Prevention of Relapse After Quitting Smoking

A Systematic Review of Trials

Tim Lancaster, MSc, MB, BS; Peter Hajek, PhD; Lindsay F. Stead, MSc; Robert West, PhD; Martin J. Jarvis, DSc

Background: After initially successful quit attempts, many people return to smoking within a year, reducing the public health benefits of investment in smoking cessation. We aimed to assess whether interventions designed to prevent relapse after a successful quit attempt reduce the proportion of recent quitters who return to smoking.

Methods: We searched the Cochrane Tobacco Addiction Review Group trials’ register. We selected randomized or quasi-randomized controlled trials of relapse prevention interventions with a minimum follow-up of 6 months. We included people who quit on their own, underwent enforced abstinence, or were in treatment programs. We included trials comparing relapse prevention interventions with no intervention or cessation plus relapse prevention with cessation intervention alone. Two of us independently extracted data from each report, with disagreements referred to a third author.

Results: Forty-two studies met the inclusion criteria. The most common interventions were skills training to identify and resolve tempting situations and extended treatment contact. A few studies tested pharmacotherapy. We separately analyzed studies that randomized abstainers and those that randomized participants before their quit date. Within subgroups of trials, pooled odds ratios ranged from 0.86 to 1.30, and in most analyses, 95% confidence intervals included 1. Most studies had limited power to detect moderate differences between interventions.

Conclusion: The evidence to date does not support the adoption of skills training or other specific interventions to help individuals who have successfully quit smoking to avoid relapse, but this is an important area for future study.

Arch Intern Med. 2006;166:828-835
DATA EXTRACTION

We extracted data on study setting, population, method of randomization, and allocation concealment; age, sex, baseline cigarette consumption, and period of quitting of participants; interventions and control condition; outcome, including length of follow-up; definition of cessation; and validation of self-reported smoking status.

DATA SYNTHESIS

The primary outcome was the number of quitters at the longest follow-up. We used biochemically validated cessation in preference to self-report where available, preferring continuous or prolonged abstinence to point prevalence abstinence where possible. We classified randomized participants who withdrew, were lost to follow-up, or failed to provide validation samples as continuing smokers. When studies reported strict and more lenient outcomes, we extracted both and conducted a sensitivity analysis on the pooled results. We expressed individual study results as an odds ratio (OR) with a 95% confidence interval (CI) and pooled study outcomes using a fixed-effect (Mantel-Haenszel) model, unless there was significant statistical or clinical heterogeneity between trials. We separately analyzed trials that randomized abstainers from those that randomized smokers. We also separated studies in which contact time was matched and those in which the relapse prevention included longer contact.

We performed subgroup analyses for longer (>4 weeks) and shorter durations of intervention, in trials randomizing smokers to matched-duration interventions, and between more (>4 sessions) and fewer intervention sessions for unmatched intervention and control programs. We also considered subgroup analyses for “skills” and social support studies, and for spontaneous quitters such as pregnant women and individuals seeking smoking cessation treatment.

DESCRIPTION OF STUDIES

We identified 42 studies for inclusion. One article9 reported 2 trials each with multiple arms relevant to different comparisons, and 48-11 included subgroups or factorial designs contributing to different comparisons. Two (5%) of the studies did not specifically describe the intervention as involving relapse prevention. One11 was a replication of an included study, and one1 randomized abstainers.

Studies Randomizing People Who Had Stopped Smoking

Twenty-six studies randomized people who had stopped smoking (Table 1). The interventions for preventing relapse included behavioral strategies and pharmacotherapy. Intensive behavioral interventions involved repeated face-to-face contact usually aiming at teaching clients to identify tempting situations and to apply a range of coping and cognitive strategies to resist relapse. Less intensive interventions included written materials and brief face-to-face or telephone contacts.

Among the studies randomizing people who had stopped smoking, 9 randomized pregnant14-19 or postpartum20-22 abstainers. Two studies6,13 randomized hospitalized inpatients with cardiovascular illness who had not smoked during hospital admission, and one13 randomized hospital patients who were abstinent on the day of discharge. Two studies24,25 randomized military recruits undergoing enforced abstinence. Five studies30-33 randomized participants recruited from local communities.

Five studies29-35 randomized abstainers who had taken part in a cessation program to behavioral interventions. Four studies randomized abstainers to pharmacological interventions, including nicotine chewing gum30,31 and bupropion hydrochloride34,35.

