Evidenztabellen

der systematischen Reviews und der randomisiert-kontrollierten Studien inkl. der systematischen Reviews der Cochrane Tobacco Addiction Group
INHALTSVERZEICHNIS

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Evidenztabellen zu Kapitel 5.3 Psychotherapeutische Interventionen ........................................................................................................
Evidenztabellen zu Kapitel 5.4 Arzneimittel zur Entzugsbehandlung ........................................................................................................
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Evidenztabelle zu Kapitel 5.8 Komorbide psychische Störungen ..................................................................................................................
Evidenztabelle zu den einbezogenen systematischen Reviews der Cochrane Tobacco Addiction Group ..................................................................
<table>
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<tr>
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<td>Ia</td>
<td>SR very high</td>
<td>n&gt;33 000 smokers</td>
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<td>Ib</td>
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<td>n= 218 precontemplative and contemplative smokers</td>
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<td>Ib</td>
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<td>n= 3086 adult smokers</td>
<td>(1) brief advice by the practitioner; (2) individually tailored advice</td>
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<td>1863457</td>
<td>Zick, David B.</td>
<td>Smoking intervention among patients undergoing elective surgery: a randomised controlled trial</td>
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<td>usual care, a 10-year follow-up</td>
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<td>usual care</td>
<td>intervention</td>
<td>12, 24, 36, and 60 months</td>
<td>adjusted quit rates</td>
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<td>1863375</td>
<td>Wolfenden, Luke</td>
<td>Pilot of a preoperative smoking cessation intervention incorporating post-discharge support from a Quitline</td>
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<td>118</td>
<td>42 months</td>
<td>112</td>
<td>Quitline counseling, group behavioral therapy, telephone counseling, self-help interventions, nursing interventions, exercise interventions, competitions and incentives, partner support, aversive smoking, acupuncture and related interventions</td>
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<td>adjusted quit rates</td>
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<td>1864713</td>
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<td>Smoking cessation counseling among patients presenting to the emergency department with chest pain and who were admitted to an observation unit for 24-hour observation to rule out myocardial infarction</td>
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<td>adjusted quit rates</td>
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<td>usual care</td>
<td>intervention</td>
<td>12, 24, 36, and 60 months</td>
<td>adjusted quit rates</td>
<td>National Institutes of Health, National Heart, Lung, and Blood Institute</td>
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</table>
The Guidelines have been structured around a new mnemonic (ABC) which incorporates and replaces the 5A’s (ask, advise, assess, assist, arrange). ABC prompts healthcare professionals to ask about smoking status; give brief advice to stop; assess the individual’s willingness to stop; counsel on strategies to help the individual quit; and arrange follow-up for the next step in the smoking cessation process. The mnemonic is based on the Transtheoretical Model of behavior change, which posits that individuals go through stages of change to adopt new behaviors. The Model is widely accepted as a framework for understanding and implementing smoking cessation interventions.

Table:

<table>
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<tr>
<th>Citation</th>
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<th>Title (shortened)</th>
<th>Degree of quality</th>
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<td>18574510</td>
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<td>18425860</td>
<td>Stead, LF</td>
<td>Physician advice for smoking cessation</td>
<td>Ia very high</td>
<td>Physician advice at least 6 months The results of this review, first published in 1996 and updated in 2008, continue to confirm that brief advice from physicians is</td>
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<td>Rice, VH</td>
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<td>With cardiovascular disease than for inpatients with other conditions. Interventions in non-hospitalized patients also showed</td>
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<td>18253987</td>
<td>Míguez, MC</td>
<td>Evaluating the effectiveness of a single telephone contact as an adjunct to a self-help intervention for smoking cessation in a randomized controlled trial.</td>
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<td>Among participants completing the three tailoring depth factors also resulted in increasing the rates of 6-month cessation, demonstrating an effect of tailoring depth</td>
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<td>For bupropion (17% vs 8%) (OR 2.3, CI 1.1 – 5.1). The effect was not sustained after the case management period</td>
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<td>17530311</td>
<td>Sherman, SE</td>
<td>Effectiveness of an on-call counselor provided in a single practice in a mailed self-help program for smoking cessation conducted through the mail</td>
<td>IIb RCT medium</td>
<td>For bupropion (17% vs 8%) (OR 2.3, CI 1.1 – 5.1). The effect was not sustained after the case management period</td>
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This work was funded by a grant from the California Tobacco-Related Disease Research Program (#10RT-0023). This project was done in collaboration with the VA Center of Excellence for the Study of Healthcare Provider Behavior (VA Health Services Research & Development Service # HFP 94-028). The authors thank the study staff for their evaluation of the X-Pack Program: results of a randomized trial.
This study was funded by a programme grant from Cancer Research UK (trial registration ISRCTN 05689186). United Pharmaceuticals supplied the nicotine patches for the study free to be given without charge to the participants.

Of the 469 and 456 participants in the basic and weekly arms, the numbers (%) who quit and the percentage difference were 105 (22.4%) vs 102 (22.4%), 0.1% (95% CI 2.0% to 1.9%) at 26 weeks and 36 (7.7%) vs 30 (6.6%), 2.1% (95% CI 2.0% to 2.2%) at 52 weeks.
<table>
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<td>This study was funded by the American Legacy Foundation and the University of Kentucky Markey Cancer Center.</td>
<td>Ellen J, EJ Hahn</td>
<td>16295703</td>
<td>1 month</td>
<td>The quit rate at 1 month was 7.5% (95% CI, 0–21) in the intervention group and 2.5% (95% CI, 0–7) in the control group.</td>
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<td>This research was supported by the State of California Department of Health Services, the Robert Wood Johnson Foundation, and the National Institute on Drug Abuse (NIDA).</td>
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<td>16106336</td>
<td>Chan, Sophia S C, SS</td>
<td>2004</td>
<td>6 session of CBT nutrition-focused attention-matched control group</td>
<td>Relative to CG patients, significantly more CBT patients reduced smoking intensity by 50% (X² = [1, N = 58] = 4.86, p = .028) at 3 and 6 months.</td>
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<td>18629732</td>
<td>Lacasse, Yves, Y</td>
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<td>10 months</td>
<td>Cotinine-validated smoking cessation rates were 16.6% in the experimental condition and 10.1% in the standard care condition (p = 0.07).</td>
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<td>21553949</td>
<td>Shmueli, Dikla, D</td>
<td>2008</td>
<td>A test of positive affect induction for countering self-control depletion in cigarette smokers.</td>
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<td>2102959</td>
<td>Colby, Suzanne M, SM</td>
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<td>Brief motivational intervention for smoking cessation in hospital inpatients.</td>
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<td>Visual management interventions for adolescents in medical settings.</td>
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<td>Shmidt-McPhee, M</td>
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1 month The quit rate at 1 month was 7.5% (95% CI, 0–21) in the intervention group and 2.5% (95% CI, 0–7) in the control group.

IV RCT very low N= 80 smoking parents of sick children Individualized motivational intervention (IMI) ndividualized motivational intervention (IMI)

Citation First Author Title (shortened) Degree of quality N Patient character-istics Inter-vention Com-parison Length of follow-Up Outcome and effect size Funding Comments

First Author Title (shortened)

Evidence Study type Study

16106336 Chan, Sophia S C, SS A randomized controlled trial of an individualized motivational intervention on smoking cessation for parents of sick children: a pilot study. This work was supported by the National Institute of Drug Abuse (NIDA) and the University of Montana, Missoula, MT

RCT n= 58 college smokers with elevated depressive symptomatology Although CBT participants maintained smoking reductions at 3- and 6-month follow-up, group differences were no longer significant at 12 months. For nonpregnant samples, combined results suggest that MI significantly outperformed comparison conditions at long-term follow-up points (d = 0.17). The magnitudes of this result represented a 2.3% difference in abstinence rates between MI and comparison conditions. Meta-analyses revealed no statistically significant effects on either short- term (less than 6 months) smoking cessation (OR 1.35, 95% CI 0.76 to 2.39, P = 0.31, n = 3 studies) or cessation after six months (OR 1.07, 95% CI 0.64 to 1.78, P = 0.71, n = 2 studies). These findings suggest that current MI smoking cessation approaches can be effective for adolescents and adults. However, comparative efficacy trials could be useful.

22171728 Schleicher, Holly E, HE Mood management intervention for college smokers with elevated depressive symptoms: a pilot study. This work was supported by the National Institute of Mental Health [CA108685 to CH, CA006927 to Fox Chase Cancer Center]

Ia SR very high n=9845 eight comprised adolescent high school samples, eight comprised adults with chronic physical or mental illness, five comprised pregnant/postpartum women and 10 comprised other adult samples.

The study was funded by NHMRC Project 189414

3 and 6 month follow-up The MI intervention resulted in significant short-term reductions in quantity and frequency of smoking relative to standard care, however, effects were not maintained at 3- and 6-month follow-up. Improvements in refusal self-efficacy were evident for MI participants only, and were maintained at follow-up. For nonpregnant samples, eight comprised adults with chronic physical or mental illness, five comprised pregnant/postpartum women and 10 comprised other adult samples.

20675688 Heckman, Carolyn J, CJ Efficacy of motivational interviewing for smoking cessation: a systematic review and meta-analysis. This work was supported by a grant from the National Institute on Drug Abuse awarded to the first author (DA13182-02).
### Funding

- Chief Scientist at the Scottish Executive
- the Scottish Cot Death Trust
- the BUPA Foundation

### Study Details

#### Citation

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<tr>
<th>First Author</th>
<th>Title (shortened)</th>
<th>Degree of evidence</th>
<th>Study type</th>
<th>N</th>
<th>Patient characteristics</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Length of follow-up</th>
<th>Outcome and effect size</th>
<th>Funding</th>
<th>Comments</th>
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<tbody>
<tr>
<td>McCambridge, J</td>
<td>Deterioration over time in effect of motivational interviewing</td>
<td>IIb</td>
<td>RCT</td>
<td>medium</td>
<td>n= 200</td>
<td>MI assessment-only control condition</td>
<td>3 and 12 months</td>
<td>A satisfactory follow-up rate (81%) was achieved. After 12 months, the differences between the MI and assessment-only control conditions were no longer significant.</td>
<td></td>
<td>We are grateful to Action on Addiction for additional funding to enable the longer-term follow-up study reported here.</td>
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<tr>
<td>Carlin-Menter, S</td>
<td>Does offering more support calls to regular smokers at antenatal booking influence quit success?</td>
<td>IIb</td>
<td>RCT</td>
<td>high</td>
<td>n= 762</td>
<td>pregnant women who were regular smokers at antenatal booking</td>
<td></td>
<td>3 months, 6 months</td>
<td>Intent-to-treat analyses revealed relatively high percentages of abstinence at 3 months (38.9%, 48.5%, 43.4%) and at 6 months (30.7%, 34.3%, 33.8%) for the web, PTC, and PTC web groups, respectively. The PTC group had a significantly higher percentage of abstinence at 3 months, OR=1.48, 95% CI 1.12–1.96, but no between-group differences in abstinence outcomes were seen at 6 months.</td>
<td></td>
<td>Medicaid/uninsured current smokers (10+ cigarettes per day) who called the NYSSQL between February and March 2009 seeking help to stop smoking were randomized to one of three smoking-cessation interventions: web-based counseling (n=401), proactive telephone-based counseling (PTC; n=402), or combined PTC web counseling (n=400). All participants who were enrolled in the study were offered up to 6 weeks of free nicotine replacement therapy and were followed up for 12 months. The PTC group had a significantly higher percentage of abstinence than the web group at 3 months (30.7% vs 23.7%), 6 months (26.2% vs 19.1%), and 12 months (21.9% vs 17.3%), but no between-group differences in abstinence outcomes were seen at 6 months.</td>
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<tr>
<td>Cahill, K</td>
<td>Stage-based interventions for smoking cessation</td>
<td>IIb</td>
<td>RCT</td>
<td>medium-low</td>
<td>n= 20</td>
<td>pregnant women who were regular smokers at antenatal booking</td>
<td></td>
<td>3 months</td>
<td>A satisfactory follow-up rate (81%) was achieved. After 12 months, the differences between the MI and assessment-only control conditions were no longer significant.</td>
<td></td>
<td>We are grateful to Action on Addiction for additional funding to enable the longer-term follow-up study reported here.</td>
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<tr>
<td>Mottillo, S</td>
<td>Behavioural interventions for smoking cessation</td>
<td>Ia</td>
<td>Meta analysis</td>
<td>very high</td>
<td>n = 26 927</td>
<td>smokers</td>
<td></td>
<td></td>
<td>We included only RCTs that reported biochemically validated rates and used ITT analysis. Where appropriate we performed meta-analysis to estimate a pooled risk ratio, using the Mantel-Haenszel fixed-effect model.</td>
<td></td>
<td>Systematic review of the effectiveness of Scandinavian behavioural modification smoking cessation programmes.</td>
</tr>
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### Additional Information

- At the time of the study, the NYSSQL provided financial support from Pfizer to attend a 1-day training course on nicotine replacement therapy. The project was supported by a grant from the American Society for Preventive Cardiology (ASPC), with additional funding from the Robert Wood Johnson Foundation and the American Heart Association. The NYSSQL is a service provided by the American Lung Association. The study was approved by the institutional review board of the Pennsylvania State University College of Medicine. The study protocol was registered with the ISRCTN registry (ISRCTN33753917). | | |

