Effectiveness of complex psycho-educational interventions for smoking relapse prevention: an exploratory meta-analysis

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ABSTRACT

Background Existing systematic reviews have concluded that psycho-educational interventions for smoking relapse prevention were ineffective. Our objective was to conduct an exploratory meta-analysis, guided by mechanisms of these complex interventions for preventing smoking relapse.

Methods Relevant trials were identified from a Cochrane review and by an updated search of MEDLINE and PsycINFO (up to August 2009). We examined theories or mechanisms underlying relapse prevention interventions, and process variables reported in trials. Odds ratios (ORs) for the rate of smoking abstinence at the longest follow-up were pooled in meta-analysis.

Results Forty-nine trials were included, and interventions were at least partly based on the cognitive-behavioural approach to coping skills training in 41 trials. Only a few trials reported data on process variables. Coping skills training for smoking relapse prevention was effective for community quitters (OR 1.27, 95% CI: 1.08–1.49), and particularly for those who stopped smoking for at least 1 week at baseline (OR 1.52, 95% CI: 1.20–1.93). These findings were interpretable with mechanisms of coping skills training for relapse prevention.

Conclusions On the basis of post hoc subgroup analyses, coping skills training for smoking relapse prevention is effective for motivated community quitters. This finding has important public health implications and needs to be confirmed by further trials.

Keywords methods, public health, smoking

Introduction

For cigarette smokers who are motivated to quit, smoking cessation could be facilitated by effective interventions including behavioural, psychological and pharmacological interventions.1–4 However, for various reasons, many initial quitters start smoking again, and the abstinence rate declines over time.5 According to data from English Stop Smoking services, 53% of smokers who set a quit date were carbon monoxide-validated as quitters at 4 weeks,6 but the relapse rate was ∼75% between 4 and 52 weeks.7

The effectiveness of smoking cessation is therefore much reduced because of smoking relapse. A Cochrane systematic review included 53 trials of psychological or pharmacological interventions for smoking relapse prevention.8 In the Cochrane review, trials were classified according to smoking status at baseline, general population or specific populations, unaided abstainers or assisted abstainers and according to types of interventions. The Cochrane review concluded that ‘there is insufficient evidence to support the use of any specific intervention for helping smokers who have successfully quit for a short time to avoid relapse’.8 Therefore, interventions for smoking relapse prevention have not been explicitly recommended in stop smoking guidelines.9,10 A recent qualitative study found that the uncertain evidence base for the effectiveness was one of the identified barriers to the use of relapse prevention interventions at Stop Smoking Services in the UK.11

Psycho-educational interventions for smoking relapse prevention are complex healthcare interventions that usually contain several interacting components and involve changes to people’s behaviours.12,13 There are great methodological
challenges in the evaluation of complex healthcare interventions. The exact contribution of each individual component in a complex intervention is often unclear, and it is usually difficult to clearly describe the intervention. The importance of theories for the development and evaluation of complex healthcare interventions has been increasingly recognized. The revised MRC guidance on complex interventions stresses that ‘a good theoretical understanding is needed of how the intervention causes change’.13

We noticed that mechanisms or rationales underlying each psycho-educational intervention for smoking relapse prevention have not been explicitly examined in the Cochrane review.8 In this paper, we conducted an updated review of randomized controlled trials on smoking relapse prevention; examined underlying theories or mechanisms of psycho-educational interventions and conducted an exploratory meta-analysis.

Methods

The criteria for study inclusion used in the Cochrane review8 were adopted in this paper. We included randomized controlled trials that explicitly evaluated psycho-educational interventions for smoking relapse prevention in former smokers or current smokers motivated to quit, and reported point prevalence or continuous abstinence at a minimum follow-up of 6 months. We only included trials published in English language.

Relevant trials were identified by a check of studies included in the existing Cochrane review and an updated search of MEDLINE, PsycINFO and Cochrane Central Register of Controlled Trials. We also examined references of recently published trials for any relevant studies. Since the Cochrane review8 has updated its comprehensive literature search recently (August 2008), we did not conduct a further search of grey literature, key journals or conference proceedings. From 53 randomized controlled trials included in the Cochrane review,8 we included 44 trials of psycho-educational interventions18–61 after excluding one trial published in Japanese,62 six trials of pharmacological interventions63–68 and two other intervention trials (rapid smoking69 or training to implement guidelines70).