Studies Randomizing Current Smokers Before Their Quit Date

Seventeen studies (including 1 also contributing to the first category9) randomized smokers who then attempted to quit with or without relapse prevention components (Table 2).

Intervention and Control Groups Matched for Contact Time. In 9 studies, intervention and control conditions were matched for the amount of contact. Seven studies (1 with 2 components)3,7,10,26-28 used a group behavioral format, and 29,40 used individual counseling. Three provided pharmacotherapy to all treatment participants (the studies by Emmons et al38 and Buchkremer et al [with 2 components]37). A factorial design tested nicotine gum against no gum.40

Intervention and Control Groups Matched for Contact Time or Duration. Most smoking cessation studies comparing more with less intensive treatments include some intervention to prevent relapse. We only included trials that specified relapse prevention as an explicit focus of the intervention. We did not include studies offering treatment proactively to special populations, such as pregnant or hospitalized smokers, because all trials using these groups provide some relapse prevention input within the active treatment arm, and they are covered in separate Cochrane reviews. Where studies had 3 or more treatment conditions, we compared the most with the least intensive interventions. Seven studies3,12,41-43 compared longer with shorter programs, all involving face-to-face contact. The relative intensity of the cessation and the relapse prevention components varied. One study49 compared group-based behavior therapy for 8 weeks plus proactive calls 1, 8, and 11 months later with group therapy alone. We excluded other studies that tested the use of telephone counseling as an adjunct to nicotine replacement therapy, because most of the behavioral support was provided during the cessation period.

SAMPLE SIZE AND STUDY DESIGN

Many trials were small and had limited power to detect realistic differences in quit rates, especially in the group that randomized smokers before the quit date.

Studies randomizing successful end-of-treatment quitters provide the most straightforward test of relapse prevention interventions designed for clinical practice. All 4 studies6,10,34,35 of pharmacological treatments used this approach, but only 2 studies30,33 of behavioral treatments randomized participants who were abstinent for more than 1 week of treatment.

DEFINITION OF SMOKING CESSATION

We required a report of smoking status a minimum of 6 months from the start of the intervention. In the case of studies that randomized smokers before quitting, this could have been from the quit date. Some studies timed follow-up from the end of treatment. Three trials9,22,28 reported 6 months of follow-up; all others had a longer follow-up. Some studies did not provide a definition of abstinence, and most others reported point prevalence rather than sustained abstinence.

VALIDATION OF SELF-REPORTED ABSTINENCE

All but 6 studies20,22,24,25,26,28,29 used some form of biochemical validation of self-reported smoking status, but in some other cases, samples were not collected from all participants, were not collected at long-term follow-up, or were not used to correct self-reports.
Randomization

Four studies used cluster-randomized designs. In the 2 among military recruitst, allocation was by training group and selection bias was unlikely. In the others, allocation was by midwife or pediatric practice, and selection bias in the subsequent enrollment of participants might have been possible. Two of the cluster-randomized trials reported that correlation between