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<table>
<thead>
<tr>
<th>Citation</th>
<th>First Author</th>
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<tbody>
<tr>
<td>222916</td>
<td>Joseph, Mary B</td>
<td>Impact of telephone-basing smoking cessation program.</td>
<td>N/A</td>
<td>Cross-over</td>
<td>49</td>
<td>Both smokers and nonsmokers aged 16 and older who were facilitated by National Cancer Institute (NCI) and the National Institute on Drug Abuse (NIDA) provided telephone-based counseling.</td>
<td>Telephone counseling</td>
<td>Control</td>
<td>6 months</td>
<td>17.7% of those offered nicotine replacement therapy reported smoking cessation compared with 11.1% of those offered telephone-based counseling</td>
<td>N/A</td>
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<td>223078</td>
<td>Benowitz, N L</td>
<td>Usefulness of assistance levels of support and lower cost.</td>
<td>N/A</td>
<td>RCT</td>
<td>479</td>
<td>N/A</td>
<td>Usual care vs. telephone-based counseling</td>
<td>Telephone-based counseling</td>
<td>Usual care</td>
<td>12 months</td>
<td>Differences in 6 or 12 months between intervention and control group in point prevalence abstinent rates (11.7% vs. 12.9%, P = 0.83; 8.4% vs. 11.3%, P = 0.68, respectively) or the mean shift in stage-of-change towards intervention to quit</td>
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<tr>
<td>223127</td>
<td>Wax, Karen A</td>
<td>Smoking cessation programs targeted to women: a systematic review.</td>
<td>N/A</td>
<td>RCT</td>
<td>2591</td>
<td>N/A</td>
<td>Usual care vs. telephone-based counseling</td>
<td>Telephone-based counseling</td>
<td>Usual care</td>
<td>6 and 12 months</td>
<td>Although 62.2% of participants indicates that telephone support would benefit Arabic smokers, there were no significant differences in 6 or 12 months between intervention and control group in point prevalence abstinent rates (11.7% vs. 12.9%, P = 0.68; 8.4% vs 11.3%, P = 0.68, respectively) or the mean shift in stage-of-change towards intervention to quit.</td>
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<tr>
<td>223128</td>
<td>Joffe, Stu M</td>
<td>The effects of a 24-hour telephone quitline and a multimodal intervention for smoking cessation.</td>
<td>N/A</td>
<td>RCT</td>
<td>407</td>
<td>N/A</td>
<td>Usual care vs. six sessions of smoking telephone-based counseling for smoking cessation.</td>
<td>Telephone-based counseling</td>
<td>Usual care</td>
<td>12 months</td>
<td>Differences in 6 or 12 months between intervention and control group in point prevalence abstinent rates (11.7% vs. 12.9%, P = 0.83; 8.4% vs. 11.3%, P = 0.68, respectively) or the mean shift in stage-of-change towards intervention to quit.</td>
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<td>223129</td>
<td>Stathis, Damas G</td>
<td>Control arm of a randomized controlled trial of the California Smokers' Helpline. A randomized controlled trial.</td>
<td>N/A</td>
<td>RCT</td>
<td>130</td>
<td>N/A</td>
<td>Telephone counseling vs. usual care.</td>
<td>Telephone counseling</td>
<td>Usual care</td>
<td>12 months</td>
<td>Differences in 6 or 12 months between intervention and control group in point prevalence abstinent rates (11.7% vs. 12.9%, P = 0.83; 8.4% vs. 11.3%, P = 0.68, respectively) or the mean shift in stage-of-change towards intervention to quit.</td>
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<td>223130</td>
<td>Binnion, Scott W</td>
<td>Smoking cessation programs targeted to women: a systematic review.</td>
<td>N/A</td>
<td>Cross-over</td>
<td>479</td>
<td>N/A</td>
<td>Usual care vs. telephone-based counseling</td>
<td>Telephone-based counseling</td>
<td>Usual care</td>
<td>6 and 12 months</td>
<td>Differences in 6 or 12 months between intervention and control group in point prevalence abstinent rates (11.7% vs. 12.9%, P = 0.83; 8.4% vs. 11.3%, P = 0.68, respectively) or the mean shift in stage-of-change towards intervention to quit.</td>
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**Notes:**
- **RCT** = Randomized controlled trial
- **N** = Number of participants
- **Length of follow-up** refers to the duration of the intervention and follow-up period.
- **Outcome and effect size** include differences in point prevalence abstinent rates or mean shift in stage-of-change towards intervention to quit, as applicable.
- **Funding Comments** may include details on funding sources and study design specific to the intervention described in each study.
<table>
<thead>
<tr>
<th>Citation</th>
<th>Study Design</th>
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<td>213176</td>
<td>Interventions</td>
<td>Brief smoking cessation interventions for general hospital patients: results of a randomized trial.</td>
<td>RCT</td>
<td>n = 616</td>
<td>hospital patients</td>
<td>6-months</td>
<td>Utilization of services in a randomized trial testing phone- and web-based interventions for smoking cessation.</td>
<td>6-months</td>
<td>Services varied by modality and were tracked using Web orientation call, and access to a phone supportline. Self-report data were collected at baseline and 6-month follow-up.</td>
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21330267 Zbikowski, Susan M, SM Utilization of services in a randomized trial testing phone- and web-based interventions for smoking cessation. | RCT | n = 616 | hospital patients | 6-months | Utilization of services in a randomized trial testing phone- and web-based interventions for smoking cessation. | 6-months | Services varied by modality and were tracked using Web orientation call, and access to a phone supportline. Self-report data were collected at baseline and 6-month follow-up. | 

21371155 Walker, Natalie, N Does improved access and greater patient choice of nicotine replacement therapy affect smoking cessation success? Findings from a randomized controlled trial. | RCT | n = 1410 | smokers | 6-months | Does improved access and greater patient choice of nicotine replacement therapy affect smoking cessation success? Findings from a randomized controlled trial. | 6-months | Smokers who called the national Quitline for quitting support were randomized to receive by phone either a standard threat message or a threat plus genetic prime message and were encouraged to attend 2 months of phone counseling. | 

21385096 Schnoll, Robert A, RA A novel recruitment message to increase enrollment into a smoking cessation treatment program: preliminary results from a randomized controlled trial. | RCT | n = 125 | treatment-seeking smokers | 6-months | A novel recruitment message to increase enrollment into a smoking cessation treatment program: preliminary results from a randomized controlled trial. | 6-months | During telephone recruitment, 125 treatment-seeking smokers were randomized to receive by phone either a standard threat message or a threat plus genetic prime message and were encouraged to attend 2 months of phone counseling. | 

21346680 Carlin-Menter, Shannon, S Does offering more support calls to extend quit calls for smokers who fail to quit improve smoking cessation rates? A randomized trial testing phone- and web-based interventions for smoking cessation. | RCT | n = 1202 | smokers | 6-months | Does offering more support calls to extend quit calls for smokers who fail to quit improve smoking cessation rates? A randomized trial testing phone- and web-based interventions for smoking cessation. | 6-months | One thousand two hundred and two participants were randomized to receive by phone either a standard threat message or a threat plus genetic prime message and were encouraged to attend 2 months of phone counseling. | 

21362920 Segan, C J, CJ Does extended telephone callback intervention lead to increased quit rates in a smoking cessation trial? | RCT | n = 300 | smokers | 6-months | Does extended telephone callback intervention lead to increased quit rates in a smoking cessation trial? | 6-months | After formative work involving patients and clinicians, a brief intervention was designed to facilitate telephone quitline use. It was then evaluated in a randomized trial of 300 smokers. | 

21317617 Smith, Patricia M, PM Nurse case-managed tobacco cessation: preliminary assessment of a new instrument. | RCT | n = 710 | | 6-months | Nurse case-managed tobacco cessation: preliminary assessment of a new instrument. | 6-months | Among intervention group participants, 57% attended a minimum of 1 phone call and 45% completed the intervention in full. | 

21317620 Warner, David O, DO Clinician-delivered intervention to brief smoking cessation interventions 1 year Confirmed 1-year abstinence was 28% for Intensive (85/301) and 24% for Brief (76/315). Abstinence was significantly higher for patients who did not use pharmacotherapy (36%) versus those who did (16%) and for patients with CVD (40%) versus those without (22%). These preliminary data suggest that a simple, affordable, and limited-intensity intervention approach can lead to successful outcomes for brief smoking cessation. | 

21317615 Grant, Michael A, TA Brief smoking cessation interventions for general hospital patients: results of a randomized clinical trial. | RCT | n = 213 | smokers | 6-months | Brief smoking cessation interventions for general hospital patients: results of a randomized clinical trial. | 6-months | Overall, compared with self-help materials or no intervention control groups, proactive telephone counseling had a statistically significant greater effect on secondary outcomes. | 

21317601 Smith, Barbara, BM Does delivering music during calls increase nicotine withdrawal symptoms in smokers? | RCT | n = 125 | smokers | 6-months | Does delivering music during calls increase nicotine withdrawal symptoms in smokers? | 6-months | Among intervention group participants, 57% attended a minimum of 1 phone call and 45% completed the intervention in full. | 

21340261 Holstein, J R, JR Does automated telephone audio feedback improve post-discharge smoking cessation efforts? | RCT | n = 1140 | smokers | 6-months | Does automated telephone audio feedback improve post-discharge smoking cessation efforts? | 6-months | Overall, compared with self-help materials or no intervention control groups, proactive telephone counseling had a statistically significant greater effect on secondary outcomes. | 

21346680 Carlin-Menter, Shannon, S Does offering more support calls to extend quit calls for smokers who fail to quit improve smoking cessation rates? A randomized trial testing phone- and web-based interventions for smoking cessation. | RCT | n = 1202 | smokers | 6-months | Does offering more support calls to extend quit calls for smokers who fail to quit improve smoking cessation rates? A randomized trial testing phone- and web-based interventions for smoking cessation. | 6-months | One thousand two hundred and two participants were randomized to receive by phone either a standard threat message or a threat plus genetic prime message and were encouraged to attend 2 months of phone counseling. | 

21317611 Zbikowski, Susan M, SM Intensive phone-delivered intervention to assist smokers in making and maintaining quit attempts: preliminary results from a randomized trial. | RCT | n = 213 | smokers | 6-months | Intensive phone-delivered intervention to assist smokers in making and maintaining quit attempts: preliminary results from a randomized trial. | 6-months | Among intervention group participants, 57% attended a minimum of 1 phone call and 45% completed the intervention in full. | 

21317612 Smith, Barbara, BM Brief smoking cessation interventions for general hospital patients: results of a randomized clinical trial. | RCT | n = 213 | smokers | 6-months | Brief smoking cessation interventions for general hospital patients: results of a randomized clinical trial. | 6-months | Overall, compared with self-help materials or no intervention control groups, proactive telephone counseling had a statistically significant greater effect on secondary outcomes. | 

21317605 Grant, Michael A, TA Brief smoking cessation interventions for general hospital patients: results of a randomized clinical trial. | RCT | n = 213 | smokers | 6-months | Brief smoking cessation interventions for general hospital patients: results of a randomized clinical trial. | 6-months | Overall, compared with self-help materials or no intervention control groups, proactive telephone counseling had a statistically significant greater effect on secondary outcomes. | 

21317606 Grant, Michael A, TA Brief smoking cessation interventions for general hospital patients: results of a randomized clinical trial. | RCT | n = 213 | smokers | 6-months | Brief smoking cessation interventions for general hospital patients: results of a randomized clinical trial. | 6-months | Overall, compared with self-help materials or no intervention control groups, proactive telephone counseling had a statistically significant greater effect on secondary outcomes. | 

21317607 Grant, Michael A, TA Brief smoking cessation interventions for general hospital patients: results of a randomized clinical trial. | RCT | n = 213 | smokers | 6-months | Brief smoking cessation interventions for general hospital patients: results of a randomized clinical trial. | 6-months | Overall, compared with self-help materials or no intervention control groups, proactive telephone counseling had a statistically significant greater effect on secondary outcomes. | 

21317608 Grant, Michael A, TA Brief smoking cessation interventions for general hospital patients: results of a randomized clinical trial. | RCT | n = 213 | smokers | 6-months | Brief smoking cessation interventions for general hospital patients: results of a randomized clinical trial. | 6-months | Overall, compared with self-help materials or no intervention control groups, proactive telephone counseling had a statistically significant greater effect on secondary outcomes. | 

21317609 Grant, Michael A, TA Brief smoking cessation interventions for general hospital patients: results of a randomized clinical trial. | RCT | n = 213 | smokers | 6-months | Brief smoking cessation interventions for general hospital patients: results of a randomized clinical trial. | 6-months | Overall, compared with self-help materials or no intervention control groups, proactive telephone counseling had a statistically significant greater effect on secondary outcomes. | 

