1925 participants, 12 physicians (n=1925 analysed) 3. Both physician and participant reminders n=1908 participants, 13 physicians(n=1908 analysed) 4. Control group, no intervention n=1576 participants, 10 physicians (n=1576 analysed)
Outcomes	Pap smear uptake
Notes	A number of biases were reported. The study was limited to analyses of attending participants; physicians in the 4 groups were in the same building (blinding was not possible and the Hawthorne effect may have contributed to some of the improvements); there were baseline differences in participant characteristics; the unit of allocation (practice group) was different from unit of analysis (participant)
Allocation concealment	D – Not used
Study	Paskett 1990
Methods	Design - Quasi-RCT Randomisation - participant number (quasi) Concealment of allocation - not concealed Assessor blinding - not blinded Baseline comparability - no significant differences between study groups in terms of demographic or medical characteristics Sample size - sample size and power calculations not performed

Characteristics	of included	studies ((Continued))

	Follow-up - 6wks-9mths depending upon women's history, abnormality and physician methods Outcome measure - administrative records and self-report via interview Losses to follow-up - no intention to intervene analysis performed; 9 women were excluded post-randomisation; an additional 47 drop-outs were included in the analysis % analysed - 95% (161/170)
Participants	Country - USA Setting - Women's care clinic Initial screening status - abnormal smear 170 women from the Women's Care Center in Washington Inclusion criteria - abnormal smear test result; resided in Washington state Exclusion criteria - pregnant; advised to have a colposcopy
Interventions	Based on Theory Hierarchical Weighted Utility Model 1. Pamphlet (with prompt) plus a notification letter and explanation sheet about Pap smears n=83 (80 analysed) 2. Control group received the letter and explanation sheet only n=87 (81 analysed)
Outcomes	Uptake of follow-up Pap smears
Notes	Majority of participants seen in the centre were self-referred (70%)
Allocation concealment	D – Not used
Study	Peters 1999
Methods	Design - RCT (cluster) Randomisation - computer-generated random numbers Concealment of allocation - adequate Assessor blinding - unclear Baseline comparability - study groups were similar in terms of age and employment status, however the proportion with the highest educational qualifications was slightly greater for the control group. The authors state however that this was unlikely to affect the results Sample size - a target size of n=120 gave 80% power to detect (5% significance level) differences between the groups of around 15% Follow-up - 6mths Outcome measure - self-report via questionnaire Losses to follow-up - no intention to intervene analysis performed; n=30 (n=10 intervention; n=20 control) women were lost to follow-up % analysed - 87% (235/270)
Participants	Country - UK Setting - General practice Initial screening status - abnormal smear result, on 6mth surveillance 573 women registered with 96 practices in South Glamorgan and Avon. Practices were randomised to the two study groups Inclusion criteria - women: received a first-time mildly dyskaryotic smear test result; considered suitable for entry into the trial by GP Exclusion criteria - not stated
Interventions	1. Invitation to consult a practice nurse training in presenting information about abnormal smears n=123 women, n=47 practices (n=108 women analysed) 2. Control received standard care (information leaflet send out with smear test result) n=147, n=49 practices (n=127 women analysed)
Outcomes	Uptake of follow-up Pap smears
Notes	Unit of allocation (practice) differed from unit of analysis (individuals) but this was appropriately considered

in the final analyses

 $Allocation\ concealment \quad A-Adequate$

Study	Pierce 1989
Methods	Design - RCT Randomisation - computer-generated random numbers Concealment of allocation - unclear Assessor blinding - blinded Baseline comparability - no significant differences were identified between the study groups for any of the characteristics examined Sample size - sample size and power calculations not performed Follow-up - 1yr Outcome measure - administrative records Losses to follow-up - intention to intervene analysis performed; 27% (38/142) of women in tagged group did not receive the intervention. 61 women were removed from practice list during the study: screening group (n=24), tagged notes group (n=20), control group (n=17), n=3 died and n=58 left the practices % analysed - 100% (416/416)
Participants	Country - UK Setting - General practice Initial screening status - due 146/1,232 women registered with a general practice Inclusion criteria - eligible for a smear test Exclusion criteria - smear in past 5yrs; hysterectomy; already on call-recall list
Interventions	1. Letter asking women to have a smear n=140 (140 analysed) 2. Physician reminder n=142 (142 analysed) 3. Control group n=134 (134 analysed)
Outcomes	Pap smear uptake
Notes	Only 73% of the women allocated to the tagged group actually received the intervention, as they did not consult their doctor during the study period
Allocation concealment	B – Unclear
Study	Pritchard 1995
Methods	Design - RCT Randomisation - random numbers table Concealment of allocation - inadequate Assessor blinding - unclear Baseline comparability - no statistically significant differences between study groups and all women who attended the practice during the study period for age, country of birth, marital status and education Sample size - no sample size and power calculations performed Follow-up - 1yr Outcome measure - administrative records Losses to follow-up - intention to intervene analysis performed; 22 women in the intervention groups had hysterectomies but were retained in the analyses; 60% of women in the tagged notes group did not receive the intervention % analysed - 100%
Participants	Country - Australia Setting - General practice Initial screening status - due 757/2139 women at a university general practice in a socio-economically disadvantaged area of Perth Inclusion criteria - women aged 36-69yrs

Characteristics	of included	studies ((Continued))

