

Self-help interventions for smoking cessation (Review)

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[Intervention Review]

Self-help interventions for smoking cessation

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ABSTRACT

Background

Many smokers give up smoking on their own, but materials giving advice and information may help them and increase the number who quit successfully.

Objectives

The aims of this review were to determine the effectiveness of different forms of self-help materials, compared with no treatment and with other minimal contact strategies; the effectiveness of adjuncts to self help, such as computer-generated feedback, telephone hotlines and pharmacotherapy; and the effectiveness of approaches tailored to the individual compared with non-tailored materials.

Search strategy

We searched the Cochrane Tobacco Addiction Group trials register using the terms 'self-help', 'manual*' or 'booklet*'. Date of the most recent search November 2008.

Selection criteria

We included randomized trials of smoking cessation with follow up of at least six months, where at least one arm tested a self-help intervention. We defined self help as structured programming for smokers trying to quit without intensive contact with a therapist.

Data collection and analysis

We extracted data in duplicate on the participants, the nature of the self-help materials, the amount of face-to-face contact given to intervention and to control conditions, outcome measures, method of randomization, and completeness of follow up.

The main outcome measure was abstinence from smoking after at least six months follow up in people smoking at baseline. We used the most rigorous definition of abstinence in each trial, and biochemically validated rates when available. Where appropriate, we performed meta-analysis using a fixed-effect model.

Main results

We identified 68 trials. Thirty-four compared self-help materials to no intervention or tested materials used in addition to advice. In 12 trials in which self help was compared to no intervention there was a pooled effect that just reached statistical significance (N = 15,711; risk ratio [RR] 1.21; 95% confidence interval [CI] 1.05 to 1.39). This analysis excluded two trials with strongly positive outcomes that introduced significant heterogeneity. Five further trials in which the control group received alternative written materials did not

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show evidence for an effect of the smoking self-help materials. We failed to find evidence of benefit from adding self-help materials to face-to-face advice, or to nicotine replacement therapy. There were 25 trials using materials tailored for the characteristics of individual smokers, where meta-analysis supported a small benefit of tailored materials (N = 28,189; RR 1.31; 95% CI 1.20 to 1.42, I² = 19%). The evidence is strongest for tailored materials compared to no intervention, but also supports tailored materials as more helpful than standard materials. Part of this effect could be due to the additional contact or assessment required to obtain individual data. A small number of other trials failed to detect benefits from using additional materials or targeted materials, or to find differences between different self-help programmes.

Authors' conclusions

Standard self-help materials may increase quit rates compared to no intervention, but the effect is likely to be small. We failed to find evidence that they have an additional benefit when used alongside other interventions such as advice from a healthcare professional, or nicotine replacement therapy. There is evidence that materials that are tailored for individual smokers are more effective than untailored materials, although the absolute size of effect is still small.

PLAIN LANGUAGE SUMMARY

Do self-help materials containing information about how to give up smoking help people to quit

Advice and behavioural counselling can help smokers to quit. Giving the same type of support via written materials or other media has not been found to be very helpful, although there is likely to be a small benefit for people given no other support. Tailoring materials to provide individualized support is more effective. Comparisons between different types of standard materials have generally failed to show differences between them.

BACKGROUND

Behavioural strategies to aid smoking cessation range from very brief interventions, such as advice from a physician, to intensive multi-component programmes. There is good evidence for the effectiveness of brief, therapist-delivered interventions, such as physician advice (Stead 2008a), and for the additional effect of more intensive behavioural interventions, such as group therapy (Stead 2005), individual counselling (Lancaster 2005) and telephone counselling (Stead 2006). However, a major limitation of therapist-delivered behavioural interventions is that they reach only a small proportion of smokers. Most successful quitters give up on their own (Fiore 1990). Methods to support otherwise unaided quit attempts therefore have the potential to help a far greater proportion of the smoking population.

Self help usually takes the form of written materials, but may include other forms of media such as video or audiotape. The aim of self-help interventions is to provide some of the benefits of intensive behavioural interventions without the need to attend treatment sessions. Such materials can be disseminated and used on a much wider scale than therapist-delivered treatment. They there-

fore represent a bridge between the clinical approach to smoking cessation oriented towards individuals, and public health approaches that target populations (Curry 1993).

Previous reviews have found limited evidence that self-help interventions, in particular written materials, have a significant effect on cessation rates (Curry 1993). New concepts have, however, led to continued interest and research in this field. The transtheoretical, or stages of change model (Prochaska 1997), stimulated interest in the concept of tailoring interventions to individual characteristics, particularly readiness to change. In this model, smokers are characterized as being in pre-contemplation, contemplation or action phases. The model hypothesizes that action-oriented materials are unlikely to be effective for those in the pre-contemplation or contemplation stages, and that tailoring of materials to the individual's readiness to change may be more effective. The development of new technologies, including video and computer, which offer a method for further personalizing self-help materials, stimulated further interest in this area (Curry 1995; Strecher 1999).

The aim of this review is to summarize existing evidence for both

the older and newer forms of self-help interventions in promoting smoking cessation.

OBJECTIVES

We set out to address the following hypotheses:

1. Self-help interventions are better than no treatment in promoting smoking cessation.
2. Different forms of self help (written materials, audio and video tape) have equivalent effects.
3. Approaches tailored to the individual are more effective than non-tailored materials.

METHODS

Criteria for considering studies for this review

Types of studies

Randomized controlled trials with a minimum follow up of six months, where at least one arm consisted of a self-help intervention without repeated face-to-face therapist contact. We included trials where allocation to treatment was by a quasi-randomized method but, where appropriate, we used sensitivity analysis to determine whether their inclusion altered the results.

Types of participants

Any smokers except pregnant smokers and adolescent smokers. Interventions in pregnant smokers (Lumley 2004) and in adolescent smokers (Grimshaw 2006) have been evaluated in separate Cochrane reviews.

Types of interventions

We defined self-help interventions as any manual or programme to be used by individuals to assist a quit attempt not aided by health professionals, counsellors or group support. They include written materials, audio- or videotape or computer programmes. Materials may be aimed at smokers in general, may target particular populations of smokers, for example different ages or ethnic groups, or may be interactively tailored to individual smoker characteristics. Brief leaflets on the health effects of smoking were not included - they were considered to be a control intervention if compared to a more substantial manual. Interventions with a minimal face-to-face contact for the purpose of supplying the self-help programme materials were regarded as self help alone. Where a face-to-face

meeting included discussion of the programme contents we categorized this as brief advice in addition to self-help materials. We excluded Interventions that provided repeated sessions of advice in addition to self-help materials. Telephone counselling or hotlines as adjuncts to self-help materials are now covered in a separate Cochrane review (Stead 2006).

Types of outcome measures

We use sustained abstinence, or two-point prevalence, where available. We included studies using either self report of cessation alone or biochemically validated cessation.

Search methods for identification of studies

We identified trials included in previous reviews and meta-analyses, and searched the Cochrane Tobacco Addiction Review Group specialized register of controlled trials for additional studies, using the terms 'self-help', 'manual*' or 'booklet*' or pamphlet* in the title or abstract, or as a keyword. The register was searched in November 2008, and included records identified from routine searches of MEDLINE and EMBASE via OVID on 19th November 2008.

Data collection and analysis

Both authors extracted data. Information extracted included details of the intervention, population recruited, method of randomization, completeness of follow up, way in which cessation was defined and whether self-reported cessation was validated.

We categorized trials according to the amount of face-to-face contact provided to both treatment and comparison intervention groups, and according to whether or not any written materials were given to the comparison group.

We summarized individual study results as a risk ratio, calculated as: (number of quitters in intervention group/ number randomized to intervention group) / (number of quitters in control group/ number randomized to control group). Where appropriate we performed meta-analysis using a Mantel-Haenszel fixed-effect method to estimate a pooled risk ratio with 95% confidence intervals (Greenland 1985). The amount of statistical heterogeneity between trials was estimated using the I² statistic (Higgins 2003). Values over 50% suggest moderate heterogeneity, and values over 75% suggest substantial heterogeneity. The comparison tables addressed the stated hypotheses and included:

- Self-help materials versus no treatment or a leaflet only, without face-to-face contact
- Self-help materials versus no treatment or a leaflet only, with face-to-face contact
- Self-help materials and brief advice versus brief advice alone
- Self-help versus brief advice

Any trials comparing self help to individual counselling were covered in a Cochrane review of individual counselling (Lancaster 2005). Self help versus group counselling has been covered in the Cochrane review of group therapy for smoking cessation (Stead 2005)

- Self help as an adjunct to pharmacotherapy:
- Self help plus nicotine replacement therapy (NRT) versus NRT alone

(Self help plus NRT versus self help alone is a test of the efficacy of NRT and is covered in the Cochrane review of NRT (Stead 2008b)

Enhancements and adjuncts to self help:

- Tailored self-help programmes versus non-tailored programmes, or no intervention controls
- Targeted materials versus standard materials
- Provision of additional materials
- Different self-help programmes or different media formats (audiotapes, video) compared to each other

We define as tailored materials those that make use of participant characteristics to provide individualized programmes. We also include in this category interventions providing individual written feedback in addition to standard materials. We define targeted materials as those tailored for a broadly defined category of smoker, for example, women with young children, older smokers, or smokers in a particular stage of change (Kreuter 2000)

The use of proactive telephone counselling or provision of telephone hotlines as an adjunct to self-help materials is now evaluated in a separate Cochrane review (Stead 2006), so trials which only compare these interventions are no longer included here.

RESULTS

Description of studies

See: [Characteristics of included studies](#); [Characteristics of excluded studies](#).

For the present update of the review we identified 89 potentially relevant records new to the Tobacco Addiction Group specialised register since the last update; 10 met the inclusion criteria. Two trials included in previous reviews are now excluded (Curry 1988; Burling 2000); neither had contributed to meta-analyses in previous versions. One previously unpublished study is now in print (Nollen 2007). The review now includes 68 trials of self-help methods; one study with a factorial design was treated as two studies for data entry (Killen 1997; Killen 1997 +NP). Thirty-four of these compared standard self-help materials to no intervention or provided standard materials as an adjunct to advice. The other

trials compared targeted or tailored self-help methods or compared other variations of programmes. Some trials used multiple interventions, testing the effect of different types of information, or the effect of increasing amounts of material. Trials of self-help materials were carried out in a range of settings. In some the materials were provided without face-to-face contact or any additional motivating strategy. Some studies tested the use of materials for people who had called quitlines; self-help materials were the main form of support offered, or were evaluated as an adjunct to counselling (Strecher 2005). In healthcare settings, self-help materials were more frequently used as an adjunct to brief advice to quit. Some studies described as being tests of self-help materials included relatively high levels of face-to-face support, though less than in formal counselling programmes. The smokers recruited to trials ranged from those who had already succeeded in quitting for 48 hours (Killen 1990), to those with no interest in quitting (Dijkstra 1999), but in most cases an interest in quitting was not a selection criterion.

The content and format of the self-help programmes were varied. The most frequently used approach was the American Lung Association (ALA) *Freedom from smoking in 20 days* cessation manual and *A lifetime of freedom from smoking* maintenance manual. Most other programmes were not named or described fully. Materials have tended to become more complex over time and to incorporate more techniques from behaviour therapy approaches. Recent research has focused on the potential to use computerized expert systems to provide tailored materials judged to be relevant to the characteristics of each smoker, using baseline data. We specified that materials should contain a structured programme for quitting. When it was not clear whether the materials provided met these criteria, we performed sensitivity analysis to determine the effect of including or excluding these trials.

Self-help materials compared to no intervention (Comparisons 1&2)

Self-help materials without face-to-face contact

We identified 19 trials in which self-help materials were sent to smokers without any personal contact. In five of these the smokers in the comparison control received a brief leaflet (Davis 1984; Cummings 1988; Orleans 1991; Lichtenstein 2000; Lichtenstein 2008), whilst in the other 14 they were not sent any materials (Cuckle 1984; Ledwith 1984; Lando 1991; Gritz 1992; Pallonen 1994; Curry 1995; Dijkstra 1998a; Humerfelt 1998; Dijkstra 1999; Schofield 1999; Becona 2001a; Becona 2001b; Lennox 2001; Willemsen 2006). In 12 trials, participants responded to promotion of smoking cessation programmes or volunteered for a trial. One of these only recruited smokers who were not planning to quit in the next six months (Dijkstra 1999). Two studies sent unsolicited materials to smokers in Health Maintenance Organi-

sations (Curry 1995; Gritz 1992). One sent either tailored or un-tailored letters from a physician to general practice patients who had answered a questionnaire about smoking behaviour (Lennox 2001); we compare the standard letter to the non-intervention control in this comparison. One study sent a booklet and a personally addressed letter from a consultant to smokers or recent quitters discharged from hospital (Schofield 1999). Three studies targeted factors which might motivate interest in quitting. One of these used a community survey to identify young (30-45) male smokers with reduced FEV1 or asbestos exposure. The intervention consisted of self-help materials accompanied by a letter from a respiratory physician, which drew attention to the individual's higher risk of smoking-related lung disease and advised quitting (Humerfelt 1998). The other two recruited households via utility bill enclosure offering radon testing, and provided a leaflet (Lichtenstein 2000) or video (Lichtenstein 2008) that highlighted the synergistic impact of radon and smoking and advised on quitting or not smoking indoors. The comparison groups received a standard leaflet about the risks of radon that did not emphasise quitting. All the studies used a single mailing of materials except Becona 2001a and one arm of Becona 2001b which sent six weekly mailings, and Pallonen 1994 which sent stage of change-based manuals at six-monthly intervals.

Self-help materials with brief contact

We identified five trials in which the self-help materials were given personally to participants, but not in the context of formal advice to stop smoking. In one study the control group were given health education materials without a specific focus on tobacco use, and the intervention group was intended to receive a single telephone call (Resnicow 1997). In the other studies the controls received no intervention (Betson 1998; Campbell 1986; Fortmann 1995; Prue 1983). Three studies recruited in outpatient clinics (Betson 1998, Campbell 1986; Prue 1983); the last of these probably included some telephone contact for the self-help group, although the extent of this is unclear. In one trial (Fortmann 1995) volunteers were recruited who had quit for 24 hours before randomization in a factorial design with a nicotine gum/no gum condition. Since there was no interaction between the gum and self-help conditions the nicotine arms have been collapsed for entry in the analysis. All these participants were offered a US\$100 incentive to quit for six months.

Self-help materials and advice versus advice alone

Eleven trials assessed self-help materials as an adjunct to brief advice about stopping smoking given by a healthcare worker. In three of these trials some written materials were given to the control group. In one study (Lando 1988) both arms were also prescribed nicotine gum and instructed in its use. Advice was given by a doctor alone in six studies, and by a doctor, nurse or both in four.

In one study student nurses advised two smokers each, one before and one after training to deliver a self-help manual (Davies 1992). In one trial (Hollis 1993) self-help smokers had additional advice from a nurse as well as a physician message. In a study of physician advice (Thompson 1988) which used a complete factorial design some smokers received structured advice with or without materials, and some received brief advice - we have combined the two levels of advice. Kottke 1989 randomized physicians to a workshop with or without a supply of self-help materials for patients. One study (Lipkus 1999) used a tailored adjunct to advice and is included in the section on tailoring below.

We did not identify any trials that directly compared standard self-help materials with brief advice.

Self-help and nicotine replacement therapy (NRT) compared to NRT alone (Comparison 3)

Two studies tested standard self-help materials as an adjunct to nicotine replacement (Fortmann 1995; Lando 1988). Both have been included in the relevant subgroup of the comparisons above, but are also compared directly here. Both studies used nicotine gum. We excluded a further study from this comparison because both groups received written materials, which we classified as self help (ICRF 1994). One study, published as an abstract (Orleans 2000), used a targeted guide for older smokers and seven tailored computer-generated mailings as an adjunct to nicotine patch. The control group received a fact sheet on patch-assisted quitting. One study tested a single tailored letter as an adjunct to stage based manuals, and nicotine patch for people identified as ready to quit (Velicer 2006). This study also contributes to the following comparison.

Tailored self-help materials (Comparison 4)

Twenty-four trials used materials tailored according to the characteristics of individual smokers. Only one of these had any face-to-face contact as part of the baseline intervention (Lipkus 1999). Four recruited people who had called a quit line. In Borland 2003 only those callers seeking written materials without counselling were recruited. In Borland 2004 some had brief counselling prior to recruitment, and in Strecher 2005 and Sutton 2007 all participants received the counselling during their initial call. About half the remaining studies included volunteers who were likely to have been seeking help to quit. Eleven recruited a mix of people, some of whom were not interested in immediate quit attempts (Curry 1995; Velicer 1999; Lennox 2001; Prochaska 2001a; Prochaska 2001b; Aveyard 2003; Etter 2004; Prochaska 2004; Prochaska 2005; de Vries 2008; Schumann 2008) and one trial specifically recruited people not interested in quitting (Dijkstra 1999). Three trials evaluated multiple risk factor interventions so only a subgroup of participants were smokers (Prochaska 2004; Prochaska 2005; de Vries 2008).

Seven studies compared tailored materials to no intervention (Prochaska 2001a; Prochaska 2001b; Etter 2004; Prochaska 2004; Prochaska 2005; Meyer 2008; Schumann 2008). Some of the 16 trials testing the incremental effect of tailoring over standard materials confounded the tailoring with additional contact, so we grouped the trials according to whether or not the number of mailings was matched. Eight trials matched contacts (Burling 1989; Owen 1989; Becona 2001a; Velicer 1999; Lennox 2001; Strecher 2005; Velicer 2006; Sutton 2007). Of the trials with additional contact, some provided the same materials initially but then provided additional tailored materials to the intervention group, so we distinguished between five where all materials were tailored (Curry 1991; Prochaska 1993; Curry 1995; Aveyard 2003; Borland 2003) and three where materials were only partially tailored (Borland 2004; Dijkstra 1999; Ledwith 1984). One study used tailored materials as an adjunct to advice (Lipkus 1999).

The method used for obtaining information, the theoretical basis for tailoring materials and the number of contacts varied. Owen and colleagues used a microcomputer to personalize a four-part mailed course on the basis of the participants' baseline questionnaires (Owen 1989). Curry and colleagues used computer-generated feedback based on a baseline survey, aimed at enhancing self-efficacy (Curry 1995). Prochaska and colleagues supplemented materials matched to stage of change with three additional computer reports based on individuals' responses to questionnaires at start of treatment and at one and six months. All participants received the first report but only those returning questionnaires had the other two (Prochaska 1993). The same research group has reported replications of this in a larger population, controlling for the effect of number of contacts (Velicer 1999b), and comparing the tailored intervention to assessment without feedback or materials of any kind (Prochaska 2001a; Prochaska 2001b; Prochaska 2004; Prochaska 2005). Etter 2004 and Schumann 2008 used similar tailoring to Prochaska's group. Similar interventions were used in the dose response study (Velicer 1999); no significant effect of number of contacts was shown so these arms have been collapsed for this analysis, and the Expert System Three contact arm is not included since the same group is one arm of the trial reported in Prochaska 2001a. Dijkstra and colleagues compared individually tailored letters and manuals with standard materials alone. Single and multiple letter conditions have been combined in this comparison (Dijkstra 1999). A trial in Spain compared two computer-generated feedback reports as an adjunct to six standard pamphlets (Becona 2001a). A Scottish study compared a single tailored four-page letter from a family physician to an untailored letter (Lennox 2001). A Swiss population-based study compared up to three personally tailored letters and stage-matched booklets to no intervention. About half the participants did not return subsequent questionnaires so only received a single letter (Etter 2004). A German study used a similar schedule and tailoring method, sent to smokers who visited a general practice (Meyer 2008). In the meta-analysis we use the control group that received no materials. In a

second intervention group, patients received brief physician advice with untailored materials; we describe this comparison separately. A Dutch study compared a series of tailored letters to untailored letters (de Vries 2008). Two Australian studies provided quitline callers with either a Quit Pack containing standard written materials, or in addition tailored advice letters. In the first there were only three letters (Borland 2003) whilst in the second there were more letters and they aimed to provide greater support around a quit date (Borland 2004). About half the participants received five or more letters. A study in UK family practices recruited unselected smokers by mail; the tailored intervention group all received the same manual based on the stage of change and an expert system tailored letter. Two further questionnaires at three-monthly intervals were used to generate additional letters. About half the participants received the additional letters. One study (Lipkus 1999) prompted healthcare providers to intervene using the 4As model and the intervention group was sent a tailored newsletter based on responses to a baseline telephone survey. In two trials smokers in the intervention group did not necessarily receive any personalized materials, since they had to return a questionnaire first. One compared self help alone with feedback based on progress reports, with or without prize incentives to promote the use of the materials (Curry 1991). The other used personalized letters based on the responses to a questionnaire sent with the self-help materials (Ledwith 1984). One study (Burling 1989) provided an individualized nicotine-fading schedule based on data which participants entered daily into a computer, as an addition to pamphlets, a help line and a prize draw.

Other enhancements or adjuncts to self-help materials (Comparison 5)

Additional written materials

Four studies examined the effect of further mailings of untailored materials. In one, smokers who had succeeded in quitting for 48 hours were given an initial module booklet *How to cope with the urge to smoke without smoking* (Killen 1990). The control group received no further intervention. The self-selecting group then chose a further seven modules on avoiding smoking in specific high-risk situations. The final group were sent a random selection of modules at weekly intervals. These factors were crossed with a nicotine gum or placebo condition. Since no interaction was reported we have collapsed the gum conditions and combined the self-selected and random module groups. Another trial compared a Quit Kit with five-day cessation plan against a staged correspondence course (Owen 1989). In the third, the American Lung Association (ALA) *Freedom from smoking in 20 days* manual used in conjunction with a televised programme and additional maintenance newsletters was compared to manual and programme alone (McFall 1993). In one trial the materials were mailed six months after the quit kit (Cuckle 1984).

Additional video

One trial (Killen 1997) tested a video as an additional component. The factorial design also tested the effect of nicotine patches, and since there was evidence for an interaction between the NRT and the self-help condition the patch and placebo arms have been entered separately.