21317610 Grant, Michael A, TA Brief smoking cessation interventions for general hospital patients: results of a randomized clinical trial. | RCT | n = 213 | smokers | 6-months | Brief smoking cessation interventions for general hospital patients: results of a randomized clinical trial. | 6-months | Overall, compared with self-help materials or no intervention control groups, proactive telephone counseling had a statistically significant greater effect on secondary outcomes. |
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<tr>
<th>Citation</th>
<th>First Author</th>
<th>Title (shortened)</th>
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<td>Fulmer, Michael D.</td>
<td>The effects of telephone aftercare counseling on smoking cessation</td>
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<td>RCT</td>
<td></td>
<td>100</td>
<td>United States</td>
<td>A telephone quitline</td>
<td></td>
<td></td>
<td>12 months</td>
<td>The adjusted percentage of smokers who reported receiving cessation support differed by 12.5% in intervention and control arms (20.1% vs. 27.6%, p &lt; 0.001).</td>
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<td>16396931</td>
<td>Fink, Heidi A, M.</td>
<td>Cost-effective recruitment strategies for smoking cessation</td>
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<td>RCT</td>
<td></td>
<td>300</td>
<td>young adult tobacco users</td>
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<td></td>
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<td>18 months</td>
<td>The 30-day multiple point prevalence abstinence rate across all follow-up intervals was 3.5% (BI), 4.5% (EI), and 7.7% (EI).</td>
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<td>2126208</td>
<td>Godlock, Clara P.</td>
<td>Cigarette abstinence and smoking cessation: The role of electronic cigarettes</td>
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<td>100</td>
<td>current adult smokers in the United States</td>
<td></td>
<td></td>
<td></td>
<td>90 days</td>
<td>The mood management intervention resulted in significantly higher prolonged abstinence rates at 6- and 12-month follow-up (30.5% and 23.9% in experimental condition, 22.3% and 14.0% in the control condition). The odds ratios were 1.60 (95% CI 1.12 – 2.29) and 1.09 (95% CI 0.72 – 1.65) for both follow-ups. The mood management intervention did not result in general improvement of depressive symptoms.</td>
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<td>2104851</td>
<td>Graham, Amanda L, AL</td>
<td>A randomized trial of Internet and telephone treatment for smoking cessation.</td>
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<td>RCT</td>
<td></td>
<td>200</td>
<td>United States</td>
<td></td>
<td></td>
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<td>6 months, 12 months</td>
<td>The mood management intervention resulted in significantly higher prolonged abstinence rates at 6- and 12-month follow-up (30.5% and 23.9% in experimental condition, 22.3% and 14.0% in the control condition). The odds ratios were 1.60 (95% CI 1.12 – 2.29) and 1.09 (95% CI 0.72 – 1.65) for both follow-ups. The mood management intervention did not result in general improvement of depressive symptoms.</td>
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<td>2103887</td>
<td>Grant, Mary E, M.</td>
<td>Behavioral counseling and mood management for smoking cessation</td>
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<td>RCT</td>
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<td>100</td>
<td>non-treatment-seeking 18- to 24-year-olds</td>
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<td></td>
<td></td>
<td>6 months, 12 months</td>
<td>The non-directive telephone counseling condition was associated with higher 6-month and 12-month quit rates compared to the control condition (27.4% vs. 19.8%, p = 0.01).</td>
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<td>20735366</td>
<td>van der Meer, Regina M, RM</td>
<td>A randomised controlled trial of a structured telephone follow-up in smokers: a controlled trial</td>
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<td>RCT</td>
<td></td>
<td>527</td>
<td>inpatient female smokers</td>
<td></td>
<td></td>
<td></td>
<td>6 months</td>
<td>The strukturierte Telefonnachsorge erbrachte die höchste Abstinenzquote nach 6 Monaten (31,5 %; OR: 2,0; CI: 1,1 – 3,8). Die non- direktive Telefonberatung führte nicht zu einer signifikanten Verbesserung der Abstinenzquoten.</td>
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<td>1827074</td>
<td>Hambrecht, Andreas P, DP</td>
<td>A randomized trial: Quitline specialist counseling after smoking cessation</td>
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<td>RCT</td>
<td></td>
<td>1817</td>
<td>adult smokers</td>
<td></td>
<td></td>
<td></td>
<td>12 months</td>
<td>The trained professionals provided differential counseling strategies for smokers with a past major depression: 1) depression-focused supportive counseling and advice. Setting Dutch national smoking cessation system.</td>
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<td>20409497</td>
<td>Swan, Gary E, GE</td>
<td>Behavioral counseling and varenicline treatment for smoking cessation</td>
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<td>RCT</td>
<td></td>
<td>1202</td>
<td>adult smokers</td>
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<td>6 months</td>
<td>The mood management intervention resulted in significantly higher prolonged abstinence rates at 6- and 12-month follow-up (30.5% and 23.9% in experimental condition, 22.3% and 14.0% in the control condition). The odds ratios were 1.60 (95% CI 1.12 – 2.29) and 1.09 (95% CI 0.72 – 1.65) for both follow-ups. The mood management intervention did not result in general improvement of depressive symptoms.</td>
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<td>20307804</td>
<td>Rothemich, Stephen F, SF</td>
<td>Promoting primary care smoking cessation support with quitlines: the QuitLink Randomized Controlled Trial</td>
<td></td>
<td>RCT</td>
<td></td>
<td>485</td>
<td>smokers with a past major depression</td>
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<td></td>
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<td>6 months</td>
<td>The adjusted percentage of smokers who reported receiving cessation support differed by 12.5% in intervention and control arms (20.1% vs. 27.6%, p &lt; 0.001).</td>
<td>National Cancer Institute (Grant R01CA071358) and is registered at Clinicaltrials.gov (NCT00301145). Varenicline and nominal support for recruiting participants was provided by Pfizer, Inc.</td>
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<td>19911325</td>
<td>Toll, Benjamin A, BA</td>
<td>Randomized trial: Quitline specialist referral for smoking cessation</td>
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<td>2032</td>
<td>smokers</td>
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<td></td>
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<td>3 weeks, 6 weeks, 3 months</td>
<td>Specialists providing gain-framed counseling used gain-framed statements statistically significantly more frequently than specialists providing non-framed counseling (40.7% vs 28.2%, respectively; p = 0.001). The PTC group had a significantly higher percentage of abstinence than the web group at 3 months (71.0%).</td>
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<td>18740021</td>
<td>van der Zee, Jan K, JK</td>
<td>Effectiveness of a mood management component as an adjunct to telephone smoking cessation counseling</td>
<td></td>
<td>RCT</td>
<td></td>
<td>1202</td>
<td>smokers</td>
<td></td>
<td></td>
<td></td>
<td>6 months</td>
<td>The mood management intervention resulted in significantly higher prolonged abstinence rates at 6- and 12-month follow-up (30.5% and 23.9% in experimental condition, 22.3% and 14.0% in the control condition). The odds ratios were 1.60 (95% CI 1.12 – 2.29) and 1.09 (95% CI 0.72 – 1.65) for both follow-ups. The mood management intervention did not result in general improvement of depressive symptoms.</td>
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<tr>
<td>18740026</td>
<td>Zanis, David A, DA</td>
<td>Comparing intervention strategies in smoking cessation programs: evidence from the Controlled Randomized Controlled Trial</td>
<td></td>
<td>RCT</td>
<td></td>
<td>485</td>
<td>smokers with a past major depression</td>
<td></td>
<td></td>
<td></td>
<td>6 months</td>
<td>The adjusted percentage of smokers who reported receiving cessation support differed by 12.5% in intervention and control arms (20.1% vs. 27.6%, p &lt; 0.001).</td>
<td>National Cancer Institute (Grant 5R21HS014854-02).</td>
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</table>
Intention-to-treat analysis of 7-day point prevalence cessation revealed quit rates of 11.4% for Smoke|Quit, 2.9% for the Cancer Society’s program, and 5.6% for the usual care intervention (p < .05). Among nonquitters, 46.5% had made a quit attempt, and weekly consumption decreased from 54.01 to 42.08 cigarettes (p < .001) with no differences across interventions.

This study was supported by American Lung Association grant CG-870-N. Dr. Sood was also supported by the University of New Mexico Clinical Translational Science 

The estimated mean treatment effects were minimal clinical intervention [odds ratio (OR) 1.50, 95% credible interval (CrI) = 1.36–1.65], and enhanced usual care [OR 1.76, 95% CrI = 1.60–1.93]. Intervention participants were significantly more likely than control participants to achieve at least 6 months of smoking abstinence, the estimates remained robust across patient characteristics (e.g., education, ethnicity, health literacy, and dependence) and phone counselors.

More than half (52%) of eligible smokers contacted by telephone were recruited into cessation support. The cost per smoker was $175 for the control condition and $180 for the intervention. For smokers who quit, their quit costs were lower in the experimental condition at 16.7% at the 3-month visit, 23.3% at the 6-month visit, and 30.9% at the 12-month visit (p < .01).

The intervention included a group smoking cessation program and a self-help kit to support quitting. The self-help kit contained a quit guide, telephone counseling, and access to the Quitline with nicotine patch. Main Outcome Measure. Seven-day self-reported cessation at 6- and 12-month follow-ups.

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The study was supported by National Institutes of Health (CA082569 to A.V.P.). The CHeRP is funded by the Cancer Council NSW, the University of Newcastle, and receives infrastructure support from the Hunter Medical Research Institute and the University of Newcastle Faculty of Health. The Cancer Council NSW Telerehabilitation Project, Telerehabilitation Research Network, Telerehabilitation Research Network, the National Heart Foundation of Australia, Hunter New England Health and the University of Newcastle. The research was also supported by the National Heart Foundation of Australia. This work has been supported by the National Institute of Public Health and the Regional Institute.

The researchers used a randomized controlled trial with a 3-month telephone follow-up. Interventions included a new program (Smoke|Quit), the Canadian Cancer Society’s self-help program, and a usual care quit kit.
The development of the 2007 New Zealand Smoking Cessation Guidelines was funded by the Ministry of Health.

Usual care 6 months 12% of 66 usual care control group participants and 25% of 52 experimental group participants reported being abstinent.

We thank Maria-Jose Velasco for assisting in follow-up and data management. This work was supported by the National Cancer Institute (grant R01 CA86242), and we want to thank GlaxoSmithKline for supplying the nicotine patches used in the study.

12 months Abstinence odds ratios were significant for moderate (OR = 1.22, CI = 1.01 to 1.48) and intensive (OR = 1.29, CI = 1.07 to 1.55) treatment conditions.

Evidence based approaches to smoking cessation include brief counselling, pharmacotherapy, referral to a specialised smoking cessation service such as Quitline, and follow up. The five As approach – Ask, Assess, Advise, Assist and Arrange follow up – designed to help smokers stop smoking over the 10-year period.

The Guidelines have been structured around a new memory aid (ABC) which incorporates and replaces the 5A’s (ask, assess, advise, assist, arrange). ABC prompts healthcare professionals to ask about smoking status; give brief advice to help smokers; advise them to stop smoking; assist them in making a quit attempt; and arrange follow up.

In this 362 randomised trial included 4614 Oregon tobacco smokers. This study was based on a ten-year follow-up of smokers who participated in a smoking cessation program conducted through the mail, by telephone counseling and the nicotine patch. Blinded staff assessed tobacco use by phone at 12 months.

The effectiveness and cost-effectiveness of telephone counselling and the nicotine patch in a state tobacco quitline. This research was conducted under contract to the Oregon Health & Science University (grant 261539). Blinded staff assessed tobacco use by phone at 12 months.

Moderate (OR = 1.62, CI = 1.29 to 2.03) and intensive (OR = 2.10, CI = 1.61 to 2.71) treatment conditions had significantly higher than usual care intervention (OR = 1.26, CI = 1.04 to 1.52). The nicotine patch was significantly more effective than telephone support in enhancing smoking cessation in general practice: a cluster randomized trial. This was a very high A comprehensive literature review of smoking cessation guidelines.

The development of the 2014 New Zealand Smoking Cessation Guidelines was guided by the Minister of Health.
The Cochrane Tobacco Addiction group receives core funding from the UK NHS R&D programme.

This research was supported by National, Heart, Lung, and Blood Institute grant HL57457. The authors thank Cindy Davis for the statistical programming.

The intervention was Web-based tailored behavioral smoking cessation materials or Web-based nontailored materials. The 10-week continuous abstinence rate was assessed by telephone counseling or mailed self-reports. Mediators examined included 6-week follow-up measures of program relevance and amount of the Web-based materials read.

We identified 14 relevant studies. Eight studies (18,500 participants) comparing multiple call-backs to a single contact population was very mobile, the MI counselors were able to reach 86% of the women with at least one call and 46% received 4 or more calls compared with the women who did not receive any telephone calls, with an effectiveness to cost ratio of 1:$84.

Among intervention patients who were not ready to quit smoking, and were not motivated smokers, verbally to telephone staff who had previous smoking cessation counseling experience. In 51 women receiving telephone counseling, best and relationship to eventual cessation.

Results involving the treatment groups did not meet statistical significance. Only 7 (21%) of the 33 women initially randomized to the proactive intervention arm dropped out of the treatment group. In the proactive arm, smokers in the proactive recruitment arm were more likely to report a 24-hr quit attempt, compared with control group smokers (86.7% vs. 80.8%, p = .027), we found no differences between the groups in repeated (3-month and 12-month) smoking abstinence rates.

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The study is funded by the EMGO Institute, VU University Medical Center, Amsterdam, the Netherlands.

The primary outcome measure is the difference between intervention and control group in change in cardiovascular risk determinants of behavior change. Differences between changes in the two groups will be analyzed according to the following needs: 1) risk profile, 2) smoking history, and 3) demographic characteristics. Cardiovascular risk profile is based on the risk for cardiovascular disease and we calculated that 97 patients should be included in every group.

Citation First Author Title (shortened) Degree of evidence 1. RCT n = 358 pregnant smokers A computer-assisted telephone interviewing program generates real-time-tailored counseling delivered by lay interviewers. Pilot participants (n = 53) were adult smokers who contacted a Web-based, computerized smoking cessation quit line: assessing the impact of comparative feedback vs general reminders.

Among intervention patients who were not ready to quit smoking, and were not motivated smokers, verbally to telephone staff who had previous smoking cessation counseling experience. In 51 women receiving telephone counseling, best and relationship to eventual cessation.

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The research discussed in this publication was funded by a grant from the National Cancer Institute (CA57586-04). The authors express their sincere gratitude to all of the members of the intervention group who participated. In particular we would like to thank Susan Baum, Alice Bradley, Hali Rohinett, and Nancy Zharen for their efforts.

The study was funded by the Robert Wood Johnson Foundation’s Smoke Free Alaska Project and the National Heart, Lung, and Blood Institute’s Midcareer Investigator Award in Patient-Oriented Research (K24-HL04440). The authors thank the members of the Center for Health Promotion at the University of Minnesota for their work on this project. The Center for Health Promotion was able to reach 49% of those in the intervention group (323/663). Of these members, 118 (36.8%) declined any participation. Therefore, in response to the proactive contact, 63% (205/323) of those reached and 31% (64/205) of those reached and who participated in telephone counseling declined to participate. In a multivariate logistic regression model included older age and using more than 30 days of medication.

The study was funded by the Robert Wood Johnson Foundation’s Smoke Free Families Program (#040667) and a National Heart, Lung, and Blood Institute Midcareer Investigator Award in Patient-Oriented Research (#K24-HL04440) to Dr. Rigotti.
**Table:**

<table>
<thead>
<tr>
<th>Study ID</th>
<th>First Author</th>
<th>Title (shortened)</th>
<th>Stage of Evidence</th>
<th>Study type</th>
<th>Study quality</th>
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<th>Patient characteristics</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Length of follow-up</th>
<th>Outcomes and effect size</th>
<th>Funding</th>
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<tr>
<td>1629872322</td>
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<td>The effects of a multilingual telephone follow-up for Asian long-term smokers: a randomized controlled trial</td>
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<td>Smoking cessation programmes designed to support a nationwide smoking cessation campaign</td>
<td>Ib RCT high</td>
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The Family Healthware Impact Trial (FHIT) was supported by 6 months of 4,248 participants, 3,344 (78%) completed the study. Participants were white (91%), female (70%), and insured (97%), and had a mean age of 50.6 years (range 35-65 years). Intervention participants were more likely to increase daily fruit intake (OR=2.50; 95% CI, 1.94-3.25; p<0.0001) and to have their blood pressure measured within 5 years (OR=0.34; 95% CI, 0.17-0.67), with an absolute difference of 15%.

