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.

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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 article reported 2 trials each with multiple arms relevant to different comparisons, and 4 studies included subgroups or factorial designs contributing to different comparisons. Two (3%) of the studies did not specifically describe the intervention as involving relapse prevention. One was a replication of an included study, and one 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 pregnant or postpartum abstainers. Two studies randomized hospital inpatients with cardiovascular illness who had not smoked during hospital admission, and one randomized hospital patients who were abstinent on the day of discharge. Two studies randomized military recruits undergoing enforced abstinence. Five studies randomized participants recruited from local communities.

Five studies randomized abstainers who had taken part in a cessation program to behavioral interventions. Four studies randomized abstainers to pharmacological interventions, including nicotine chewing gum and bupropion hydrochloride.

**Studies Randomizing Current Smokers Before Their Quit Date**

Seventeen studies (including 1 also contributing to the first category) 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) used a group behavioral format, and 2 used individual counseling. Three provided pharmacotherapy to all treatment participants (the studies by Emmons et al and Buchkremer et al with 2 components).

A factorial design tested nicotine gum against no gum.

**Intervention and Control Groups Not 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 studies 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.
### Table 1. Details of Studies Randomizing Abstainers

<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, third prenatal visit and 6 and 38 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 “buddy”; 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, 1.62 (0.93-2.82); and postpartum, intervention 1, 0.99 (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, 1.62 (0.93-2.82); and postpartum, intervention 1, 0.99 (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>Usual midwife care</td>
<td>Birth (12 wk SA) and 12 mo (SA/CO)</td>
<td>Birth, 1.35 (0.82-2.24); and postpartum, 0.88 (0.49-1.58)</td>
<td></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>Usual care</td>
<td>12-mo postpartum (SA/CO)</td>
<td>1.17 (0.62-2.22)</td>
<td></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>Unique: 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 (part)</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</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>1.20 (0.57-2.64)</td>
</tr>
<tr>
<td>Kiesges et al., 1999</td>
<td>United States/18010 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 (681 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)

### Randomization

Four studies used cluster-randomized designs. In the 2 among military recruits, 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 1. Details of Studies Randomizing Abstainers (cont)

<table>
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<tr>
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</tr>
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<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 Urge to Smoke: Without Smoking,” Behavioral control: no further contact. Pharmacotherapy control: placebo gum or no gum</td>
<td>12 mo (PPA/saliva cotinine)</td>
<td>Effect of S-H materials: 1.19 (0.88-1.61); 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.</td>
<td>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 and at 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>
</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.</td>
<td>1. Repeated mailings; 8 booklets mailed 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>
</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 abstainers</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 abstainers (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 abstainers (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/877 abstainers (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 (0.43-1.08)</td>
</tr>
<tr>
<td>Mermelstein et al. 2003</td>
<td>United States/341 abstainers</td>
<td>Tailored proactive telephone counseling: 3 weekly sessions, and then 2-6 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 abstainers 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 abstainers after an 8-wk tapered-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.
Table 2. Studies Randomizing Participants Before Their Quit Attempt