Materials targeted at particular populations of smokers

Five trials compared a manual targeted at a particular population to a standard one. Davis 1992 compared a programme intended for mothers with young children with ALA or National Cancer Institute (NCI) materials. Orleans 1998 compared a guide addressing the quitting needs and barriers of African-American smokers with a standard guide, mailed to smokers calling the NCI Cancer Information Service. Prochaska 1993 provided manuals tailored to the smoker's stage of change compared to standard materials. Another trial of manuals tailored for older smokers was excluded as no long-term follow up has been reported (Rimer 1994). Nollen 2007 compared culturally sensitive to standard materials for African-American smokers who also received nicotine patches and two phone calls.

Comparisons between different types of self-help material

We identified eight trials that compared different types of self-help materials that were neither tailored nor personalized, or delivered over different time periods (Glasgow 1981; Omenn 1988; ICRF 1994; Berman 1995; Becona 2001b; Sykes 2001; Clark 2004; Smith 2004). In two of these, three different sets of materials were compared (Glasgow 1981; Omenn 1988). ICRF 1994 compared a standard 16-page booklet with a larger manual containing more information about quitting with the use of a nicotine patch. Berman 1995 compared two types of materials for smokers volunteering for heart health screening and cessation. The intervention group received a minimally tailored message and letter, but not until after the three-month follow up, so we have not treated it as tailored. Becona 2001b compared a manual with a weekly mailing of six booklets, both based on the same cognitive behavioural approach. Sykes 2001 compared a cognitive behavioural programme consisting of a handbook, reduction cards, a progress chart and an audiotape, which summarized the programme and provided relaxation music, with a leaflet developed by the UK Health Education Authority, both used as an adjunct to a single introductory session in a group format. Clark 2004 compared a handout listing Internet sites providing useful resources to standard self-help materials. Smith 2004 compared materials produced by the Canadian Cancer Society; a 44-page booklet or a single page advice pamphlet. These were tested in a factorial design along with two different intensities of telephone counselling (which are collapsed in this review).

Risk of bias in included studies

Full descriptions of randomization and allocation concealment methods that we judged to have low risk of bias were provided in only 10 study reports (BTS 1983; ICRF 1994; Schofield 1999; Lennox 2001; Aveyard 2003; Borland 2004; Smith 2004; Velicer 2006; Sutton 2007; Schumann 2008). The majority of studies did not explicitly describe the way in which the randomization sequence was generated or concealed until patient enrolment. In many of the studies there was no face-to-face contact with participants and the likelihood of biased allocation was probably low. In three studies (Campbell 1986; Pederson 1983; Meyer 2008) a pseudo-random method of allocation by day or week of attendance was used, and one study (Hollis 1993) used numbers in the patient record. One study randomized physicians to intervention groups (Kottke 1989) and two randomized households (Lichtenstein 2000; Lichtenstein 2008). Two studies randomized by recruitment site (Berman 1995; Resnicow 1997). In some of these studies we judged that the method of generating the allocation could have led on to selection bias in the recruitment or assignment of patients. Excluding studies where we judged there could be a risk of bias due to an inadequate method of allocation concealment does not alter the conclusions from any meta-analysis.

Some reports give quit rates based only on those people contacted at follow up. In population-based studies it has been argued that it may be pessimistic, and introduce bias, to classify all drop-outs as continuing smokers if those data are missing at random (Velicer 1999). In this review we have followed the methods of the Cochrane Tobacco Addiction review group in reporting analyses based on the total number randomized wherever possible, with drop-outs and participants lost to follow up classified as smokers. We have noted in the Risk of Bias table the number of drop-outs by group, and whether the data used in this review included all randomized participants. Where the proportion of drop-outs was high and differed across treatment conditions we performed sensitivity analyses to assess whether excluding drop-outs would affect the conclusions. It should be noted that if the proportion of drop-outs is similar across conditions, including losses as treatment failures does not affect the risk ratio.

Studies reported a range of measures of abstinence. A minimum period of follow up of six months was required for inclusion in the review, but 44/68 (65%) had a longest follow up at 12 months or more. Thirty-one of these required abstinence to have been sustained for a period. Trials that used strict criteria for self-reported sustained abstinence, with validation at one or more follow-up points, tended to report lower quit rates for both experimental and comparison interventions. In minimal contact programmes, obtaining saliva samples for biochemical validation was often reported to be a problem. Participants may have declined to provide samples for reasons unrelated to their smoking status. Validated quit rates may therefore be particularly low, and are likely to underestimate success rates if all those for whom samples are

not available are classified as smokers. Measures using abstinence from the first follow up may underestimate the long-term effect of having access to the self-help materials, which may prompt a quit attempt some time after they were supplied. Trials with long follow up which only use point prevalence abstinence rates may show a trend of increasing quit rates as more smokers make attempts over time.

Biochemical validation of all self reports of quitting, or sufficient data to adjust quit rates for the level of misreport in a sample, were available in 22 studies (Glasgow 1981; BTS 1983; Cuckle 1984; Campbell 1986; Harackiewicz 1988; Omenn 1988; Burling 1989; Kottke 1989; Curry 1991; Orleans 1991; Davies 1992; Hollis 1993; ICRF 1994; Fortmann 1995; Killen 1997; Humerfelt 1998; Schofield 1999; Becona 2001a; Lennox 2001; Sykes 2001; Clark 2004; Nollen 2007). In three cases quitting was confirmed by a significant other (Prue 1983; Cummings 1988; Davis 1992). Amongst those that did not report fully biochemically verified quit rates, 11 studies (Pederson 1983; Prue 1983; Janz 1987; Thompson 1988; Owen 1989; Lando 1991; Resnicow 1997; Orleans 1998; Dijkstra 1999; Lipkus 1999; de Vries 2008) used self-reported abstinence at a single follow-up point. In the other studies without validation, participants classified as nonsmokers had either reported sustained abstinence, or been abstinent at one or more points prior to the final follow up.

Effects of interventions

Trials varied in the amount of face-to-face advice or counselling given to both experimental and comparison interventions, and in whether or not control materials were given to smokers in the comparison group. In considering the effects of self help, we grouped trials by these categories. In Comparison 1 we calculated a pooled risk ratio (RR) separately for each level of personal contact with subgroups for the type of control. In Comparison 2 we used the same trial data and pooled all subgroups in order to estimate an overall pooled RR from all trials comparing self help to no self help.

Self-help materials compared to no intervention (Comparisons 1&2)

Self-help materials without face-to-face contact

There were 14 trials with a total of over 15,500 participants where standard non-tailored self-help manuals or materials were provided by post, and control groups did not receive any materials. There was substantial heterogeneity ($I^2 = 70\%$) attributable to the inclusion of two trials conducted in Spain (Becona 2001a; Becona 2001b) that showed very strong effects. Both trials enrolled treatment-seeking smokers, and those in the control group knew they

would be offered treatment after six months, a possible disincentive to make an unaided quit attempt. Quit rates were also very high in the intervention groups (16% and 25%). We have therefore excluded these studies from this meta-analysis and calculated a pooled estimated effect for the other 12 trials amongst which there was no evidence of heterogeneity ($I^2 = 0\%$). Amongst these trials the control quit rate ranged from 1% to 11%, with an average of 5%, and the intervention quit rate from 2% to 10%. The pooled risk ratio favoured the self-help intervention, although the confidence interval (CI) only narrowly excluded 1.0 (N = 15,711; RR 1.21; 95% CI 1.05 to 1.39; comparison 2.1.1). Five trials in which the controls received some form of written materials did not show any trend towards a benefit of more structured materials, with the pooled risk ratio for this subgroup being less than 1.0 (N = 6,626; RR 0.85; 95% CI 0.70 to 1.05; comparison 2.1.2). If these two subgroups are pooled there is no longer evidence for a benefit of structured materials, (RR 1.08; 95% CI 0.97 to 1.21). (Note: Analysis 01.01.01 includes both Becona studies, analysis 02.01.01 excludes their data; subgroup analyses reported in text may not match forest plots.)

Self-help materials with brief contact

In the group of five trials in which the materials were delivered in person rather than by post there were almost 4000 participants, and an average control group quit rate of 9%. There was no evidence of heterogeneity and we failed to find evidence for a significant effect of self-help materials given with face-to-face contact whether or not controls received some written materials (N = 3,866, RR 1.17; 95% CI 0.96 to 1.42, comparison 1.2).

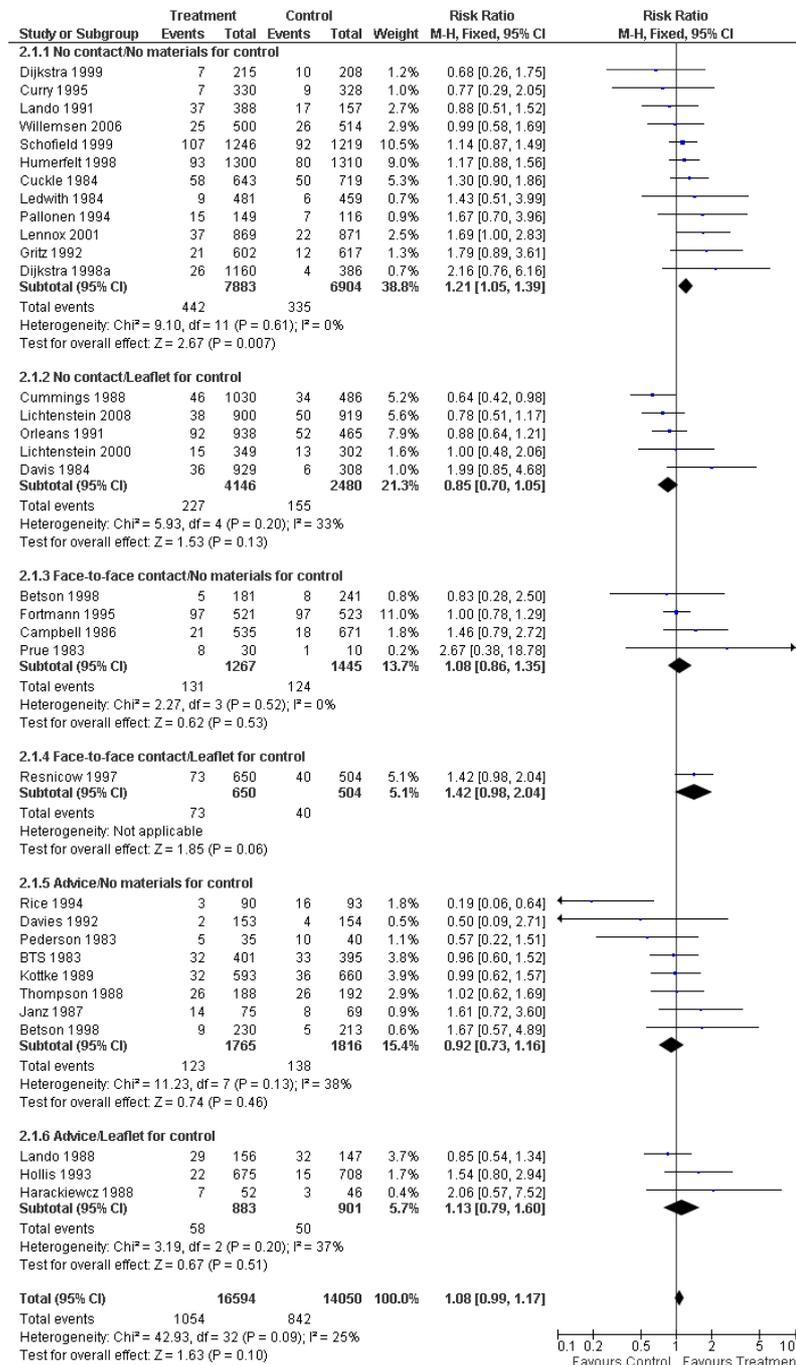
Self-help materials and advice versus advice alone

There were 11 trials with a total of over 5,000 participants in which self-help materials were tested as an adjunct to face-to-face advice from a healthcare provider. There was little heterogeneity and we did not find evidence that the additional self-help materials significantly increased quit rates whether controls did (N = 1,784; RR 1.13; 95% CI 0.79 to 1.60 $I^2 = 38\%$; comparison 1.3.2), or did not (N = 3,581; RR 0.92; 95% CI 0.73 to 1.16, $I^2 = 37\%$; comparison 1.3.1) get some materials. The control group quit rates ranged from 2% to 25% with an average of 7%. As would be expected, this is higher than the rates seen in control groups that received no intervention.

Effect of self-help, alone or as adjunct to advice

When we pooled 32 trials of self-help materials compared to no self help (excludes Becona 2001a and Becona 2001b, Betson 1998 contributes to two subgroups), irrespective of level of contact and support common to the control group (Comparison 2) there was no evidence of an effect and little heterogeneity (N = 31,568; RR 1.08; 95% CI 0.99 to 1.17, $I^2 = 25\%$). Figure 1

Figure 1. Forest plot of comparison: 2 Self-help vs no self-help, pooling all studies, outcome: 2.1 Long term abstinence.



Self-help materials plus nicotine replacement therapy (NRT) compared to NRT alone (Comparison 3)

The four trials that specifically examined self-help materials in addition to NRT did not show any evidence of an additional benefit from the materials over the relatively high quit rates achieved by use of NRT (N = 2,291; RR 1.05; 95% CI 0.88 to 1.25, $I^2 = 0\%$; comparison 3.1) The control group quit rate was over 20% in three of the four studies. There was no difference in results between the two trials using standard materials and the two that tailored materials. One study relevant to this category was excluded because follow up was too short (Strecher 2005b). This study compared an Internet-based tailored programme to internet-based non-tailored material for smokers who had purchased nicotine patch and logged on to use the behavioural support programme. In this large study the difference between continuous abstinence rates was significant after 12 weeks (23% versus 18%). It is not known whether this advantage would have been maintained had there been longer follow up.

Tailored self-help materials (Comparison 4)

Based on seven studies, participants receiving tailored self-help materials had higher quit rates than those receiving no materials at all (N = 10,872; RR 1.36; 95% CI 1.19 to 1.55, $I^2 = 0\%$; comparison 4.1.1). Control group quit rates were 4-7% largely based on sustained but self-reported abstinence with the exception of Prochaska 2005 which only reported point prevalence quit rates. In other trials of tailored materials the control groups received standard self-help materials. The subgroup of eight trials in which the intervention and control groups were matched for number of contacts showed an effect of borderline significance with some evidence of heterogeneity ($I^2 = 44\%$) largely contributed by Becona 2001a where there was a significant effect of weekly feedback reports. Excluding this trial reduced heterogeneity and the effect was no longer significant (N = 9,584, RR 1.09; 95% CI 0.95 to 1.26, $I^2 = 12\%$; comparison 4.1.2 with Becona excluded). One trial (Sutton 2007) included some recent quitters for whom the effect of intervention was smaller but restricting inclusion to those still smoking at enrolment had little impact on the pooled estimate. Velicer 1999 showed an almost significant effect based on numbers randomized. Excluding drop-outs from the denominators increased the estimated effect a little because more people were lost from the expert system intervention groups. This trial also tested different numbers of tailored versus untailored mailings, but did not detect a consistent dose response effect (data not shown). Amongst the five studies where tailored materials were compared to a non-tailored control, but with the effect potentially confounded by the increased contact, results were consistent. Although none of these studies individually had statistically significant results, the pooled estimate suggested a small benefit of the intervention (N = 4,682; RR 1.47; 95% CI 1.11 to 1.94; comparison 4.1.3). In the group of three studies where only the additional materials were

tailored, there was also evidence of benefit (N = 1,787; RR 1.72; 95% CI 1.25 to 2.37; comparison 4.1.4). The study that sent tailored newsletters as well as prompting physician advice showed a benefit of the materials (Lipkus 1999, RR 2.48; 95% CI 1.13 to 5.45; comparison 4.1.5).

If the differences in the details of tailoring, and amount of contact are taken to be of limited importance, and all 25 studies are pooled, there is only limited statistical heterogeneity and there is evidence of an overall benefit from tailored materials (comparison 4.1). The estimate remains almost unchanged if we exclude the trials (subgroup 4.1.1) where there was a no-intervention control (N = 17,317; RR 1.27; 95% CI 1.14 to 1.43, $I^2 = 35\%$). This supports a conclusion both that tailored materials increase the number of quitters and that they do so more than standard materials.

Tailored materials compared to brief advice and standard materials

Meyer 2008 reported similar effects on prolonged quitting (abstinent for 6 months at 24 month follow-up) for tailored materials (10.2%) and brief advice from a physician and stage matched materials (9.7%) (RR 1.06, 95% CI 0.71 to 1.57)

Other enhancements or adjuncts to self-help materials (Comparison 5)

Additional written materials

Pooling four trials of additional written materials failed to detect a significant benefit (RR 1.01; 95% CI 0.87 to 1.17; comparison 5.1.1). One of the trials (Cuckle 1984) did not send further materials until six months after the initial 'quit kit', but excluding this does not affect the estimate.

Additional video

The trial that used a video as an adjunct to written materials (Killen 1997) did not detect a significant overall benefit. There was a non-significantly lower quit rate in the active nicotine patch group amongst those who received the video as well as written materials.

Materials targeted at particular populations of smokers

Five trials of materials targeted at specific populations failed to show evidence for a significant benefit compared to standard materials (N = 3,101; RR 1.11; 95% CI 0.90 to 1.37; comparison 5.1.3). In two of the studies callers to quitlines were given telephone counselling before being sent materials (Davis 1992; Orleans 1998 (in which the counselling was also tailored)), and in one, all participants received nicotine replacement therapy (Nollen 2007). These common components may have contributed to the success in quitting in all groups and limited the potential to detect effects of small differences in adjunct materials.

Comparisons between different types of self-help material

We did not perform meta-analysis of this heterogeneous group of trials. Two small trials each compared three variants of materials (Glasgow 1981, N = 88; Omenn 1988, N = 243); neither detected statistical differences in quit rates between any conditions. A trial with 1,686 participants also found no significant difference in outcome between those given a longer or a shorter booklet when used in conjunction with either a nicotine or placebo patch and nurse support (ICRF 1994). Berman 1995 compared two types of materials for 348 smokers volunteering for heart health screening and cessation. There were no significant differences in any measure of quitting. Clark 2004 (N = 171) did not detect the hypothesized benefit of a list of internet resources over standard material. The results favoured the standard materials but with wide confidence intervals. A study comparing weekly mailings to a single manual detected no significant difference at six or 12 months (Becona 2001b, N = 482). There was no evidence of a difference between a 44-page booklet or a pamphlet when used as adjuncts for motivated quitters receiving an extended telephone counselling session and one of two intensities of follow-up counselling (Smith 2004 N = 632). One trial (Sykes 2001, N = 260) showed a statistically significant effect after six months with a more than three-fold increase in the odds of quitting using a cognitive behavioural programme compared to a standard leaflet, with both used as an adjunct to a single introductory session in a group format. This was not sustained at 12-month follow up (Marks 2002).

DISCUSSION

In this review, we defined self-help materials as those providing structured approaches to smoking cessation. Using this definition, there was little evidence that such materials, used on their own, increased the number of people able to quit smoking.

In trials in which mailed materials were compared with a no-intervention control, the quit rate increased by 20%. This result just reached statistical significance as the confidence interval around this estimate just excluded 1.0. The results of most of these trials were reasonably consistent, but we excluded two trials (both by the same authors) from the pooled estimate because they were the source of significant heterogeneity: these two trials showed benefits for self-help materials. None of the other trials had significant results for the outcome used in this review. While it is probable that there was a small effect of the materials compared to no treatment, this corresponds to an absolute difference in quit rates of about 1% at best (Number needed to treat = 100). This effect was lost if we included trials where controls received some alternative written materials about the health effects of smoking.

There was no evidence of a significant effect when the materials were handed out with face-to-face contact but without advice

about smoking cessation. In this comparison there were four trials without, and one with, materials for the control group. The trial contributing the greatest weight (Fortmann 1995) only included smokers who had successfully quit for 24 hours, and where some smokers were additionally receiving nicotine gum - excluding gum groups did not affect the summary outcome. However this trial design was testing the effectiveness of self-help materials in preventing relapse, not in motivating a quit attempt or aiding immediate success.

Another Cochrane systematic review has shown that physician advice increases quitting compared to no advice or usual care (Stead 2008a). The present review suggests that providing additional self-help materials in addition to advice from a healthcare professional does not improve the outcome. This set of comparisons includes 11 trials with over 5000 participants. The upper limit of the 95% confidence interval for the pooled estimate of an effect is a risk ratio of 1.18, but when calculated as an absolute difference, the increase in quit rates would be no more than 1%. Russell's widely quoted study of the effects of advice from doctors in primary care (Russell 1979), suggested that the addition of a leaflet along with a warning of follow up produced an incremental benefit. This effect was not consistently replicated in later studies. Russell's trial was not included in the present review, as the information leaflet was not substantial enough to qualify as self help. However its inclusion in a sensitivity analysis did not alter the conclusions.

There is similarly little evidence of an effect for self-help materials in addition to nicotine replacement therapy (NRT). There have been other trials using personally tailored materials instead of standard materials combined with nicotine gum or patch (Shiffman 2000; Shiffman 2001; Strecher 2005b). They report only short follow up and are therefore not included in this review, but combining tailored materials with NRT may be a promising field for further research.

One reason that it may be difficult to show efficacy for standard self-help programmes is the level of 'contamination'. Materials encouraging smokers to quit and giving tips are already relatively widely disseminated, so that smokers in a control arm who are motivated to try to give up may well have access to the same kinds of materials that experimental group smokers have been given. On the other hand, there may be more fundamental reasons why behavioural interventions are more effective when delivered by face-to-face contact. Killen has suggested, for example, that the self-regulatory skills required to withstand the urge to smoke may be better learnt, rehearsed and retained under direct supervision from a therapist than through the simple modelling offered by self-help materials (Killen 1997). Strecher has suggested that the length of generic self-help manuals and pamphlets may discourage effective use of materials (Strecher 1994). Meade 1989 suggested that self-help materials may be too advanced for many readers and that comprehension can be improved by adjustment of the reading grade level. Tailored materials may have the potential to address

these issues.