Patients in the control group received an age- and sex-specific health message related to lifestyle and screening.

The study took place between September 2005 and April 2009 and had a final enrollment of 1,112. Based on the outcome assessed at 50 weeks, there was no significant difference in 30-day smoking cessation between the Internet (11%) and booklet (13%) groups (intent-to-treat [ITT] difference = 6% to 2%). In post-hoc analysis, quitting was higher in the intervention group (OR=2.0; CI 1.1-3.8; p=.02).

Three studies used non-PDA handheld computers to target anxiety. Compared with those in the control group (OR=0.4; CI 0.2-0.9; p=.006), those in the PDA group had significantly higher anxiety scores in the first week of the intervention, which was maintained at 4 weeks (OR=2.9; CI 1.4-5.9; p=.002). The PDA intervention was more effective in patients with higher risk of depression and anxiety.

The control group also set a quit date and received a general health video message sent to their phone every 2 weeks.
At 18 months, the 30-day multiple point prevalence abstinence rate across all follow-up intervals was 3.5% (BI), 4.5% (EI), and 6.0% (EI+PTC) for the web, PTC, and PTC+web conditions, respectively. The PTC group had a significantly higher abstinence rate than the web group (OR=1.59, 95% CI 1.26–1.98) at 12 months. The effect was similar among participants not receiving pharmacotherapy (OR=1.73, 95% CI 1.25–2.35) or EI; however, the between-group difference in abstinence outcomes was taken at 6 months.

This study aimed to determine the relative effect of Internet and Internet plus telephone treatment for smoking cessation on smoking abstinence among US adults. A randomized trial of Internet and telephone treatment for smoking cessation in the United States who smoked five or more cigarettes per day, with participants randomized to one of three smoking-cessation interventions: web-based counseling (n=401); proactive telephone-based counseling (PTC; n=402); or combined PTC and web-based counseling (PTC–web; n=402). The effectiveness of each intervention was compared at 3 and 6 months. The results of this study confirmed the findings for the original ChewFree trial and highlighted the use of different types of interventions to address different needs and vulnerabilities of smokers.

The methods included a description of the inclusion criteria, the randomization process, and the follow-up procedures. The effectiveness of each intervention was compared at 3 and 6 months. The results of this study confirmed the findings for the original ChewFree trial and highlighted the use of different types of interventions to address different needs and vulnerabilities of smokers.

More treatment condition participants were abstinent (30-day point prevalence) than control site participants (12.9% vs. 11.3%) at 3 months. This effect was similar among participants not receiving pharmacotherapy (12.9% vs. 11.3%) or EI; however, the between-group difference in abstinence outcomes was taken at 6 months.

This work was funded, in part, by grants from the National Cancer Institute (Grant R01CA071358) and is registered at Clinicaltrials.gov (NCT00301145). Varenicline and nominal support for recruiting participants was provided by Pfizer, Inc.

The different types of interventions were effective compared with untailored booklet or e-mail interventions [rate ratio (RR) 1.8; 95% confidence interval (CI) 1.4–2.3] increasing 6-month abstinence by 17% (95% CI 12–21%). No overall effect was found for non-automated interventions. However, there was strong evidence for non-automated interventions for smoking cessation rates (RR 1.4, 95% CI 1.0–2.0), but evidence was less clear-cut for non-automated interventions.

The role of depressed affect. In a randomized controlled trial sponsored by the American Cancer Society, a treatment condition (n=1,106) was compared to a control site (n=1,047). The effectiveness of each intervention was compared at 3 and 6 months. The results of this study confirmed the findings for the original ChewFree trial and highlighted the use of different types of interventions to address different needs and vulnerabilities of smokers.

The effects observed were not attributable to differences in program delivery methods or the role of depressed affect. In a randomized controlled trial sponsored by the American Cancer Society, a treatment condition (n=1,106) was compared to a control site (n=1,047). The effectiveness of each intervention was compared at 3 and 6 months. The results of this study confirmed the findings for the original ChewFree trial and highlighted the use of different types of interventions to address different needs and vulnerabilities of smokers.
This study was funded by NCI grant R21CA124881 from the Netherlands Foundation for a Smoke Free Future.

Process improvements were reported in lower failed appointments, quicker diagnosis and treatment, and improved teaching and training. Cost per text message was provided by two studies. The findings that enhancing standard care with the text message service can help improve health outcomes and care processes have implications for both patients and providers.

The median number of replies to the weekly SMS assessments was 12.5 in the 1SMS group and 13.0 in the 3SMS group. Participants reported not having smoked in the last 24 hours (21.5%) and 7 days (20.4%) in contrast with participants in the control group (17.0% and 16.0%, respectively). The acceptance of the program did not differ between the intervention groups. At postassessment, no significant differences between the three study groups emerged on the examined smoking variables.

Participants (n = 35) in the Abstinence Contingent (AC) group received monetary incentives contingent on recent smoking abstinence (i.e., CO of 4 parts per million or below). Participants (n = 33) in the Yoked Control (YC) group received non-contingent monetary incentives.

Of 287 articles searched, 22 RCTs, which included 29,549 participants with 16,050 enrolled in Web- or computer-based smoking cessation program groups and 13,499 enrolled in control groups, were included in the final analyses. In a meta-analysis of all 22 trials, the intervention group had a significant effect on smoking cessation (relative risk [RR], 1.44; 95% confidence interval [CI], 1.27-1.64). Similar findings were observed in 9 trials using a Web-based intervention (RR, 1.10; 95% CI, 1.05-1.16). The response rate at 4 weeks was 96% and at 6 months was 92%. The results at 4 weeks show a doubling of self-reported quitting relative risk (RR) 2.08 (95% CI 1.11 to 3.89), 26% vs 12%.

The study was conducted by the first author of the current study, Drs. Myung, McDonnell, Kazinets, and Moskowitz, receiving funding from the Centers for Disease Control and Prevention through Cooperative Agreement U48/DP000033.
Contrary to our hypotheses, no between-condition differences in smoking abstinence were found at 3- and 6-month follow-up assessments. While participants in the QSN intervention condition spent more time than controls visiting the online website, these findings were not reflected in increased quit rates. Despite these findings, reductions in smoking prevalence rates were observed in all conditions (11.4% for Smoke|Quit, 2.9% for the usual care condition, and 5.6% for the usual care intervention), and self-reported consumption decreased from 51.7% to 51.0% (p = .001) with no difference across conditions.

This investigation was supported by NCI grant R01 CA81934-01A2 (Alexander V. Prokhorov, M.D., Ph.D., Principal Investigator; Steven H. Kelder, Ph.D., Co-Principal Investigator). The study was a two-arm randomized controlled trial that compared two Web-based smoking cessation programs: (1) the QSN intervention condition (delivered through internet and cell phone without nicotine replacement therapy) and (2) a Web-based exercise enhancement program (Active Lives) adapted somewhat to encourage smoking cessation.

At 18-month follow-up, among baseline nonsmokers, smoking initiation rates were significantly lower in the ASPIRE condition (8.4% vs. 12.9%, p < .05). Students receiving ASPIRE also demonstrated significantly higher decisional balance against smoking (odds ratio = 1.33; 95% CI: 1.04, 1.70) and higher self-efficacy for smoking cessation (odds ratio = 1.40; 95% CI: 1.16, 1.69) compared with the control condition. However, self-efficacy remained for self-efficiency maintained long-term cessation effects. For post-intervention 1-month follow-up, increased coping planning and self-efficacy increased a partial mediation of the treatment effect.

Cancer Society's program, and 5.6% for the usual care intervention (p < .05). Among nonquitters, 46.5% had made a quit attempt, and weekly consumption decreased from 54.01 to 42.08 cigarettes (p < .001) with no differences across interventions.

Controlling for depression severity (the less interactive ACS site: 13% vs 10% (P = .04) among 4490 enrolled and 32% vs 26% (P = .06) among 1798 followed.

The intervention group received HE, and the control group received a booklet with no access to the website. Participants were randomly assigned to receive emailed access to one of five tailored interactive sites provided by cooperating research partners or to a targeted, minimally interactive ACS site with text, photographs, and graphics providing stage-based quitting advice and peer modeling.

Ib RCT n = 290 Inclusion criteria were willingness to quit smoking on a prescribed day without using nicotine replacement therapy and being aged 14 years or older. The intervention condition received the Smoke|Quit website, which included a new program (Smoke|Quit), the Canadian Cancer Society's self-help program, and a usual care quit kit.

Access to one of five tailored interactive sites provided by cooperating research partners or to a targeted, minimally interactive ACS site with text, photographs, and graphics providing stage-based quitting advice and peer modeling.

Evidence Study type Study comparison Length of follow-Up Outcome and effect size Funding Comments

Ib RCT high n = 290 Inclusion criteria were willingness to quit smoking on a prescribed day without using nicotine replacement therapy and being aged 14 years or older. The intervention condition received the Smoke|Quit website, which included a new program (Smoke|Quit), the Canadian Cancer Society's self-help program, and a usual care quit kit.

Ib RCT high n = 290 Inclusion criteria were willingness to quit smoking on a prescribed day without using nicotine replacement therapy and being aged 14 years or older. The intervention condition received the Smoke|Quit website, which included a new program (Smoke|Quit), the Canadian Cancer Society's self-help program, and a usual care quit kit.
The role of engagement in a tailored web-based smoking cessation intervention predicts 6-month abstinence, (2) whether engagement in the sequentially delivered web program was related to subsequent smoking cessation, and (3) whether particular components of a Web-based smoking cessation program influenced engagement.

The intervention system was able to generate a total of 1040 unique letters with normative feedback only, and almost half a million unique letters with normative and ipsative feedback. Almost every single smoker in contemplation, preparation, and action to quit was engaged and was offered content and feedback relevant to their stage of change. In contrast, many smokers in precontemplation shared a combination of tailoring variables and received identical letters.

Usual care 6 months 12% of 66 usual care control group participants and 25% of 52 experimental group participants reported being abstinent at 6 months (p=0.019).

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The study was supported by grant 70-18008 from the National Institute on Drug Abuse. Additional support by matching funds provided by the University of Minnesota Tobacco Education and Research Centers (N01-RR-1-0055) and the National Cancer Institute (U01 CA123671), and by the Global Tobacco Industry Research Collaborative (N01-RR-1-0055). Thanks are extended to Christian Goeze for programming the expert system software and the survey management software.
The intervention resulted in a significantly lower self-reported saturated fat intake ($b = -0.76, p < 0.01$) and a higher likelihood of meeting the PA guidelines among respondents who were insufficiently active at baseline ($OR = 1.34, 95%CI = 1.00-1.80$). No significant intervention effects were found for self-reported smoking status. Of the participants, 81% actually visited the website.

Compared to the HRI only group, the MI and TTM groups had significantly more participants in the Action stage for exercise 3, 6, 12, 18 and 24 months. Based on 7-day point-prevalence abstinence and 6-month prolonged abstinence as the outcome measures, the study showed a significant increase in smoking cessation rates in the MI and TTM groups compared to the control group. The overall cessation rates that were yielded by the brief protocol including booster sessions were equivalent to those obtained with the American Cancer Society's standard protocol with boosters.

The study evaluated the short-term (1 month) efficacy of an internet-delivered, computer-tailored lifestyle intervention targeting saturated fat intake, physical activity (PA), and smoking cessation. Results were compared to an active control group who received a website with general health information. The data were analyzed using multiple linear and logistic regression analysis.

Overall, the interventions were associated with a significantly higher cessation rate vs control at the three to six month follow-up. The model-based smoking cessation intervention, as delivered in this study and in this special setting, was ineffective.

The study was funded by the National Cancer Institute, grant number R01-CA84225.

In this randomized controlled trial, 6322 smokers were enrolled in a six-month cessation program including pharmacotherapy, counseling, educational literature and postoperative telephone follow-up. The primary outcome measure was 6-month prolonged abstinence, defined as not smoking for 365 days, including 21 days prior to the 6-month follow-up interview. The primary intervention was a computer-tailored smoking cessation intervention, as delivered in this study and in this special setting, was ineffective.

The study, as part of the Research Collaboration in Early Substance Use Intervention (EARLINT), has been funded by the German Federal Ministry of Education and Research (Grant No. 01EB0120, 01EB0420) and the Social Ministry of the State of Mecklenburg-West Pomerania (Grant no. IX311a 406.68.43.05).

The study enrolled 611 smokers from an existing general population health examination survey in a university hospital. The sample consisted of current, former and never smokers, involved up to three individualized feedback letters, and was created using expert-system technology.
The trial was funded by the National Heart Foundation of New Zealand, the Cancer Society of New Zealand, Vodafone NZ, Alcatel, and Auckland UniServices. Anthony Rodgers held a Senior Fellowship from the National Heart Foundation.

The main trial outcome was current non-smoking (that is, not smoking in the past week) six weeks after randomisation. Secondary outcomes included current non-smoking at 12 and 26 weeks. Results: More participants had quit at six weeks in the intervention group than in the control group (44.9% vs 37.8%, respectively; p = 0.03). The relative risk estimates were similar in sensitivity analyses adjusting for missing data and salivary cotinine verification tests. Reported quit rates remained high at six months, but there was some uncertainty about between group differences because of incomplete follow up.

This research was supported in part by the Office of Research and Development and the National Heart, Lung, and Blood Institute of the National Institutes of Health (RO1-HL061216-01). The study was conducted by the Comstock Research Group.

This study was supported by the National Cancer Institute, National Institute on Aging, the National Institute on Minority Health and Health Disparities, and the Veterans Affairs Special Medical Research Center.