	Randomisation - random number tables Concealment of allocation - not concealed
Methods	Design - RCT
Study	Robson 1989
Allocation concealment	B – Unclear
All	many of whom had to be excluded because their telephone line had been disconnected. Difficult to assess which part of the invention is effective
Notes	The information presented seem to be part of a larger study looking at the uptake of cancer screening in general, although only data on female participants attending mammography, Pap smear and CBE were presented. The use of a telephone to collect information about participants, as well as part of the interventions may not have been appropriate as the study looked at screening behaviour among low income participants.
Outcomes	Pap smear uptake
Interventions	Based on Transtheoretical Model 1. Provider prompting intervention only n=? (202 analysed) 2. Provider prompting and tailored educational print communications n=? (204 analysed) 3. Provider prompting, tailored educational print communications and tailored telephone counselling n=: (213 analysed)
	Initial screening status - unclear Adult users (over the age of 18 years) of the Lincoln Community Health Centre (which serves 30% of the Black population and is the most important provider of care for low-income Inclusion criteria - aged 18yrs or over; client of medicial center who had visited center in previous 18mths Exclusion criteria - not stated
Participants	Country - USA Setting - Community health centre
D. C. C.	up interview, and a further 24% could not be reached due to disconnected phones, 2% were not eligible for follow-up interview due to health reasons and 2% refused to participate % analysed - 47% (619/1318)
	Follow-up - 16mths Outcome measure - self-report via questionnaire Losses to follow-up - no intention to intervene analysis performed; 37/889 women died before the follow-up - no intention to intervene analysis performed; 37/889 women died before the follow-up - no intention to intervene analysis performed; 37/889 women died before the follow-up - no intention to intervene analysis performed; 37/889 women died before the follow-up - no intention to intervene analysis performed; 37/889 women died before the follow-up - no intention to intervene analysis performed; 37/889 women died before the follow-up - no intention to intervene analysis performed; 37/889 women died before the follow-up - no intention to intervene analysis performed; 37/889 women died before the follow-up - no intention to intervene analysis performed; 37/889 women died before the follow-up - no intention to intervene analysis performed; 37/889 women died before the follow-up - no intention to intervene analysis performed; 37/889 women died before the follow-up - no intention to intervene analysis performed; 37/889 women died before the follow-up - no intention to intervene analysis performed; 37/889 women died before the follow-up - no intention to inte
	Assessor blinding - unclear Baseline comparability - not stated Sample size - sample size and power calculation not performed
Methods	Design - RCT Randomisation - method not stated Concealment of allocation - unclear
Study	Rimer 1999
Allocation concealment	C – Inadequate
Notes	Follow-up period was 1yr and recommended screening interval 2yrs, so some women may have been screened after study period but within recommended interval
Outcomes	Pap smear uptake
Interventions	 Physician reminder (tagged notes) group n=198 (198 analysed) Letter with invitation to make an appointment n=206 (206 analysed) Letter with fixed appointment n=168 (168 analysed) Control group (usual care) n=185 (185 analysed)
T	Exclusion criteria - Pap smear in past 2yrs; hysterectomy; no attendance at practice for 3yrs or more; known to attend another practice; terminally ill

Characteristics of included studies (Continued)

Characteristics of inc	cluded studies (Continued)
	Assessor blinding - blinded Baseline comparability - no significant differences were found between the study groups in terms of the variables examined Sample size - sufficient numbers of patients to have a 95% chance of detecting a 10% difference in uptake (0.05 significance level) Follow-up - 2yrs Outcome measure - administrative records Losses to follow-up - intention to treat analysis performed; women with hysterectomies excluded from analyses. Trial discontinued after 2yrs (vs 3yrs), as GPs were no longer willing to exclude half the patients from accessing the health promotion nurse % analysed - 100% (1605/1605)
Participants	Country - UK Setting - General practice Initial screening status - due Men and women registered with a general practice in inner London (UK) Inclusion criteria - aged 30-65yrs; registered with practice and living in area Exclusion criteria - hysterectomy
Interventions	1. Patients had open access to a health promotion nurse and had their risk factors assessed and followed up by both their GP and the nurse n=799 (799 analysed) 2. Control, usual care (i.e. managed by GP alone) n=806 (806 analysed)
Outcomes	Pap smear uptake
Notes	No comments
Allocation concealment	D – Not used
Study	Segnan 1998
Methods	Design - RCT Randomisation - computerised random block design Concealment of allocation - adequate Assessor blinding - not blinded Baseline comparability - no significant differences were found between the study groups in terms of the variables examined Sample size - sample size and power calculations not performed Follow-up - 1yr Outcome measure - administrative records Losses to follow-up - none % analysed - 100%
Participants	Country - Italy Setting - GP practice in national screening programme Initial screening status - due

Initial screening status - due

8,385 women attending GPs in Turin who were part of the population based screening programme ('Prevenzione Serena')

Inclusion criteria - aged 25-64yrs; resident of Turin

Exclusion criteria - previously diagnosed cervical cancer; suffering from terminal illness or severe psychiatric symptoms

Interventions 1. Personal letter signed by GP with prefixed appointment (Control) n=2100 (2100 analysed)

- 2. Personal letter, signed by GP prompting appointment, n=2093 (2093 analysed)
- 3. Personal letter signed by program co-ordinator with prefixed appointment n=2094 (2094 analysed)
- 4. Personal letter with extended text signed by GP with prefixed appointment n=2098 (2098 analysed)

Outcomes Pap smear uptake

Characteristics of included studies (Continued)