Enhancing self-help programmes

One of the main criticisms of traditional self-help materials is that they do not take account of individual characteristics and problems in dealing with smoking cessation. This could account for the failure of self-help materials to match the effect of counselling delivered individually or in groups. Tailoring materials to individuals' habits and motivations is an attractive theoretical approach to enhancing the efficacy of such materials. In this review, individually tailored materials appeared to be effective compared to no self-help intervention. One limitation of the conclusions on the benefit of tailoring compared to standard materials is that in a number of studies the tailoring is confounded with additional contact. The small number of studies where contacts were matched had heterogeneous outcomes. One of these studies tested different number of contacts without detecting a dose response effect, but the tailored materials tended to outperform the standard ones whatever the number of contacts. We are inclined to the view that contact or assessment alone is unlikely to contribute much to the impact of tailoring, and has to form part of the tailoring process. Under this assumption pooling all studies of tailored materials versus standard materials can be justified and the evidence suggests not only that they are more effective than no intervention, but also that they are more effective than standard materials. It should be noted though that even large individual studies have mostly failed to detect statistically significant long-term effects, and the absolute increase in quit rates attributable to the use of tailored materials is still small. Two of the authors of studies included in this meta-analysis are cautious about the effects of some types of tailoring. Aveyard is sceptical about the benefit of the expert system tailoring based on the transtheoretical ('stages of change') model (TTM) as implemented in their trial in unselected smokers (Aveyard 2003). Borland (Borland 2003) also concluded that tailoring using the TTM did not improve quit rates for smokers calling a quitline. However in a second trial using an improved system of tailoring this group did detect an improvement over standard materials (Borland 2004).

There is as yet insufficient evidence to determine which elements of personalizing information to individual smokers may be important, and which theories should inform the tailoring of materials (Skinner 1999; Strecher 1999). The authors of a study using personalization as a placebo for individualized tailoring whilst manipulating expectancies suggest that the non-specific effects of tailoring may be relevant (Webb 2005). Another study amongst students who were told they were evaluating messages to be used in self-help materials suggested that both personalizing and feedback might contribute to the effect of tailored materials (Dijkstra 2005). Although three of the largest studies have been conducted by Prochaska and colleagues, other groups have also shown similar sizes of effect. In one study where tailoring did not appear beneficial the intervention materials were very brief and did not give

much information about how to quit. The authors have discussed a number of explanations for this negative finding (Reiter 2003). In considering whether and how to tailor materials it appears to be important to consider the broad characteristics of the population who will be targeted. Callers to a quitline are likely to require advice geared to making their quit attempt successful rather than the motivational elements which may be appropriate to a broader population-based intervention. One group of researchers has noted that whilst tailoring based on the transtheoretical model typically generates a large proportion of unique materials for smokers in contemplation, preparation, action, and maintenance, even if only normative data is used, the variability in materials is much smaller for smokers in precontemplation (Schumann 2008b). Absolute increases in quit rates depend to some extent on the population recruited to the intervention. In one of the largest studies (Velicer 1999), which recruited 85% of identified smokers in a Health Maintenance Organisation, there was a 1.5% to 3% increase in six-month sustained abstinence at 18 months compared to standard materials, depending on assumptions about the smoking status of smokers lost to follow up. This is similar to the average absolute increase in quit rate of 1% to 3% when all tailored trials are pooled. Self-help interventions are probably most appropriately used as an intervention for smokers who are not already in contact with a healthcare system, but tailored interventions depend on the ability to obtain some baseline data. It is possible to proactively recruit substantial numbers of smokers, including those who are not already planning to quit in the near future. In a large Swiss study using postal recruitment, 74% of the recruits were precontemplators, and 60% did not report a quit attempt in the previous year (Etter 2004). Prochaska and colleagues used telephone to recruit a group of smokers, 42% of whom were precontemplators (Prochaska 2001b).

Methodological considerations

Our conclusions about the effect of self-help materials are based on an intention to treat analysis in which all randomized participants are included whether or not they received the intended intervention. A number of studies reported subgroup analyses showing that quit rates were higher amongst those who made more use of the programme. However, we cannot assume that this is a causal relationship, since it may be that those prepared to read a manual were those already most motivated and equipped to quit successfully. Tailored materials may produce a benefit because they are more appealing and readable so that more people use them. We also make the assumption that participants who cannot be reached for follow up or who decline further participation are all still smoking. It has been argued that in minimal contact population-based studies participants may be unreachable for reasons unrelated to their smoking status, and that the assumption that they are all smokers leads to unnecessarily conservative quit rates (Hall 2001; Prochaska 2001a). Prochaska, Velicer and colleagues

distinguish between those lost to follow up and those who withdraw from the trial. We have used numbers randomized in our primary analysis, but conducted a sensitivity analysis of the effect of using numbers followed up as the denominator. This of course increases the average quit rates in both intervention and control groups, but since drop-out rates are typically quite similar across study arms it has only a small impact on the estimate of the relative effect. It has no effect on the conclusions about tailoring.

It is well recognized that the majority of ex-smokers state that they have given up without the aid of a formal cessation programme. As Fisher and colleagues have pointed out (Fisher 1993) 'they have quit amongst a substantial array of health education messages, encouragement from health professionals ...changes in norms related to smoking ... and the experience gained from their own prior quit attempts'. Information is an important part of individual participation in all forms of health care, and the provision of written and other forms of information to smokers has important face validity. However, the effects of providing standardized self-help materials are modest at best. Smokers who seek help are likely to benefit more from brief advice or counselling, or from tailored materials. Trials of internet-based systems offering tailored support are due to be evaluated in a separate Cochrane review (Civljak 2009). This may prove to be a powerful way to give smokers access to individualized resources.

AUTHORS' CONCLUSIONS

Implications for practice

Access to information, in understandable formats, is important for individuals who smoke, as it is for those with other kinds of medical problem. This review examined the specific effect of materials which aimed to provide a structured approach to smoking cessation beyond simple information. Such materials may provide a very small increase in quitting compared to no intervention. We did not find evidence that self-help materials produce incremental benefits over other minimal interventions such as advice from a healthcare professional, or nicotine replacement therapy. There is increasing evidence that materials that are tailored for individual smokers are more effective than no intervention, and more effective than non-tailored materials, although the absolute increase in quit rates is still small.

Implications for research

Future research in this field is likely to focus on ways of further individualizing self-help materials, delivered in a variety of formats.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Aveyard 2003

Methods	Setting: 65 general practices, UK Recruitment: volunteers from random selection of smoking patients, not selected for motivation
Participants	2471 smokers, 1373 in relevant arms, >80% in precontemplation or contemplation, 10-14% in preparation. 54% F, av. age 41, av. cpd 20
Interventions	No face-to-face contact. 1. Standard S-H materials, single mailing 2. S-H manual based on Transtheoretical (SoC) model, expert system letter tailored on baseline questionnaire. Further questionnaires at 3m & 6m for additional letters (approx 50% received 3 letters).
Outcomes	Abstinence at 12m, sustained for 6m Validation: saliva cotinine < 14.2 ng/ml
Notes	2 vs 1, tailored S-H vs standard S-H

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Randomization using minimization to balance SoC, addiction and socio-economic status
Allocation concealment?	Yes	Baseline questionnaires were read optically and data transferred automatically to the Access database that performed the minimization.
Incomplete outcome data addressed? All outcomes	Yes	24% of S-H and 24% control lost to follow up. Included in ITT analysis here, sensitivity analyses allowing for differential drop-out did not change findings

Becona 2001a

Methods	Setting: community, Spain Recruitment: community volunteers, mainly in contemplation or preparation SoC
Participants	300 smokers; 48% F, Av. age 37, av. cpd 26

Becona 2001a (Continued)

Interventions	1. No intervention. Treatment offered after 6m follow up 2. Standard S-H pamphlets, 6 mailed weekly with personalized letter 3. As 2 with individual feedback based on weekly reports + 2 additional 1 page reports.	
Outcomes	Abstinence at 6m or 12m, sustained since initial quit. Validation: CO < 9ppm	
Notes	2 vs 1, S-H vs control, excluded from MA comparison 2 due to heterogeneity. Quit rates 16% vs 0% at 6m 3 vs 2, 12m outcome, tailored materials	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomization method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	<10% lost to follow-up, included in ITT analyses

Becona 2001b

Methods	Setting: community, Spain Recruitment: smokers interested in quitting within 6m	
Participants	724 smokers; 42% F, av. age 37, av. cpd 26	
Interventions	1. Waiting List control (only followed for 6m) 2. S-H Manual 3. S-H brochures sent weekly	
Outcomes	Abstinence at 12m (30 day PP) or 6m (7 day PP) Validation: CO at 12 m	
Notes	3+2 vs 1, S-H vs control, 6m follow up. Excluded from MA comparison 2 due to heterogeneity. 2 vs 3 comparison between materials, not included in MA	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomization method not described
Allocation concealment?	Unclear	No details given

Becona 2001b (Continued)

Incomplete outcome data addressed? All outcomes	Yes	All randomized participants included in ITT analysis
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Berman 1995

Methods	Setting: multi-ethnic community, USA Recruitment: via schools, smokers interested in health screening and cessation
Participants	348 smokers; 51% F, average 37
Interventions	All participants received cardiovascular health screening and educational materials. 1. Freedom from Smoking for you and Your Family or Spanish equivalent. Minimally tailored message at completion of 3m telephone follow up and tailored letter (Group class offered after 6m follow up) 2. How to Double your Quitting Power and Spanish equivalent.
Outcomes	Abstinence at 6m, continuous (other outcomes also reported, no differences in findings) Validation: attempted unsuccessfully at 12m
Notes	No non-S-H control so does not contribute to main analysis. No differences at any time point or definition of abstinence.

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	No	Randomized by school using coin toss; but for cluster randomized trials this does not ensure balance of participant individuals
Allocation concealment?	No	Participants were enrolled proactively after randomization so potential for selection bias. Fewer participants in control (179) than experimental (267) conditions
Incomplete outcome data addressed? All outcomes	Yes	218 (62.6%) reached at 12m follow up

Betson 1998

Methods	Setting: government outpatient clinic, Hong Kong Recruitment: smokers aged < 65
Participants	865 smokers; 92%M, 49% smoking >10 cpd

Betson 1998 (Continued)

Interventions	<ol style="list-style-type: none"> 1. No intervention 2. S-H materials (Chinese translation of American Cancer Society booklet) 3. Physician advice (1min, based on 4As) 4. Physician advice and S-H booklet 	
Outcomes	Abstinence at 1 yr (sustained from 3m) Validation: poor response to request for urine specimen so data based on self report	
Notes	2 vs 1, S-H with face-to-face contact 4 vs 3, S-H as adjunct to advice Full paper provided by Professor Lam.	
Risk of bias		
Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Table of random numbers used to allocate questionnaires to four groups placed in sealed numbered envelopes
Allocation concealment?	Unclear	'Every doctor was given a set of sealed envelopes'. There was considerable imbalance in numbers in each group, unclear whether this was due to randomization procedure or selection bias.
Incomplete outcome data addressed? All outcomes	Yes	36% lost to follow up, included in ITT analysis

Borland 2003

Methods	Setting: Quitline, Australia Recruitment: smokers seeking materials or counselling	
Participants	1578 smokers, 1050 in relevant arms; 54% F, modal age 30-49, av. cpd 23	
Interventions	<ol style="list-style-type: none"> 1. Standard S-H Quit pack based around SoC 2. Additional tailored letters at baseline, and at 3m and 6m based on mailed assessments 3. Additional proactive TC (not incl in this review) Some participants in all groups received brief reactive counselling before enrolment	
Outcomes	Abstinence at 1 yr (sustained for 9m) Validation: none	
Notes	2 vs 1, tailored S-H vs standard S-H.	
Risk of bias		

Borland 2003 (Continued)

Item	Authors' judgement	Description
Adequate sequence generation?	No	'Shuffling questionnaires'
Allocation concealment?	Unclear	'no opportunity for interviewers to influence choice of condition' so bias judged unlikely
Incomplete outcome data addressed? All outcomes	Yes	Follow up 78.9% for 1. 76.9% for 2. Losses included in ITT analysis. Excluding losses would marginally lower effect size

Borland 2004

Methods	Setting: Quitline, Australia Recruitment: Callers wanting written S-H materials
Participants	772 baseline smokers (baseline quitters not included in this review); 54% F (all participants), approx 47% aged < 30, av.cpd 19
Interventions	1. Standard S-H quit pack 2. Additional tailored letters, based on assessment phone calls. Av number 5.7 (SD 4.6)
Outcomes	Abstinence at 12m (sustained for 6m) Validation: none
Notes	2 vs 1, tailored S-H vs standard S-H. No control for effect of multiple contact

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Computer-generated ID numbers, even numbers allocated to intervention
Allocation concealment?	Yes	ID number generated after agreement to participate obtained
Incomplete outcome data addressed? All outcomes	Yes	Follow up 71.3% for 1. 63.8% for 2. Losses included in ITT analysis. Excluding losses would lower effect size

BTS 1983

Methods	Setting: Hospital chest clinics and inpatient wards, UK Recruitment: Patients with smoking-related conditions
Participants	748 smokers (in relevant arms); av age 49, av cpd 24
Interventions	1. Brief advice to quit from a physician 2. Advice and S-H booklet containing information and advice 3. Same as 2. plus placebo chewing gum (not included in this review) 4. Same as 2. plus nicotine gum (not included in this review)
Outcomes	Sustained abstinence 6-12m (2m PP) Validation: venous carboxyhaemoglobin and thiocyanate
Notes	2 vs 1, S-H vs control.

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Centrally generated, 'each physician initially received a balanced block of 12 treatments'
Allocation concealment?	Yes	Numbered envelopes, opened after eligibility assessed
Incomplete outcome data addressed? All outcomes	Yes	48 withdrawals reincluded in this analysis but has no impact on effect size

Burling 1989

Methods	Setting: Veterans Administration Medical Centre, USA Recruitment: VA employees
Participants	58 smokers; av age 44, av cpd 27
Interventions	1. American Cancer Society and ALA pamphlets about smoking, a telephone hotline, and a stop-smoking contest which gave vouchers for a draw, for each day when expired CO < 8ppm. 2. As 1 + use of a computer to enter data on smoking behaviour and smoke a cigarette through a filter attached to the computer; this produced an individualized nicotine fading programme, explained in an accompanying manual.
Outcomes	Abstinence at 6m Validation: CO < 8ppm
Notes	2 vs 1, tailored S-H vs standard S-H.

Burling 1989 (Continued)

<i>Risk of bias</i>		
Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	4 drop-outs reincluded in denominators for this review

Campbell 1986

Methods	Setting: Two chest clinics in Scotland, UK Recruitment: Smokers attending outpatient clinic (unselected)
Participants	1206 smokers referred for chest radiography; 44% aged > 50
Interventions	1. S-H. 13 page booklet. 2. No treatment control
Outcomes	Abstinence at 1 yr (self report of no smoking for 6m) Validation: expired CO < 10ppm, non-attenders classified as smokers.
Notes	Face-to-face contact but no advice

<i>Risk of bias</i>		
Item	Authors' judgement	Description
Adequate sequence generation?	No	Quasi-random (interventions alternated fortnightly)
Allocation concealment?	No	All smoking patients attending were eligible so potential for selection bias probably low, but there was an imbalance in age distribution between groups
Incomplete outcome data addressed? All outcomes	Yes	Follow up 74.5% intervention, 74.1% control, losses included in ITT analysis

Clark 2004

Methods	Setting: Lung cancer screening centre, USA Recruitment: smokers enrolled in a screening study 1 yr previously
Participants	171 smokers; 21% in precontemplation, 29% F, av age 57, 46% smoked 11-20 cpd
Interventions	1. List of internet cessation resources, 10 sites with brief descriptions. 2. S-H manuals <i>Clearing the Air</i> and <i>Quit Smoking Action Plan</i>
Outcomes	Abstinence at 12m (7 day PP) Validation: CO
Notes	Comparison between S-H interventions. Not in MA. Authors' hypothesis was that 1. would be superior. OR 0.44, 95% CI 0.12 to 1.43

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	Number lost to follow up not reported but all included in ITT analysis

Cuckle 1984

Methods	Setting: Community exposed to a 15min tv programme with offer of a smoking quit kit, UK Recruitment: Random sample of individuals requesting a kit
Participants	4492 smokers randomized. Results based on 2117 (47%) who replied to a baseline and follow-up questionnaire.
Interventions	1. Control - letter apologising for shortage of kits 2. Quit Kit 3. Quit Kit and additional material 6m later.
Outcomes	Abstinence at 12m Saliva cotinine from 66% of quitters. Quit rates corrected by the disconfirmation rate found for each group
Notes	2 vs 1, S-H vs control. 3 vs 2, additional materials

Risk of bias

Item	Authors' judgement	Description
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Cuckle 1984 (Continued)

Adequate sequence generation?	Unclear	'One-third were chosen at random as controls and did not receive a kit'
Allocation concealment?	Unclear	No details given, but no personal contact so selection bias unlikely
Incomplete outcome data addressed? All outcomes	No	Low response rate in a population-based study so only participants who replied to baseline questionnaire and follow-up questionnaire were included. Response rate to baseline questionnaire was 70% in control group compared to 39% for those receiving a kit.

Cummings 1988

Methods	Setting; Stop smoking hotline, USA Recruitment: Callers who accepted offer of a stop smoking booklet and who agreed to follow up
Participants	1895 smokers; 65% F, av age 42, av cpd 28, 89% had made at least 1 prior quit attempt
Interventions	First 4 groups received similar length (+/- 50 pages) and format booklets, differing in precise instructions 1. High structure (day by day plan) recommending 'cold turkey' quitting 2. High structure recommending gradual reduction 3. Low structure (menu of exercises), gradual reduction 4. Low structure, 'cold turkey' 5. Control booklet, 15 pages stressing health effects of smoking
Outcomes	Abstinence from 1m-6m, self report by telephone interview with blinded assessors. No biochemical validation, confirmation by a significant other used
Notes	1-4 vs 5 in main analysis

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	Analyses based on participants reached at 1m and 6m follow up, 89% of those randomized. Drop-out rates similar in all groups.

Curry 1991

Methods	Setting: HMO, USA Recruitment: Advertisement for study in HMO magazine
Participants	1217 smokers; av age 44, av cpd 25
Interventions	Factorial design 1. S-H programme, <i>Breaking Away</i> 2. S-H and up to 3 sets of personalized feedback based on baseline questionnaire and progress reports (intrinsic motivation) 3. S-H and incentives including a prize draw for returning progress reports (extrinsic motivation) 4. S-H and intrinsic and extrinsic motivation
Outcomes	Sustained abstinence at 12m (7-day at 3m and 12m) Validation: Saliva cotinine ≤ 10 ng/ml at 12m for abstainers in locality. Correcting for disconfirmation rates did not affect sustained abstinence numbers.
Notes	4&2 vs 3&1 for effect of personalized feedback (tailoring). Extrinsic motivation did not increase quit rates. Aim was to increase use of materials.

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, stratified by gender and cpd, no other information
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	No information on number lost, all randomized participants included in ITT analysis

Curry 1995

Methods	Setting: HMO, USA Recruitment: Smokers identified via a telephone survey of health behaviour in a random sample of HMO members (unselected)
Participants	1137 smokers; 53% F, av age 41, av cpd 17
Interventions	No face-to-face contact 1. Control - no materials 2. S-H booklet (<i>Breaking Away</i>) with units to complete, relevant to all stages of readiness to quit. 3. As 2 plus feedback based on computer analysis of initial survey. Included a hand-written form, and a list of relevant parts of booklet. 4. As 3 plus up to 3 counsellor-initiated phone calls (not included in this review)

Curry 1995 (Continued)

Outcomes	Sustained abstinence 3m-12m Validation: saliva cotinine requested but not obtained for all participants. Disconfirmation rates not significantly different between groups.	
Notes	12m rather than 21m follow up used for comparability with other studies. Author confirmed numbers quit 2 vs 1 in S-H vs control, 3 vs 2 in effect of tailoring	
Risk of bias		
Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	No information on number lost, all randomized participants included in ITT analysis, sensitivity analysis excluding non-respondents did not alter results

Davies 1992

Methods	Setting: Community, Ottawa, Canada Recruitment: Each of 156 nursing students recruited 2 non-hospitalized smokers (selected)	
Participants	307 smokers; Av age 36, av cpd 20	
Interventions	1. List of community resources, delivered during a home visit by a nursing student 2. <i>Time to Quit</i> (TTQ) S-H booklet + list of community resources, delivered by a nursing student following training in the TTQ programme.	
Outcomes	Abstinence at 9m Validation: saliva cotinine <100ng/ml	
Notes	It is unclear what advice was given to the control group. Marginal to include since S-H confounded by student training, but does not affect MA	
Risk of bias		
Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given

Davies 1992 (Continued)

Incomplete outcome data addressed? All outcomes	Yes	Participants lost to follow up reincluded as smokers for MA
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Davis 1984

Methods	Setting: Local communities with Lung Associations, USA Recruitment: Media advertisements for American Lung Association (ALA) S-H materials
Participants	1237 smokers who completed a questionnaire and paid a refundable deposit.
Interventions	No face-to-face contact 1. ALA leaflets (8 leaflets including 2 brief cessation brochures <i>Me Quit Smoking? Why?</i> and <i>Me Quit Smoking? How?</i> 2. Leaflets and maintenance manual <i>A Lifetime of Freedom from Smoking</i> 3. Cessation manual <i>Freedom from Smoking in 20 days.</i> 4. Cessation and maintenance manuals
Outcomes	Sustained abstinence at 12m (PP at all 5 follow-up points), self report in telephone interview Validation: none
Notes	2+3+4 vs 1, S-H vs leaflet only

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Unclear	No information on number lost, all randomized participants included in ITT analysis.