This research was funded by a partnership with the National Cancer Institute. This study was supported by the VA Office of Academic Affiliations, Veterans Affairs Special Medical Research, Education, and Clinical Centers Fellowship, and the National Institutes of Health Grants K02-AA00171, P50-DA13334, and R01-AA11197.

This research was supported in part by the Tobacco-Related Disease Research Program (Munoz). The authors would like to acknowledge the National Academic Affiliations, Veterans Affairs Special Medical Illness Research, Education, and Clinical Centers Fellowship. The University of California, San Diego Veterans Affairs Geriatric Research Center also allowed the ongoing support of the U.S. National Library of Medicine. This study was funded by the Office of Research and Development and the National Heart, Lung, and Blood Institute of the National Institutes of Health (RO1-HL061216-01).

The authors would like to acknowledge the National Academic Affiliations, Veterans Affairs Special Medical Research, Education, and Clinical Centers Fellowship. The University of California, San Diego Veterans Affairs Geriatric Research Center also allowed the ongoing support of the U.S. National Library of Medicine.

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This research was supported by grant #R01 CA80323 from the National Cancer Institute. The study was supported by the National Cancer Institute, National Institute on Aging, the National Institute on Minority Health and Health Disparities, and the Veterans Affairs Special Medical Research Center.

This study was funded by the Australian National Health and Medical Research Council (Grant 620350).

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The authors would like to acknowledge the National Academic Affiliations, Veterans Affairs Special Medical Illness Research, Education, and Clinical Centers Fellowship. The University of California, San Diego Veterans Affairs Geriatric Research Center also allowed the ongoing support of the U.S. National Library of Medicine.

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<table>
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<tr>
<th>Citation</th>
<th>First Author</th>
<th>Title (shortened)</th>
<th>Degree of Evidence</th>
<th>Study type</th>
<th>Study quality</th>
<th>N</th>
<th>Patient characteristics</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Length of follow-up</th>
<th>Outcome and effect size</th>
<th>Funding</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>15829474</td>
<td>Etter, JF</td>
<td>Comparing the efficacy of two Internet-based, computer-tailored smoking cessation programs: a randomized trial.</td>
<td>RCT</td>
<td>n = 11969</td>
<td>Visitors to a smoking cessation website</td>
<td>High</td>
<td>Interactive smoking cessation program or to a modified program. Both programs consisted of online, computer-based counseling letters based on participants' characteristics, and telephone counseling was available for both groups.</td>
<td>Length of follow-up</td>
<td>The baseline questionnaire was answered by a total of 11969 current (74%) and former (26%) smokers, and the follow-up survey by 4237 people (35%). In an ITT analysis, abstinence rates at baseline current smokers were respectively 10.9% and 10.0% (p=.66), confidence interval (CI) -0.03 to 0.26. For the original and modified programs, and for participants assigned to the standard and modified programs, we found no significant differences in quit rates at 6 months. In an ITT analysis, abstinence rates at 6 months were respectively 20.6% and 20.1% (p=.46), with no statistical differences in quit rates between the 2 programs. We report results from intention-to-treat (ITT) analyses, where all non-respondents at follow-up were counted as failures.</td>
<td>Internal funding</td>
<td>The authors declared no conflict of interest.</td>
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<tr>
<td>18280668</td>
<td>Prokhorov, AV</td>
<td>&quot;Look at your health&quot;: outcomes associated with a computer-assisted smoking cessation counseling intervention for community college students.</td>
<td>RCT</td>
<td>n = 426</td>
<td>Smoking college students</td>
<td>High</td>
<td>A group-randomized, controlled, counselor-delivered smoking cessation program that addresses personal health risks and readiness to change smoking behavior among community college students.</td>
<td>Length of follow-up</td>
<td>At the 10-month follow-up assessment, the cotinine-validated smoking cessation rates were 16.6% in the experimental condition and 10.1% in the standard care condition (p=0.07). Our results indicate that our computer-assisted intervention holds considerable promise in reducing smoking among community college students.</td>
<td>Internal funding</td>
<td>This research was supported by NCI grant # CA69425-03.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>21069681</td>
<td>Cahill, K</td>
<td>Stage-based interventions for smoking cessation.</td>
<td>Ia SR</td>
<td>very high</td>
<td>n &gt; 50,000 Smokers, of any age, race or gender.</td>
<td>High</td>
<td>We searched the Cochrane Tobacco Addiction Group's specialised register for trials, using the terms ('stage* of change', 'transtheoretical model*', 'preparation', 'preparatory stage', 'precontemplation', 'contemplation', 'action', 'change', 'habit' and 'smoking in the role of addiction') in the title or abstract, or as keywords. The latest search was in August 2010.</td>
<td>Length of follow-up</td>
<td>We found 41 trials (&gt;33,000 participants) which met our inclusion criteria. Four trials, which directly compared the same stage-based and standard interventions, found no clear advantage for the staging component. Stage-based versus standard interventions (two trials) gave a relative risk (RR) of 1.00 (95% CI 0.82 to 1.22). Stage-based versus standard interventions (two trials) gave a relative risk (RR) of 1.00 (95% CI 0.82 to 1.22). These findings are consistent with the previous effectiveness of these interventions in randomized controlled trials. The evidence was found for telephone counseling, computer-supported programmes and training of doctors or lay supporters. This uncertainty may be due in part to greater numbers of trials.</td>
<td>Internal funding</td>
<td>Within the last 5 years Tim Coleman has undertaken consultancy work for Pierre Fabre Laboratories, France and also receives authorship payments for providing training to smoking cessation specialists and receives royalties from books on smoking cessation.</td>
<td></td>
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</tr>
<tr>
<td>27006259</td>
<td>Coleman, T</td>
<td>Relapse prevention in UK Stop Smoking Services: current practice, systematic reviews of effectiveness and cost-effectiveness analysis.</td>
<td>IIb SR</td>
<td>medium</td>
<td>Smokers willing to quit</td>
<td>High</td>
<td>To assess the effectiveness and cost-effectiveness of relapse prevention in NHS SSS. To update current estimates of effectiveness on interventions for preventing relapse to smoking. To identify the factors that determine the economic impact of relapse prevention interventions. The systematic review included 36 studies providing evidence on effectiveness and cost-effectiveness of relapse prevention interventions for maintaining smoking abstinence.</td>
<td>Length of follow-up</td>
<td>Qualitative research with 16 NHS SSS managers indicated that there was no shared understanding of what relapse prevention meant or of the kinds of interventions that should be used for this. The systematic review included 36 studies (349,600 participants) and found that relapse prevention interventions were effective for maintaining smoking abstinence (two trials) (RR 1.00, 95% CI 0.82 to 1.22). Stage-based versus standard interventions (two trials) gave a relative risk (RR) of 1.00 (95% CI 0.82 to 1.22). Stage-based versus standard interventions (two trials) gave a relative risk (RR) of 1.00 (95% CI 0.82 to 1.22). These findings are consistent with the previous effectiveness of these interventions in randomized controlled trials. The evidence was found for telephone counseling, computer-supported programmes and training of doctors or lay supporters. This uncertainty may be due in part to greater numbers of trials.</td>
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<tr>
<td>200563</td>
<td>Vartanian, A</td>
<td>Smoking cessation programs for smoking cessation: an evidence synthesis</td>
<td>Ia</td>
<td>SR</td>
<td>very high</td>
<td>adult smokers</td>
<td>For every intervention strategy, only the most recent publications were included. For each study, the proportion of those who were contactable to their follow-up, the percentage who were contactable, the percentage who were lost to follow-up, and the percentage of follow-up data were compared. A random-effects model was used to estimate the pooled odds ratio for each intervention strategy. The results were consistent across all regions.</td>
<td>Continued abstinence was also higher in the intensive behavioral treatment group (12.9%), although these differences were not statistically significant.</td>
<td>Long-term (12-18 months)</td>
<td>Continued abstinence was also higher in the intensive behavioral treatment group (12.9%), although these differences were not statistically significant.</td>
<td>NCI R01 CA 193175</td>
<td>No relevant comments.</td>
<td></td>
</tr>
<tr>
<td>20099536</td>
<td>Secades-Villa, R</td>
<td>Effectiveness of three intensities of behavioral smoking cessation treatments: a randomized controlled trial</td>
<td>Ia</td>
<td>SR</td>
<td>very high</td>
<td>adult smokers</td>
<td>The results found that participants in the experimental condition were more likely to report eating and drinking for the purpose of smoking, and that these differences were significant at the 1-month and 3-month follow-up points. The difference in weight loss between the two groups was also significant at the 3-month follow-up point.</td>
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<td>NCI R01 CA 193175</td>
<td>No relevant comments.</td>
<td></td>
</tr>
<tr>
<td>20653619</td>
<td>Agboola, S A</td>
<td>A systematic review of the effectiveness of workplace interventions on quitting smoking</td>
<td>IIb</td>
<td>RCT</td>
<td>medium</td>
<td>N = 682 New York State Smokers' Quitline</td>
<td>The results found that participants in the experimental condition were more likely to report eating and drinking for the purpose of smoking, and that these differences were significant at the 1-month and 3-month follow-up points. The difference in weight loss between the two groups was also significant at the 3-month follow-up point.</td>
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<td>NCI R01 CA 193175</td>
<td>No relevant comments.</td>
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The "Proactive interventions for smoking cessation in patients who did not use pharmacotherapy (36%) versus those who did (16%) and for patients with CVD (40%) versus ... 15% recruitment of identified smokers, 90% plus completion for Intensive, 15% drop-out, and 75% abstinence corroboration.

6-, 12-, 18- and 24-month Among participants completing the last follow-up, 6-month prolonged abstinence was 18.3% in the tailored letters intervention This work was supported by the CDC (Cooperative agreements # 1-U48-DP000033 and 1-U48-DP001908).

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Results of Cox regression analysis revealed that participants in the lapse condition relapsed more quickly than participants in the no lapse condition (hazard ratio = 1.4; P = 0.047).

Agreements # 1-U48-DP000033 and 1-U48-DP001908) (1) brief advice by the practitioner; (2) individually tailored computer-generated letters; or (3) a combination of both interventions.

No Lapse (a no smoking control/30 minute waiting period) or Lapse (smoking two cigarettes of their favored brand during a 30 minute period). In post-hoc analysis, quitting was higher among participants in the Internet intervention (n = 562) who completed the online program: 26% quit compared with 10% who did not complete the program (ITT difference = 16%, 95% CI = 3%–29%).

Citation First Author Title (shortened) Degree of

Funding Comments

Intervention Comparison Length of follow-Up Outcome and effect size

6 months We found 41 trials (>33,000 participants) which met our inclusion criteria. Four trials, which directly compared the same interventions, found that the combination of computer-generated letters and telephone intervention was associated with higher quit rates compared with the control group: 31% (95% CI 25%–36%) vs. 21% (95% CI 17%–25%) (p = .002) for the first 12 months, and 21% (95% CI 17%–25%) vs. 10% (95% CI 6%–13%) (p = .005) for the second 12 months. These findings are consistent with the finding that computerized interventions to reduce tobacco use are more effective than usual care controls.

The evidence was too limited for telephone counseling, interactive computer programs or training of doctors or lay counselors. This uncertainty may be due in part to smaller numbers of trials.

RCT n = 63 adult smokers who quit smoking with a brief cognitive-behavioral intervention and self-help materials; standard counselling compared with those receiving a similar program via booklet. The study had 11 online surveys administered every 5 weeks.

After formative work involving patients and clinicians, a brief computer-based intervention was designed to facilitate telephone pledges support. We found 41 trials (>33,000 participants) which met our inclusion criteria. Four trials, which directly compared the same interventions, found that the combination of computer-generated letters and telephone intervention was associated with higher quit rates compared with the control group: 31% (95% CI 25%–36%) vs. 21% (95% CI 17%–25%) (p = .002) for the first 12 months, and 21% (95% CI 17%–25%) vs. 10% (95% CI 6%–13%) (p = .005) for the second 12 months. These findings are consistent with the finding that computerized interventions to reduce tobacco use are more effective than usual care controls.

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<th>Length of follow-up</th>
<th>Outcome and effect size</th>
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<tr>
<td>Shahab, Lion, L</td>
<td>Online support for smoking cessation: a systematic review of the literature.</td>
<td>SR A</td>
<td></td>
<td>There was no evidence of publication bias in any of the studies. Intervention and control groups did not differ significantly in terms of abstinence rates.</td>
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<tr>
<td>Haug, Severin, S</td>
<td>Continuous individual support of smoking cessation using text messaging: a pilot experimental study.</td>
<td>IIb RCT</td>
<td></td>
<td>The median number of replies to the weekly SMS assessments was 12.5 in the 1SMS group and 13.0 in the 3SMS group (not significant). The acceptance of the program did not differ between the intervention groups.</td>
</tr>
<tr>
<td>Sood, Akshay, A</td>
<td>&quot;Real-world&quot; effectiveness of reactive telephone counseling for smoking cessation: a randomized controlled trial.</td>
<td>RCT n</td>
<td>1, 3, 6, and 12 months</td>
<td>There was no evidence of publication bias. Intervention and control groups did not differ significantly in terms of abstinence rates.</td>
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<tr>
<td>Travis, Heather E</td>
<td>Randomized controlled trial examining the effectiveness of a tailored self-help smoking-cessation intervention for postsecondary smokers.</td>
<td>RCT n</td>
<td></td>
<td>The intention-to-treat analysis revealed quit rates of 11.4% for Smoke</td>
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<tr>
<td>Boyle, Raymond G</td>
<td>A randomized controlled trial of Telephone Counseling with smokeless tobacco users: the ChewFree Minnesota study.</td>
<td>IIb RCT</td>
<td></td>
<td>There was no evidence of publication bias. Intervention and control groups did not differ significantly in terms of abstinence rates.</td>
</tr>
</tbody>
</table>
This research was supported by GlaxoSmithKline.

The authors would like to sincerely thank Tess Player and Joseph Matthias for their assistance. Dr. Strecher is a...and research for, and travel funds from, manufacturers of smoking cessation products including the sponsor of this study and core funding from the UK NHS R&D programme.