No comments
A – Adequate
Somkin 1997
Design - RCT
Randomisation - computer-generated random numbers
Concealment of allocation - adequate
Assessor blinding - not blinded
Baseline comparability - no differences between study groups in terms of age
Sample size - n=1188 per study group was of sufficient size to detect a 5% increase in uptake with 80%
power (5% level of significance)
Follow-up - 6mths
Outcome measure - administrative records
Losses to follow-up - none
% analysed - 100%
Country - USA
Setting - HMO
Initial screening status - due
7,077 female HMO members
Inclusion criteria - aged 20-64yrs; no prior Pap smear in the previous 36mths; residents of study area; were
continuously enrolled as a member of the HMO for the previous 36mths Exclusion criteria - not stated
1. Letter inviting women to make an appointment n=1188 (1188 analysed)
2. Physician reminder and letter to patient inviting appointment n=1188 (1188 analysed)
3. Usual care (required a referral from physician) n=1188 (1188 analysed)
Pap smear uptake
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chart reminder intervention required the health provider to review the chart; the study had insufficient power
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chart reminder intervention required the health provider to review the chart; the study had insufficient power
A – Adequate
chart reminder intervention required the health provider to review the chart; the study had insufficient power to detect interactions effects between interventions and covariates, and within strata A – Adequate Sung 1997
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chart reminder intervention required the health provider to review the chart; the study had insufficient power to detect interactions effects between interventions and covariates, and within strata A – Adequate Sung 1997 Design - RCT Randomisation - method not stated
chart reminder intervention required the health provider to review the chart; the study had insufficient power to detect interactions effects between interventions and covariates, and within strata A – Adequate Sung 1997 Design - RCT Randomisation - method not stated Concealment of allocation - unclear
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chart reminder intervention required the health provider to review the chart; the study had insufficient power to detect interactions effects between interventions and covariates, and within strata A – Adequate Sung 1997 Design - RCT Randomisation - method not stated Concealment of allocation - unclear Assessor blinding - unclear Baseline comparability - no significant differences between study groups in terms of those variables examined
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chart reminder intervention required the health provider to review the chart; the study had insufficient power to detect interactions effects between interventions and covariates, and within strata A – Adequate Sung 1997 Design - RCT Randomisation - method not stated Concealment of allocation - unclear Assessor blinding - unclear Baseline comparability - no significant differences between study groups in terms of those variables examined Sample size -assuming a 30% baseline rate of Pap smear uptake and a 15% increase post-intervention, a sample size of 150 per study group was calculated to be sufficient to detect an impact of the intervention with 80% power at the 0.05 significance level Follow-up - 6mths
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chart reminder intervention required the health provider to review the chart; the study had insufficient power to detect interactions effects between interventions and covariates, and within strata A – Adequate Sung 1997 Design - RCT Randomisation - method not stated Concealment of allocation - unclear Assessor blinding - unclear Baseline comparability - no significant differences between study groups in terms of those variables examined Sample size -assuming a 30% baseline rate of Pap smear uptake and a 15% increase post-intervention, a sample size of 150 per study group was calculated to be sufficient to detect an impact of the intervention with 80% power at the 0.05 significance level Follow-up - 6mths Outcome measure - self-report via interview Losses to follow-up - no true intention to intervene analysis performed; stated intention to intervene analysis included (assuming status as per pre-survey). However the analysis excluded those patients lost to follow-up
chart reminder intervention required the health provider to review the chart; the study had insufficient power to detect interactions effects between interventions and covariates, and within strata A – Adequate Sung 1997 Design - RCT Randomisation - method not stated Concealment of allocation - unclear Assessor blinding - unclear Baseline comparability - no significant differences between study groups in terms of those variables examined Sample size -assuming a 30% baseline rate of Pap smear uptake and a 15% increase post-intervention, a sample size of 150 per study group was calculated to be sufficient to detect an impact of the intervention with 80% power at the 0.05 significance level Follow-up - 6mths Outcome measure - self-report via interview Losses to follow-up - no true intention to intervene analysis performed; stated intention to intervene analysis included (assuming status as per pre-survey). However the analysis excluded those patients lost to follow-up (23 refused, 9 died or ill, 94 moved away)
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chart reminder intervention required the health provider to review the chart; the study had insufficient power to detect interactions effects between interventions and covariates, and within strata A – Adequate Sung 1997 Design - RCT Randomisation - method not stated Concealment of allocation - unclear Assessor blinding - unclear Baseline comparability - no significant differences between study groups in terms of those variables examined Sample size -assuming a 30% baseline rate of Pap smear uptake and a 15% increase post-intervention, a sample size of 150 per study group was calculated to be sufficient to detect an impact of the intervention with 80% power at the 0.05 significance level Follow-up - 6mths Outcome measure - self-report via interview Losses to follow-up - no true intention to intervene analysis performed; stated intention to intervene analysis included (assuming status as per pre-survey). However the analysis excluded those patients lost to follow-up (23 refused, 9 died or ill, 94 moved away)

Characteristics of	included studies (Continued)
	321 low income African- American women from an inner-city community health centre Inclusion criteria - African- American; aged 18yrs or older Exclusion criteria - hysterectomy; history of cervical cancer
Interventions	 Lay health workers visited women three times to provide a culturally sensitive educational program emphasising need for screening through printed material and video n=163 (93 analysed) Control group received educational information on completion of follow-up n=158 (102 analysed)
Outcomes	Pap smear uptake
Notes	Loss to follow-up and Hawthorne effect may have biased the effects of the intervention, however an intention

to intervene analysis was also carried out with the aim of providing a conservative estimate of the effect size

Allocation concealment B – Unclear

Study	Ward 1991	
Methods	Design - RCT Randomisation - random number tables Concealment of allocation - unclear Assessor blinding - not blinded Baseline comparability - no significant differences between the study groups in terms of factors studied Sample size - sample sizes were calculated to detect a 20% difference in uptake during the consultation or within the subsequent month Follow-up - 1mth Outcome measure - administrative records Losses to follow-up - no intention to intervene analysis performed; in total 184 women were included in the final analyses % analysed - 91% (184/202)	
Participants	Country - Australia Setting - General practice Initial screening status - due 204 female patients of 16 GPs in the inner metropolitan region of Sydney Inclusion criteria - women: aged 20-65yrs; provided consent physicians: provided consent; complied with study procedures Exclusion criteria - women: pregnant; had smear in past year; attending for smear that day; hysterectomys never sexually active with male partner; insufficient command of English to complete questionnaire physicians: worked <20hrs/wk; were on leave/sick leave at time or recruitment; were expected to take leave during the study period; did not have the equipment to take smears	
Interventions	1. Minimal intervention: GP advised eligible women of need for smear and offered to perform it immediately. Those not consenting advised to make appointment for smear within a week n=99 (95 analysed) 2. Maximal intervention: GP advised woman of need for smear and offered to perform it immediately; GF attempted to persuade those not consenting during that consultation by exploring barriers and reasons for self-exclusions. If still did not consent, GP advised making an appointment for smear within a week n=103 (89 analysed)	
Outcomes	Pap smear uptake	
Notes	Fidelity of intervention implementation could not be checked; audiotapes were available for only a figure consultations. One of the audiotapes recorded a time of 6sec taken to give the maximal intervention (short time in minimal intervention was 10sec)	
Allocation concealment	B – Unclear	
Study	Ward 1999	

Design - Quasi-RCT

Methods

Characteristics of included studies (Continued)	
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Characteristics of inc	cluded studies (Continued)
	Randomisation - stratified by blocks of women attending in 5-7 day periods in each hospital to avoid contamination (quasi) Concealment of allocation - inadequate Assessor blinding - not binded Sample size - sample size and power calculations not performed Baseline comparability - not stated Follow-up - 4wks Outcome measure - self-report via telephone interview Losses to follow-up - intention to intervene analysis not performed; 232/276 (84%) of women were excluded post-randomisation because they were ineligible, outcome data was missing for 14/53 eligible women, missing outcome data was assumed to indicate that a Pap smear had not been performed % analysed - 39/276 (14%)
Participants	Country - Australia Setting - Hospital Initial screening status - overdue 285/399 women attending emergency departments in five urban hospitals in Sydney, who consented to take part in the study. Women were randomised to one of two study groups prior to assessment of their eligibility (via questionnaire) Inclusion criteria - aged 18-70yrs; at 'risk' of developing cervical cancer; overdue for screening Exclusion criteria - women in obvious distress; urgent cases for medical treatment; did not understand written English; not heard of a Pap smear
Interventions	1. Questionnaire (assessing risk and current screening status) completed and returned to doctor before leaving hospital. Doctor invites women as appropriate to attend for screening n=22 (n=15 analysed) 2. Questionnaire (assessing risk and current screening status) completed and returned to research assistant n=31 (n=24 analysed)
Outcomes	Pap smear uptake
Notes	Eligibility of women was not assessed prior to randomisation and exposure to the intervention, therefore a large number of those women initially randomised were not included in the final analysis.
	Women who had never heard of Pap smears were excluded, however these women represented a group particularly at risk and who are a prime target for interventions to increase uptake.
Allocation concealment	C – Inadequate
Study	Wilson 1987
Methods	Design - RCT Randomisation - computer-generated random numbers Concealment of allocation - adequate, centralised allocation, physician and participants not blinded Assessor blinding - not blinded Baseline comparability - no significant differences between the study groups in terms of mean age Sample size - the sample size was chosen so as to allow the study to be completed in a reasonable length of time, without creating an excessive demand for smears in the practices in the short term Follow-up - 3wks from final invitation letter Outcome measure - administrative records Losses to follow-up - no intention to intervene analysis performed; 10 women were dropped from the study, and not included in the analysis (n=3 letter only; n=7 appointment group) % analysed - 96% (240/250)
Participants	Country - UK Setting - National Screening Programme Initial screening status - due, recorded as never having a smear 250 randomly selected women from five general practices (50 women per practice) in the Nottingham Health Authority area