Davis 1992

Methods	Setting: Community, USA Recruitment: Advertisements for the Cancer Information Service hotline
Participants	Women smokers with children under 6 calling hotline. Results based on 630/873 (72%) of those recruited who were followed up at 6m.
Interventions	1. <i>Quitting Times</i> , a S-H guide developed to meet the special needs of women smokers with young children. 65 pages in magazine format 2. ALA <i>Freedom from Smoking for You and Your Family</i> 3. National Cancer Institute <i>Clearing the Air</i>

Davis 1992 (Continued)

Outcomes	Abstinence at 6m (7-day PP) Validation: no biochemical validation. Confirmation by surrogate. Those refusing to give a surrogate were classified as smokers	
Notes	Does not contribute to main analysis, 1 vs 2&3, impact of targeting to population All 3 guides covered similar topics, no significant differences were found between any of them.	
Risk of bias		
Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	'Preassigned list randomized by day of week'. No significant differences in participants measured variables at baseline.
Allocation concealment?	Yes	Counsellors who recruited participants during calls were blinded to the S-H guide that would be received
Incomplete outcome data addressed? All outcomes	Yes	72% of participants reached at follow up, similar for all three groups. Analyses based on those reached.

de Vries 2008

Methods	Setting: Community, Netherlands Recruitment: Telephone recruitment for a multiple risk factor health promotion intervention	
Participants	156 smokers amongst 2827 participants of whom 1331 (47%) responded at T4. Baseline all participants; 55% F, av age 49	
Interventions	1. Printed tailored letters on smoking as an identified risk factor (other targets were physical activity, nutrition) (Half group had action planning component in 3rd letter) 2. Printed generic letters	
Outcomes	Abstinence at 9m (not defined) Validation: none	
Notes	New for 2009. Effect of tailoring. Numbers of smokers at baseline and quitters provided by author	
Risk of bias		
Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described

de Vries 2008 (Continued)

Allocation concealment?	Unclear	Details not given
Incomplete outcome data addressed? All outcomes	No	Only baseline smokers who responded to follow-up survey included in analysis

Dijkstra 1998a

Methods	Setting: Community, Netherlands Recruitment: Newspaper adverts, not selected by level of motivation to quit
Participants	1546 smokers; 59% F, av age 40, av cpd 20.3
Interventions	No face-to-face contact 1. Letter with information on positive outcomes of quitting (OC) 2. Letter with information on skills for quitting (SE) 3. Letter with outcomes and skills information (BO) All letters were computer-generated, 4-7 page reports, personalized and tailored from baseline questionnaire 4. No information (CO)
Outcomes	12m sustained abstinence at 14m, self report by postal questionnaire Validation: None, participants were told that a sample would be tested for CO levels
Notes	1&2&3 vs 4 in S-H vs control Results are sensitive to the outcome used, PP do not differ

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	64% responded at 14m, no difference across groups. Attrition predicted by perceived pros of quitting and intention to quit but did not differ between groups. Denominator in meta-analysis based on all randomized.

Dijkstra 1999

Methods	Setting: Community, Netherlands Recruitment: Newspaper adverts for smokers not planning to quit in next 6m (unmotivated volunteers)
Participants	843 smokers not planning to quit; 63% F, av age 42, av cpd 22
Interventions	No face-to-face contact 1. Three tailored letters (MT) 2. Single tailored letter (ST) 3. S-H manual, 48 page colour (SHG) 4. No intervention (CO)
Outcomes	Abstinence at 6m (7-day PP), self report by postal questionnaire Validation: none Primary outcome for trial was SoC and intention to quit
Notes	3 vs 4 in S-H vs control. 1&2 vs 3 in effect of tailoring

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	89% responded at 6m. Attrition predicted by yrs smoking and group. Denominator used in MA includes all randomized

Etter 2004

Methods	Setting: Community, Switzerland Recruitment: Mailing to population registers (not selected)
Participants	2934 smokers aged 15+; 74% precontemplators, 40% tried to quit in previous yr, 51% F, av age 36, av cpd 20
Interventions	1. Tailored 8 page letter + SoC-matched booklets. At 2m, 4m, 12m repeat questionnaire to initiate further letter. 2. No intervention
Outcomes	Abstinence at 24m (in maintenance stage, quit for > 6m). 4w and 7-day abstinence also reported. Validation: none
Notes	Tailored S-H vs nothing. Approx half of group 1. recvd 1 letter only. Effect at 6m (Etter Arch Int Med 2001) not sustained at 24m. Relative difference smaller

Etter 2004 (Continued)

		if shorter term abstinence used.
Risk of bias		
Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomization: 'list of random numbers'
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	Loss to follow up 14.0% in 1 and 10.7% in 2. All non-responders included in ITT analysis.

Fortmann 1995

Methods	Setting: Community, USA Recruitment: Smokers identified via a random telephone survey, (volunteers)
Participants	1044 smokers able to quit for 24 hours; av age 40, av cpd 20
Interventions	All participants were offered an incentive of US\$100 for quitting for 6m 1. Nicotine gum 2mg (NG) 2. S-H materials 3. NG and S-H materials 4. Monetary incentive only
Outcomes	Abstinence at 12m (PP) Validation: CO < 9ppm, salivary cotinine < 20ng/ml
Notes	2&3 vs 1&4 in S-H vs control. 3 vs 2 for effect of S-H materials added to gum

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized in a 2X2 factorial design, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	6.2% failed to complete telephone interviews. 12% of self-reported nonsmokers refused confirmation. Follow up and confirmation rates did not differ by conditions.

Glasgow 1981

Methods	Setting: Community, USA Recruitment: media advertisements
Participants	88 smokers (40 in S-H conditions)
Interventions	Factorial trial of 3 different S-H materials, with or without additional group support 1. Danaher & Lichtenstein manual 2. Pomerleau & Pomerleau manual 3. I Quit Kit
Outcomes	Abstinence at 6m Validation: CO < 15ppm
Notes	3 different S-H conditions and no strong hypothesis about direction of treatment difference between D&L and P&P so not used in the MA of different programmes. No statistical difference between quit rates. Also included in group therapy review.

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	'Randomly assigned', method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	3/88 lost to follow up, group not specified so not included as smokers.

Gritz 1992

Methods	Setting: HMO, USA Recruitment: Members of HMO agreeing to participate in a Preventive Health Behavior Study and completing a baseline survey (unselected - not informed that focus of study was on smoking)
Participants	1396 F smokers; av age 38, 42% smoked 15-24 cpd
Interventions	No face-to-face contact, 5 follow-up interviews in 2 yrs 1. S-H programme mailed in 6 weekly instalments. Manuals were tailored to the concerns of female smokers and addressed weight gain, social support, stress and coping mechanisms. 2. Control - no materials - same schedule of follow-up phone calls
Outcomes	Sustained abstinence at 1m, 6m, 12m & 18m. Validation: saliva cotinine < 15ng/ml, but due to low success in obtaining samples, unadjusted rates used. No difference in disconfirmation rates between intervention and control groups.

Gritz 1992 (Continued)

Notes	The strictest measure of abstinence extracted gives the lowest P value for the difference between the groups; all other measures give a smaller difference in quit rates.	
Risk of bias		
Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	12.7% lost to follow up at 18m. Number in each group at baseline not stated so losses not included as smokers in MA. Similar losses across groups so no effect on estimate

Harackiewicz 1988

Methods	Setting: University campus health centre/medical centre, USA Recruitment: Smokers applying for free cessation programme.	
Participants	98 smokers in relevant arms; 61% F, av age 35, av cpd 27 for all trial participants	
Interventions	All received advice from a doctor or nurse to quit by using the written materials, which were different for each group 1. S-H manual employing intrinsic motivation approach (<i>Stopping smoking on your own with Nicorette</i>), and nicotine gum 2. S-H manual employing extrinsic motivation approach (<i>The Doctor's program for stopping smoking with Nicorette</i>), and nicotine gum 3. Intrinsic motivation S-H manual only 4. Control - short booklet only, with no motivational element	
Outcomes	Sustained abstinence at 12m, (3m-12m) Validation CO < 8ppm at each visit, saliva thiocyanate < 10mg/dl at 3m & 6m. 2 subjects reclassified as smokers.	
Notes	3 vs 4 for S-H compared to control. 1 & 2 not used.	
Risk of bias		
Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	'Randomly assigned', method not described
Allocation concealment?	Unclear	No details given

Harackiewicz 1988 (Continued)

Incomplete outcome data addressed? All outcomes	Yes	22/197 trial participants who did not attend any follow up & excluded from analyses; 'drop-out rates did not differ according to condition'. Other losses assumed to be smoking
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Hollis 1993

Methods	Setting - HMO, USA Recruitment - Smokers visiting primary care physicians (unselected)
Participants	2707 smokers (1383 in relevant arms) who received provider advice; av age 40, av cpd 18
Interventions	All received 30-second quit smoking advice from physician. 1. Self-quit training from a nurse or health counsellor who showed a video, gave a choice of S-H manuals + quit kit. One follow-up phone call. 2. Group referral 3. Choice of group referral or a S-H kit. 4. Control - provider advice and 2-page pamphlet from nurse.
Outcomes	Abstinence at 12m (3m & 12m PP) Validation: Saliva cotinine. Subjects not providing samples counted as smokers.
Notes	1 vs 4, comparison of S-H with control

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	No	Pseudo-randomization (two random digits in health record number) of smokers receiving provider advice. More allocated to control than each other condition
Allocation concealment?	No	Allocation was not concealed but no evidence of selection bias; baseline characteristics similar. Physicians remained blind to treatment assignment
Incomplete outcome data addressed? All outcomes	Yes	14% lost to follow up at 12m; response rates did not differ significantly across treatment groups, all participants included in analysis. 55% of reported quitters provided saliva sample, no difference by group.

Humerfelt 1998

Methods	Setting: Community, Norway Recruitment: From participants in a community survey of men aged 30-45 who had increased risk of obstructive lung disease or lung cancer
Participants	2610 M with reduced FEV1 and/or occupational asbestos exposure; av age 37, av cpd 16
Interventions	1. Mailed S-H pamphlet, 15 pages, emphasizing behavioural modification techniques in smoking cessation and recommending an early quit date, accompanied by a letter from a respiratory physician advising of the high risk status established by the survey. 2. No intervention
Outcomes	Abstinence at 15m (PP) Validation: subjects in 1 geographical area invited for CO measurement (CO < 10ppm)
Notes	For the MA number of quitters has been adjusted for the validated rate found in the sample who were tested (63% in expt/67% in control). Subjects who stopped smoking prior to receiving materials were included. The authors give 12m sustained abstinence rates of 5.6% vs 3.5% but these rates are based on self report by responders.

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	Loss to follow up higher in the intervention group (17%) than control (8%). The probability of responding to the follow-up questionnaire was inversely related to the baseline cpd consumption in the intervention but not in the control group. Losses included as smokers.

ICRF 1994

Methods	Setting: Primary care, UK Recruitment: Patients registered with practice invited to join
Participants	1686 smokers (over 15 cpd)
Interventions	2x2 factorial design: 1. Nicotine patch and 16 page Health Education Authority (HEA) pamphlet 2. Placebo patch and HEA pamphlet 3. Nicotine patch and 46 page booklet with more detailed information on cessation with the use of patches All participants seen once by a doctor and x4 by a nurse.

ICRF 1994 (Continued)

Outcomes	Sustained abstinence at 12m Validation: salivary cotinine or expired CO	
Notes	Comparison between different S-H materials. Not used in a MA. No clinical or statistically significant difference between the materials in either patch condition.	
Risk of bias		
Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Random allocation of study numbers to intervention groups
Allocation concealment?	Yes	Sequential allocation of study numbers and precoded packages
Incomplete outcome data addressed? All outcomes	Yes	Only early abstainers were followed up at 6 & 12m. 9.2% lost to follow-up at 12 weeks. All losses included as smokers.

Janz 1987

Methods	Setting: Two outpatient medical clinics, USA Recruitment: All smokers attending and giving informed consent for a study of health practices (unselected)	
Participants	250 smokers; av age 46, av cpd 24	
Interventions	1. Control - no intervention - clinic physicians not aware of study (not included in review) 2. Advice from physician and brief consultation from a nurse 3. As 2 and the Step-by-Step Quit Kit.	
Outcomes	Abstinence at 6m (ascertainment by telephone by independent interviewer) Validation: none	
Notes	3 vs 2 for effect of S-H as adjunct to advice. The graphed percentages are based on numbers followed up. It has not been possible to obtain data from the authors.	
Risk of bias		
Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Pseudo-random assignment of half-day clinic sessions to expt or control (control does not contribute to this review).

Janz 1987 (Continued)

		Within expt clinics participants randomized to manual or no manual condition, method not described.
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	39 (16%) lost to follow up at 6m. 'Drop-out rates did not vary significantly across study groups'. Losses not given by group so not included in MA

Killen 1990

Methods	Setting: Community, USA (Stanford Stop Smoking Project) Recruitment: Media advertisements for volunteers for S-H relapse prevention research programme (selected). To be eligible for randomization had to have quit for 48 hours unaided. (Quit validated by CO < 9ppm)
Participants	1218 smokers who had quit for 48 hours; av age 43, av cpd 25
Interventions	4x3 factorial design crossing gum and S-H conditions: Nicotine gum (2mg) conditions: Adlib schedule, whenever strong need to smoke/ Fixed schedule (1 piece per hour for at least 12h/day)/ Placebo gum/ No gum S-H intervention was based on 16 specially written modules. All participants were given the first <i>How to cope with the urge to smoke without smoking</i> booklet. Then randomized to: Self selected - chose 7 more to receive in weekly mailings/ Random - sent 7 modules at random/ No modules - no further contact
Outcomes	Abstinence at 12m (no smoking in 7 days prior to follow up) Validation: By saliva cotinine, except for participants who had moved away.
Notes	'No module' condition received booklet judged to be S-H, so only used for effect of additional materials. Uncollapsed data sought. Reported that no difference by module condition.

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, fully crossed factorial design, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Unclear	Number lost to follow up not described. All surviving participants included in MA

Killen 1997

Methods	Setting: community, USA Recruitment: advertisements
Participants	424 smokers; 50% F, av age 42-47, av cpd 24
Interventions	2x2 factorial design. All participants received S-H materials designed to help develop self-control skills 1. S-H and placebo patch 2. S-H and nicotine patch (21mg) 3. As 1. and video, watched during initial office visit, and for use at home 3. As 2. and video
Outcomes	Sustained abstinence (6m and 12m) Validation: Saliva cotinine < 20ng/ml
Notes	Test of additional materials. Since there was evidence of an interaction between nicotine and video conditions, the nicotine arms are entered separately using a dummy study

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized in a 2X2 fully crossed factorial design, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Unclear	Number lost to follow up not specified, but all participants included in denominators

Killen 1997 +NP

Methods	Dummy study to enter results of Killen 1997 arms with nicotine patch
Participants	
Interventions	
Outcomes	
Notes	

Kottke 1989

Methods	Setting: Family practices, USA Recruitment: Physicians recruited for trial. Target population all patients seen during month (unselected)
Participants	66 physicians, 1653 smoking patients; '2/3rds female, av age slightly over 40 yrs, just under one pack/day'
Interventions	1. Physicians attended 6 hour workshop 2. Physicians attended workshop and given copies of 'Quit and Win' for their patients 3. Physicians received no support, but were asked to advise patients during the study period
Outcomes	Abstinence at 1 yr Validation: Serum cotinine
Notes	2 vs 1, effect of self-help in addition to advice from a trained physician. Including 3. in control group does not affect results. (RR for trial becomes 1.02 rather than 0.99).

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	No	Cluster randomized by physician not smoker, method not described, potential for imbalance in patient characteristics but number patients per physician low
Allocation concealment?	No	Researchers attempted to contact all patients seen by physicians during one month
Incomplete outcome data addressed? All outcomes	Yes	Over 87% of smokers identified at baseline were reach at 1 yr, similar across groups.

Lando 1988

Methods	Setting: Family practice or pulmonary specialists, USA Recruitment: Physicians' patients wishing to use nicotine gum as a cessation aid
Participants	304 smokers; 62% F, av age 42, av cpd 31
Interventions	1. Nicotine gum (NG) and expt S-H materials emphasizing behavioural strategies, as well as correct use of gum 2. NG and control pamphlet <i>Danger: the facts about smoking</i> (American Cancer Society).
Outcomes	Abstinence at 12m Validation: proportion asked to provide saliva for thiocyanate, 5 discrepant, 2 in S-H, 3 in control, but not clear if these were at 6 or 12m so self-reported outcome used

Lando 1988 (Continued)

Notes	In main comparison with advice and leaflet for control, and comparison of NG+SH vs NG alone	
Risk of bias		
Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described.
Allocation concealment?	Unclear	No details given. Physicians remained blind to condition
Incomplete outcome data addressed? All outcomes	Unclear	No mention of number lost to follow up

Lando 1991

Methods	Setting: Community cardiovascular risk factor screening programme, USA Recruitment: Smokers identified from screening programme who agreed to take part	
Participants	570 smokers; approx 50% F, av age 42, av cpd 20	
Interventions	No face-to-face contact. 1. S-H Quit for Good materials (NCI) 2. S-H Quit and Win materials - a more extensive and structured programme 3. Wait-list control	
Outcomes	Abstinence 7m after randomization (but only 3-4m after receipt of materials) Validation: none	
Notes	Both 1 and 2 treated as S-H programmes. There was no difference in results between them. Both expt and control subjects likely to have been exposed to simultaneous community Quit and Win contests. Author notes that a number of participants quit between randomization and receipt of materials. This study is also included in the Quit and Win review (Cahill 2008).	
Risk of bias		
Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given; there were significant differences between intervention & control for sex and education, and higher confidence in quitting among controls

Lando 1991 (Continued)

Incomplete outcome data addressed? All outcomes	Yes	25 lost to follow up, of which 13 were in control groups. Denominators are those followed up.
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Ledwith 1984

Methods	Setting: Community, Scotland UK Recruitment: Newspaper advertisements for a smoker's advice centre
Participants	1839 smokers responding to offers of advice on stopping smoking
Interventions	No face-to-face contact. 1. No advice control 2. S-H leaflet with standard letter 3. S-H leaflet and offer of individual advice by returning a questionnaire
Outcomes	Abstinence at 12m (for 10m or more - based on self report) Validation: attempt to obtain saliva for thiocyanate but not complete, data based on self report only.
Notes	2 vs 1, S-H. 3 vs 2, effect of tailored advice. Only 34% returned baseline questionnaire to initiate tailored component. No information about contents of leaflet. Borderline whether this counts as a structured S-H programme.

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	'Assigned at random', method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Unclear	16% lost to follow up. Non-respondents included as smokers.

Lennox 2001

Methods	Setting: General practice, Scotland UK Recruitment: smokers in general practices who returned questionnaires
Participants	2610 smokers; no demographic details
Interventions	No face-to-face contact. 1. Tailored letter from physician. 4 pages, based on SoC, decisional balance and other indicators from questionnaire.

Lennox 2001 (Continued)

	2. Untailored letter from physician. Same format, included specific behavioural advice on quitting 3. Control, letter acknowledging questionnaire	
Outcomes	Abstinence at 12m. (24m data reported but PP so does not represent a more conservative measure) Validation: saliva cotinine	
Notes	2 vs 3 , S-H no contact. 1 vs 2, tailoring	
Risk of bias		
Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Computer-generated random numbers
Allocation concealment?	Yes	'After the questionnaires were returned, we randomised the participants to the groups'. No participant contact, low risk of selection bias.
Incomplete outcome data addressed? All outcomes	Yes	22% loss to follow up, similar across groups, non-responders counted as smokers.

Lichtenstein 2000

Methods	Setting: Community, USA Recruitment: via electric utility mailing to identify households with smokers and low radon concentrations
Participants	1006 smokers in 714 households; av cpd 20
Interventions	No face-to-face contact. 1. Standard Environmental Protection Agency leaflet on risks of radon 2. Pamphlet highlighting risk of smoking in low concentrations of radon, with tips for quitting, or not smoking indoors 3. as 2. + up to 2 brief proactive telephone calls. All groups got standard letter with radon results.
Outcomes	Abstinence at 12m, sustained at 3 & 12m Validation: none
Notes	2 vs 1, S-H vs other control. 3 contributes to telephone counselling review (Stead 2006). Cluster randomization, 54% of smokers lived with another smoker. Intraclass correlation for sustained abstinence was .010. Analyses did not correct for this.
Risk of bias	

Lichtenstein 2000 (Continued)

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized by household, method not described.
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Unclear	80% of households completed both surveys. Relation between attrition and baseline variables did not vary by condition. Households lost considered to have continuing smokers

Lichtenstein 2008

Methods	Setting: Community, USA Recruitment: via electric utility mailing with offer of radon test kit to identify households with smokers
Participants	1364 households with 1821 smokers, ~18 cpd
Interventions	Factorial design crossing +/- brief phone counselling with video S-H materials. All households given <i>A Citizens Guide to Radon</i> and letter tailored to results of radon level test 1. Video, 15min, explaining risk of smoking & radon combination, encouraging quitting and/or household smoking bans. 2. No video
Outcomes	Abstinence at 12m, sustained at 3 & 12m Validation: none
Notes	New for 2009 update. Results of analyses accounting for clustering of multiple smokers in households reported to yield results generally consistent with simple analyses. We were unable to get data for arms with and without phone counselling so the collapsed data contributes to comparisons 1.1.2 & 2.1.2

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Responding households sequentially randomized to 4 conditions subject to stratification on radon test status
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	83% of households completed 12m assessment, 76% completed both 3 & 12m

Lipkus 1999

Methods	Setting: Health centre, USA Recruitment: from telephone survey of patients
Participants	266 randomized, 160 followed up; Low income African-American smokers, unselected by motivation, 52% F, 49% aged > 50
Interventions	1. Physician prompts attached to chart (included other screening tests). Providers trained to use 4As model 2. As 1 + mailing of tailored print communication around birthday 3. As 2, + TC
Outcomes	Abstinence 16m after last intervention, 30 day quit Validation: none
Notes	2 vs 1, S-H adjunct to advice. (3 vs 2 in telephone counselling review) Reported rates based on numbers followed up, not randomized. Provider compliance reported to be 48%

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not stated
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	40% loss to follow up, largely due to disconnected phone numbers, 'loss to follow-up did not appear to be a function of any demographic, psychosocial of smoking pattern, nor was it a function of the intervention smokers received'. Losses not included as smokers.