This work was supported by Cancer Research UK grant number C1345/A5809. The authors had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Usual care 6 months 12% of 66 usual care control group participants and 25% of 52 experimental group participants reported being abstinent...

The primary meta-analysis pooled 12 trials comparing usual care (median quit rate 4.9%) with self-help (median quit rate...and 12 months. Additional cost per quitter (relative to Usual Care) ranged from several hundred dollars to $6,450.

The tailored letters intervention group received up to three individualised smoking cessation letters over a period of 12 months. Intervention materials were regularly updated, and participants were asked to keep a smoking cessation diary and telephone support was available from a Quitline.

We included 12 trials of which eight had a parallel group design and four were cluster-randomised trials. The percentage of participants who had smoked cigarettes in the past 7 days at baseline was 1.6% (95% CI 1.2–2.1) and 1.8% (95% CI 1.3–2.3) for the intervention and control groups, respectively. We found no differences between the intervention and control groups at any of the follow-up periods (p < 0.05). The intervention was significantly more effective than brief advice for 24-hour [odds ratio (OR) = 1.4; P = 0.047] but not for 7-day point prevalence abstinence, or for alternative assumptions about participants lost to follow-up.
At 12-month follow-up, using intent-to-treat, imputed, and per-protocol analyses, no differences were found among the four intervention groups (p = 0.106). The researchers believed this was due to the large sample size, which allowed for the detection of even small differences between the groups. Additionally, the lack of differences may have been due to the difficulties associated with tailoring the interventions to individual participants.

Most participants in the intervention group agreed with: “What I learned in this booklet is outrageous” (74%) and “alarming” (70%). These findings suggest that the booklet was effective in raising awareness and concern among participants.

The research discussed in this publication was funded by a grant from the National Cancer Institute (CA127964). The authors express their sincere gratitude to all of the research assistants and participants for their valuable contributions. In particular, we would like to thank Susan Baum, Alice Bradley, Hari Rohinett, and Nancy Zharen for their efforts.

The results revealed high correlations between reports of smoking behavior, as assessed by IVR and TLFB. Compliance with TLFB was superior to compliance with the IVR system. This problem should be addressed if researchers wish to use an IVR system in future smoking cessation clinical trials.

Evidence Study type Study quality n Patient characteristics Intervention Comparison Length of follow-Up Outcome and effect size Funding Comments

- **RCT**
- **n = 1978 Smokers**
- **A single, untailored smoking cessation guide (SU): a single, tailored smoking cessation guide (ST): a series of four (multiple) printed materials tailored only to baseline data (MT): a standard booklet, minimally personalized booklet, or extensively personalized booklet.**
- **The interventions varied in their degree of ostensible tailoring, yet the actual smoking-related content of the booklets was identical.**
- **The primary outcome was the 7-day point-prevalence smoking abstinence at longest follow-up (≥ 6 months).**

The primary study hypothesis was that higher levels of participantreported smoking reduction will be associated with higher levels of participant-reported tailoring. The results of this study support this hypothesis and suggest that tailoring may be especially effective in this context.

The studies included in this meta-analysis were randomized controlled trials or quasi-experimental studies of behavioral, psychosocial, and/or pharmacological interventions for smoking cessation. The quality of the studies was assessed using the Cochrane Risk of Bias Tool. The quality of the evidence was assessed using the GRADE system.

The included studies were published between 1990 and 2019. The heterogeneity among studies was assessed using the I² statistic. The effect sizes were calculated using the standardized mean difference (SMD) and the risk ratio (RR) with 95% confidence intervals (CI).

Ten trials were included; six tested pharmacologic interventions, one evaluated a behavioral intervention, and three evaluated combined interventions. Results: Pharmacologic (2732 participants; OR 2.33, 95% CI 1.43 to 3.79) and combined (638 participants; OR 3.19, 95% CI 1.57 to 6.50) interventions showed a greater effect compared to the control group. The effect of the pharmacologic interventions was larger than that of the combined interventions (OR 2.33, 95% CI 1.43 to 3.79 vs. OR 3.19, 95% CI 1.57 to 6.50).

The authors concluded that tailoring interventions for smoking cessation may be effective in increasing smoking reduction rates. However, further research is needed to confirm these findings and to identify the most effective methods for tailoring interventions.
<table>
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<th>Funding</th>
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<tr>
<td>1727908</td>
<td>Morris, Chad R</td>
<td>Smoking reduction for tobacco users with mental illness and a smoking history: a controlled trial</td>
<td>IIb RCT</td>
<td>medium</td>
<td>2 - 145</td>
<td>adult smokers 18–70 years who smoked a mean of 24 cigarettes/day, with a mean of 31 pack-years</td>
<td>Brief telephone counseling and computer-generated tailored letter</td>
<td>Brief counseling and computer-generated tailored letter group compared to those who received brief counseling alone.</td>
<td>6 months</td>
<td>cessation rates were not significantly different between groups ( p ¼ 0.7), but all groups had a significant reduction in tobacco use.</td>
<td>Morbidity and a community-based group counseling intervention with adults currently receiving community mental health services.</td>
<td></td>
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<tr>
<td>1727909</td>
<td>Alpat, Shonuyi S</td>
<td>Effects of smoking cessation interventions in different settings: a randomized controlled trial</td>
<td>IIb RCT</td>
<td>medium</td>
<td>2 - 145</td>
<td>adult smokers</td>
<td>Brief intensive intervention with 4 sessions of cognitive-behavioral therapy and 8 sessions of motivational interviewing</td>
<td>Brief intensive intervention group compared to those who received a control condition</td>
<td>6 months</td>
<td>Quit rates were significantly higher and heavier rates than the general population, and suffer greater tobacco-related morbidity and mortality.</td>
<td>Funding for this study was provided by the United States Department of Health and Human Services, Agency for Healthcare Research and Quality (5 R18 HS010736-04).</td>
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<tr>
<td>1727910</td>
<td>Fagerstrom, Karl O</td>
<td>Snus as a smoking cessation aid: a randomized controlled trial</td>
<td>IIb RCT</td>
<td>medium</td>
<td>250</td>
<td>Subjects were followed up through 28 weeks after randomization. In total, 5 clinical visits and 8 telephone contacts were scheduled. Primary outcome measure was biologically verified continuous smoking abstinence from Week 6 through 28.</td>
<td>Snus group compared to nicotine gum group</td>
<td>28 weeks</td>
<td>The main outcome measure was smoking status (smoker, former smoker, ex-smoker). Snus group significantly reduced smoking (OR 5.25, 95% CI: 1.9–14.3) compared to nicotine gum group (OR 1.23, 95% CI: 0.3–4.6). The results of this study suggest that snus can be an effective smoking cessation aid, especially for young and heavy smokers.</td>
<td>National Center for Tobacco Control and Promotion</td>
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<tr>
<td>1727911</td>
<td>Wilson, Julie S</td>
<td>Does additional support by nurses enhance the effect of a brief smoking cessation intervention in people with moderate to severe chronic obstructive pulmonary disease? A randomized controlled trial.</td>
<td>IIb RCT</td>
<td>medium</td>
<td>53</td>
<td>adult smokers</td>
<td>Additional support by nurses facilitated by nurse telephone calls and nurse-issued reminder letters</td>
<td>Additional support group compared to intervention group</td>
<td>12 months</td>
<td>Similar to past clinic-based studies of motivational interviewing with teenage smokers, our study found negative results in smoking reduction: development and pilot results of an innovative intervention.</td>
<td>Funding was provided by the National Institutes of Health.</td>
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<tr>
<td>1727912</td>
<td>Horn, Kimberly</td>
<td>Efficacy of an emergency department-based smoking intervention in a university-affiliated emergency department: a randomized controlled trial of 300 smoking patients admitted to the Colorado Department of Public Health and Environment (CDPHE). CDPHE disclaims responsibility for any analyses, interpretations, or conclusions.</td>
<td>IIb RCT</td>
<td>medium</td>
<td>50</td>
<td>adult smokers</td>
<td>Three anonymous smoking cessation aides located in the Emergency Department and supervised by trained providers delivered the intervention to all eligible patients (n = 253). The results of this study suggest that smoking cessation aides can be effective in reducing smoking in the emergency department setting.</td>
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<td>1727913</td>
<td>Morris, Chad R</td>
<td>Smoking reduction for tobacco users with mental illness and a smoking history: a controlled trial</td>
<td>IIb RCT</td>
<td>medium</td>
<td>2 - 145</td>
<td>adult smokers 18–70 years who smoked a mean of 24 cigarettes/day, with a mean of 31 pack-years</td>
<td>Brief intensive intervention with 4 sessions of cognitive-behavioral therapy and 8 sessions of motivational interviewing</td>
<td>Brief intensive intervention group compared to those who received a control condition</td>
<td>6 months</td>
<td>Cessation rates were not significantly different between groups ( p ¼ 0.7), but all groups had a significant reduction in tobacco use.</td>
<td>Morbidity and a community-based group counseling intervention with adults currently receiving community mental health services.</td>
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<td>1727914</td>
<td>Alpat, Shonuyi S</td>
<td>Effects of smoking cessation interventions in different settings: a randomized controlled trial</td>
<td>IIb RCT</td>
<td>medium</td>
<td>2 - 145</td>
<td>adult smokers</td>
<td>Brief intensive intervention with 4 sessions of cognitive-behavioral therapy and 8 sessions of motivational interviewing</td>
<td>Brief intensive intervention group compared to those who received a control condition</td>
<td>6 months</td>
<td>Quit rates were significantly higher and heavier rates than the general population, and suffer greater tobacco-related morbidity and mortality.</td>
<td>Funding for this study was provided by the United States Department of Health and Human Services, Agency for Healthcare Research and Quality (5 R18 HS010736-04).</td>
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<tr>
<td>1727915</td>
<td>Fagerstrom, Karl O</td>
<td>Snus as a smoking cessation aid: a randomized controlled trial</td>
<td>IIb RCT</td>
<td>medium</td>
<td>250</td>
<td>Subjects were followed up through 28 weeks after randomization. In total, 5 clinical visits and 8 telephone contacts were scheduled. Primary outcome measure was biologically verified continuous smoking abstinence from Week 6 through 28.</td>
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<td>28 weeks</td>
<td>The main outcome measure was smoking status (smoker, former smoker, ex-smoker). Snus group significantly reduced smoking (OR 5.25, 95% CI: 1.9–14.3) compared to nicotine gum group (OR 1.23, 95% CI: 0.3–4.6). The results of this study suggest that snus can be an effective smoking cessation aid, especially for young and heavy smokers.</td>
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<tr>
<td>1727916</td>
<td>Wilson, Julie S</td>
<td>Does additional support by nurses enhance the effect of a brief smoking cessation intervention in people with moderate to severe chronic obstructive pulmonary disease? A randomized controlled trial.</td>
<td>IIb RCT</td>
<td>medium</td>
<td>53</td>
<td>adult smokers</td>
<td>Additional support by nurses facilitated by nurse telephone calls and nurse-issued reminder letters</td>
<td>Additional support group compared to intervention group</td>
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<td>Similar to past clinic-based studies of motivational interviewing with teenage smokers, our study found negative results in smoking reduction: development and pilot results of an innovative intervention.</td>
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<td>N</td>
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<td>21382516</td>
<td>Williams, Geoffrey C, GC</td>
<td>The smoker’s health project: a self-determination theory intervention to facilitate maintenance of tobacco abstinence.</td>
<td>IIb</td>
<td>RCT</td>
<td>medium</td>
<td>Community Care (CC), which includes the 6 month SDT-based intervention previously shown to promote autonomous decision-making, perceived competence, motivation, and self-regulation among youth who do not want to stop smoking completely. This study examines the effects of a brief SDT-based intervention on 12 markers, including...</td>
<td>1 year</td>
<td>This research was supported by grants from the National Cancer Institute [R01-CA106668] awarded to Dr. Geoffrey Williams, MD, PhD; the National Institute of Mental Health [R01-MH080126] awarded to Dr. Geoffrey Williams; and the National Cancer Institute Research Resources [R01-CA106668], awarded to the University of Rochester's School of Medicine and Dentistry. The study was also supported by the Research Training Fellowship awarded by the NHS Executive (London/South Thames) to the first author under the mentorship of Dr. Geoffrey Williams and Jenny Abbey for assistance with interviewing. We are also grateful for helpful comments from anonymous reviewers.</td>
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<td>15784061</td>
<td>McCambridge, Jim, J</td>
<td>Deterioration over time in effect of Motivational Interviewing in reducing drug consumption and related risk among young people.</td>
<td>IIb</td>
<td>RCT</td>
<td>medium</td>
<td>n = 200 young people who were current users of illegal drugs (age range 16–20 years) with whom contact was established through peers trained for the project.</td>
<td>3 an 12 months</td>
<td>A satisfactory follow-up rate (81%) was achieved. No differences between MI and assessment-only groups were observed. Unexpected improvements by the assessment-only control group on a number of outcomes suggest the probability of availability to the research personnel of 12-month follow-up.</td>
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Ten trials were included; six tested pharmacologic interventions, one evaluated a behavioral intervention, and three evaluated combined smoking-reduction interventions. Smoking-reduction interventions significantly increased long-term abstinence from smoking, with ORs ranging from 1.28 to 3.60. Insufficient evidence was available on the efficacy of behavioral smoking-reduction interventions (320 participants; OR 1.49, 95% CI 0.56 to 3.93).

Among participants who made a quit attempt (immediately or in the next month), smoking-reduction interventions did not differ from the control condition (quarterly reminder letters) on any of the quit outcomes assessed. Between-condition differences using intent-to-treat analysis were not statistically significant.

The program was well received by outpatients who were not ready to quit smoking, and was implemented successfully by telephone staff who had no previous smoking cessation counseling experience. An ongoing trial is evaluating effectiveness, cost and relationship to eventual cessation.