<table>
<thead>
<tr>
<th>Source</th>
<th>Country/No. of Participants</th>
<th>RP Interventions</th>
<th>Common Components and Control</th>
<th>Longest Follow-up (Type of Abstinence/Validation)</th>
<th>OR (95% CI) for Abstinence at Longest Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ershoff et al, 1995</td>
<td>United States/171 females (early pregnancy)</td>
<td>Self-help booklets, 4 on cessation at the baseline visit and 4 RP-focused booklets mailed</td>
<td>All: 2-min discussion on smoking and pregnancy with health educator. Control: 1-page tip sheet</td>
<td>Late in third trimester (PPA/cotinine)</td>
<td>1.32 (0.61-2.89)</td>
</tr>
<tr>
<td>Secker-Walker et al, 1995</td>
<td>United States/165 females (early pregnancy)</td>
<td>Counseling, skills rehearsal, 10-15 min at the first, second, and third prenatal visit and 8 and 36 wk postpartum</td>
<td>Control: usual care</td>
<td>36 wk of pregnancy, 8-54 mo postpartum/ cotinine-creatinine ratio prepartum only</td>
<td>Prepartum, 0.88 (0.46-1.68); and postpartum, 1.02 (0.53-1.96)</td>
</tr>
<tr>
<td>Lowe et al, 1997</td>
<td>United States/78 females (early pregnancy)</td>
<td>Counseling, 10-min RP materials at the fifth-grade reading level enhance social support with materials, and choose a &quot;buddy&quot;: reinforcement at routine visits by clinic staff</td>
<td>Control: usual care, including nurse advice</td>
<td>End of pregnancy, sustained/saliva thiocyanate</td>
<td>1.24 (0.42-3.64)</td>
</tr>
<tr>
<td>Secker-Walker et al, 1998</td>
<td>United States/125 females (early pregnancy)</td>
<td>Structured intervention from a physician, counseling by nurse counselor: first, second, third, fifth, and 36-wk prenatal visits</td>
<td>Control: usual care from physician, prompted at first visit</td>
<td>Sustained abstinence at 36-wk pregnancy, 1 y postpartum, CO for 36 wk (urine cotinine)‡</td>
<td>Prepartum, interventions 1 and 2, 1.97 (0.93-2.22); and postpartum, intervention 1, 1.99 (0.63-1.55), and intervention 2, 1.04 (0.66-1.63)</td>
</tr>
<tr>
<td>McBride et al, 1999</td>
<td>United States/897 females (44% already quit in early pregnancy and RP postpartum for end-of-pregnancy quitters)</td>
<td>1. Prepartum intervention: tailored letter, S-H book; after 28 wk, sent RP kit; 3 telephone counseling calls, approximately 2 wk after S-H mailing and 1 and 2 mo later (average, 8.5 min). 2. Prepartum/postpartum intervention: as done in 1, plus 3 calls within the first 4 mo postpartum (average, 7.7 min). 3. Newsletters Advice from a midwife with an explanation of CO reading, a pamphlet, and a prompt placed in notes for reinforcement</td>
<td>Self-help booklet only</td>
<td>28-wk pregnancy, 12 mo postpartum (PPA/saliva cotinine)*</td>
<td>Prepartum, interventions 1 and 2, 1.97 (0.93-2.22); and postpartum, intervention 1, 1.99 (0.63-1.55), and intervention 2, 1.04 (0.66-1.63)</td>
</tr>
<tr>
<td>Hajek et al, 2001</td>
<td>England/249 cluster-randomized females (early pregnancy)</td>
<td>Self-help booklets, 4 on cessation at the baseline visit and 4 RP-focused booklets mailed</td>
<td>Usual midwife care</td>
<td>Birth (12 wk SA) and 12 mo (SA/CO)</td>
<td>Birth, 1.35 (0.82-2.44); and postpartum, 0.88 (0.49-1.98)</td>
</tr>
<tr>
<td>Severson et al, 1997</td>
<td>United States/1026 cluster-randomized females (postpartum)</td>