McFall 1993

Methods	Setting: community, USA Recruitment: during a TV cessation programme
Participants	Smokers who registered and received the manual or reported viewing at least 1 part of programme
Interventions	1. TV programme and ALA FFS 2. Maintenance; as 1. and 10 newsletters over following 6m
Outcomes	Abstinence at 12m. (24m data reported but PP with increase over time so does not represent a more conservative measure. RR similar) Validation: none

McFall 1993 (Continued)

Notes	2 vs 1. effect of additional materials	
Risk of bias		
Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	24% lost in maintenance condition, 27% in control. MA includes responders; Including losses would give less conservative effect.

Meyer 2008

Methods	Setting: Primary health care centres, Germany Recruitment: smoking patients attending practices during 3 study weeks	
Participants	Smokers, unselected for motivation; 48% F, av age 34, av cpd 16	
Interventions	1. Assessment only control 2. Up to 3 letters individually tailored to SoC. First used baseline assessment, 3m & 6m depended on further assessment. Stage-matched S-H manuals 3. Brief physician advice & S-H manuals	
Outcomes	Abstinence at 24m (sustained for 6m) Validation: none	
Notes	New for 2009. Analyses in paper allowing for clustering give slightly larger estimates than use of crude numbers quit. Different assumptions about losses to follow up did not substantially alter any results. Abstinence rates increased over time in all groups. Prolonged abstinence at all follow ups is very low, not used here. 63% got 3 letters, 21% got 2 and 17% only 1.	
Risk of bias		
Item	Authors' judgement	Description
Adequate sequence generation?	No	Quasi-random & clustered based on time of attendance. Fixed sequence of assessment-only, tailored letters, advice. At least 2 weeks between each study week.
Allocation concealment?	No	Condition known at time of recruitment. All patients screened so recruitment bias

Meyer 2008 (Continued)

		should have been avoided, no evidence of difference in baseline characteristics
Incomplete outcome data addressed? All outcomes	Yes	56% of letters & 64% of control reached at 24m. Different approaches to missing data did not alter conclusions.

Nollen 2007

Methods	Setting: hospital, USA Recruitment: smokers visiting hospital, interested in quitting in next 6m
Participants	500 African-American smokers; 60% F, av age 43, av cpd 20
Interventions	All participants received 8w nicotine patch and 2 phone calls 1. Standard materials; ALA FfS + <i>How to Quit</i> video 2. Culturally sensitive guide <i>Pathways to Freedom: Winning the Fight against Tobacco</i> and Harlem Health Connection's <i>Kick-It</i> video (40 min) targeted for African-Americans
Outcomes	Abstinence at 6m (30 day PP) Validation: CO < 10ppm
Notes	Study ID was Ahluwalia 1999 until publication of full report. Minor change to results. Comparison between targeted and untargeted materials. Significantly more participants used the targeted materials (68.8% vs 59.6%) but no difference detected in salience or perceived materials

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Randomization codes computer-generated by study statistician in blocks of 20
Allocation concealment?	Unclear	Described as investigator blind but no explicit statement
Incomplete outcome data addressed? All outcomes	Yes	66% lost to follow up at 6m, included in ITT analysis, no evidence of differential loss by group.

Omenn 1988

Methods	Setting: Single worksite (13,000 workers, 9 employers), USA Recruitment: worksite volunteers
Participants	243 with preference for a S-H programme

Omenn 1988 (Continued)

Interventions	(Only S-H format conditions considered in this review) 1. Multiple component programme 2. Relapse prevention programme 3. Minimal treatment programme (American Cancer Society's <i>Quitter's Guide</i> , 7-day plan)
Outcomes	Abstinence at 12m Validation: saliva cotinine \leq 35 ng/ml
Notes	Comparison between S-H materials; not in MA. No clinical or statistically significant differences between quit rates in the 3 groups.

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	'nurses at aid stations using randomized assignment lists generated by research centre, within preference for format'
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	At least 89% followed up in each arm, non-respondents counted as smokers

Orleans 1991

Methods	Setting: HMO, USA Recruitment: Largely through publicity in HMO magazine
Participants	2021 smokers; 63% F, av age 44, av cpd 26
Interventions	1. <i>Free & Clear</i> , 28 page guide incorporating nicotine fading and standard behavioural abstinence and relapse prevention techniques. Also a Quit Kit and ALA <i>A Lifetime a Freedom from Smoking</i> 2. Same materials as 1. plus 2 copies of a social support guide to be given to 'allies'. 3. As 2. + TC +quitline 4. Control - Referral guide describing available S-H guides and local resources, plus NCI <i>Clearing the Air</i>
Outcomes	Abstinence at 16m for over 6m, by blinded telephone interview. Validation: Saliva cotinine < 10ng/ml, or thiocyanate < 2,400 umol/l for gum users.
Notes	1+2 vs 4, effect of S-H alone. (3 assessed in TC review) By 16m, 59% of participants in the control group reported that they had used an additional treatment method.

Orleans 1991 (Continued)

<i>Risk of bias</i>		
Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not stated, stratified by living alone/not, advice to quit in last 12m/not and nicotine content of cig brand
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	Loss to follow up 6% at 16m, did not differ across treatment groups. Analyses based on respondents; including losses would marginally increase estimated effect

Orleans 1998

Methods	Setting: Community, USA Recruitment: African-American smokers calling a Cancer Information Service telephone counselling line in response to targeted campaign
Participants	1422 African-American smokers; av age not stated, 62% in 20-39 age group, median cpd 20
Interventions	1. 36 page <i>Pathways to Freedom</i> guide and tailored TC. Guide used African-American models and addressed specific obstacles 2. Standard guide <i>Clearing the Air</i> and standard NCI TC
Outcomes	Abstinence at 6m, 7-day PP, telephone questionnaire (12m abstinence also assessed in sample of 445 smokers) Validation: none
Notes	Test of population targeting. Counselling was also different for the 2 groups. At 12m there were significant differences (15.0% vs 8.8% for sample selected for follow up)

<i>Risk of bias</i>		
Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized by last digit of caller's contact phone number; risk of bias probably low
Allocation concealment?	Unclear	Presumably recruited before phone number and thus allocation known, so risk of bias probably low

Orleans 1998 (Continued)

Incomplete outcome data addressed? All outcomes	Yes	37% lost to follow up at 6m. No differential drop out, MA includes non-responders as smokers.
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Orleans 2000

Methods	Setting: community, USA Recruitment: smokers aged > 65 using nicotine patch
Participants	720 smokers; 'mostly F', av age 72, av cpd 22
Interventions	All participant had filled a prescription for nicotine patch 1. Clear Horizons guide for older smokers + 7 personalized tailored computer-generated mailings over 6m. 2. Fact sheet on patch-assisted quitting
Outcomes	Abstinence at 12m, ?7-day PP Validation: ?none (Limited information in abstract)
Notes	Follow-up rates supplied by N Boyd. Considered with other studies testing S-H adjuncts to pharmacotherapy, not with other tailored studies.

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not stated
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	Loss to follow up 21% expt, 23% control, not significantly different. Non-responders included as smokers.

Owen 1989

Methods	Setting: community, Australia Recruitment: advertisements for smokers wishing to quit
Participants	208 smokers; av age 42, av cpd 28
Interventions	1. 'Quit Kit' along with apology that course full. Kit included a 5-day cessation plan 2. S-H programme in 4 mailed parts 3. As 2. but personalized with additional text, based on registration form. Option to send for additional materials

Owen 1989 (Continued)

Outcomes	Abstinence at 9m (PP) Validation: some cotinine assays, but no correction for a possible 15% misreport level.	
Notes	Intervention 1 meets criteria for basic S-H, so 2 vs 1 for effect of additional materials and 3 vs 2 for effect of personalized materials.	
Risk of bias		
Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Unclear	12% lost to follow up at 9m, similar between groups. Non-respondents included as smokers

Pallonen 1994

Methods	Setting: Community cardiovascular risk factor study, Finland Recruitment: Male smokers identified via survey	
Participants	165 M smokers who were classified as precontemplators or contemplators according to the SoC model; av age 52, av cpd 19	
Interventions	1. SH. Five 10-20 page S-H manuals matched to SoC, mailed after each 6m assessment. 2. Usual care and annual telephone assessment	
Outcomes	Sustained abstinence at 2 yrs (2 PP) Validation: none	
Notes	Included in main analysis although targeted materials. Ns are smokers for whom complete follow-up data were available	
Risk of bias		
Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized in 2:1 ratio, but prepared smokers in treatment condition then offered clinic so groups were not balanced by SoC
Allocation concealment?	Unclear	No details given

Pallonen 1994 (Continued)

Incomplete outcome data addressed? All outcomes	No	37% lost to follow up by 2 yrs and not re-included in MA as group not given. Authors report sensitivity analysis of effect of excluding people with incomplete follow up and state that bias is not introduced
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Pederson 1983

Methods	Setting: Respiratory specialist outpatient clinic, USA Recruitment: All smokers attending (unselected)	
Participants	75 smokers; av age 52, av cpd 25	
Interventions	1. Advice to quit, and effects of smoking on present health, from respiratory specialist 2. Advice and S-H manual, <i>Break the Smoking Habit: A behavioral program for giving up cigarettes</i> (Pomerleau & Pomerleau)	
Outcomes	Abstinence at 6m, (self report of no smoking for 3m via telephone interview) Validation: none	
Notes	Due to quasi-random allocation a sensitivity analysis of the effect of excluding this study is reported in the discussion.	

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	No	Quasi-random assignment by week of attendance, possibility of baseline differences
Allocation concealment?	No	Not concealed so risk of bias although all eligible patients at a clinic supposed to be recruited thus avoiding selection bias
Incomplete outcome data addressed? All outcomes	Yes	5 lost in expt, 1 in control, included as non-responders in MA

Prochaska 1993

Methods	Setting: Community, USA Recruitment: Advertisements for volunteers to test S-H materials	
Participants	756 smokers (93 precontemplation, 435 contemplation, 228 preparation) (569 in relevant arms); av age 43, av cpd 27	

Prochaska 1993 (Continued)

Interventions	<p>1. Standard S-H. ALA FfS, <i>A Lifetime of Freedom from Smoking, 50 most often asked questions ...</i></p> <p>2. Targeted manuals - 5 covering precontemplation, contemplation, action, maintenance, relapse. Participants sent manual for their SoC and subsequent ones, except for relapse which was sent following an assessment at which relapse occurred.</p> <p>3. Tailored Interactive - in addition to manuals, sent personalized reports in response to questionnaires</p> <p>4. Counsellor telephone calls - same as 3. with short calls at 0,1,3,6m (not included in this review)</p>	
Outcomes	<p>Sustained abstinence at 18m (12m and 18m)</p> <p>Validation: none. Participants asked for names of significant others but these not contacted</p>	
Notes	<p>2 vs 1 targeting, 3 vs 2 tailoring</p> <p>Ns randomized and quit rates as shown in graphs obtained from authors.</p>	
Risk of bias		
Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not stated, stratified by SoC
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	Attrition at each assessment averaged 5.5%, not significantly different across conditions. Non-respondents included as smokers in MA

Prochaska 2001a

Methods	<p>Setting: Managed care organisation, USA</p> <p>Recruitment: Smokers identified by survey of members. 85% recruited to a study</p>	
Participants	<p>1447 smokers (967 at 18m follow up); 56% F, av age 38, av cpd 20</p>	
Interventions	<p>1. Assessment only (completed questionnaires on 4 occasions)</p> <p>2. Expert System. Tailored 2-3 page report at 0,3,6m, and SoC-matched manual</p> <p>3. As 2+ TC</p> <p>4. As 3 + computer for scheduled cig reduction.</p>	
Outcomes	<p>Abstinence at 18m, sustained for 6m (Other measures of abstinence also reported)</p> <p>Validation: None</p>	
Notes	<p>2 vs 1, tailoring. 3 contributes to telephone counselling review. 4 not included</p> <p>Arm 2 is also evaluated in Velicer 1999 results</p>	

Prochaska 2001a (Continued)

<i>Risk of bias</i>		
Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	MA includes losses to follow up and refusals. Author analysis suggests ITT analysis is biased. A sensitivity analysis (comparison 99) tests impact on outcome

Prochaska 2001b

Methods	Setting: Community, USA Recruitment: random digit dialling. 80% of smokers reached recruited
Participants	4144 smokers (2571 at 24m follow up); 55% F, av age 41, av cpd 20
Interventions	1. Assessment only (questioned at 6m intervals) 2. Expert System. See Prochaska 2001a
Outcomes	Abstinence at 24m, sustained for 6m (Other measures of abstinence also reported) Validation: none
Notes	2 vs 1, tailoring

<i>Risk of bias</i>		
Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	Similar rates of loss to follow up but slightly higher refusal in expt. Non-respondents included as smokers in MA. A sensitivity analysis (comparison 99) tests impact on outcome

Prochaska 2004

Methods	Setting: Community, USA Recruitment: Parents of 9 th grade students in a separate study, at risk for one of the targeted health behaviours
Participants	711 smokers from total of 2460 participants; 75% F (full sample), av age 43 (full), av CPD 18, 41% precontemp, 41% contemplators, 18% preparation
Interventions	1. Assessment only (completed questionnaires on 3 occasions) 2. Expert System. Tailored 3-5 page report at 0,6 & 12m and manual
Outcomes	Abstinence at 24m, sustained for 6m (Other measures of abstinence also reported) Validation: none
Notes	2 vs 1, tailoring

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	Higher loss to follow up in Intervention (45% than control (40%). All participants included in this MA

Prochaska 2005

Methods	Setting: Community, USA Recruitment: primary care patients proactively recruited by phone, at risk for one of the targeted health behaviours
Participants	1211 smokers from total of 5407 participants; 70% F (full sample), av age 45 (full), av cpd 17, 31% precontemp, 46% contemplators, 23.5% preparation
Interventions	1. Assessment only (completed questionnaires on 3 occasions) 2. Expert System. Tailored 3-5 page report at 0,6 & 12m and manual
Outcomes	Abstinence at 24m, PP Validation: none
Notes	2 vs 1, tailoring. Sustained abstinence also an outcome; 'same pattern of results' but details not reported. Number of smokers by group at baseline not reported. Data requested.

Risk of bias

Item	Authors' judgement	Description
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Prochaska 2005 (Continued)

Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	No	35% loss to follow up at 24m. Insufficient data to include non-respondents in MA but no interaction between missing data and intervention.

Prue 1983

Methods	Setting: Veterans Administration Medical Centre outpatients clinic, USA Recruitment: Smokers referred to smoking treatment programme who could not attend clinic sessions (selected)	
Participants	40 smokers (likely to be predominantly M); av age 45, av cpd 32	
Interventions	1. S-H programme (Pomerleau & Pomerleau) preceded by brand fading schedule. There were also telephone calls from psychologists. 2. Wait list control	
Outcomes	PP abstinence at 6m follow up (wait list treated after 6m) Validation: significant other only	
Notes	This is a minimal contact programme rather than a strict S-H one, marginal for inclusion; very small impact on MA effects	

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described, unbalanced group size
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	All participants included in analyses

Resnicow 1997

Methods	Setting: Predominantly African-American community in USA Recruitment: In healthcare, church and public housing settings. Presented as 'health promotion' not smoking cessation.	
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Resnicow 1997 (Continued)

Participants	650 smokers recruited in treatment channels and 504 in control channels who completed follow-up interviews. (Attrition similar between groups) av age 45, av cpd 16
Interventions	1. S-H kit including <i>Kick It</i> guide, video and aids. Bi-monthly mailings and single booster telephone call 2. Health education materials not exclusively addressing smoking, and a cholesterol education video
Outcomes	PP at 6m Validation: none
Notes	Less than a third of intervention group received telephone call. A post hoc analysis reported significantly higher quit rates amongst call than no call group. Multivariate analysis controlling for intracluster correlation gives OR of quitting in treatment group as 1.36, 95% CI 0.87 to 2.11, compared to OR 1.42 95% CI 0.98 to 2.04 from figures used in MA

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Cluster randomized stratified by type of site, prior to recruitment of smokers
Allocation concealment?	No	Allocation known at time of recruitment, unclear that this introduced high risk of bias; all participants received smoking cessation materials
Incomplete outcome data addressed? All outcomes	Yes	Attrition similar between treatment (7.5%) and control (6.8%) conditions. Non-respondents did not differ on baseline characteristics; not included in MA denominators.

Rice 1994

Methods	Setting: hospital clinic, USA Recruitment: By health professional and self referral
Participants	406 smokers with a cardiovascular health problem
Interventions	1. S-H materials <i>Smokeless 6</i> booklet programme and individual nurse counselling 2. S-H materials and group meetings 3. S-H alone. Prompted to open envelope containing booklets on same schedule as other groups met 4. Advice to quit from nurse only

Rice 1994 (Continued)

Outcomes	Abstinence at 12m Validation; saliva thiocyanate tested but rates not corrected for misreport	
Notes	3 vs 4, S-H vs control. 1&2 not used in this review	
Risk of bias		
Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not stated. Stratified by sex, smoking history and history of cardiovascular incident.
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	34% dropped after randomization and prior to treatment. Ns randomized supplied by author. All drop-outs included

Schofield 1999

Methods	Setting: hospital, Australia Recruitment: Smokers discharged from hospital, (unselected)	
Participants	2465 smokers or recent quitters. Excludes 1693 randomized but lost at 12m follow up. No differential drop out, 59% followed up in each arm. No demographic data	
Interventions	1. S-H 31 page SoC-based booklet + personally addressed letter from consultant stating health risks and urging to quit 2. Usual care	
Outcomes	Abstinence at 12m, and at 6m Validation: urine cotinine \leq 50ng/ml or CO \leq 8ppm for sample. Refusers (22% in each group) classified as smokers.	
Notes	S-H, no contact. Authors report a benefit for subgroup for whom quitting highly relevant for diagnosis	
Risk of bias		
Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Randomized: 'alternately allocated to intervention or control conditions by computer'

Schofield 1999 (Continued)

Allocation concealment?	Yes	Smokers were identified at time of admission and allocation was determined at that time. Mailing of materials done by medical records office.
Incomplete outcome data addressed? All outcomes	Yes	Some people discovered to be ineligible at follow up and excluded. Loss to follow up 41% identical in each group. MA based on eligible respondents.

Schumann 2008

Methods	Setting: Community, Germany Recruitment: from participants in a general population health examination survey
Participants	847 smokers (exsmokers in study not included here); 46% F (full sample), av age 44 (full), av cpd 15. Controls more likely to be in preparation (32 % vs 20%) & with past yr quit attempt
Interventions	1. Assessment only (completed questionnaires on 3 occasions) 2. Expert System. Tailored 3-4 page letter and 8-26 page SoC matched booklet at 0,3 & 6m
Outcomes	Abstinence at 24m, sustained 18m follow up (other measures of abstinence also reported) Validation: none
Notes	Tailoring. 67% got 3 letters, 21% 2, 13% only 1. 72% reported reading some of materials.

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Each participant was assigned a unique computer-generated random number between 0 and 1, the data file was sorted by ascending random numbers, and participants were then consecutively assigned to the 3 study conditions.'
Allocation concealment?	Yes	No opportunity to alter allocation or exclude
Incomplete outcome data addressed? All outcomes	Yes	Greater loss in intervention (34%) than control (27%). MA includes lost as smokers. Authors report GEE gave similar results.

Smith 2004

Methods	Setting: 10 communities, Canada Recruitment: Volunteers intending to quit
Participants	632 smokers (423 in relevant arms); 61% F, av age 42, 61% had prior use of NRT
Interventions	Factorial design comparing 2 intensities of TC and 2 types of print materials: 1. Booklet (Canadian Cancer Society [CCS] <i>One step at a Time</i> , 44 pages) 2. Pamphlet (CCS <i>How to Quit Smoking</i> , single page) TC conditions collapsed, booklet-only control group not used in review
Outcomes	Abstinence at 12m, sustained at 3m & 6m follow ups Validation: none
Notes	No non-S-H control, comparison between materials. Results not reported by group; 'no significant interactions or main effects'.

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Randomized, stratified by community
Allocation concealment?	Yes	Centralized, sequential envelopes
Incomplete outcome data addressed? All outcomes	Yes	'Collapsing across telephone counseling groups, significantly more participants receiving print only were available for follow-up at 12 months (73%) than those receiving telephone counselling (62%). Those not available for follow-up were considered smokers for the intention-to-treat analyses.'

Strecher 2005

Methods	Setting: community, USA Recruitment: telephone callers to NCI Cancer Information Service, interested in quitting
Participants	1978 smokers; 70% F, av age 41, 46% smoked > pack/day, FTND 5.9
Interventions	All participants received approx 15min of telecounseling. Control: Single untailed 24 page booklet (<i>Clearing the Air</i>) Intervention 1: Single 8 page tailored booklet, addressing motives and barriers cited by smoker Intervention 2: Single untailed 24 page booklet (<i>Clearing the Air</i>) 2: Multiple tailored materials (booklet, 2 newsletters, letter), 5m, 8m, 12m. Tailored on baseline data Intervention 3: Single untailed 24 page booklet (<i>Clearing the Air</i>) 3: Multiple re-tailored materials (same components and schedule as 2, used data from 5m follow up for

Strecher 2005 (Continued)

	retailoring)	
Outcomes	Abstinence at 12m (7day PP, but had also reported abstinence at 5m follow up) Validation: none	
Notes	New for 2009. To derive numbers quit, assumed equal numbers in each condition. 2+3+4 vs 1 in tailored vs untailored. Slightly more evidence of effect when comparing multiple to single (3+4 vs 1+2), and also for retailored materials amongst subgroup who were quit at 5m	
Risk of bias		
Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	Only respondents at 5m eligible for 12m follow up. 56% loss at 12m, no difference by condition. Losses included as smokers.