	Inclusion criteria - aged 45-65yrs; no record of having a previous smear Exclusion criteria - hysterectomy or other medical condition
Interventions	Letter of invitation to make an appointment + two reminders, n=125 (122 analysed) Sent an appointment + two reminders, n=125 (118 analysed)
Outcomes	Pap smear uptake
Notes	Only published as a letter. Final numbers of study participants is small compared to the initial study population (588 women who fulfilled the study criteria were not included)
Allocation concealment	A – Adequate
Study	Yancey 1995
Methods	Design - Quasi-RCT Randomisation - weeks of clinic time (quasi) Concealment of allocation - inadequate Assessor blinding - unclear Baseline comparability - no significant differences between study groups were evident within sites. Between sites one site's patients were older and more likely to have insurance, whilst the other site had more African-American women Sample size - sample size and power calculations not performed Follow-up - 3-5mths Outcome measure - administrative records Losses to follow-up - none reported % analysed - 100%
Participants	Country - USA Setting - Health clinic Initial screening status - due Two community health clinics serving low-income inner-city African-American and Latino populations in Los Angeles and New York Inclusion criteria - attending one of the two study clinics Exclusion criteria - not stated
Interventions	 Culturally sensitive health education videos dealing with breast and cervical cancer played in waiting room n=868 (868 analysed) Control, no intervention n=876 (876 analysed)
Outcomes	Pap smear uptake
Notes	Other effects not accounted for include the effects of dissemination by word of mouth, women exposed to intervention may have obtained services elsewhere. Unit of allocation different from unit of analysis and no appropriate consideration was given to this in the final analysis

Characteristics of excluded studies

Allocation concealment C – Inadequate

Study	Reason for exclusion
Campbell 1997	Intervention aimed at both the participants and the physician and data does not allow effects of the two components to be examined independently. Interventions aimed at physicians are excluded from this review.
Del Mar 1995	Intervention more concerned with obtaining more up to date addresses for participants rather than strictly increasing the uptake of screening.

Characteristics of excluded studies (Continued)

Dignan 1996	Attendance for screening over the previous year was measured, but data were gathered only 6mths post-intervention. Therefore, it is unclear how the intervention affected uptake as participants may have been screened before they received the intervention.
Dignan 1998	Attendance for screening over the previous year was measured, but data were gathered only 6mths post intervention. Therefore, it is unclear how the intervention affected uptake as participants may have been screened prior to receiving the intervention.
German 1995	The study examines the effect of the intervention on the uptake of overall preventive visits and the data is not specifically broken down into individual screening tests and procedures.
Mitchell 1991	Not an RCT or quasi-RCT. The educational campaign was not randomly assigned and 2000 women were only randomly selected within each of the campaign study groups to receive the personal invitation letter.
Powers 1992	Study examined attendance for a number of screening tests and did not separate data according to the type of test.

ADDITIONAL TABLES

Table 01. Quality of studies

Study	Randomisa- tion	Conceal- ment	Blinding	% Analysed	Intention to treat	Compara- bility	Outcome	Analysis
Baele 1998	Inadequate (quasi)	Inadequate	Inadequate	83%	Unclear	Unclear	Adequate	Unclear
Binstock 1997	Adequate	Adequate	Inadequate	100%	Not applicable	Adequate	Adequate	Adequate
Bowman 1995	Unclear	Unclear	Adequate	72%	Inadequate	Adequate	Adequate	Inadequate
Buehler 1997	Unclear	Unclear	Unclear	87.5%	Inadequate	Adequate	Adequate	Inadequate
Burack 1998	Adequate	Adequate	Adequate	66%	Inadequate	Adequate	Adequate	Inadequate
Byles 1994	Adequate	Inadequate	Adequate	Unclear	Unclear	Adequate	Adequate	Inadequate
Byles 1995	Adequate	Inadequate	Inadequate	100%	Adequate	Adequate	Adequate	Inadequate
Byles 1996	Adequate	Inadequate	Inadequate	Unclear	Unclear	Adequate	Adequate	Inadequate
Clementz 1990	Adequate	Adequate	Unclear	81%	Inadequate	Adequate	Adequate	Inadequate
Del Mar 1998	Adequate	Adequate	Adequate	100%	Not applicable	Adequate	Adequate	Adequate
Greene 1999	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Adequate	Inadequate
Hicks 1997	Inadequate (quasi)	Inadequate	Inadequate	100%	Not applicable	Adequate	Adequate	Adequate
Hunt 1998	Adequate	Adequate	Adequate	98%	Inadequate	Adequate	Adequate	Inadequate
Kreuter 1996	Unclear	Unclear	Unclear	15.6%	Inadequate	Adequate	Inadequate	Inadequate
Lancaster 1992	Unclear	Unclear	Unclear	94%	Inadequate	Adequate	Adequate	Inadequate
Lantz 1995	Inadequate	Inadequate	Inadequate	100%	Adequate	Adequate	Adequate	Adeuqate

Table 01. Quality of studies (Continued)