One reviewer (F.S.) updated the literature search on 20 August 2009, which was limited to studies published in English (see Appendix 1, Supplementary data, for search strategies). Since the most recent literature search in the Cochrane review8 on smoking relapse prevention was conducted on 20 August 2008, our updated literature search of MEDLINE and PsycINFO was limited to studies published from 2004 to 2009, and search of Cochrane Central Register of Controlled Trials limited to years 2008 and 2009. After excluding duplicates, the updated search of these bibliographic databases yielded a total of 261 references. On the basis of titles and abstracts of the 261 references, we identified 21 studies that were possibly relevant. Of these, nine were not relevant, eight had already been included in the Cochrane review8 and four additional trials were identified.71–74 A check of the references of the four newly identified studies yielded one additional relevant trial.75

From the included 49 trials, one reviewer (F.S.) abstracted and another reviewer (M.H.-L. or R.H.) checked data on participant and intervention characteristics, and results of smoking abstinence. Methodological quality of included trials was assessed in terms of randomization method, allocation concealment, loss to follow-up, validation of smoking abstinence, explicit consideration of theory or not and whether process evaluation was conducted. We focused on the examination of theories or mechanisms that underlie the psycho-educational interventions for smoking relapse prevention. Data about process or intermediate variables reported in trials were also extracted and discussed.

Meta-analysis may be categorized as being analytic or exploratory.76 The objective of analytic meta-analysis is to combine results from primary studies, and exploratory meta-analysis to investigate differences between primary studies. This review is an exploratory meta-analysis, using post hoc subgroup analyses to explore the impact of effect modification variables. Although we considered only randomized controlled trials, this review is observational and retrospective in nature.

The outcome of interest was the rate of smoking abstinence at the longest follow-up. Point prevalence abstinence is usually defined as no smoking (without even a puff) during the previous 7 days, and continuous abstinence may be defined as no smoking during the entire period of follow-up.77 For the purpose of smoking relapse prevention, the point prevalence abstinence was considered preferable in our analyses, although continuous abstinence outcome can be used when necessary. Meta-analyses were conducted using RevMan5 to test heterogeneity and to estimate pooled odds ratios (ORs). Standard errors in cluster randomized trials were inflated by using the method described in the Cochrane Handbook.78 Fixed-effect (inverse variance weighted) method was used in meta-analysis because there was no significant heterogeneity after separating studies into various subgroups.79

Carpiano and Daley80 suggested that ‘a theory may be defined as logically related propositions that aim to explain and predict a fairly general set of phenomena’, and they further distinguished conceptual frameworks, theories and
models. The purpose of this paper is to explore the usefulness of a good understanding of reasons why a complex intervention can be effective for smoking relapse prevention. Therefore, we will not explicitly distinguish conceptual frameworks, theories and models.

Most of the included trials evaluated relapse prevention interventions that were based on the cognitive-behavioural approach to coping skills training. With coping skills training, participants were trained to identify high-risk situations for smoking relapse (such as going out with friends, or feeling frustrated), and to develop and practice skills to cope with identified high-risk situations. Therefore, the effectiveness of coping skills training for relapse prevention depends on (1) the delivery and receipt of interventions, (2) the acquirement of coping skills by quitters and (3) the application of such skills in high-risk situations. This delineation of mechanisms of coping skills training interventions was used to investigate the association between measured process variables and clinical outcomes. In addition, we set out to investigate whether certain baseline characteristics were related to smoking outcome.

**Results**

**Methodological quality of included trials**

Results of assessment of methodological quality of included trials are summarized in Appendix 2, Supplementary data. Seven of the 49 trials were cluster randomized trials. Randomization method was unclearly reported in 27 trials. Allocation was clearly concealed in only six trials. In many trials, a large proportion of participants were lost to follow-up, although intention-to-treat analysis was possible in most cases. Smoking abstinence was at least partially validated in 34 trials. Theories or possible mechanisms underlying the investigated interventions were not explicitly considered in 14 trials, and process variables were not evaluated in 12 trials (Appendix 2, Supplementary data).

**Interventions and their underlying mechanisms**

Main characteristics of participants and interventions in the included trials are shown in Appendix 3, Supplementary data. Psycho-educational interventions for smoking relapse prevention had two forms: self-help materials and counseling. The latter can be further classified as telephone or face-to-face, individual or group sessions. The intensity of interventions varied considerably in terms of frequency of contact, length of material or time and duration.

Theories or mechanisms that underlie interventions for smoking relapse prevention in trials included coping skills training, self-regulation and motivation, problem solving, abstinence violation effect, cue exposure, health beliefs, trans-theoretical model, contingency management, mood management, social support and extended contact (Appendix 3, Supplementary data). One intervention programme may comprise multiple components based on different theories. In 41 of the 49 trials, relapse prevention interventions were at least partly based on the cognitive-behavioural approach to coping skills training.