<td>Counseling plus follow-up at 2-, 4-, and 5-mo visits, plus materials</td>
<td>All: information pack, including letter from pediatrician on risks of passive smoking</td>
<td>12-mo postpartum (SA); no validation (losses to follow-up 25% assumed to have relapsed)</td>
<td>1.38 (1.05-1.82); and corrected for clustering, 1.25 (0.93-1.68)</td>
</tr>
<tr>
<td>Ratner et al, 2000</td>
<td>Canada/215 females (postpartum)</td>
<td>Counseling session in the hospital, plus 8 telephone calls (weekly for 1 mo and biweekly for 2 mo); skills training, S-H pamphlets, and no smoking materials</td>
<td>Usual care</td>
<td>12-mo postpartum (SA/CO)</td>
<td>1.17 (0.62-2.22)</td>
</tr>
<tr>
<td>Van’t Hof et al, 2000</td>
<td>United States/277 females (postpartum)</td>
<td>Counseling from a visiting nurse, 15-50 min, after baseline interview; reinforcement by pediatric care provider at 2-wk and 2- and 4-mo well-baby clinics; written materials; chart sticker used to prompt intervention</td>
<td>Usual care, baseline assessment from a visiting nurse</td>
<td>6-mo postpartum/no validation</td>
<td>0.83 (0.51-1.34)</td>
</tr>
<tr>
<td>Schmitz et al, 1999</td>
<td>United States/53 females (hospitalized for coronary artery disease)†</td>
<td>RP intervention with focus on coping skills and stress management (6 sessions that were 1 h long)</td>
<td>Intervention based on Health Belief model; smoking-related health information related to disease: focus on benefits of stopping smoking and health effects, costs, social impact, and role play</td>
<td>6 mo (PPA/CO and urine cotinine)*</td>
<td>0.81 (0.15-4.42)</td>
</tr>
<tr>
<td>Hajek et al, 2002</td>
<td>England/540 males and females (hospitalized for myocardial infarction or coronary artery bypass grafting)</td>
<td>Intervention from cardiac nurses during routine work (20 min); CO reading, booklet on smoking, and cardiac recovery, written quiz, other to find support “buddy”: commitment, and reminder in notes</td>
<td>All: verbal advice and “Smoking and Your Heart” booklet</td>
<td>12 mo (SA)/saliva cotinine</td>
<td>0.86 (0.60-1.23)</td>
</tr>
<tr>
<td>Hasuo et al, 2004</td>
<td>Japan/106 males and females (hospitalized, quit on day of discharge)</td>
<td>Additional telephone contact (5 min at 7, 21, and 42 d postdischarge)</td>
<td>All: intervention from public health nurse during hospitalization (3 times, for 20 min)</td>
<td>12 mo/urine nicotine</td>
<td>1.29 (0.57-2.64)</td>
</tr>
<tr>
<td>Klesges et al, 1999</td>
<td>United States/18 010 Air Force recruits (smokers before training)</td>
<td>Single 50-min intervention during the final week of training, 50 per group (including nonsmokers); discussed health effects, costs, social impact, and role play</td>
<td>All: 6-wk smoking ban and 2 videos, Control: general health video</td>
<td>12 mo/no validation</td>
<td>OR not estimable, no significant benefit</td>
</tr>
<tr>
<td>Conway et al, 2004</td>
<td>United States/1682 female naval recruits (661 reached at follow-up)</td>
<td>6 S-H mailings over 12 mo, 1-page flyers, cognitive-behavioral RP, stress management, weight, and fitness, tailored for naval women</td>
<td>All: 2-mo smoking ban. Control: no intervention</td>
<td>12 mo/no validation (PPA)</td>
<td>OR not estimable, no significant benefit</td>
</tr>
</tbody>
</table>