Study	Randomisa- tion	Conceal- ment	Blinding	% Analysed	Intention to treat	Compara- bility	Outcome	Analysis
	(quasi)							
Marcus 1992	Inadequate (quasi)	Inadequate	Unclear	Unclear	Unclear	Unclear	Adequate	Unclear
Margolis 1998	Inadequate (quasi)	Inadequate	Adequate	82%	Inadequate	Inadequate	Adequate	Inadequate
McAvoy 1991	Unclear	Unclear	Unclear	73%	Inadequate	Unclear	Adequate	Inadequate
McDowell 1989	Adequate	Unclear	Inadequate	100%	Adequate	Adequate	Adequate	Adequate
Navarro 1995	Unclear	Unclear	Unclear	70.5%	Inadequate	Adequate	Inadequate	Inadequate
Ornstein 1991	Adequate	Inadequate	Inadequate	100%	Adequate	Inadequate	Adequate	Inadequate
Paskett 1990	Inadequate (quasi)	Inadequate	Inadequate	95%	Inadequate	Adequate	Adequate	Inadequate
Peters 1999	Adequate	Adequate	Unclear	87%	Inadequate	Adequate	Inadequate	Inadequate
Pierce 1989	Adequate	Unclear	Adequate	100%	Adequate	Adequate	Adequate	Adequate
Pritchard 1995	Adequate	Inadequate	Unclear	100%	Adequate	Adequate	Adequate	Adequate
Rimer 1999	Unclear	Unclear	Unclear	47%	Inadequate	Unclear	Inadequate	Inadequate
Robson 1989	Adequate	Inadequate	Adequate	100%	Adequate	Adequate	Adequate	Adequate
Segnan 1998	Adequate	Adequate	Inadequate	100%	Not applicable	Adequate	Adequate	Adequate
Somkin 1997	Adequate	Adequate	Inadequate	100%	Not applicable	Adequate	Adequae	Adequate
Sung 1997	Unclear	Unclear	Unclear	61%	Inadequate	Adequate	Inadequate	Inadequate
Ward 1991	Adequate	Unclear	Inadequate	91%	Inadequate	Adequate	Adequate	Inadequate
Ward 1999	Inadequate (quasi)	Inadequate	Inadequate	14%	Inadequate	Unclear	Inadequate	Inadequate
Wilson 1987	Adequate	Adequate	Inadequate	96%	Inadequate	Adequate	Adequate	Inadequate
Yancey 1995	Inadequate (quasi)	Inadequate	Unclear	100%	Not applicable	Adequate	Adequate	Adequate

Study details	Interventions	Secondary outcome(s)	Results
Binstock 1997	1. Telephone call n=1,526 (1,526 analysed) 2. Letter n= 1,526 (1,526 analysed) 3. Memo to woman's primary provider n=1,526 (1,526 analysed) 4. Chart reminder affixed to outside of woman's medical record n=1,526 (1,526 analysed) 5. Control group n=1,526 (1,526)	Costs	Total estimated costs (\$US) per intervention: 1.\$4,282; 2 \$1,918; 3. \$8,933; 4. \$1,0.90; 5. Not stated. Estimated cost (\$US) per additional Pap smear performed: 1. \$7.99 2. \$4.76; 3. \$22.96; 4. \$2.99; 5. Not applicable
Byles 1995	1. Personally addressed letter with simple information about Pap smears n=? (1,128 analysed) 2. Personally addressed letter combined with a series of targeted behavioural prompts (e.g. prompt cards) designed to address aspects believed to be associated with poor screening rates n=?(1,098 analysed) 3. Control n=? (1,414 analysed)	Acceptability of the intervention	Number (%) of responding women receiving the intervention: 1. 154 (72%); 2. 134 (78%) letter, 100 (58%) card, 109 (64%) pamphlet; 3. Not applicable. Number (%) of women responders who said they had reather material sent: 1. 147 (69%); 2. 128 (75%) letter, 7 (4%) card, 101 (59%) pamphlet; 3. Not applicable. For intervention 1. 118/151 (78%) of the women said that the were pleased to have the intervention personally addresse to them, only 1/151 (1%) said they were displeased and the remainder were not sure. In intervention 2. 89/132 (68%) were pleased, 3/132 (2%) were displeased and the remainder were unsure. In intervention 1. 152/155 (98% of the women thought that the intervention should be set to all women, 2/155 (1.3%) did not and the remainder were unsure. In intervention 2. 124/130 (95%) of wome thought the intervention should be sent to all women, 1/130 (1%) did not and the remainder were unsure.
McDowell 1989	 GP letter and reminder letter after 21 days n=367 (367 analysed) Physician reminder n=332 (332 analysed) Telephone call n=377 (377 analysed) Control group n=330 (330 analysed) 	Costs	The costs for the GP letter were \$14.23 per screening gained, compared with \$11.75 assuming a salary of \$60 p hour (or \$5.88 at \$30 per hour) per screening gained.
Greene 1999	1. Usual care n=79 (? analysed) received general dietary and health information 2. Cancer education n=97 (? analysed) received general information about cervical cancer risk factors and screening recommedations 3. Cognitive behavioral intervention n=97 (? analysed) received feedback about personal risk for cancer and engaged in a clinical interview to enhance self-efficacy for	Booking of appointments	Women in group 1. were more likely to schedule an appointment for a Pap smear than those in group 3. (grou 1.=79.4% vs. group 3.=36.7%, p =0.0001). Women in group 1. were also more likely to attend without rescheduling the appointment (group 1.=63.9% vs. group 3.=35.4%, p</=0.001). Group 2. did not differ from group 3. on these measures.</td

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Suidy details	interventions preventative behaviour	SECON	econdary outcome(s)

Results

ANALYSES

Comparison 01. Invitation letter vs control

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Uptake of screening			Relative Risk (Random) 95% CI	Totals not selected
Comparison 02. GP invit	tation letter vs	invitation le	etter from other authority sources	
Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Uptake of screening			Relative Risk (Random) 95% CI	Totals not selected
Comparison 03. Telepho	ne invitation v	vs control		
Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Uptake of screening	2	3759	Relative Risk (Random) 95% CI	1.89 [1.34, 2.65]
Comparison 04. Face to	face invitation	vs control		
Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Uptake of screening			Relative Risk (Random) 95% CI	Totals not selected
Comparison 05. Invitation	No. of	No. of participants	Statistical method	Effect size
01 Uptake of screening	Studies	participants	Relative Risk (Random) 95% CI	Cl
			Milative Misk (Mandonn) 77/0 Ci	Subtotals only
Comparison 06. Letter w	vith open invit	ation to mak	e an appointment vs control	Subtotals only
Comparison 06. Letter w	vith open invit No. of studies	ation to mak No. of participants		Effect size
Outcome title	No. of	No. of	e an appointment vs control	
Outcome title 01 Uptake of screening	No. of studies	No. of participants	Statistical method Relative Risk (Random) 95% CI	Effect size
-	No. of studies	No. of participants	Statistical method Relative Risk (Random) 95% CI	Effect size
Outcome title 01 Uptake of screening Comparison 07. Letter w Outcome title	No. of studies vith fixed appo	No. of participants sintment vs co	Statistical method Relative Risk (Random) 95% CI	Effect size Totals not selected
Outcome title 01 Uptake of screening Comparison 07. Letter w Outcome title 01 Uptake of screening	No. of studies with fixed apporation of studies	No. of participants sintment vs co	Statistical method Relative Risk (Random) 95% CI ontrol Statistical method	Effect size Totals not selected Effect size Totals not selected
Outcome title 01 Uptake of screening Comparison 07. Letter w Outcome title 01 Uptake of screening	No. of studies with fixed apporation of studies	No. of participants sintment vs co	Statistical method Relative Risk (Random) 95% CI Ontrol Statistical method Relative Risk (Random) 95% CI	Effect size Totals not selected Effect size Totals not selected