**Process and mediating variables**

We extracted data on process and mediating variables reported in the included trials, including delivery/receipt of interventions, and the acquisition and use of coping skills (Appendix 4, Supplementary data). Process variables reported in most trials were the delivery and receiving of planned interventions. The recorded attendance of counseling sessions was generally satisfactory. About 57–98% of the participants reported that they had read self-help educational booklets sent to them. The use of telephone helplines was low; only 20% of the participants ever initiated a telephone contact in one trial and only 29 of the 921 participants (3%) used a telephone helpline in another trial. It also seemed difficult to arrange buddy support to ex-smokers. For example, Hajek et al. found that only 4% of participants arranged buddy contact.

Smith et al. found that people in the cognitive-behavioural group reported greater skill acquisition, when compared with participants in the motivational group. It was reported that participants in the skills training group improved their competence of coping with high-risk situations, or had higher ratings of confidence on smoking abstinence. However, there were no significant differences in self-efficacy strength or confidence in staying abstinent in several other trials.

Only two trials provided data on the actual use of coping skills. In a trial that compared skills training and discussion sessions, Hall et al. found that participants in the skills training group were more likely to report the use of specific relapse prevention strategies, and abstainers tended to be more likely to use coping skills than smokers. Another trial of self-guided written modules in unaided quitters reported that trial participants often failed to use these skills in practice, despite considering relapse prevention strategies as sensible.

**Smoking abstinence results**

Meta-analyses were conducted using data from individual trials (Appendix 5, Supplementary data). Ideally, the final
outcome of smoking abstinence would have been analysed according to the acquisition and use of coping skills for relapse prevention. However, there was a lack of data from the clinical trials on these process measures (Appendix 4, Supplementary data). We separated trials into subgroups according to participant characteristics at baseline: pregnant or postpartum quitters, hospitalized ex-smokers, forced short-term quitters, drug abusers, mental health illnesses, community smokers motivated to quit and community quitters.

Figure 1 shows that coping skills training for smoking relapse prevention was ineffective in special population groups, including pregnant or postpartum women, hospitalized patients, forced quitters, mental illness or drug abusers.

There was no significant heterogeneity in results across studies within each of the subgroups.

Coping skills training was not associated with a higher rate of smoking abstinence in community smokers motivated to quit and in smokers who quit <1 week at baseline (Fig. 2). However, results from five trials in which quitters were abstinent for at least 1 week at baseline showed that coping skills training was associated with a higher rate of smoking abstinence at the end of follow-up (pooled OR 1.52, 95% CI: 1.20–1.93). The difference between the three subgroups was statistically significant (P = 0.02, I² = 74%).

The five trials that included community quitters who had quit for at least 1 week were further separated into two

![Graph showing the effectiveness of coping skills training in special population groups.](https://example.com/graph.png)
subgroups: two trials of self-help material and three trials of counselling (Fig. 3). The pooled OR of coping skills training was 1.68 (95% CI: 1.17–2.40) for self-help material trials and 1.41 (95% CI: 1.02–1.94) for counselling trials. There was no statistically significant difference between the two subgroups (subgroup interaction test $P = 0.48$).

Interventions with coping skills training tended to show greater effect than other psycho-educational interventions, although the difference between the two sets of trials was not statistically significant (Fig. 4).

### Discussion

**Main findings of this meta-analyses**

Coping skills training is clearly ineffective when it is delivered at the early stage of smoking cessation for smokers who are motivated to quit (Fig. 2). However, the results of our meta-analyses revealed that coping skills training reduced smoking relapse in motivated quitters. Because participants in control groups often received low-intensity relapse prevention interventions, the effect of coping skills...
training for smoking relapse prevention in community quitters may have been underestimated by the available evidence from trials.22

What is already known on this topic
Smoking relapse is an important public health problem because a large proportion of initial quitters start smoking again.7 A Cochrane systematic review concluded that available psycho-educational interventions were not effective for preventing smoking relapse.8 Therefore, the current clinical guidelines for smoking cessation do not recommend specific interventions for relapse prevention,10 and lack of supportive evidence on effectiveness has hampered the use of psycho-educational interventions for smoking relapse prevention in clinical and public health practice.11
What this study adds
Theories and mechanisms underlying psycho-educational interventions for smoking relapse prevention have been used in this review to interpret evidence from trials. Pawson et al.\textsuperscript{14} recommended the method of a realist review to synthesize evidence on complex interventions, which emphasizes the explicit consideration of theory or theories underlying complex interventions. Relevant theories may help guide what might be the essential components of a complex intervention, how different components are related, and by what mechanism that a complex intervention works.\textsuperscript{15,80} In systematic reviews of complex interventions, the use of relevant theory is important to decide clear criteria for study inclusion, to meaningfully categorize studies of different interventions and to interpret results of meta-analysis.