(continued)
<table>
<thead>
<tr>
<th>Source</th>
<th>Country/No. of Participants</th>
<th>RP Interventions</th>
<th>Common Components and Control</th>
<th>Longest Follow-up (Type of Abstinence)/Validation</th>
<th>OR (95% CI) for Abstinence at Longest Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Killen et al, 1990</td>
<td>United States/1218 community volunteer smokers who quit unaided for 48 h</td>
<td>Factorial trial, contributes to 2 comparisons: behavioral intervention, RP-focused S-H materials, 16 modules prepared (either self-selected modules in weekly mailings or 7 random modules); and pharmacotherapy intervention, 2 mg nicotine gum, fixed or ad libitum schedule</td>
<td>All: S-H booklet, “How to Cope With the Uprise to Smoke Without Smoking.” Behavioral control: no further contact. Pharmacotherapy control: placebo gum or no gum</td>
<td>12 mo (PPA/salvia cotinine)*</td>
<td>Effect of S-H materials: 1.19 (0.88-1.61); and effect of nicotine gum, 1.23 (0.93-1.64)</td>
</tr>
<tr>
<td>Fortmann and Killen. 1995</td>
<td>United States/1044 proactively recruited smokers, who quit unaided for 24 h</td>
<td>Factorial trial, contributes to 2 comparisons: behavioral intervention, RP-focused S-H materials; and pharmacotherapy intervention, 2 mg of nicotine gum</td>
<td>All: $100 incentive for 6-mo quit. Behavioral control: no S-H materials. Pharmacotherapy control: no gum</td>
<td>12 mo (PPA/CO and saliva cotinine)</td>
<td>S-H, 1.00 (0.73-1.37); and nicotine gum, 1.39 (1.02-1.91)</td>
</tr>
<tr>
<td>Brandon et al, 2000</td>
<td>United States/584 unaided ex-smokers (median abstinence, 6.5 mo)</td>
<td>2 × 2 factorial design testing mail and hotline interventions. 1. Mailings condition: 8 Stay Quit booklets mailed at 1, 2, 3, 5, 7, 9, and 12 mo. 2. Stay Quit hotline. Participants called if not registered within 2 wk at and 3 mo if no call made. 3. Combined mailing and hotline.</td>
<td>No true control; minimal contact condition received first Stay Quit booklet</td>
<td>12 mo (PPA/CO)*</td>
<td>Interventions vs minimal contact, 0.99 (0.66-1.50); S-H mailings vs not, 1.05 (0.74-1.48) (includes dropouts as relapsed)</td>
</tr>
<tr>
<td>Brandon et al, 2004</td>
<td>United States/431 unaided ex-smokers (mean abstinence, 75 d)</td>
<td>2 × 2 factorial design testing the effects of high vs low content and high vs low contact. 1. Repeated mailings: 8 booklets at enrollment and 1, 2, 3, 5, 7, 8, and 12 mo. 2. Mass mailings. Same 8 booklets all at enrollment. 3. Repeated letters, single booklet, 7 supportive letters, same schedule as in 1.</td>
<td>No true control; minimal contact condition received 1 booklet at enrollment</td>
<td>24 mo (SA, since 18 mo)/CO (local volunteers only)*</td>
<td>Interventions vs minimal contact, 1.20 (0.77-1.85); S-H mailings vs not, 1.74 (1.09-2.97) (including dropouts as relapsed)</td>
</tr>
<tr>
<td>Borland et al, 2004</td>
<td>Australia/215 quitters (calling quitline; 63% had quit in the previous week)†</td>
<td>S-H: tailored advice letters based on standardized telephone assessment; 2-3 pages, tailored in part by stage of change, timing varied</td>
<td>All: quit pack after contact with the quitline, 1-2 d before recruitment. Control: no further intervention.</td>
<td>12 mo (SA/no validation)</td>
<td>1.65 (0.98-2.80)</td>
</tr>
<tr>
<td>Powell and McCann, 1981</td>
<td>United States/51 assisted abisters</td>
<td>1. 4-wk support group. 2. Telephone contact system allowing participants to telephone each other</td>
<td>All: cessation program before randomization. Control: no further contact</td>
<td>12 mo/no validation</td>
<td>1.00 (0.24-4.08)</td>
</tr>
<tr>
<td>Stevens and Hollis, 1989</td>
<td>United States/587 assisted abisters (confirmed abstinent 4 d after CP)</td>
<td>Three 2-h weekly meetings covering skills development and active rehearsal of coping strategies</td>
<td>All: cessation program before randomization. Active control: discussion condition; three 2-h social support meetings. Control: no further contact</td>
<td>12 mo (SA/saliva thiocyanate)</td>
<td>1.44 (0.95-2.19)</td>
</tr>
<tr>
<td>Razavi et al, 1999</td>
<td>Belgium/344 abisters (3 mo after CP)</td>
<td>1. Ten monthly sessions, including group discussion and role play led by a professional counselor. 2. Ten sessions of group discussion led by former smokers</td>
<td>All: CP before randomization. Control: no further intervention</td>
<td>9 mo (SA/CO and urine cotinine)</td>
<td>1.41 (0.85-2.33)</td>
</tr>
<tr>
<td>Smith et al, 2001</td>
<td>United States/677 abisters (1 wk after quit day)</td>
<td>1. Cognitive-behavioral skills training (6 times, from 1 wk post-TQD), including managing negative effect, homework, and manual. 2. Motivational interviewing, supportive group counseling (6 times from 1-wk post-TQD), No homework or manual</td>
<td>All: 3 brief individual counseling sessions, nicotine patches, and S-H materials. Control: no further intervention</td>
<td>12 mo (PPA/CO)</td>
<td>0.67 (0.43-1.06)</td>
</tr>
<tr>
<td>Mermelstein et al, 2003</td>
<td>United States/341 abisters</td>
<td>Tailored proactive telephone counseling: 3 weekly sessions, and then 3-6 alternate weekly sessions (15 min each)</td>
<td>All: 7-wk group CP. Control: supportive but nonspecific proactive counseling (same schedule)</td>
<td>15 mo (PPA/no validation)</td>
<td>0.76 (0.49-1.16)</td>
</tr>
<tr>
<td>Hays et al, 2001</td>
<td>United States/429 abisters after 7 wk of bupropion hydrochloride therapy</td>
<td>Bupropion, 300 mg/d, for 45 wk</td>
<td>All: physician advice, S-H, and brief counseling during cessation phase. Control: placebo</td>
<td>2 y, 1 y after EOT (SA)/CO validation</td>
<td>1.16 (0.76-1.77)</td>
</tr>
<tr>
<td>Hurt et al, 2003</td>
<td>United States/176 abisters after an 8-wk tailored-dose nicotine patch</td>
<td>Bupropion, 300 mg/d, for 6 mo</td>
<td>All: brief advice and S-H during the cessation phase. Control: placebo</td>
<td>12 mo, 6 mo after EOT (PPA/CO) validation</td>
<td>1.59 (0.73-3.46)</td>
</tr>
</tbody>
</table>