Comparison 10. Education vs control

Outcome title	No. of studies	No. of participants	Statistical method	Effect size			
01 Uptake of screening			Relative Risk (Random) 95% CI	Subtotals only			
Comparison 11. Education vs	other						
Outcome title	No. of studies	No. of participants	Statistical method	Effect size			
01 Uptake of screening			Relative Risk (Random) 95% CI	Totals not selected			
Comparison 12. Counselling	vs contro	1					
Outcome title	No. of studies	No. of participants	Statistical method	Effect size			
01 Uptake of screening	2	601	Relative Risk (Random) 95% CI	1.23 [1.07, 1.41]			
Comparison 13. Counselling	vs other						
Outcome title	No. of studies	No. of participants	Statistical method	Effect size			
01 Uptake of screening			Relative Risk (Random) 95% CI	Totals not selected			
Comparison 14. Offer of scree	Comparison 14. Offer of screening where gender of smear taker specified vs control No. of No. of						
01 Uptake of screening	studies	participants	Statistical method Relative Risk (Random) 95% CI	Totals not selected			
Comparison 15. Offer of scree	ening wit No. of studies	h female vs m No. of participants		Effect size			
01 Uptake of screening		1	Relative Risk (Random) 95% CI	Totals not selected			
Comparison 16. Enhanced risk assessment vs control							
Outcome title	No. of studies	No. of participants	Statistical method	Effect size			
01 Uptake of screening			Relative Risk (Random) 95% CI	Totals not selected			
Comparison 17. Enhanced ris	sk assessn	nent vs other					
Outcome title	No. of studies	No. of participants	Statistical method	Effect size			
01 Uptake of screening			Relative Risk (Random) 95% CI	Totals not selected			

Comparison 18. Access to health promotion nurse vs control

Outcome title	No. of	No. of	Statistical method	Effect size
Outcome true	studies	participants	Statistical method	Effect Size
01 Uptake of screening			Relative Risk (Random) 95% CI	Totals not selected

INDEX TERMS

Medical Subject Headings (MeSH)

Mass Screening [*utilization]; *Patient Acceptance of Health Care; Randomized Controlled Trials; Reminder Systems; Uterine Cervical Neoplasms [*diagnosis]

MeSH check words

Female; Humans

COVER SHEET

Title Interventions targeted at women to encourage the uptake of cervical screening

Authors Forbes C, Jepson R, Martin-Hirsch P

Contribution of author(s) Carol Forbes and Ruth Jepson selected the studies, assessed study quality, extracted and

analysed the data, and wrote the protocol and final review. Pierre Martin-Hirsch commented

on the protocol and will be responsible for updating the review.

Issue protocol first published

Review first published 2002/3

Date of most recent amendment 10 May 2007 15 May 2002

Date of most recent

SUBSTANTIVE amendment

Information not supplied by author

Date new studies sought but

none found

What's New

Information not supplied by author

Date new studies found but not

yet included/excluded

Information not supplied by author

Date new studies found and

included/excluded

Information not supplied by author

Date authors' conclusions

section amended

Information not supplied by author

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GRAPHS AND OTHER TABLES

Analysis 01.01. Comparison 01 Invitation letter vs control, Outcome 01 Uptake of screening

Review: Interventions targeted at women to encourage the uptake of cervical screening

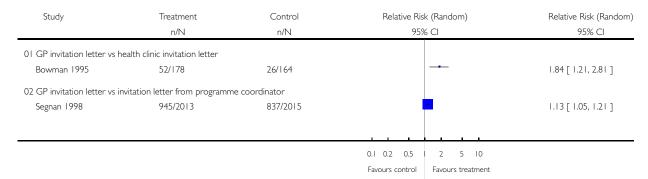
Comparison: 01 Invitation letter vs control
Outcome: 01 Uptake of screening

Study	Treatment	Control	Relative Risk (Random)	Relative Risk (Random)
	n/N	n/N	95% CI	95% CI
Binstock 1997	403/1526	249/1526	-	1.62 [1.41, 1.86]
Bowman 1995	52/178	26/155	-	1.74 [1.15, 2.65]
Buehler 1997	19/178	13/208	+-	1.71 [0.87, 3.36]
Burack 1998	280/964	270/964	•	1.04 [0.90, 1.19]
Del Mar 1998	36/359	39/330	-	0.85 [0.55, 1.30]
Hunt 1998	3/125	0/122		6.83 [0.36, 30.92]
Lancaster 1992	151/908	89/886	+	1.66 [1.30, 2.12]
McDowell 1989	76/367	35/330	-	1.95 [1.35, 2.83]
Pierce 1989	45/140	20/134		2.15 [1.35, 3.45]

Analysis 02.01. Comparison 02 GP invitation letter vs invitation letter from other authority sources, Outcome 01 Uptake of screening

Review: Interventions targeted at women to encourage the uptake of cervical screening Comparison: 02 GP invitation letter vs invitation letter from other authority sources

Outcome: 01 Uptake of screening



Analysis 03.01. Comparison 03 Telephone invitation vs control, Outcome 01 Uptake of screening

Review: Interventions targeted at women to encourage the uptake of cervical screening