Sutton 2007

Methods	Setting: Community, UK Recruitment: Callers to UK Quitline (smokers planning to quit in next 30 days or quit in last 14 days)	
Participants	1506 including 344 (23%) recent quitters; 66% F, av age 38, av cpd 21	
Interventions	All participants received telephone counselling and QUIT information pack 1. Standard letter 2. Tailored 3 page letter (based on social cognitive theory and perspectives on change model. Aimed to encourage & support smokers. Medium or high dependence smokers advised to talk to their GP about cessation products)	
Outcomes	Abstinence at 6m, self-reported as sustained for 3m Validation: none	
Notes	New for 2009. Tailoring. Subgroup of baseline smokers showed larger effect of intervention, but still not significant	
Risk of bias		
Item	Authors' judgement	Description

Sutton 2007 (Continued)

Adequate sequence generation?	Yes	'Randomization was effected by dividing days randomly within each of a series of consecutive 56-day blocks into two equal sets, with allocation to group depending on which day the participant called the Quit-line.'
Allocation concealment?	Yes	'Randomization was carried out by a member of the research team who had no direct contact with the counsellors or the participants. Counsellors were unaware of which condition the participant was allocated to and would have remained blind unless the participant had happened to mention during a subsequent telephone conversation that they had or had not received a tailored letter.'
Incomplete outcome data addressed? All outcomes	Yes	Loss to follow up nonsignificantly higher in control (24.4%) than intervention (20.8%). Losses treated as smoking

Sykes 2001

Methods	Setting: cessation clinic, UK Recruitment: community volunteers interested in quitting
Participants	260 smokers, high proportion low SES; 64% F, av age not stated; av cpd 25
Interventions	1. <i>Quit for Life</i> . Cognitive behavioural manual, audiotape. Gradual reduction pre-quit day, stresses psychological addiction. 2. <i>Stopping Smoking Made Easier</i> . leaflet, SoC-based, abrupt quit
Outcomes	Abstinence at 12m (Sykes 2001 reports 6m) Validation: CO < 9ppm
Notes	Comparison between S-H materials. Does not contribute to MA. 1 yr data from Marks 2002.

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Cluster randomized by orientation group attended, method not described

Sykes 2001 (Continued)

Allocation concealment?	Unclear	Although potential for selection bias 'the receptionist was unaware of which intervention each group of participants would receive'.
Incomplete outcome data addressed? All outcomes	Yes	15% loss to follow up at 1 yr, similar across groups

Thompson 1988

Methods	Setting: HMO, USA Recruitment: consecutive attenders (unselected)
Participants	379 smokers (in relevant arms); av cpd not stated, 68% smoked > 15 cpd
Interventions	Complete factorial design of 3 interventions: A - Physician advice - structured and interactive, 3-5 mins B - S-H materials (NCI <i>Calling it Quits</i> and <i>Why do you Smoke</i> , and a personalized follow-up letter. C - referral to group cessation classes Control - brief advice only
Outcomes	Abstinence at 8-9m by telephone survey Validation: none
Notes	A+B & B vs A & Control in S-H + advice vs advice only

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	'physician used a randomized folder placed in the patient chart', unclear when and how randomization schedule generated
Allocation concealment?	Unclear	Participants enrolled before visiting physician so selection bias by physician avoided
Incomplete outcome data addressed? All outcomes	No	8% lost of follow up, not included in final analyses

Velicer 1999

Methods	Setting: Managed care organisation, USA Recruitment: Smokers identified by survey of members. 85% recruited to study
Participants	2882 smokers in a managed care organisation; av age 38, av cpd 20
Interventions	1. Interactive expert system, generated 2-4 page reports based on SoC model, and stage-based manuals. 4 different levels of contact - 1,2,3 or 4 occasions at 3m intervals 2. Stage-based manuals only, same 4 levels of contact
Outcomes	Abstinence at 18m, sustained for 6m (Other measures of abstinence also reported) Validation: None
Notes	1 vs 2, tailoring. There was no evidence of a dose response to the number of contacts in either condition, and expert system conditions were better than stage-based at each contact level so these are collapsed in MA.

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not described
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	Authors report numbers refusing follow up and numbers not reached. The size and significance of the results is sensitive to whether or not those lost to follow up or refusing to respond are included in the denominator as continued smokers, see sensitivity analysis 99. Including all non-responders in denominator gives a more conservative estimate and is used in the MA

Velicer 2006

Methods	Setting: Community, USA Recruitment: Proactive approach to smokers at Veterans Administration Medical Centre
Participants	2054 smokers (1031 in relevant arms); 23% F, av age 51, 40% precontemplators, 40% contemplators, 20% preparers
Interventions	1. Stage-based S-H manuals; participants sent manual for current stage and next stage on 2. As 1. plus 6w nicotine patch if in appropriate stage, reassessed fro NRT eligibility at 6 & 10M 3. As 2. plus one expert system feedback report (see Prochaska trials) 4. As 3. plus regular automated telephone counselling

Velicer 2006 (Continued)

Outcomes	Abstinence at 30m, sustained for 6m Validation: none	
Notes	New for 2009 update. 3 vs 2 for tailored adjunct to targeted S-H. In NRT groups 350 (67%) received NRT at baseline and 448 (86%) received NRT at some point	
Risk of bias		
Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Computer-based random number generator
Allocation concealment?	Yes	Allocation done after completion of survey. Randomized participants who did not return consent form are excluded from further analyses
Incomplete outcome data addressed? All outcomes	Yes	39% lost incl 8% refused by 30m, no significant differences between groups. Different treatments of missing data reported not to have altered pattern of results. Sensitivity analyses in comparison 999

Willemsen 2006

Methods	Setting: Community, Netherlands Recruitment: Smokers identified from a market research database, willing to participate in the evaluation of an 'information aid'	
Participants	1014 smokers 'intending to quit'; 46% F, modal age 35-44, modal cpd 18-22, 86% daily smokers	
Interventions	1. Mailed <i>Decision Aid; Starter's kit</i> including information about all major available treatment methods, classified into known effective & unknown. Samples of materials, and information on how to obtain them. Video with descriptions of quitting experiences. 2. No intervention	
Outcomes	Sustained abstinence at 6m (quit for more than ~4m) Validation: none	
Notes	New for 2009 update. S-H vs control. Aid had no effect on prolonged abstinence outcome used in MA but there was an effect on PP abstinence. Aim of intervention was to increase use of efficacious aids, but it had no effect. Authors note aid 'did not contain any concrete self-help information that the smokers might have put into practice'.	
Risk of bias		

Willemsen 2006 (Continued)

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomized, method not stated
Allocation concealment?	Unclear	No details given
Incomplete outcome data addressed? All outcomes	Yes	11.8% lost at 6m, intervention participants more likely to be missing at 2w but not 6m follow up. Losses included as smokers.

4As: Ask, Advise, Assist, Arrange

ALA FFS: American Lung Association Freedom from Smoking programme

av: average (mean)

CI: confidence interval

CO: carbon monoxide

cpd: cigarettes per day

expt: experimental

F: female

HMO: Health Maintenance Organization

ITT: intention to treat

m: month(s)

M: male

MA: meta-analysis

min: minute(s)

NCI: National Cancer Institute

NRT: nicotine replacement therapy

OR: odds ratio

PP: point prevalence abstinence

ppm: parts per million

SES: socio-economic status

S-H: self-help

SoC: Stage of Change

TC: telephone counselling

w: week(s)

yr: year(s)

Characteristics of excluded studies [ordered by study ID]

Armitage 2008	Follow up only 1m. Intervention borderline for inclusion.
Balanda 1999	Follow up only 1m after provision of one of two S-H guides to quitline callers. No differences between groups found.
Brandon 2000	Only recent quitters recruited. Included in Cochrane review of relapse prevention.

(Continued)

Brandon 2004	Only recent quitters recruited. Included in Cochrane review of relapse prevention (Hajek 2009).
Brown 1992	Both arms received S-H materials. Test of telephone counselling, included in Cochrane review of telephone counselling (Stead 2006).
Burling 2000	Evaluated an internet-based intervention. Previously included in review but not in a meta-analysis. Falls within scope of separate Cochrane protocol (Koshy 2008)
Conway 2004	Intervention targeted at relapse prevention.
Curry 1988	Compares S-H materials with a relapse prevention approach to abstinence-based approach. Now included in relapse prevention review (Hajek 2009)
Dijkstra 1998b	Follow up only 4m (6w from last contact for multiple tailored letters condition). The study compared combinations of tailored letters and a S-H guide for a population of smokers not planning to quit.
Dijkstra 2001	Follow up only 3m. Compares different types of information in S-H materials.
Dijkstra 2005	Not a structured S-H intervention, outcome is 'quitting activity' at 4m. Participants were students recruited to evaluate smoking cessation messages.
Dijkstra 2006	Outcome is change in stage, not abstinence.
Edwards 1999	The intervention was directed at relapse prevention in female naval recruits required to quit smoking during basic training. Included in review of relapse prevention interventions (Hajek 2009).
Etter 2007	Intervention provided information about additives in cigarettes, focus on motivating rather than assisting quitting.
Garcia 2000	Trial of group therapy-based interventions. S-H manuals provided in addition to group therapy in order to test effect of therapist contact. Included in Cochrane Group therapy review (Stead 2005).
Gritz 1988	No control group.
Hall 2003	Smoking cessation was not an outcome.
Jeffery 1982	No long-term follow up. The control was a group programme.
Jeffery 1990	Compared the offer of a S-H programme at a nominal cost with the same programme for a US\$60 payment, refundable if successful. There was a very low recruitment rate to the incentive programme (9 participants, 0.09% of households randomly assigned to receive the incentive option).
Johs 2003	No long- term follow up.
Jordan 1999	Only 3m follow up planned. Compared an internet-based programme with an ALA printed manuals, 54 participants.

(Continued)

Kreuter 1996	Intervention provided single page of cessation information for participants who were smokers (22%) and interested in quitting. Not a S-H intervention by the criteria for this review. (Neither standard nor enhanced feedback increased quit rates over control)
Lenert 2004	Not randomized; used consecutive series of participants.
Lipkus 2004	S-H was the control condition.
McBride 1999	The intervention included 3 proactive telephone calls in addition to provision of S-H materials. No effect of the intervention was found.
McDonald 2003	Unpublished study, insufficient data to include
McMahon 2000	Tested incentives and social support as adjuncts to self-help. Included in Cochrane review of support (Park 2004)
Meade 1989	Compared smokers' ability to understand materials written at different grade levels. Cessation was not an outcome.
Moore 2002	Participants were pregnant women.
Murphy 2005	Only 3m follow up, and marginal to classify as S-H intervention; provided information on access to pharmacotherapy and cessation support
O'Hara 1993	Follow up only 3w after receipt of materials
Ossip-Klein 1991	Both arms received S-H materials. Test of hotline availability, included in Cochrane review of Telephone Counselling (Stead 2006).
Ossip-Klein 1997	Both arms received S-H materials. Test of telephone counselling, included in Cochrane review of Telephone Counselling (Stead 2006).
Pallonen 1998	Intervention targeted for adolescents. Two S-H computer-based interventions were compared. Included in a Cochrane review of cessation interventions for adolescents and young people (Grimshaw 2006).
Pederson 1981	Although this is described as a trial of behavioural S-H manuals, the treatment conditions included an introductory and 2 further group meetings.
Rimer 1994	No long-term follow up data reported in full.
Russell 1979	The leaflet used as an adjunct to physician advice did not meet study criteria for a structured S-H intervention. Smokers given the leaflet were also warned that they would be followed up. The study found a non-significant increase in the quit rate amongst patients who were given the leaflet in addition to advice, but including it would not alter the results of the MA, which found no effect of materials as an adjunct to advice.
Sallis 1986	Only 2m follow up then wait list control offered treatment.

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Shiffman 2000	Only 6w follow up. Tested materials tailored to individual smokers, in addition to nicotine gum, compared to gum and standard written materials.
Shiffman 2001	Only 6w follow up. Tested materials tailored to individual smokers, in addition to nicotine patches, compared to patches and standard written materials.
Strecher 1994	Did not meet review criteria for S-H materials. Compared health letters tailored to individual recipient's smoking behaviour with no intervention (Study 2) or a standardized health letter from a physician (an adaptation of NCI <i>Quit for Good</i> pamphlet addressing general benefits of and barriers to quitting smoking) (Study 1). Study 1 had less than 6m follow up.
Strecher 2000	Participants were pregnant women.
Strecher 2005b	Short follow up
Strecher 2008	Did not meet review criteria for S-H materials; Web-based programme.
Travis 2004	Short follow up; S-H was an adjunct to telephone counselling.
Webb 2005	Smoking status was not a measured outcome.
Webb 2007	Smoking status was not a measured outcome.
Weissfeld 1991	'Self-help' condition received several individual counselling sessions.
Willemsen 1995	Not a randomized trial.
Windsor 1989	All groups received the same S-H intervention, differed on additional support or incentives.
Zhu 1996	All arms received S-H materials. Test of telephone counselling, included in Cochrane review of Telephone Counselling (Stead 2006).

ALA: American Lung Association

NCI: National Cancer Institute

m: month(s)

S-H: self help

w: week(s)

DATA AND ANALYSES

Comparison 1. Self help vs no self help, pooled by amount of contact

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Neither group had face-to-face contact (long term abstinence)	19	22337	Risk Ratio (M-H, Fixed, 95% CI)	1.24 [1.11, 1.39]
1.1 Control group given no materials	14	15711	Risk Ratio (M-H, Fixed, 95% CI)	1.45 [1.27, 1.66]
1.2 Control group given leaflet/pamphlet	5	6626	Risk Ratio (M-H, Fixed, 95% CI)	0.85 [0.70, 1.05]
2 Both groups had face-to-face contact (long-term abstinence)	5	3866	Risk Ratio (M-H, Fixed, 95% CI)	1.17 [0.96, 1.42]
2.1 Control group given no materials	4	2712	Risk Ratio (M-H, Fixed, 95% CI)	1.08 [0.86, 1.35]
2.2 Control group given leaflet/pamphlet	1	1154	Risk Ratio (M-H, Fixed, 95% CI)	1.42 [0.98, 2.04]
3 Both groups had face-to-face contact with advice (long term abstinence)	11	5365	Risk Ratio (M-H, Fixed, 95% CI)	0.97 [0.80, 1.18]
3.1 Control group given no materials	8	3581	Risk Ratio (M-H, Fixed, 95% CI)	0.92 [0.73, 1.16]
3.2 Control group given leaflet/pamphlet	3	1784	Risk Ratio (M-H, Fixed, 95% CI)	1.13 [0.79, 1.60]

Comparison 2. Self help vs no self help, pooling all studies

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Long-term abstinence	32	30644	Risk Ratio (M-H, Fixed, 95% CI)	1.08 [0.99, 1.17]
1.1 No contact/No materials for control	12	14787	Risk Ratio (M-H, Fixed, 95% CI)	1.21 [1.05, 1.39]
1.2 No contact/Leaflet for control	5	6626	Risk Ratio (M-H, Fixed, 95% CI)	0.85 [0.70, 1.05]
1.3 Face-to-face contact/No materials for control	4	2712	Risk Ratio (M-H, Fixed, 95% CI)	1.08 [0.86, 1.35]
1.4 Face-to-face contact/Leaflet for control	1	1154	Risk Ratio (M-H, Fixed, 95% CI)	1.42 [0.98, 2.04]
1.5 Advice/No materials for control	8	3581	Risk Ratio (M-H, Fixed, 95% CI)	0.92 [0.73, 1.16]
1.6 Advice/Leaflet for control	3	1784	Risk Ratio (M-H, Fixed, 95% CI)	1.13 [0.79, 1.60]

Comparison 3. Self help plus NRT vs NRT alone

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Long-term abstinence	4	2291	Risk Ratio (M-H, Fixed, 95% CI)	1.05 [0.88, 1.25]
1.1 Standard materials	2	825	Risk Ratio (M-H, Fixed, 95% CI)	0.95 [0.73, 1.24]
1.2 Tailored materials	2	1466	Risk Ratio (M-H, Fixed, 95% CI)	1.13 [0.89, 1.43]

Comparison 4. Tailored self-help materials

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Long-term abstinence	25	28189	Risk Ratio (M-H, Fixed, 95% CI)	1.31 [1.20, 1.42]
1.1 Individually tailored materials versus no materials	7	10872	Risk Ratio (M-H, Fixed, 95% CI)	1.36 [1.19, 1.55]
1.2 Individually tailored versus standard or stage-matched materials (matched for number of contacts)	9	9740	Risk Ratio (M-H, Fixed, 95% CI)	1.14 [0.99, 1.30]
1.3 Individually tailored initial and additional materials versus standard or stage-matched single mailing	5	4682	Risk Ratio (M-H, Fixed, 95% CI)	1.47 [1.11, 1.94]
1.4 Individually tailored additional materials versus standard or stage-matched single mailing	3	2787	Risk Ratio (M-H, Fixed, 95% CI)	1.72 [1.25, 2.37]
1.5 Individually tailored materials as an adjunct to advice	1	108	Risk Ratio (M-H, Fixed, 95% CI)	2.48 [1.13, 5.45]

Comparison 5. Other enhancements/adjuncts to self-help materials

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Long-term abstinence	10		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.1 Additional written materials	4	4085	Risk Ratio (M-H, Fixed, 95% CI)	1.01 [0.87, 1.17]
1.2 Additional video	2	424	Risk Ratio (M-H, Fixed, 95% CI)	0.72 [0.41, 1.28]
1.3 Targeted or stage-matched materials versus standard materials	5	3101	Risk Ratio (M-H, Fixed, 95% CI)	1.11 [0.90, 1.37]

Comparison 99. Sensitivity analyses

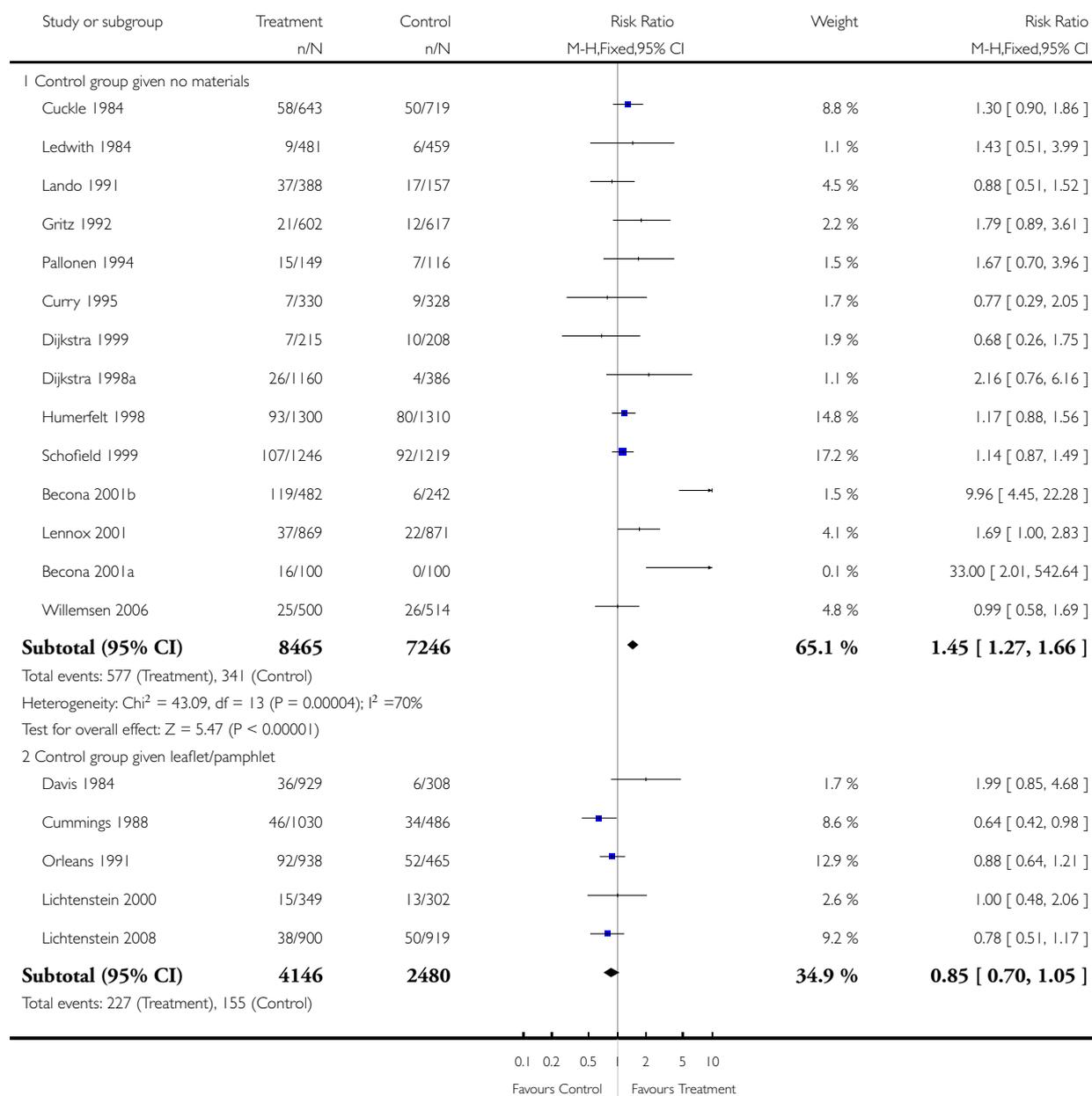
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Prochaska group studies, comparison of assumptions	5		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.1 Including all randomized, all losses as failures	5	8754	Risk Ratio (M-H, Fixed, 95% CI)	1.42 [1.21, 1.68]
1.2 Excluding people lost to follow up, refusals as failures where reported	5	6990	Risk Ratio (M-H, Fixed, 95% CI)	1.40 [1.19, 1.65]
1.3 Excluding lost to follow up and refusals	5	5946	Risk Ratio (M-H, Fixed, 95% CI)	1.53 [1.30, 1.81]
2 Comparison 4.1 with Prochaska/Velicer studies drop-outs excluded	21		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
2.1 Individually tailored materials versus no materials	7	8761	Risk Ratio (M-H, Fixed, 95% CI)	1.61 [1.40, 1.85]
2.2 Individually tailored vs standard or stage-matched materials	9	8389	Risk Ratio (M-H, Fixed, 95% CI)	1.16 [1.02, 1.33]
2.3 Individually tailored initial and additional materials versus standard or stage-matched single mailing	5	4636	Risk Ratio (M-H, Fixed, 95% CI)	1.49 [1.12, 1.97]

Analysis 1.1. Comparison 1 Self help vs no self help, pooled by amount of contact, Outcome 1 Neither group had face-to-face contact (long term abstinence).