We would like to thank the Smith & Nephew Foundation for providing support in the form of travel and financial assistance to the principal investigator (Klein G, Gudrun). The manuscript was written by the principal investigator (Klein G, Gudrun) and another investigator (Levinson A, Arnold H). The study was supported by grants from the National Institute on Drug Abuse (DA033889), the National Institute of Diabetes and Digestive and Kidney Diseases (DK073067), the National Institute on Deafness and Other Communication Disorders (DC011901), and the National Institute on Aging (AG025183). In the writing of the report and in the decision to submit the paper for publication, all authors were responsible for the conduct of the research, the interpretation of the data, and the final content of the manuscript. The manuscript was peer-reviewed.

12 months Both intervention and control conditions continued to improve from 3- to 12-month assessments. Between-condition differences using intent-to-treat analysis were not statistically significant.

The study team consists of a team of experienced researchers and clinicians who have successfully conducted similar trials in the past. The study was approved by the institutional review boards at all participating sites. The study is registered in ClinicalTrials.gov (NCT01208144).

The "Proactive interventions for smoking cessation in General Medical Practices" project is part of the German research network EARLINT (EARLY substance use INTervention) and was supported by the Federal Ministry of Education and Research (BMBF, 01EB0701). The study was also supported by the German Federal Ministry of Education and Research (BMBF, 01EB0701).

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<th>Intervention</th>
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<th>Length of follow-up</th>
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<td>This research was supported by grants from the National Cancer Institute [R01-CA106668] awarded to Dr. Geoffrey Williams, MD, PhD; the National Institute of Mental Health [R01-MH086330] awarded to Dr. Geoffrey Williams, MD, PhD; the National Center for Research Resources (2007-P50RR17530) awarded to the University of Rochester Center for Clinical and Translational Science; and the American Recovery and Reinvestment Act Supplement (24001-R24DS06) awarded to the University of Rochester's Clinical and Translational Science Institute.</td>
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<td>15784061</td>
<td>McCambridge, Jim</td>
<td>Deterioration over time in effect of Motivational Interviewing in reducing drug consumption and related risk among young people.</td>
<td>IIb</td>
<td>RCT</td>
<td>medium</td>
<td>Young people who are current users of illegal drugs (age range 16–20 years) with whom contact was established through peers trained for the project. The intervention was adapted from MI in the form of a topic-based 1-hour single-session discussion.</td>
<td>3 months</td>
<td>A satisfactory follow-up rate (81%) was achieved. After 12 months, 3-month differences between MI and assessment-only control groups were almost entirely disappeared. Unexpected improvements by the assessment-only control group on a number of outcomes suggest the possibility of reactivity to the research assessment at 3-month follow-up.</td>
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CBT is effective. At weeks 64 and 104, the 2 CBT conditions produced significantly higher abstinence rates than did the other 3 conditions. Conclusions. Brief contact with providers can increase abstinence during treatment. CBT may increase long-term abstinence after extended treatment is terminated.

This study was supported by the National Institute on Drug Abuse (awards R01 DA02538, K05 DA016752, K23 DA018691, and P50 DA09253). In the CoLaus study 988 smokers were assessed comparing

The A-CBT condition had significantly higher abstinence rates than did the ST condition over time (OR = 13.97; 95% CI nicotine replacement, bupropion treatment, physician or group consultations with acupuncture, hypnosis and autogenic training (13%) is much higher. However, there is no evidence in intervention trials that behavioral therapy is not favored to a high grade.

Participants were assessed at baseline and at weeks 12, 24, 52, 64, and 104. The CoLaus study was supported by research grants from GlaxoSmithKline and the Faculty of Biology and Medicine of Lausanne, Switzerland and is currently supported by the Swiss National Science Foundation (grant no. 33CSCO-122661).
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<th>Funding</th>
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<tr>
<td>19492280</td>
<td>Hendricks, Peter S</td>
<td>Mechanisms of change in extended cognitive behavioral treatment for tobacco dependence</td>
<td>IIb</td>
<td>RCT</td>
<td>medium</td>
<td>n = 199</td>
<td>Participants were older cigarette smokers (≥50 years old).</td>
<td>Tree treatment groups: brief counseling plus information pamphlet, self-help program with telephone follow-up, and intensive behavioral treatment.</td>
<td>Length of follow-up: 64 weeks Analyses revealed that extended CBT increased abstinence self-efficacy over the first 52 weeks postcessation. This effect, in turn, was positively associated with 7-day point prevalence abstinence at week 64 while controlling for treatment condition. Results indicated that abstinence self-efficacy accounted for 61% to 83% of the total effect of treatment condition on smoking abstinence.</td>
<td>20096510 Hendricks, Peter S, PS Mechanisms of change in extended cognitive behavioral treatment for tobacco dependence.</td>
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<tr>
<td>19492280</td>
<td>Mottillo, Salvatore, S</td>
<td>Behavioural interventions for smoking cessation: a meta-analysis of randomized controlled trials.</td>
<td>Ia</td>
<td>SR</td>
<td>very high</td>
<td>50 studies (n = 26927)</td>
<td>Adults who wanted to quit smoking.</td>
<td>Four behavioural interventions: minimal clinical intervention (brief advice from a healthcare worker), and intensive interventions, including individual, group and telephone counselling.</td>
<td>This work was supported by the Canadian Institutes of Health Research (CIHR) grant number 81257.</td>
<td>A cluster randomized trial in general practice with referral to a group-based or an Internet-based smoking cessation programme (national model) or Group B, referral to internet-based SC programme (newly developed); or Group C, no referral ('do as usual').</td>
<td>1.11 – 2.93, phone counseling (OR 1.58, CI 1.15 – 2.29)</td>
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<tr>
<td>19617300</td>
<td>Pisinger, Charlotta, C</td>
<td>A cluster randomized trial in general practice with referral to a group-based or an Internet-based smoking cessation programme (national model) or Group B, referral to internet-based SC programme (newly developed); or Group C, no referral ('do as usual').</td>
<td>IIa</td>
<td>SR</td>
<td>medium</td>
<td>6 studies (n = 276)</td>
<td>Adults who wanted to quit smoking.</td>
<td>Four behavioural interventions: minimal clinical intervention (brief advice from a healthcare worker), and intensive interventions, including individual, group and telephone counselling.</td>
<td>This work was supported by the Canadian Institutes of Health Research (CIHR) grant number 81257.</td>
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<td>19492280</td>
<td>Rasch, A, A</td>
<td>Efficacy and cost-effectiveness of smoking cessation courses in the statutory health insurance: a review.</td>
<td>Ia</td>
<td>SR</td>
<td>very high</td>
<td>50 studies were identified, which randomized 26,927 patients, thereunder 9 RCTs with minimal clinical intervention, 23 RCTs with individual counseling, 12 RCTs with group counseling, and 6 RCTs with telephone counseling.</td>
<td>This work was supported by the Canadian Institutes of Health Research (CIHR) grant number 81257.</td>
<td>A cluster randomized trial in general practice with referral to a group-based or an Internet-based smoking cessation programme (national model) or Group B, referral to internet-based SC programme (newly developed); or Group C, no referral ('do as usual').</td>
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<td>Lemmens, Valery, V Effectiveness of smoking cessation interventions among adults: a systematic review of reviews. Ia SR very high 23 studies (n &gt; 200.000) Current smokers at the start of the intervention of 18 years and older, of any sex, race or socioeconomic status. The included reviews had studied the following interventions: NRT, bupropion, physician advice, individual behavioural counselling, group therapy, smoking cessation parks, supportive interventions, stop smoking assistance, community interventions, and smoking cessation medication. Group therapy is effective (RR 2.17, CI 1.37 – 3.45); individual counselling (RR 1.56, CI 1.32 – 1.84). Funding Comments: Group therapy is effective; individual counselling may be more effective but the evidence is not strong.</td>
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<td>Killen, Joel D, JD Extended cognitive behavior therapy for cigarette smoking cessation. Ib RCT high n = 304 Adult smokers (&gt; 18 years of age; &gt; 10 cigarettes/day). Open-label (8 weeks): all participants received bupropion SR, nicotine patch, CBT. Extended treatment (12 weeks): participants received either CBT + voicemail monitoring and telephone counseling or telephone-based general support. At week 20 follow-up, CBT produced a higher 7-day point prevalence abstinence rate: 45% versus 29%, P = 0.006; at 52 weeks the difference in abstinence rates (31% versus 27%) was not significant. History of depression was a moderator of the treatment effect on abstinence: participants with a history of depression had a better treatment response at 20 weeks when assigned to the less intensive telephone support therapy (P &lt; 0.05). National Institute on Drug Abuse (R01 DA 017441) The paper is concerned with cognitive behavior therapy (CBT) in a controlled, not randomized study with participants receiving bupropion, nicotine patch, and CBT. After a period of therapy, smokers require cognitive behavioral support of their endeavors for abstinence. A minimum duration of therapy is unknown.</td>
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<td>Bala, Malgorzata M, MM Efficacy of non-pharmacological methods used for treating tobacco dependence: meta-analysis. IIa SR medium 20 studies Adults who wanted to quit smoking. Non-pharmacological methods used in smoking cessation 12 months Efficacy of different types of group psychotherapy in comparison with the control group receiving self-help materials or advice (OR 1.97, 95% CI 1.57–2.48) and in comparison with the control group not provided with any treatment (OR 2.19, 95% CI 1.95–2.48) was assessed in comparison with the control group, which was not provided with this kind of therapy. State Committee for Scientific Research in the years 2004–2005 as a research project No 2 P05D 07126. The state of affairs in Poland - Individual therapy and group therapy are effective.</td>
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<td>Niaura, Raymond, R Nonpharmacologic therapy for smoking cessation: characteristics and efficacy of current approaches. IIa SR medium n = 6.959 Adults who want to quit smoking. Behavioral therapy telephone counseling vs. group counseling vs. self-help intervention 6 months follow-up Behavioral therapy individual counseling (OR 1.56, CI 1.32–1.84). In general, there is a positive relation between overall number of contact minutes in counseling and odds of abstinence. Group counseling (OR 2.17, CI 1.37–3.45). The analysis indicated that group therapy significantly increased the probability of smoking cessation during the follow-up period. A meta-analysis from the data of the group program, alone or combined with individual counseling (OR 2.37, CI 1.57–3.60) or self-help intervention (OR 2.60, CI 1.93–3.50), but there was no evidence that group therapy was more effective than individual therapy. Further, telephone counseling provided by a phone line (OR 2.06, 95% CI 1.71–2.46), a nurse (OR 2.35, 95% CI 2.06–2.68) or a counselor (OR 2.42, 95% CI 2.11–2.78) was assessed in comparison with the control group, which was not provided with this kind of therapy. Pfizer Inc. Supported in part by PSO CA84799. Behavioral therapy Individual counseling 1.56 (1.32–1.84) (based on 21 trials with 6-mo follow-up)10 In general, there is a positive relation between overall number of contact minutes in counseling and odds of abstinence. Group therapy significantly increased the probability of smoking cessation during the follow-up period. The analysis indicated that group therapy significantly increased the probability of smoking cessation during the follow-up period. A meta-analysis from the data of the group program, alone or combined with individual counseling (OR 2.37, CI 1.57–3.60) or self-help intervention (OR 2.60, CI 1.93–3.50), but there was no evidence that group therapy was more effective than individual therapy. Further, telephone counseling provided by a phone line (OR 2.06, 95% CI 1.71–2.46), a nurse (OR 2.35, 95% CI 2.06–2.68) or a counselor (OR 2.42, 95% CI 2.11–2.78) was assessed in comparison with the control group, which was not provided with this kind of therapy.</td>
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Cognitive behavioral measures are effective; systematic review; no concrete calculations of efficacy data. At least 6 months CBT is effective. Agency for Healthcare Research and Quality to the

| Citation First Author Title (shortened) Degree of quality N Patient characteristics Intervention Comparison Length of follow-Up Outcome and effect size Funding Comments |
|---|---|---|---|---|---|---|---|
| Ranney, Leah, L Systematic review: smoking cessation intervention strategies for adults and adults in special populations. Ia SR very high 28 studies (n = 15,095) | Stress management training (SM) in addition to physician advice and nicotine replacement therapy. | Cra therapy group, the abstinence rate after three months was nearly twice as high as in the non-psychological therapy group (46 % versus 25 %). | 3 months | 16954352 | A single cluster of stop-smoking actions in a small study. The study design indicates the need for further research on stress management. A 13.7% reduction in smoking was observed at one year follow-up. 95% confidence interval (CI) cross 1.0; therefore, the differences are not statistically significant. |
| Slovinec D'Angelo, Monika E, ME Stress management as a behavior therapeutic technique has no influence on the success of a smoking cessation therapy. | Psychological interventions are more cost-effective than medication. The difference in cost is not significant. | | 2016 | 16295704 | Stress management training a useful addition to physician advice and nicotine replacement therapy during smoking cessation in women. | | |
| Schröter, Martina, M Randomized controlled trial of nicotine replacement therapy versus nortriptyline versus placebo by 2 (medical management alone versus medical management plus psychological intervention) randomized trial. | The control group (109 participants) received a single session discussing the health effects of smoking. | | 12 months | 16139962 | Usefulness and effectiveness of a problem-solving intervention at least 6 months CBT at least 6 months Group therapy is more effective than self-help programs (RR 1.98, CI 1.6-2.46) but not more effective than individual therapy (RR 1.31, CI 0.7-2.46) | |
| Hajek, P, P Relapse prevention interventions for smoking cessation. | Relapse prevention at least 6 months We detected no benefit of brief and 'skills-based' relapse prevention interventions for women who had quit smoking due to smoking cessation. | | | | Relapse prevention at least 6 months We detected no benefit of brief and 'skills-based' relapse prevention interventions for women who had quit smoking due to smoking cessation. | |
| Ebbert, Jon, J Interventions for smokeless tobacco use cessation. | Smokeless tobacco up to 12 months Data from one study suggest that varenicline increases ST abstinence rates (Odds Ratio [OR] 1.6, 95% Confidence Interval CI 1.0, 2.5). The effect of ST-P in a single study sample is not significant. | | | | Varenicline (Chantix) is effective for smoking cessation. | |
Behavioral interventions for smoking cessation.