Comparison: 03 Telephone invitation vs control

Outcome: 01 Uptake of screening

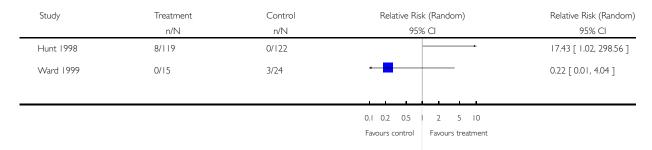
Study	Treatment n/N	Control n/N	Relative Risk (Random) 95% CI	Weight (%)	Relative Risk (Random) 95% CI
Binstock 1997	536/1526	249/1526	•	63.4	2.15 [1.89, 2.46]
McDowell 1989	60/377	35/330	-	36.6	1.50 [1.02, 2.22]
Total (95% CI)	1903	1856	•	100.0	1.89 [1.34, 2.65]
Total events: 596 (Treatm	ent), 284 (Control)				
Test for heterogeneity chi	i-square=2.95 df=1 p=0.	09 2 =66.1%			
Test for overall effect z=3	3.65 p=0.0003				

Analysis 04.01. Comparison 04 Face to face invitation vs control, Outcome 01 Uptake of screening

Review: Interventions targeted at women to encourage the uptake of cervical screening

Comparison: 04 Face to face invitation vs control

Outcome: 01 Uptake of screening

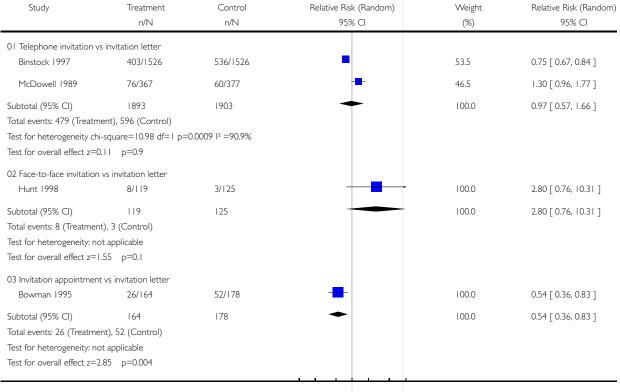


Analysis 05.01. Comparison 05 Invitation vs other invitation, Outcome 01 Uptake of screening

Review: Interventions targeted at women to encourage the uptake of cervical screening

Comparison: 05 Invitation vs other invitation

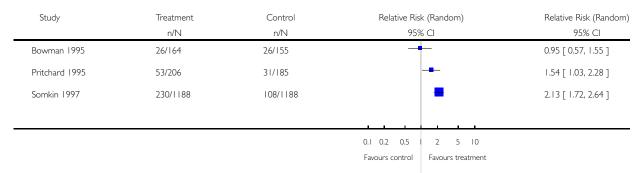
Outcome: 01 Uptake of screening



Analysis 06.01. Comparison 06 Letter with open invitation to make an appointment vs control, Outcome 01 Uptake of screening

Review: Interventions targeted at women to encourage the uptake of cervical screening Comparison: 06 Letter with open invitation to make an appointment vs control

Outcome: 01 Uptake of screening



Analysis 07.01. Comparison 07 Letter with fixed appointment vs control, Outcome 01 Uptake of screening

Review: Interventions targeted at women to encourage the uptake of cervical screening

Comparison: 07 Letter with fixed appointment vs control

Outcome: 01 Uptake of screening

Study	Treatment	Control	Relative Risk (Random)	Relative Risk (Random)
	n/N	n/N	95% CI	95% CI
Pritchard 1995	51/168	31/185	-	1.81 [1.22, 2.69]

Analysis 08.01. Comparison 08 Letter with fixed appointment vs letter with open invitation to make an appointment, Outcome 01 Uptake of screening

Review: Interventions targeted at women to encourage the uptake of cervical screening

Comparison: 08 Letter with fixed appointment vs letter with open invitation to make an appointment

Outcome: 01 Uptake of screening

Study	Treatment	Control	Relative Risk (Random)	Weight	Relative Risk (Random)
	n/N	n/N	95% CI	(%)	95% CI
Pritchard 1995	51/168	53/206	-	18.8	1.18 [0.85, 1.63]
Segnan 1998	759/2100	474/2093	•	62.0	1.60 [1.45, 1.76]
Wilson 1987	56/118	39/122	-	19.2	1.48 [1.08, 2.05]
Total (95% CI)	2386	2421	•	100.0	1.49 [1.27, 1.75]
Total events: 866 (Treatr	ment), 566 (Control)				
Test for heterogeneity cl	ni-square=3.10 df=2 p=0	0.21 I ² =35.6%			
Test for overall effect z=	4.81 p<0.00001				
			0.1 0.2 0.5 2 5 10		

Favours control Favours treatment

Analysis 10.01. Comparison 10 Education vs control, Outcome 01 Uptake of screening

Review: Interventions targeted at women to encourage the uptake of cervical screening

Comparison: 10 Education vs control Outcome: 01 Uptake of screening

Study	Control n/N	Treatment n/N	Relative Risk (Random) 95% Cl	Weight (%)	Relative Risk (Random) 95% Cl
01 Education (printed m	aterial) vs control				
Bowman 1995	26/162	26/155	+	27.6	0.96 [0.58, 1.57]
McAvoy 1991	14/131	6/124	-	10.7	2.21 [0.88, 5.57]
Rimer 1999	106/204	113/204	•	61.7	0.94 [0.78, 1.12]
Subtotal (95% CI)	497	483	+	100.0	1.03 [0.75, 1.43]
Total events: 146 (Contr	ol), 145 (Treatment)				
Test for heterogeneity ch	ni-square=3.29 df=2 p=	=0.19 l² =39.3%			
Test for overall effect z=	0.20 p=0.8				
02 Education (video/slide	e) vs control				
Yancey 1995	168/268	120/876	-	100.0	4.58 [3.78, 5.53]
Subtotal (95% CI)	268	876	•	100.0	4.58 [3.78, 5.53]
Total events: 168 (Contr	ol), 120 (Treatment)				
Test for heterogeneity: n	ot applicable				
Test for overall effect z=	15.68 p<0.00001				
03 Education (format un	known) vs control				
			0.1 0.2 0.5 1 2 5 10		(-

Favours treatment Favours control

(... Continued)

Study	Control n/N	Treatment n/N	Relative Risk (Random) 95% Cl	Weight (%)	Relative Risk (Random) 95% CI
Greene 1999	54/97	19/79	73/6 Cl	100.0	2.31 [1.51, 3.56]
			_		
Subtotal (95% CI)	97	79		100.0	2.31 [1.51, 3.56]
Total events: 54 (Control), 19	(Treatment)				
Test for heterogeneity: not ap	plicable				
Test for overall effect $z=3.82$	p=0.0001				
04 Education (face-to-face ho	ome visits) vs cont	rol			
McAvoy 1991	272/964	6/124		48.5	5.83 [2.65, 2.8]
Sung 1997	27/44	26/52	-	51.5	1.23 [0.86, 1.76]
Subtotal (95% CI)	1008	176		100.0	2.61 [0.35, 19.38]
Total events: 299 (Control), 3	32 (Treatment)				
Test for heterogeneity chi-squ	uare=21.49 df=1	o=<0.0001 l ² =95.3%			
Test for overall effect z=0.94	p=0.3				
			0.1 0.2 0.5 1 2 5 10		