Review: Self-help interventions for smoking cessation

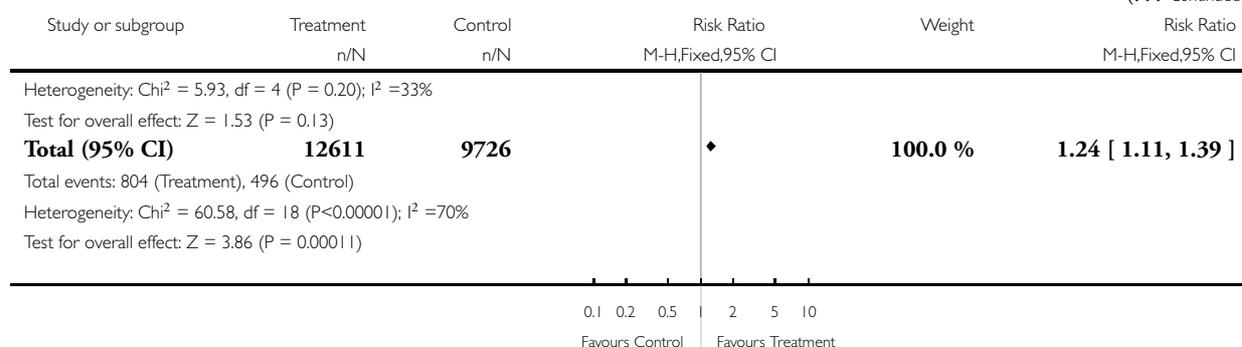
Comparison: 1 Self help vs no self help, pooled by amount of contact

Outcome: 1 Neither group had face-to-face contact (long term abstinence)



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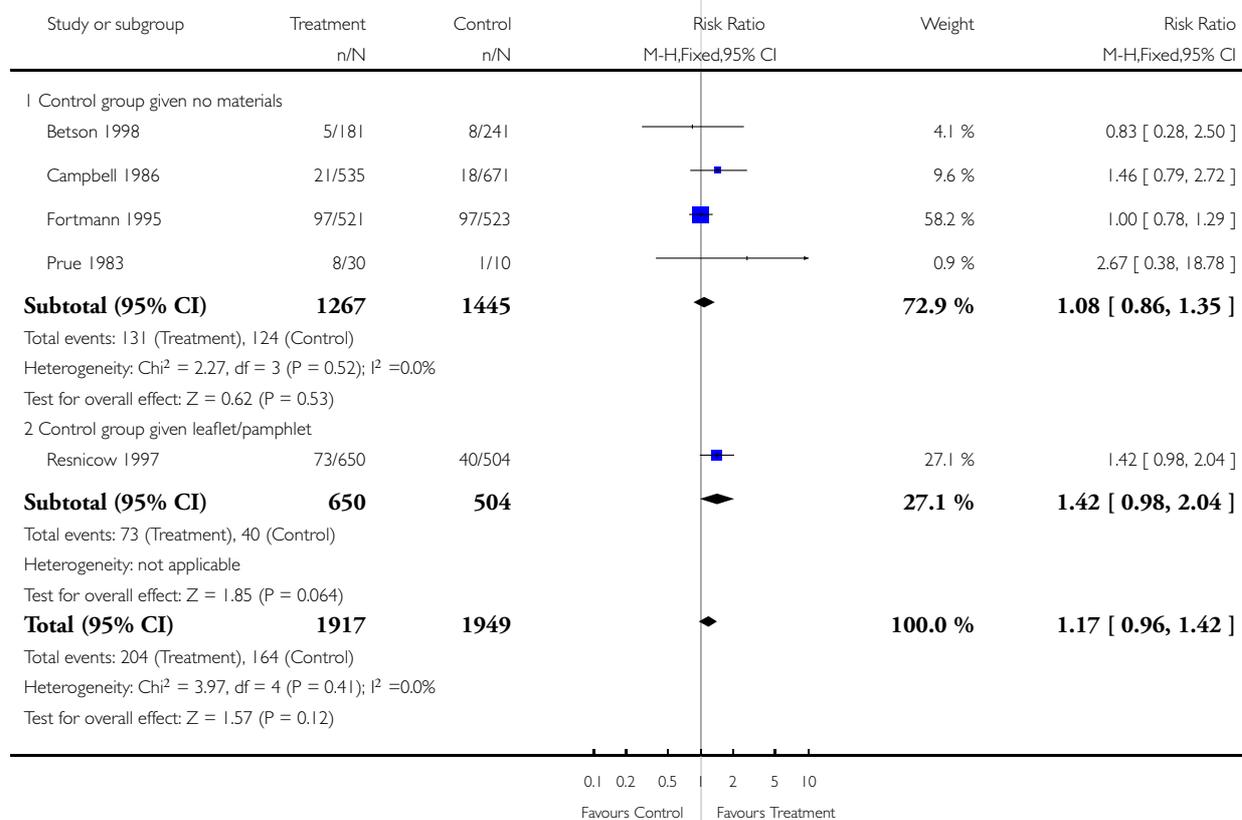


Analysis 1.2. Comparison 1 Self help vs no self help, pooled by amount of contact, Outcome 2 Both groups had face-to-face contact (long-term abstinence).

Review: Self-help interventions for smoking cessation

Comparison: 1 Self help vs no self help, pooled by amount of contact

Outcome: 2 Both groups had face-to-face contact (long-term abstinence)

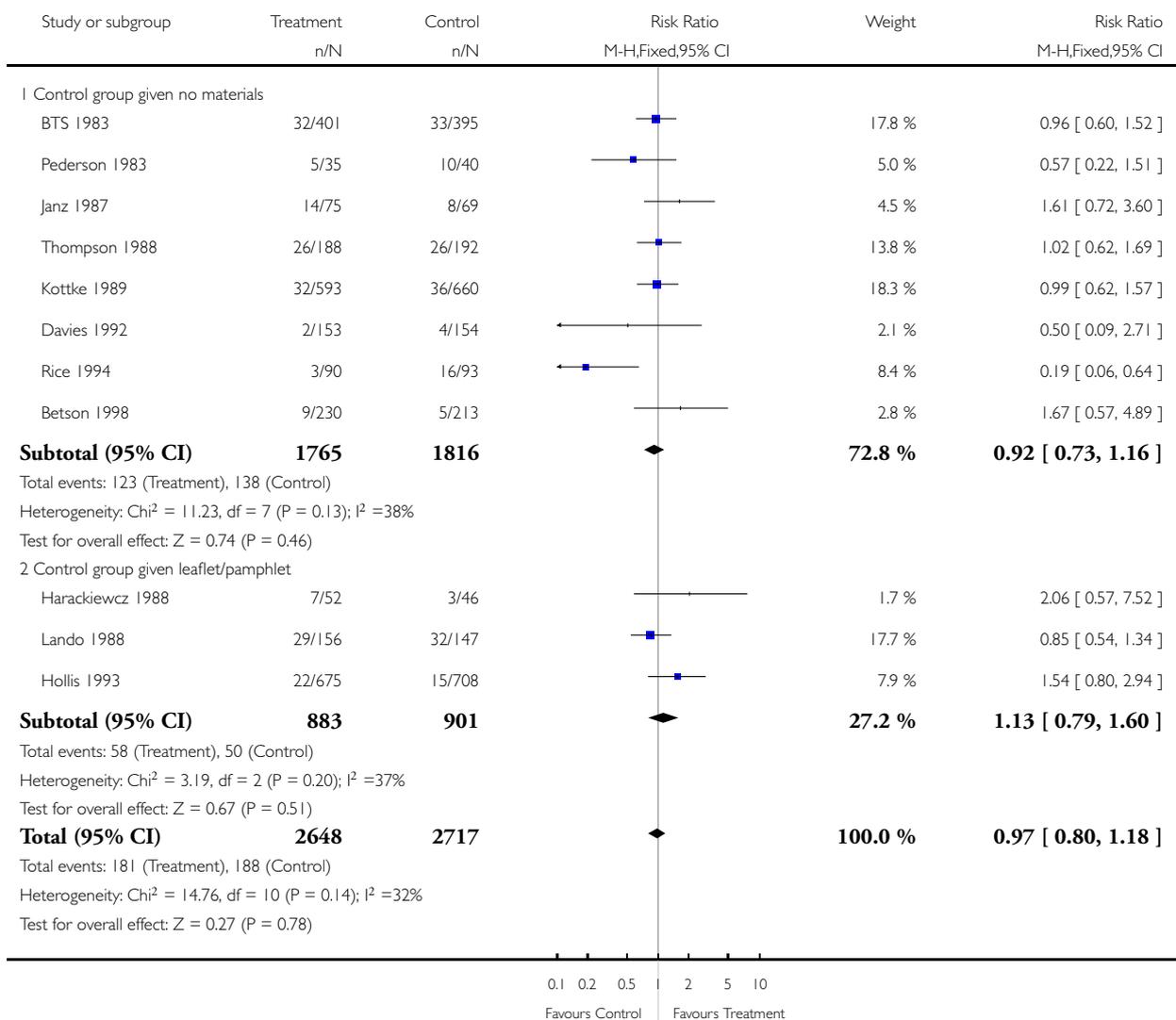


Analysis 1.3. Comparison 1 Self help vs no self help, pooled by amount of contact, Outcome 3 Both groups had face-to-face contact with advice (long term abstinence).

Review: Self-help interventions for smoking cessation

Comparison: 1 Self help vs no self help, pooled by amount of contact

Outcome: 3 Both groups had face-to-face contact with advice (long term abstinence)

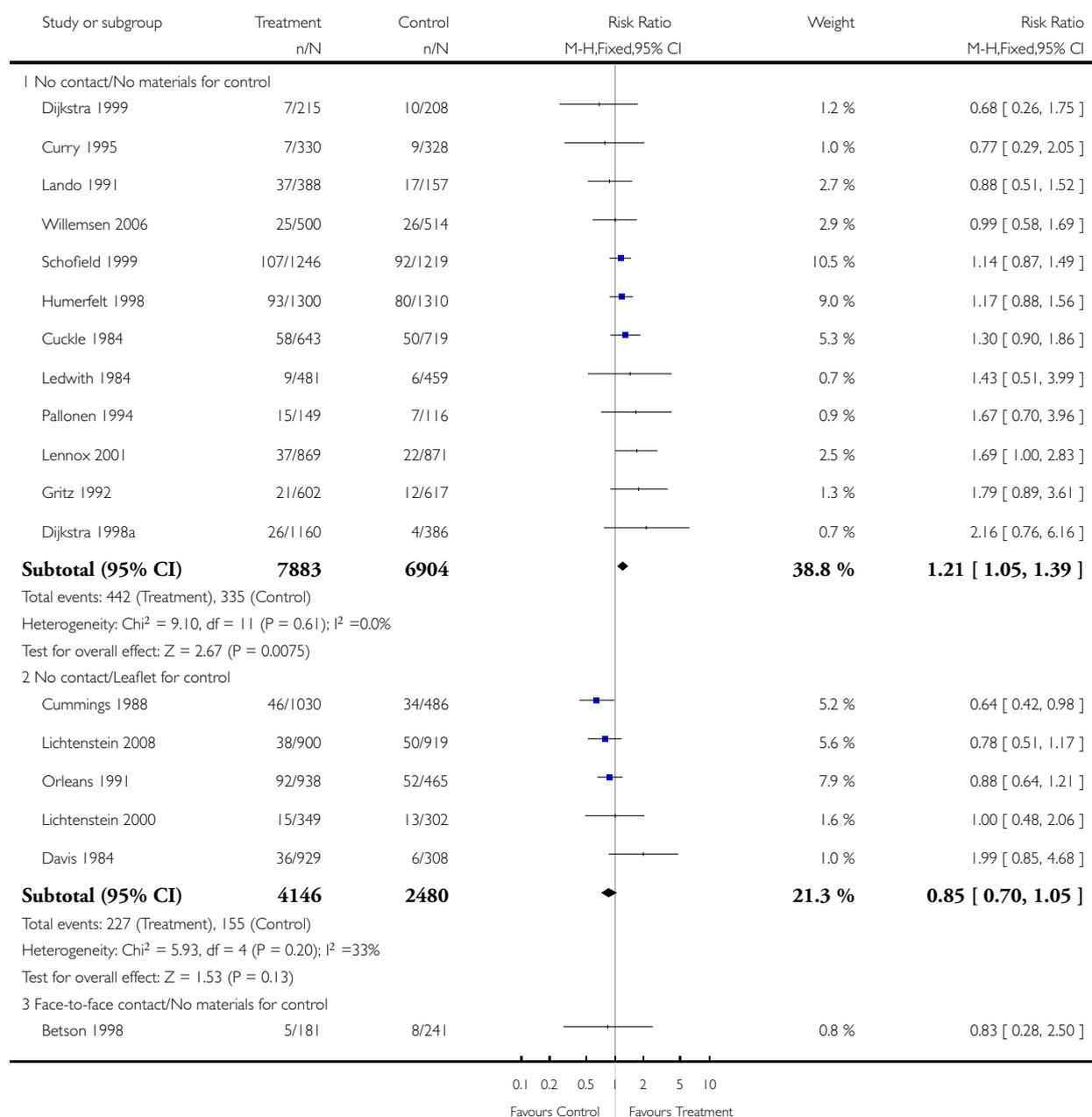


Analysis 2.1. Comparison 2 Self help vs no self help, pooling all studies, Outcome 1 Long-term abstinence.

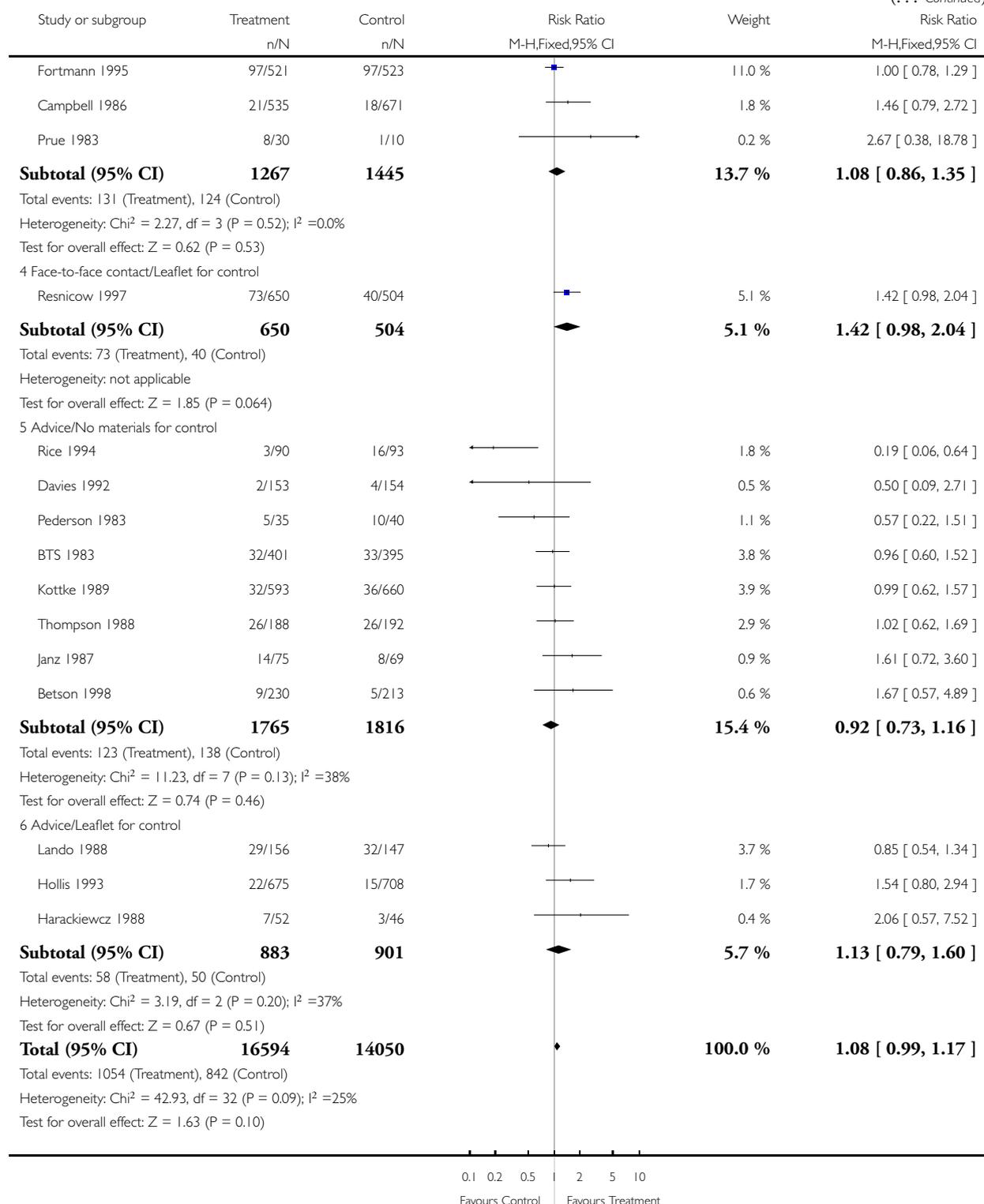
Review: Self-help interventions for smoking cessation

Comparison: 2 Self help vs no self help, pooling all studies

Outcome: 1 Long-term abstinence



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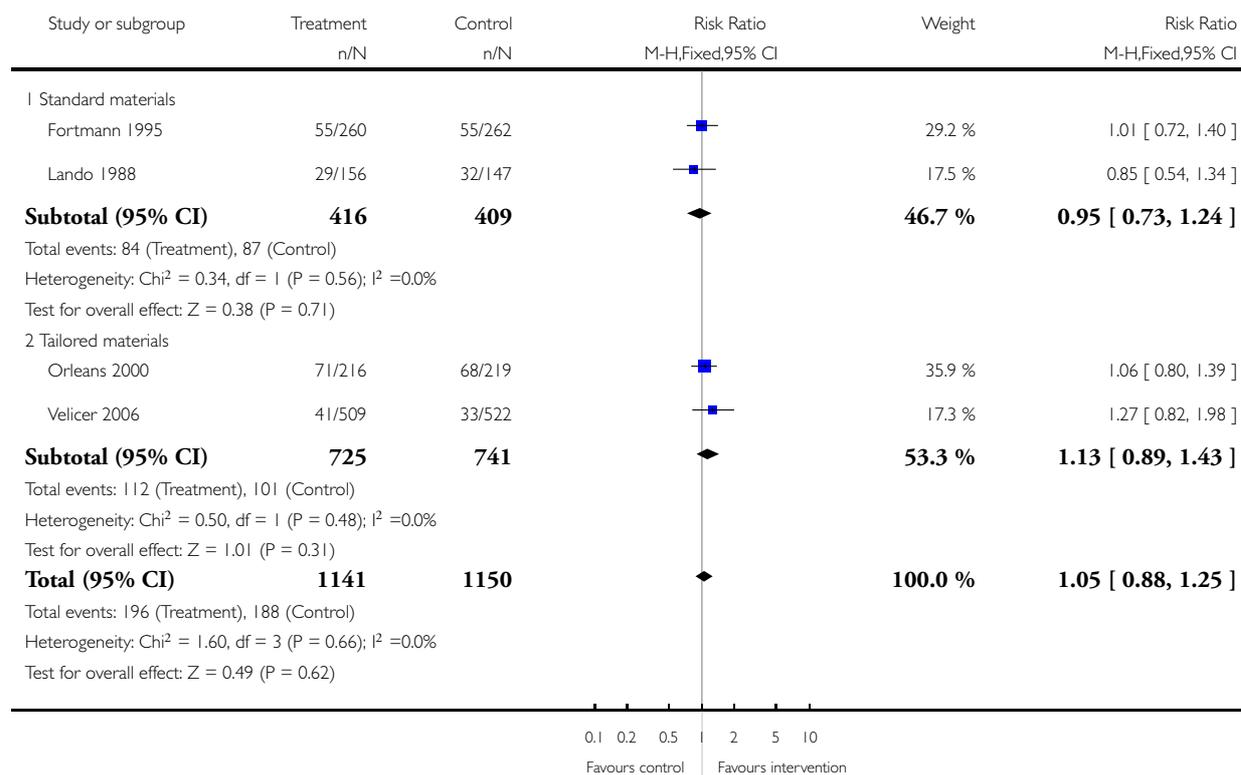


Analysis 3.1. Comparison 3 Self help plus NRT vs NRT alone, Outcome 1 Long-term abstinence.