Abbreviations: CI, confidence interval; CO, carbon monoxide; CP, cessation program; EOT, end of treatment; OR, odds ratio; PPA, point prevalence abstinence; RP, relapse prevention; SA, continuous, multiple point prevalence, or sustained abstinence; S-H, self-help; TQD, target quit date.

*Incomplete validation or validated rates not reported.
†Trial also recruited smokers, not included herein.
‡Excludes postrandomization dropouts.
outcomes in individuals in the same cluster was small so that reporting individual outcomes was acceptable. These 2 trials also had high loss to follow-up, although there was no evidence of differential loss between arms.

In the absence of significant findings in meta-analysis subgroups, we did not attempt to explore the influence of study quality on outcomes.

### RESULTS

#### TRIALS IN ABSTINERS

**Specific Populations**

**Pregnant and Postpartum Ex-smokers.** We did not detect a significant benefit at the end of pregnancy from 6 trials (14-19) (n = 1183; OR, 1.17; 95% CI, 0.90-1.53). We also failed to detect an effect in the studies (15,17-22) that included postpartum follow-up (n = 2695; OR, 1.08; 95% CI, 0.92-1.27).

**Hospital Inpatients.** We failed to detect an effect of intervention in hos-
Military Personnel. Neither trial detected a benefit of intervention. In both trials, the period of enforced abstinence gave rise to a higher quit rate than the spontaneous rate expected in these populations of young smokers, but no effect was detected from the additional interventions. Less than 3% of participants used the telephone support offered in one trial.25

**Behavioral Interventions for Unaided Abstainers**

We detected no evidence of a benefit of interventions to prevent relapse in people who had quit unaided (n = 3,561; OR, 1.14; 95% CI, 0.96-1.34). All 5 studies used self-help interventions, although in one, the materials were individually tailored based on information collected via telephone questionnaires. Using different comparator groups in the 2 factorial studies of different types of self-help did not substantially alter the pooled effect.

**Behavioral Interventions for Assisted Abstainers**

We detected no long-term effect of skills-based interventions to prevent relapse in 5 studies in which abstinence was determined via telephone questionnaires. We found no evidence of a long-term effect of interventions to prevent relapse in people who had quit with self-help (n = 356; OR, 1.05; 95% CI, 0.80-1.38). The 3 studies used 3 telephone calls for relapse prevention among patients abstaining from 3 telephone calls for relapse prevention.