Analysis 11.01. Comparison 11 Education vs other, Outcome 01 Uptake of screening

Favours treatment Favours control

Review: Interventions targeted at women to encourage the uptake of cervical screening

Comparison: I I Education vs other
Outcome: 01 Uptake of screening

Study	Treatment	Control	Relative Risk (Random)	Relative Risk (Random)
	n/N	n/N	95% CI	95% CI
01 Education (printed mate	erial) vs health clinic invitation l	etter		
Bowman 1995	29/162	26/164	-	1.13 [0.70, 1.83]
02 Education (printed mate	erial) vs GP invitation letter			
Bowman 1995	29/162	52/178	-	0.61 [0.41, 0.92]
03 Education (format unkn	own) vs enhanced risk assessn	nent		
Greene 1999	54/97	62/97	+	0.87 [0.69, 1.10]
05 Education (printed mate	erial) vs education (video/slide))		
McAvoy 1991	57/219	80/263	-	0.86 [0.64, 1.14]
			0.1 0.2 0.5 2 5 10	

Favours treatment

Favours control

Analysis 12.01. Comparison 12 Counselling vs control, Outcome 01 Uptake of screening

Review: Interventions targeted at women to encourage the uptake of cervical screening

Comparison: 12 Counselling vs control
Outcome: 01 Uptake of screening

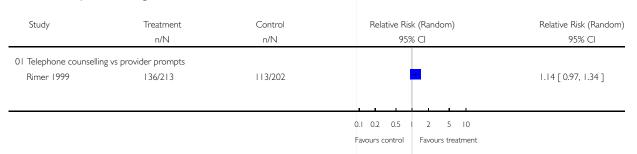
Study	Treatment n/N	Control n/N	Relative Risk (Random) 95% CI	Weight (%)	Relative Risk (Random) 95% Cl
01 Face-to-face counsell	ing vs control				
Ward 1991	60/89	52/95	-	33.7	1.23 [0.98, 1.55]
Subtotal (95% CI)	89	95	•	33.7	1.23 [0.98, 1.55]
Total events: 60 (Treatm	ent), 52 (Control)				
Test for heterogeneity: n	ot applicable				
Test for overall effect z=	1.75 p=0.08				
02 Telephone counselling	g vs control				
Rimer 1999	136/213	106/204	-	66.3	1.23 [1.04, 1.45]
Subtotal (95% CI)	213	204	•	66.3	1.23 [1.04, 1.45]
Total events: 136 (Treatr	nent), 106 (Control)				
Test for heterogeneity: n	ot applicable				
Test for overall effect z=	2.43 p=0.02				
Total (95% CI)	302	299	•	100.0	1.23 [1.07, 1.41]
Total events: 196 (Treatr	nent), 158 (Control)				
Test for heterogeneity ch	ni-square=0.00 df=1 p=0	0.99 2 =0.0%			
Test for overall effect z=	3.00 p=0.003				
			0.1 0.2 0.5 1 2 5 10		

Analysis 13.01. Comparison 13 Counselling vs other, Outcome 01 Uptake of screening

Favours control Favours treatment

Review: Interventions targeted at women to encourage the uptake of cervical screening

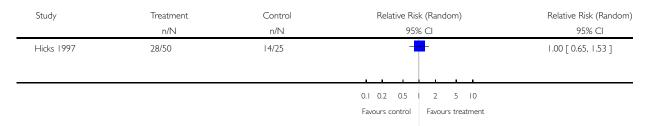
Comparison: 13 Counselling vs other Outcome: 01 Uptake of screening



Analysis 14.01. Comparison 14 Offer of screening where gender of smear taker specified vs control, Outcome 01 Uptake of screening

Review: Interventions targeted at women to encourage the uptake of cervical screening Comparison: 14 Offer of screening where gender of smear taker specified vs control

Outcome: 01 Uptake of screening

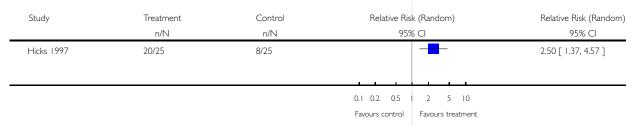


Analysis 15.01. Comparison 15 Offer of screening with female vs male smear taker, Outcome 01 Uptake of screening

Review: Interventions targeted at women to encourage the uptake of cervical screening

Comparison: 15 Offer of screening with female vs male smear taker

Outcome: 01 Uptake of screening

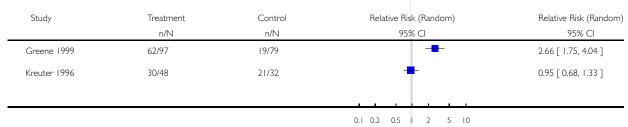


Analysis 16.01. Comparison 16 Enhanced risk assessment vs control, Outcome 01 Uptake of screening

Review: Interventions targeted at women to encourage the uptake of cervical screening

Comparison: 16 Enhanced risk assessment vs control

Outcome: 01 Uptake of screening



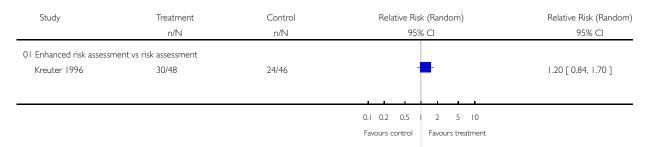
Favours control Favours treatment

Analysis 17.01. Comparison 17 Enhanced risk assessment vs other, Outcome 01 Uptake of screening

Review: Interventions targeted at women to encourage the uptake of cervical screening

Comparison: 17 Enhanced risk assessment vs other

Outcome: 01 Uptake of screening



Analysis 18.01. Comparison 18 Access to health promotion nurse vs control, Outcome 01 Uptake of screening

Review: Interventions targeted at women to encourage the uptake of cervical screening

Comparison: 18 Access to health promotion nurse vs control

Outcome: 01 Uptake of screening

Study	Treatment	Control	Relative Risk (Random)	Relative Risk (Random)
	n/N	n/N	95% CI	95% CI
Peters 1999	92/108	105/127	•	1.03 [0.92, 1.15]
Robson 1989	606/799	392/608	•	1.18 [1.10, 1.26]