Results of our meta-analyses indicated that coping skills training may be effective for community quitters who are highly motivated to remain abstinent. For other categories of participants, there was no significant difference in the rate of smoking abstinence between coping skills training and control interventions. These findings are interpretable with the possible mechanisms of coping skills training for relapse prevention. Clearly, the acquisition of coping skills itself is not sufficient, and only those who use these skills benefit.\textsuperscript{17} The results of trials of smoking relapse prevention are generally negative for pregnant and postpartum quitters. A qualitative study found that many postpartum quitters relapsed, not because they lacked skills to cope with high-risk situations, but because they desired to fully re-join their friends for social life.\textsuperscript{82}

At the early stage of smoking cessation, coping skills training for relapse prevention was not beneficial. For short-term quitters, the effect of coping skills training differed according to the length of smoking abstinence at baseline (Fig. 2). There was no significant difference in smoking abstinence at 12 months between the relapse prevention and control interventions in two trials that included smokers who quit just for 24\textsuperscript{29} or 48 h.\textsuperscript{38} In contrast, smoking relapse prevention interventions were effective for those who were able to quit for at least 1 week (Fig. 2). In addition, self-help materials for skills training may be as effective as and much cheaper than face-to-face counselling sessions.

Findings from this exploratory research synthesis have important public health implications. About 50\% of smokers who used NHS Stop Smoking Services are abstinent at 4 weeks and this declined to only 12.5\% at 12 months.\textsuperscript{6,7} According to the results of our meta-analysis, the coping skills training for quitters at 4 weeks may improve this quit rate from 12.5\% to 16.8\% at 12 months (based on an OR of 1.52). The number of short-term quitters needed to treat for one additional long-term quitter would then be about 12. The NHS Stop Smoking Services produced about 83 000 short-term quitters at 4 weeks (or about 20 750 quitters at 12 months) in 2008 in England.\textsuperscript{83} Relapse prevention interventions may result in more than 7000 additional long-term quitters per year in England. A previous cost-effectiveness analysis estimated that two life-years could be saved on average by one life-long quitter.\textsuperscript{84} Assuming only 25\% of the 7000 quitters at 12 months never smoke again, the life-years saved is about 3500 by providing relapse prevention interventions to 80 000 short-term quitters.

Limitations of this review
Methodological quality was poor and the risk of bias was moderate or high in most of the included trials. For example, patient allocation was not clearly concealed in four of the five trials that included community quitters who were already abstinent at least 1 week at baseline (Appendix 2, Supplementary data). Therefore, findings from this exploratory meta-analysis should be interpreted with caution.

We planned to conduct analyses according to underlying mechanisms of relapse prevention interventions. However, due to inadequate and inconsistent reporting of process variables in trials, planned analyses based on process variables were not conducted. Findings of this review were based on post hoc subgroup analyses in an exploratory meta-analysis, and such subgroup analyses may sometimes produce dubious findings.\textsuperscript{76} However, to a certain extent, our results could be explained by theories or mechanisms that underlie relapse prevention interventions.

Important mediating variables for coping skills training include measures of self-efficacy, skills learnt to cope with high-risk situations and the actual use of coping skills when required. Only a few trials reported data on process and mediating variables (Appendix 4, Supplementary data). When measured in terms of self-efficacy or confidence in staying abstinent, the results from different trials were inconsistent. Only two trials reported the actual use of coping skills by participants. Limited evidence suggested that participants in the skills training group and abstainers may be more likely to use these skills than those in the control group and those who relapsed.\textsuperscript{32,38}

Conclusions
On the basis of post hoc subgroup analyses and data from trials with moderate to high risk of bias, coping skills...
training for smoking relapse prevention may be effective for motivated quitters. This finding has important public health implications and needs to be confirmed by further well-designed studies.

**Authors’ contribution**

F.S. conceived the idea, extracted, analysed data from included trials, and prepared the manuscript. M.H.L. and R.H. checked data and commented on the manuscript.

**Supplementary data**

Supplementary data are available at the *Journal of Public Health* online.

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