Review: Self-help interventions for smoking cessation

Comparison: 3 Self help plus NRT vs NRT alone

Outcome: 1 Long-term abstinence

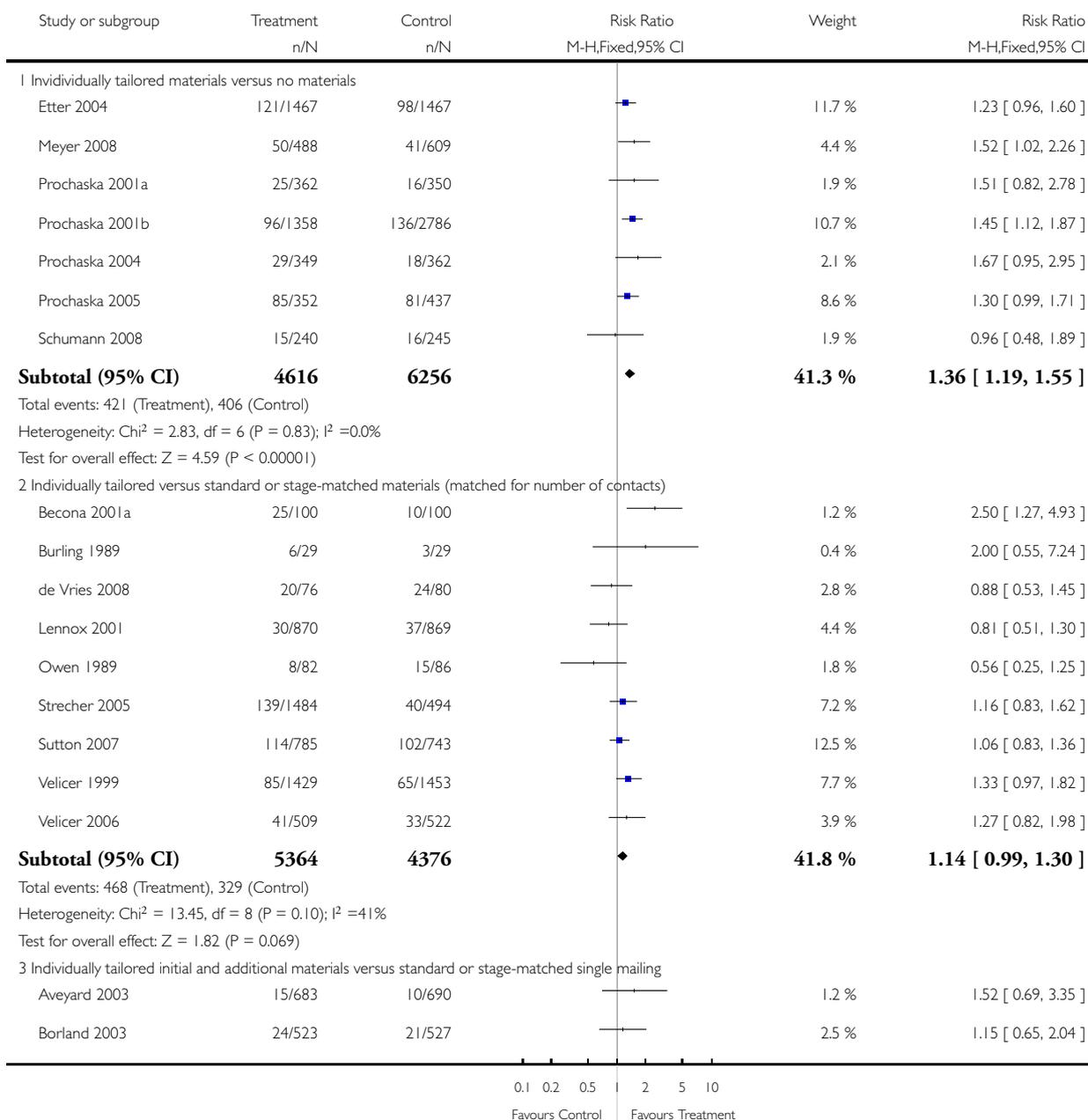


Analysis 4.1. Comparison 4 Tailored self-help materials, Outcome 1 Long-term abstinence.

Review: Self-help interventions for smoking cessation

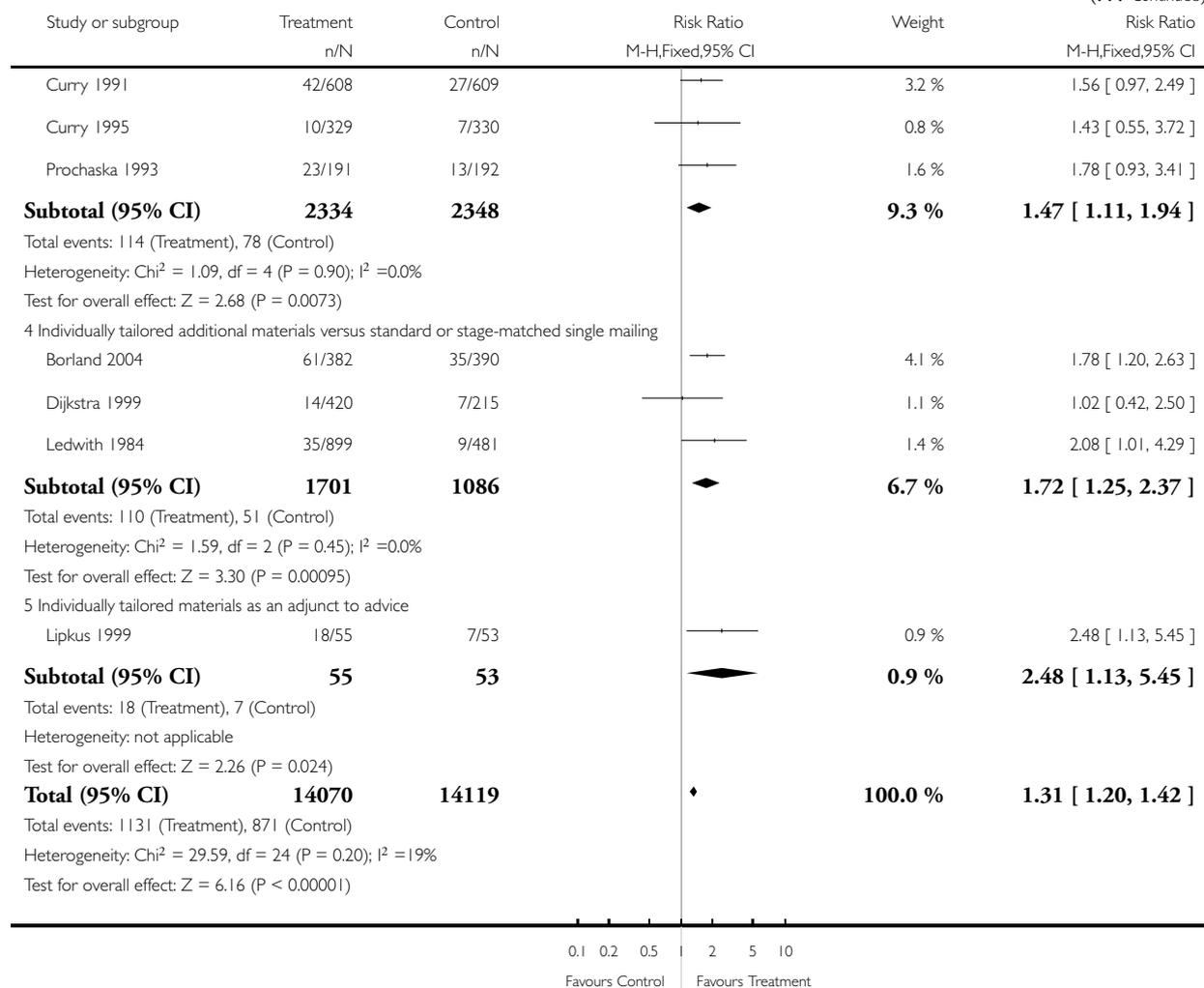
Comparison: 4 Tailored self-help materials

Outcome: 1 Long-term abstinence



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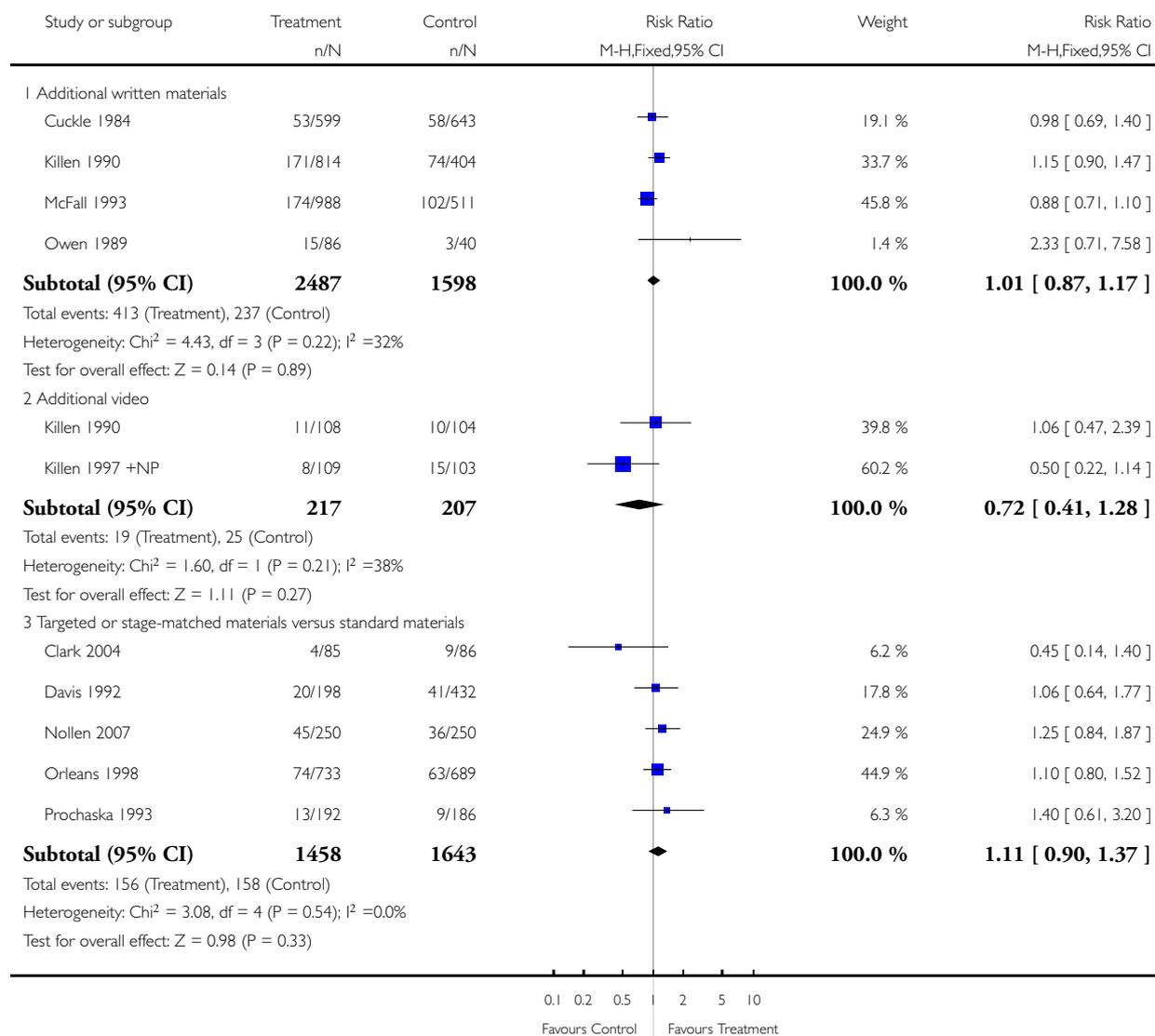


Analysis 5.1. Comparison 5 Other enhancements/adjuncts to self-help materials, Outcome 1 Long-term abstinence.

Review: Self-help interventions for smoking cessation

Comparison: 5 Other enhancements/adjuncts to self-help materials

Outcome: 1 Long-term abstinence

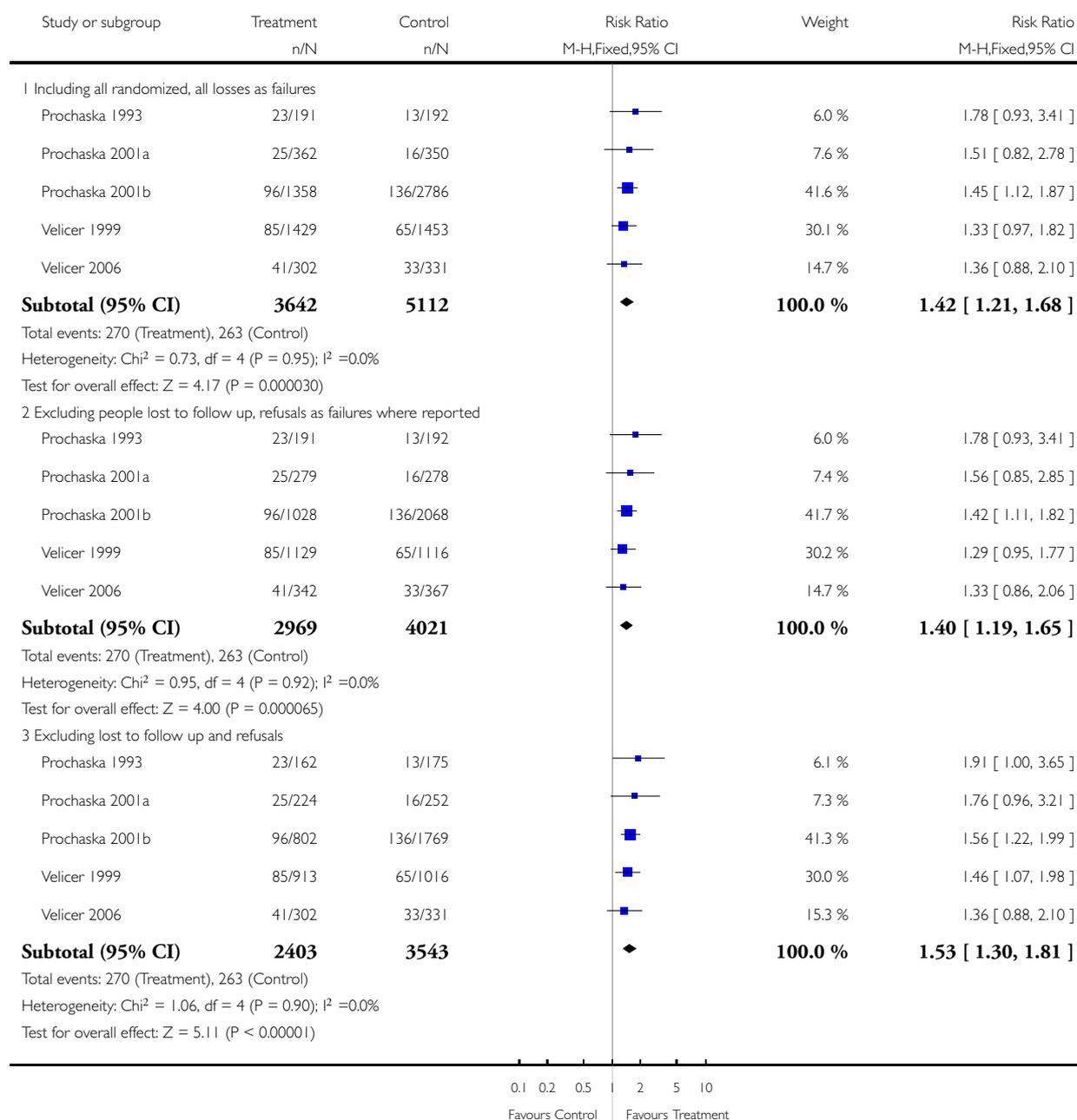


Analysis 99.1. Comparison 99 Sensitivity analyses, Outcome 1 Prochaska group studies, comparison of assumptions.

Review: Self-help interventions for smoking cessation

Comparison: 99 Sensitivity analyses

Outcome: 1 Prochaska group studies, comparison of assumptions

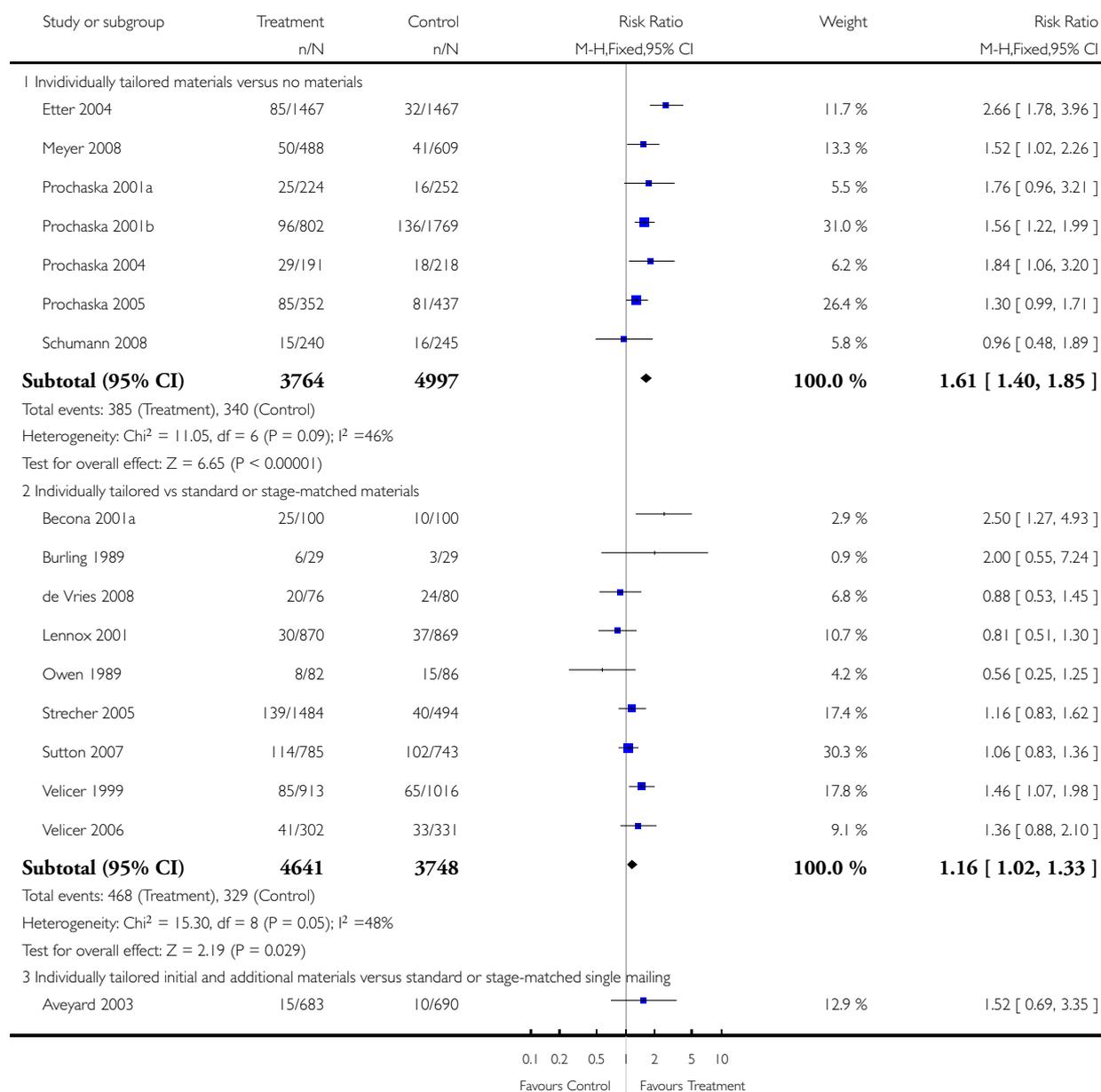


Analysis 99.2. Comparison 99 Sensitivity analyses, Outcome 2 Comparison 4.1 with Prochaska/Velicer studies drop-outs excluded.

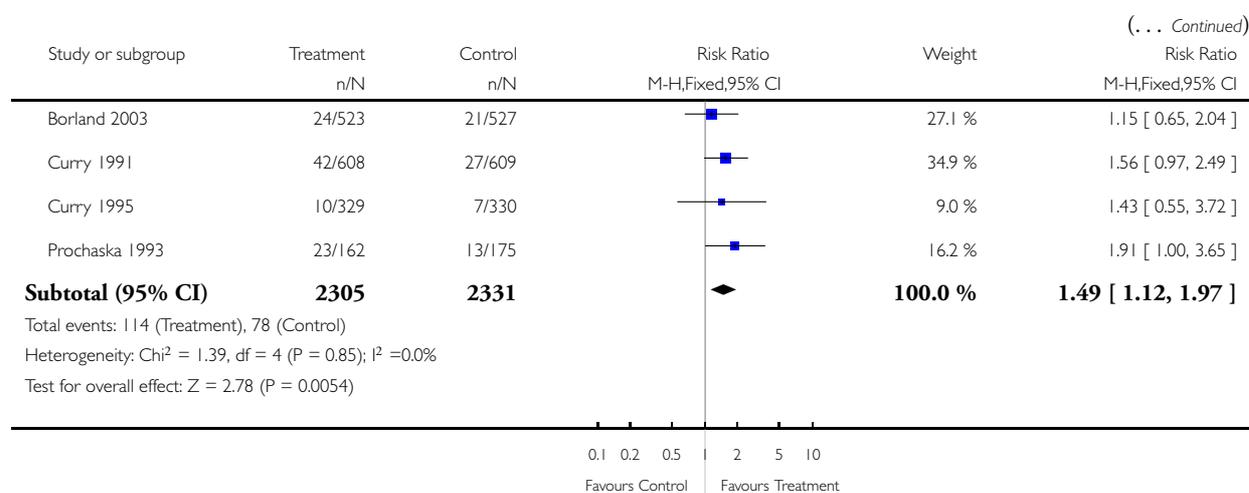
Review: Self-help interventions for smoking cessation

Comparison: 99 Sensitivity analyses

Outcome: 2 Comparison 4.1 with Prochaska/Velicer studies drop-outs excluded



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WHAT'S NEW

Last assessed as up-to-date: 29 November 2008.

28 January 2009	New search has been performed	Updated with ten new studies for Issue 2, 2009. No major changes to results
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HISTORY

Protocol first published: Issue 2, 1998

Review first published: Issue 4, 1998

29 October 2008	Amended	Converted to new review format.
28 April 2005	New citation required and minor changes	Updated for issue 3, 2005 with 9 new studies. Most used tailored interventions and strengthen the evidence that tailored materials are more useful than standard ones.
10 April 2002	New citation required and minor changes	Updated for issue 3, 2002 with 10 new studies. Most used tailored interventions and strengthen the evidence that tailored materials are more useful than standard ones.
13 October 1999	New search has been performed	Updated for issue 1, 2000 with 4 new trials.

CONTRIBUTIONS OF AUTHORS

TL and LS jointly undertook data extraction and drafting of review. LS conducted searches for trials.

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

- Department of Primary Health Care, University of Oxford, UK.
- National Institute for Health Research (NIHR) School for Primary Care Research, UK.

External sources

- NHS Research & Development Programme, UK.

INDEX TERMS

Medical Subject Headings (MeSH)

*Self Care; Behavior Therapy; Chewing Gum; Nicotine [analogs & derivatives; therapeutic use]; Patient Education as Topic; Polymethacrylic Acids [therapeutic use]; Polyvinyls [therapeutic use]; Randomized Controlled Trials as Topic; Smoking [*prevention & control]; Smoking Cessation [*methods]

MeSH check words

Humans