<table>
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<tr>
<th>Source</th>
<th>Country/No. of Participants</th>
<th>Intervention and Control Matched for Contact Time</th>
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<tr>
<td>Hall et al,24 1984</td>
<td>United States/ 135 smokers</td>
<td>Skills training, 14 (75-min) sessions</td>
<td>Discussion control, same schedule</td>
<td>12 mo (PPA/CO and plasma thiocyanate)</td>
<td>1.67 (0.81-3.42)</td>
</tr>
<tr>
<td>Davis and Glareo,27 1986</td>
<td>United States/ 45 smokers</td>
<td>Active cognitive-behavioral skills training focusing on 11 problem situations. Enhanced control with discussion of same problems</td>
<td>All: 6 (1.5- to 2-h) weekly sessions of a broad-spectrum cessation package, with a TQD of wk 5. Control: no additional components</td>
<td>12 mo (PPA/CO)</td>
<td>1.08 (0.13-8.80)</td>
</tr>
<tr>
<td>Curry et al,4 1988</td>
<td>United States/ 48 smokers in group format and 91 in S-H format</td>
<td>RP focusing on smoking as a learned behavior; quit day in group format at third session. Additional elements included identifying high-risk situations, cognitive restructuring, and role playing</td>
<td>All groups: 8 (2-h) weekly sessions, including relaxation training, social support, and practicing alternative behaviors. All S-H: same components in 8 weekly workbooks. Control: “Absolute abstinence” approach. Focused on addictive component of smoking. Quit day in group format at fifth session. Additional elements included focused smoking, health education, and contingency contract</td>
<td>12 mo (SA/saliva thiocyanate and 2 collateral verifiers)</td>
<td>Group format, 0.56 (0.16-1.92); S-H format, 1.71 (0.61-4.78)</td>
</tr>
<tr>
<td>Emmons et al,28 1988</td>
<td>United States/ 49 smokers</td>
<td>RP-focused cessation program, 8 (1.5-h) weekly sessions, TQD between weeks 3 and 4; prequit self-monitoring. Choice of “cold turkey” or gradual reduction. Relaxation, role play, and cognitive coping</td>
<td>“Broad-spectrum” cessation program. There were 12 (1-h) sessions over 8 wk. TQD between weeks 3 and 4. Included nicotine fading</td>
<td>6 mo (PPA/saliva thiocyanate)</td>
<td>0.52 (0.15-1.88)</td>
</tr>
<tr>
<td>Buchkremer et al,7 1991</td>
<td>Study 1: Germany/ 94 smokers*</td>
<td>Relapse coping training included within sessions</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 RP component</td>
<td>12 mo post-EOC (PPA/urine nicotine†)</td>
<td>1.33 (0.58-3.05)</td>
</tr>
<tr>
<td></td>
<td>Study 2: Germany/ 124 smokers*</td>
<td>1. Relapse coping training using role play and TQD at wk 6. Modified relapse coping. Rapid abstinence, TQD at session 4, covert sensitization, and thought stopping</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 RP component</td>
<td>12 mo post-EOC (PPA/urine nicotine†)</td>
<td>0.52 (0.23-1.19)</td>
</tr>
<tr>
<td>Becona and Vasquez,39 1998</td>
<td>Spain/ 76 smokers</td>
<td>Program included problem-solving skills training</td>
<td>All: 8 weekly group sessions, including a motivational contract, nicotine fading, stimulus control, and TQD at wk 4. Control: no further RP component</td>
<td>12 mo CO during treatment informants at follow-up</td>
<td>1.32 (0.51-3.44)</td>
</tr>
<tr>
<td>Nauru et al,40 1999</td>
<td>United States/ 120 smokers</td>
<td>1. CBT with imagined cue exposure (75-min sessions). 2. CBT with cue exposure and nicotine gum (90 min)</td>
<td>All: 1 brief individual counseling session 1 wk before TQD, plus S-H: 5 individual sessions over 2 wk post-TQD. Control: brief CBT (15-min sessions) or CBT (60 min) plus nicotine gum</td>
<td>12 mo (SA/CO)</td>
<td>0.38 (0.09-1.48)</td>
</tr>
<tr>
<td>Schmitz et al,4 1999</td>
<td>United States/ 107 female smokers with CAD risk factors‡</td>
<td>Coping skills RP including stress management and homework</td>
<td>All: 6 (1-h) group sessions. Control: Health Belief model; smoking-related health information-related CAD profile. Focus on quit benefits</td>
<td>6 mo (PPA/urine cotinine and CO†)</td>
<td>0.75 (0.26-2.17)</td>
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(continued)

RESULTS

TRIALS IN ABSTainers

Specific Populations

Pregnant and Postpartum Ex-smokers. We did not detect a significant benefit at the end of pregnancy from 6 trials (n = 1183; OR, 1.17; 95% CI, 0.90-1.53). We also failed to detect an effect in the studies 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-
Table 2. Studies Randomizing Participants Before Their Quit Attempt (cont)

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<tr>
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<tr>
<td>Killen et al, 1984</td>
<td>United States/ 44 smokers*</td>
<td>RP training: 2 sessions in 2 wk, then 4 weekly drop-in sessions, 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>
</tr>
<tr>
<td>Hall et al, 1985</td>
<td>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>1 y (PPA)/CO and serum thiocyanate</td>
<td>1.32 (0.55-3.16)</td>
</tr>
<tr>
<td>Brandon et al, 1987</td>
<td>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>1 y/CO during treatment, 2 informants</td>
<td>1.14 (0.31-4.16)</td>
</tr>
<tr>
<td>Hall et al, 1987</td>
<td>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>1 y/thiocyanate, CO, significant other</td>
<td>0.68 (0.33-1.40)</td>
</tr>
<tr>
<td>Buchkremer et al, 1991</td>
<td>Study 1: 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 RP component</td>
<td>1 y post-EOT (PPA)/urine nicotine</td>
<td>0.78 (0.38-1.58)</td>
</tr>
<tr>
<td>Lifrak et al, 1997</td>
<td>United States/ 69 smokers</td>
<td>Extended support; 16 weekly 45-min cognitive-behavioral RP therapy sessions</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>1 y (PPA)/urine cotinine</td>
<td>1.49 (0.54-4.11)</td>
</tr>
<tr>
<td>Shoptaw et al, 2002</td>
<td>United States/ 175 smokers undergoing methadone maintenance therapy</td>
<td>Group BT, 12 (1-h) weekly sessions, including mood management</td>
<td>All: 12-wk nicotine patch. Control: no counseling, factorial study, and contingency management arms collapsed</td>
<td>1 y (PPA)/CO and urine cotinine</td>
<td>0.57 (0.13-2.44)</td>
</tr>
<tr>
<td>Lando et al, 1996</td>
<td>United States/ 183 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>
</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.

Patients who had not smoked in the hospital, based on 2 studies (n=558; OR, 0.86; 95% CI, 0.60-1.22). One further study offering 3 telephone calls for relapse prevention among patients abstinent at discharge failed to detect evidence of benefit (n=106; OR, 1.20; 95% CI, 0.96-1.34).

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.

Behavioral Interventions for Unaided Abstainers

We detected no evidence of a benefit of interventions to prevent relapse in people who had quit unaided (n=3561; 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 ab-
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=699; 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 approach studied 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 abstinence's 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 stop-
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.

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