**Table 2. Studies Randomizing Participants Before Their Quit Attempt (cont)**

<table>
<thead>
<tr>
<th>Source</th>
<th>Country/No. of Participants</th>
<th>RP Interventions</th>
<th>Common Components and Control</th>
<th>Longest Follow-up (Type of Abstinence)/Validation</th>
<th>OR (95% CI) for Abstinence at Longest Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Killen et al, 1984 United States/44 smokers*</td>
<td>RP training; 2 sessions in 2 wk, including identification of high-risk situations and coping strategies; homework</td>
<td>All: CP, 4 (1.5-h) sessions over 4 d, including CBT, skills training, and nicotine gum. Control: no further intervention</td>
<td>10.5 mo (4-wk prevalence)/CO (serum thiocyanate at 6 wk only)</td>
<td>3.40 (0.93-12.49)</td>
<td></td>
</tr>
<tr>
<td>Hall et al, 1985 United States/84 smokers*</td>
<td>Intensive BT, 14 (75-min) sessions over 8 wk, including RP skills training, relaxation, and 2 mg of nicotine gum</td>
<td>Control: 4 sessions in 3 wk, educational materials, written exercises, group discussion, and nicotine gum</td>
<td>1y (PPA/CO) and serum thiocyanate</td>
<td>1.32 (0.55-3.16)</td>
<td></td>
</tr>
<tr>
<td>Brandon et al, 1987 United States/39 smokers‡</td>
<td>Additional 4 (1.5-h) sessions at 2, 4, 8, and 12 wk postcessation: self-monitoring, advice, assignment of exposure, and coping exercises</td>
<td>All: group CP, 6 (2-h) sessions over 2 wk. Control: no maintenance sessions</td>
<td>1y/CO during treatment, 2 informants</td>
<td>1.14 (0.31-4.16)</td>
<td></td>
</tr>
<tr>
<td>Hall et al, 1987 United States/139 smokers</td>
<td>Group behavioral treatment, 14 (75-min) sessions, including 6-second aversive smoking, RP skills training, and written exercises, with or without nicotine gum</td>
<td>Factorial trial: nicotine gum conditions collapsed. Control: “low contact,” 5 (60-min) sessions, including exercises, materials, group discussions, and quit techniques</td>
<td>1y/thiocyanate, CO, significant other</td>
<td>0.68 (0.33-1.40)</td>
<td></td>
</tr>
<tr>
<td>Buchkremer et al, 1991 Germany/149 smokers*</td>
<td>Additional 3 booster sessions 6 mo after TQD, with or without RP component CP</td>
<td>All: nicotine patch, dose individualized, 9 weekly sessions, including reduction, self-monitoring, contract management, and risk avoidance. TQD after 6 wk. Control: no further intervention</td>
<td>1y post-EOT (PPA/urine nicotine</td>
<td>0.78 (0.38-1.58)</td>
<td></td>
</tr>
<tr>
<td>Lifra et al, 1997 United States/69 smokers</td>
<td>Extended support; 16 weekly 45-min cognitive-behavioral RP therapy sessions</td>
<td>1y (PPA/urine cotinine</td>
<td>1.49 (0.54-4.11)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shoptaw et al, 2002 United States/175 smokers undergoing methadone maintenance therapy</td>
<td>Group BT, 12 (1-h) weekly sessions, including mood management</td>
<td>All: 4 individual sessions with a nurse to review S-H materials and use of NRT. Nicotine patch for 10 wk. Control: no further intervention</td>
<td>1y (PPA/CO and urine cotinine</td>
<td>0.57 (0.13-2.44)</td>
<td></td>
</tr>
<tr>
<td>Lando et al, 1996 United States/1083 smokers</td>
<td>Telephone counseling at 3, 9, and 21 mo. At each point, up to 3 calls could be made if requested</td>
<td>All: 15-session 8-wk group CP. Control: no further intervention</td>
<td>34 mo (12 mo after EOT, PPA/saliva cotinine at 12 mo†</td>
<td>1.11 (0.86-1.43)</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: BT, behavioral therapy; CAD, coronary artery disease; CBT, cognitive-behavioral therapy; CO, carbon monoxide; CP, cessation program; EOT, end of treatment; NRT, nicotine replacement therapy; PPA, point prevalence abstinence; RP, relapse prevention; SA, continuous, multiple point prevalence, or sustained abstinence; S-H, self-help; TQD, target quit date.

*In relevant arms.
†Incomplete validation or validated rates not reported.
‡Excludes postrandomization dropouts.

**Downloaded From:** http://archinte.jamanetwork.com/pdfaccess.ashx?url=/data/journals/intemed/5531/ on 06/15/2017
staining smokers were randomized after participation in a formal treatment program (n = 1121; OR, 1.00; 95% CI, 0.80-1.25). This meta-analysis compared the most intensive intervention with the least intensive control in the trials with more than 2 arms. Using a different comparison did not change the conclusion.

Pharmacotherapies for Abstainers

Two trials detected a small effect of nicotine gum (n = 2261; OR, 1.30; 95% CI, 1.06-1.61). We failed to detect a significant benefit of bupropion when we pooled data from 2 trials (n = 605; OR, 1.25; 95% CI, 0.86-1.81).

STUDIES RANDOMIZING SMOKERS BEFORE THEIR QUIT DATE

Behavioral Interventions Matched for Contact Time

We found no benefit from the use of specific relapse prevention components in group or individual format interventions, based on 9 trials (with 1 trial that included 2 components) (n = 793; OR, 0.91; 95% CI, 0.65-1.27). There was no evidence of heterogeneity. Because all but 1 of the studies involved treatment contact for more than 4 weeks, we did not conduct a subgroup analysis by treatment duration. Most trials used a skills training approach.

One study comparing different versions of a self-help program did not detect a difference in quit rates (OR, 1.71; 95% CI, 0.61-4.78).

Behavioral Intervention Not Matched for Contact Time or Duration

We detected no effect of relapse prevention in 7 trials involving extended face-to-face contact (n = 609; OR, 1.01; 95% CI, 0.71-1.44). We detected no significant heterogeneity.

Extended Contact Using Proactive Telephone Calls

One trial failed to detect a benefit of providing extended contact by telephone after an intensive 8-week group program (OR, 1.11; 95% CI, 0.86-1.43).

COMMENT

Through meta-analysis of randomized trials, we failed to detect a clinically significant effect of existing relapse prevention interventions in sustaining successful attempts to stop smoking. Because most studies concerned only 1 particular type of intervention (skills training), the volume of work is modest (to our knowledge, there exists only 1 study randomizing smokers at the end of a formal treatment period), and because many of the studies have serious limitations, there is a strong need for continuing research in this area.

Most studies included in this review evaluated low-intensity interventions, such as brief face-to-face encounters, written materials, mailings, and telephone contact. Although only a few included studies had adequate sample sizes to detect the expected effects, the CIs around the pooled estimates suggest that it is unlikely that the analysis failed to detect a significant benefit of low-intensity interventions. However, it is more difficult to exclude a clinically useful effect of more intensive interventions, because these have been less extensively studied.

Any negative verdict is limited to the only treatment study conducted extensively so far, the skills training approach. Other approaches, which have not been studied well or at all, have been proposed; these include opportunistic use of nicotine replacement, contingency contracting, social support, cue exposure (only imaginary exposure has been studied so far), and interventions aimed at maintaining abstainers’ morale.

We included all studies that randomized abstainers, because these provide the best test of interventions aimed at maintaining abstinence. We also included studies randomizing smokers before quitting, which were described as tests of relapse prevention treatments, although there is not a clear-cut distinction between those interventions and others tested as pure cessation interventions.

There are 2 arguments in favor of randomizing smokers before stopping smoking. From a theoretical perspective, it may be difficult to separate cessation and relapse prevention advice; and from a practical perspective, sample sizes are usually much higher at the start than at the end of treatment. The methodological disadvantage of integrating cessation and relapse prevention is that it reduces power to detect specific relapse prevention effects. The primary outcome variable is normally the abstinence rate at follow-up. It is difficult to differentiate effects of the intervention on the initial smoking cessation from effects on preventing relapse in smokers who were initially successful. One solution to this problem is to provide a separate analysis of those achieving initial success. However, none of the existing studies used this approach, and it also poses problems with randomization if the initial cessation rate is unequal in the 2 groups.

Randomizing only those smokers who have made a successful quit attempt provides a stronger design for isolating the effects of relapse prevention, because true effects are not masked by other factors related to the initial success or skewed by uneven initial cessation rates. Of the existing studies using this approach, most recruited spontaneous abstainers, such as pregnant women. Of the studies of behavioral methods for relapse prevention, only 1 randomized smokers abstinent at the end of an initial treatment episode and randomized smokers abstinent 5 to 8 days after their quit date.

The studies randomizing abstainers varied considerably in the periods for which participants had already abstained from smoking, from 24 hours to 16 months. This reflects the lack of a consistent definition of a successful quit attempt.

Future studies should consider randomizing smokers who were abstinent continuously and completely for at least 4 weeks, and use as the primary outcome measure continuous lapse-free abstinence of at least 6 months if the intervention was aimed at avoiding lapses. Where the intervention aimed at helping patients to cope with lapses should these occur, a period of grace (eg, 6 months) should be included, followed by another 6 months of lapse-free abstinence.
In summary, this review does not exclude a small effect of some relapse prevention interventions, but neither does it provide evidence to support inclusion of relapse prevention interventions in smoking treatment programs.

Accepted for Publication: September 16, 2005.

Correspondence: Tim Lancaster, MSc, MB, BS, Department of Primary Health Care, University of Oxford, Old Road Campus, Headington, Oxford OX3 7LF, England (tim.lancaster@dphc.ox.ac.uk).

Author Contributions: Dr Lancaster had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Financial Disclosure: None.

Funding/Support: The Cochrane Tobacco Addiction Review Group is supported by the National Health Service of the United Kingdom.

Role of the Sponsor: The funding body had no role in data extraction and analyses, in the writing of the manuscript, or in the decision to submit the manuscript for publication.

REFERENCES

32. Davis JR, Glaros AG. Relapse prevention and smoking cessation. Addict Behav. 1988;11:105-114.