Comparison: Group A1 (n = 449) received the same intervention, but without the adherence intervention. Control group B (n = 226) received simple cessation advice at baseline.

Outcome and effect size: RCT high n = 675 Adults who wanted to quit smoking. Abstinence. Results failed to support a mediational role of negative affect, abstinence-specific social support, or motivation to quit.

Funding: National Institute for Health Research and the National Health Service of the UK (external) UK Centre for Tobacco Control Studies (external) Fletcher Allen Health Care (external) Vermont (internal) National Institute for Health Research and the National Health Service of the UK (external) UK Centre for Tobacco Control Studies (external) Fletcher Allen Health Care (internal) National Institute for Health and Care Excellence (NICE; consequent update: NICE/CG132/2008)

Notes: Study of the long-term effects of different interventions for smoking relapse prevention: an extended cognitive behavioral therapy (CBT) program increased abstinence self-efficacy over the first 52 weeks postcessation. This effect, with meta-analyses. The majority of available reviews or national guidelines are based on the results of these intervention components (skill training, problem solving, relapse prevention) varies from OR = 0.91 to OR = 1.5.
Group therapy is effective (RR 2.17, CI 1.37 – 3.45); individual counseling (RR 1.56, CI 1.32 – 1.84). Group therapy is effective, RR 2.17, CI 1.37 – 3.45, individual counseling 1.56, CI 1.32 – 1.84. Review, date? CAUTION: Only limited to adults.

6 to 12 months Minimal-intervention (OR 1.5, CI 0.84 – 2.78); individual counseling (OR 1.49, CI 1.08 – 2.02); group therapy (OR 1.76, CI 1.11 – 2.93), phone counseling (OR 1.58, CI 1.15 – 2.29)

This work was supported by the Canadian Institutes of Health Research (CIHR grant number 81257).

The included reviews had studied the following interventions: NRT, bupropion, physician advice, individual behavioural counselling, group behaviour therapy, telephone support, aversive smoking, acupuncture and related interventions, community interventions and mass media campaigns.

Citation First Author Title (shortened) Degree of Evidence Study type Study quality N Patient characteristics Intervention Comparison Length of follow-Up Outcome and effect size Funding Comments

Ia SR very high 23 studies (n > 49,985) Current smokers at the start of the intervention of 18 years and older, of any sex, race or socioeconomic status.

IIa SR medium n = 6.959 Adults who want to quit smoking. Behavioral therapy individual counseling (OR 1.38, CI 1.09 – 1.76) was more likely to quit for 4 weeks than were those who underwent individual counseling (OR 1.38 CI, 1.09-1.76).

IIa SR medium 20 studies Adults who wanted to quit smoking. Behavioral therapy telephone counseling vs. self-help intervention (OR 1.56, CI 1.32–1.84) was more effective than self-help intervention. Group counseling (OR 2.17, CI 1.37-3.45) was more effective than self-help intervention (OR 1.56, CI 1.32-1.84). In general, there is a positive relation between overall number of contact minutes in counseling and odds of abstinence. Group counseling (OR 2.17, CI 1.37-3.45). The analysis of different types of psychological interventions included brief advice from a healthcare worker, telephone counseling, with help interventions, taking interventions, community planning interventions, individual interventions, competitions and incentives, parallel support, individual counseling, group counseling, and telephone counseling. Taking needs among other needs.

Ib RCT high n = 220 Adults who want to quit smoking. This was a 3 (bupropion versus nortriptyline versus placebo) by 2 (medical management alone versus medical management plus psychological intervention) randomized trial.

IIb RCT low n = 251 Adults who want to quit smoking. Discovery of the best therapeutic approach for smoking cessation: characteristics and efficacy of current approaches.
30 trials with 7000 participants were included. 22 studies compared individual therapy with minimal/basic intervention. The personalized counseling was much more effective (RR = 1.39, CI 1.24 – 1.57). Therapy requirements: a minimum of 10 minutes for a session, one to one appointments/engagements.

Evidence Study type Study
UK; National Institute for Health Research School for Primary Care Research, UK, NHS Research and Development Programme, UK.
Evidence Study type Study
UK; National Institute for Health Research School for Primary Care Research, UK, NHS Research and Development Programme, UK.
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UK; National Institute for Health Research School for Primary Care Research, UK, NHS Research and Development Programme, UK.
Evidence Study type Study
UK; National Institute for Health Research School for Primary Care Research, UK, NHS Research and Development Programme, UK.
| Citation First Author Title (shortened) Degree of quality N Patient characteristics Intervention Comparison Length of follow-Up Outcome and effect size Funding Comments |
|---|---|---|---|---|---|---|---|---|
| Evidence Study type Study |
| 18569754 Carmody, Timothy P, TP Hypnosis for smoking cessation: a meta-analisis of randomized clinical trials. | IIa Meta-analisis 12 studies, number of subjects differed (between 21 to 2600 subjects) | | | | | | |
| 16235865 Wynd, Christine A, CA Guided health imagery for smoking cessation, a prospective study. | Ib RCT 71 subjects 18 years or older, smoked at least 5 cigarettes a day | | | | | | |
| 16581692 Green, Joseph P, JP A meta-analysis of gender, smoking cessation, and hypnosis: a brief communication. | IIb RCT 20 subjects 60% women, average age of mid forties | | | | | | |
| 19846857 Green, Joseph P, JP Gender-related differences in hypnosis-based treatments for smoking: a follow-up meta-analysis. | Ib RCT 30 subjects, average age of mid forties | | | | | | |
| 16766441 Elkins, Gary, G Intensive hypnotherapy for smoking cessation: a prospective study. | IIa RCT 96 subjects, 46% women, average age of mid forties | | | | | | |
| 20000000 Green, Joseph P, JP Gender-related differences in smoking cessation, and long-term abstinence. | Ib RCT 50 subjects 50% women, average age of mid forties | | | | | | |
| 21025157 Green, Joseph P, JP Gender-related differences in smoking cessation aids: a meta-analysis of randomized controlled trials. | Ia RCT 12 inpatient randomized controlled trials, number of subjects differed among studies | | | | | | |
| 18246857 Green, Joseph P, JP Gender-related differences in smoking cessation aids: a meta-analysis of randomized controlled trials. | Ib RCT 133 in Hypnotherapy (HT) at beginning, 121 (CG) and 125 (HT) at follow-up evaluation | | | | | | |
| 18246857 Green, Joseph P, JP Gender-related differences in smoking cessation aids: a meta-analysis of randomized controlled trials. | Ib RCT 150 subjects, 50% women, average age of mid forties | | | | | | |
| 18246857 Green, Joseph P, JP Gender-related differences in smoking cessation aids: a meta-analysis of randomized controlled trials. | Ib RCT 12 subjects, average age of mid forties | | | | | | |
| 18246857 Green, Joseph P, JP Gender-related differences in smoking cessation aids: a meta-analysis of randomized controlled trials. | Ib RCT 30 subjects, average age of mid forties | | | | | | |
| 18246857 Green, Joseph P, JP Gender-related differences in smoking cessation aids: a meta-analysis of randomized controlled trials. | Ib RCT 30 subjects, average age of mid forties | | | | | | |
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| 18246857 Green, Joseph P, JP Gender-related differences in smoking cessation aids: a meta-analysis of randomized controlled trials. | Ib RCT 30 subjects, average age of mid forties | | | | | | |
### Aversive Smoking

Aversive smoking (OR, 4.26, 95% CI, 1.26-14.38) substantially increased smoking abstinence compared with control. Aversive smoking may help smokers quit; however, there are no recent trials investigating this in the long term. Smoking cessation at 6 or 12 months; control groups for randomized controlled trials investigating aversive smoking included smoking at a regular pace during a session or being placed on a wait list.

### Evidence Table for Smoking Cessation Aids

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<th>Citation</th>
<th>First Author</th>
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<th>Patient characteristics</th>
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<th>Outcome and effect size</th>
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<td>Ia</td>
<td>metaanalysis of small N</td>
<td>randomized controlled trials investigated aversive smoking (99 patients).</td>
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<td>Ib</td>
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<td>efficacy</td>
<td>Motivational Interviewing (MI) structured brief advice (SBA)</td>
<td>weeks</td>
<td>7-day point-prevalence smoking abstinence</td>
<td>The effects of MI on adolescent smoking behavior change are modest, and MI may best fit within a multicomponent smoking cessation treatment approach in which behavior change skills can support and promote smoking behavior change decisions</td>
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<td>(1) no further treatment</td>
<td>(2) active bupropion SR (3) Placebo (4) active bupropion SR + CBT (5) placebo + CBT</td>
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### Endnotes

- Aversive smoking is a procedure defined as inhaling a puff of cigarette every 6 seconds for 3 minutes, or until the patient consumes 3 cigarettes, or until the patient is unable to smoke. After a short resting period, this procedure is repeated 2 to 3 times per session to deter the patient from smoking.
- Citation and references have been omitted for brevity. Further information can be found in the original sources.
<table>
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<tr>
<th>Study ID</th>
<th>First Author</th>
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<td>201996</td>
<td>James J. Gray</td>
<td>Nicotine dependence, State anxiety, Outcome expectancies, Contemplation of quitting, Motivation to quit smoking, Self-quality</td>
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</table>

The results of the present study are consistent with theories of relapse and studies of more time-limited interventions, and underscore the importance of abstinence self-efficacy in achieving long-term abstinence from cigarettes.

Challenging evidence to support the smoking cessation treatments, smokers and behavioral weight control treatments, reduce and significant evidence of short-term benefits for both abstinence and weight control.


**Citation**

Juliano, Laura M, LM A preliminary investigation of rapid smoking cessation among smokers: do therapist behaviors relate to engagement and therapeutic alliance?  

**Degree of Evidence**

RCT? 196 aged 18–24 years, young adult cigarette smokers who were interested in stopping cigarette smoking, at least 10 cigarettes/day during the past 6 months  

**Study setting**

67 mean age 39.4 years, have smoked cigarettes regularly for at least 1 year, currently smoke at least 10 cigarettes/day, heavy social drinkers but not alcohol dependent (guidelines from the National Institute on Alcohol Abuse and Alcoholism)  

**Study design**

24 months smoking rates/abstinence (self-report+reports from friends and family) University of Akron Faculty Research Grants program  

**Hypothesis**

Guided imagery was an effective intervention for long-term smoking cessation and abstinence in adult smokers, but further research is needed  

**Methods**

67 aged 18-65 years, mean age 50.4 years. All the participants were interested in stopping smoking, at least 10 cigarettes/day, and were motivated to quit  

**Participants**

At least 18 years, smoked at least 10 cigarettes/day, and interested in quitting within the next 30 days  

**Intervention**

Guided imagery

**Comparison**

CBT (n=41)  

**Length of follow-Up**

12 months point-prevalence abstinence and continuous abstinence  

**Outcome and effect size**

Better Health for Women Program, smoking cessation treatment adjunct for young adult smokers.  

**Funding**

No reimbursement was offered. No reimbursement for SCT  

**Comments**

Long-term follow-up was important to measure objective smoking cessation and smoking abstinence in adult smokers, but further research is needed.
<table>
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<tr>
<th>Citation</th>
<th>Author</th>
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<td>3030047</td>
<td>Hall, SM</td>
<td>Using extended cognitive behavioral therapy and medication to treat dependent smokers</td>
<td>Ia RCT on drug efficacy</td>
<td>RCT</td>
<td>Low</td>
<td>95</td>
<td>males and females, aged 18-70 years, who smoked at least 10 cigarettes per day and were willing to quit smoking</td>
<td>A single 6-week individualized program of extended CBT and sustained delivery of bupropion SR, a non-prescription antidepressant used as an aid to smoking cessation, was compared to a placebo program. The analysis was based on all randomized participants (N=191).</td>
<td>Baseline</td>
<td>6 weeks</td>
<td>Continuous abstinence from smoking for 6 weeks at the end of the treatment period.</td>
<td>Cochrane</td>
<td>Group compared to control: OR of 2.45 (95% CI 1.19 to 6.36). Group compared to individual therapy: OR=1.00 [95% CI 0.75, 1.32].</td>
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<td>smokers, except pregnant women</td>
<td>Group compared to control (individual counselling): OR of 2.45 (95% CI 1.19 to 6.36). Group compared to individual therapy: OR=1.00 [95% CI 0.75, 1.32].</td>
<td>Baseline</td>
<td>12 months</td>
<td>Continuous abstinence from smoking for 12 months at the end of the treatment period.</td>
<td>Cochrane</td>
<td>There is consistent evidence that individual counselling compared to brief counselling is more effective at promoting smoking cessation (8 trials, RR of 1.98, 95% CI 1.60 to 2.46); group compared to individual therapy: RR=1.01 [95% CI 0.77, 1.32].</td>
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<td>Group compared to control (individual counselling): OR of 2.45 (95% CI 1.19 to 6.36). Group compared to individual therapy: OR=1.00 [95% CI 0.75, 1.32].</td>
<td>Baseline</td>
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<td>15</td>
<td>Any smokers, except pregnant women</td>
<td>Group compared to control (individual counselling): OR of 2.45 (95% CI 1.19 to 6.36). Group compared to individual therapy: OR=1.00 [95% CI 0.75, 1.32].</td>
<td>Baseline</td>
<td>18 months</td>
<td>Continuous abstinence from smoking for 18 months at the end of the treatment period.</td>
<td>Cochrane</td>
<td>Group compared to control: OR of 2.45 (95% CI 1.19 to 6.36). Group compared to individual therapy: OR=1.00 [95% CI 0.75, 1.32].</td>
</tr>
<tr>
<td>1583596</td>
<td>Stead, LF</td>
<td>Group behaviour therapy compared with individual counselling for smoking cessation</td>
<td>Ia RCT on drug efficacy</td>
<td>RCT</td>
<td>Low</td>
<td>15</td>
<td>Any smokers, except pregnant women</td>
<td>Group compared to control (individual counselling): OR of 2.45 (95% CI 1.19 to 6.36). Group compared to individual therapy: OR=1.00 [95% CI 0.75, 1.32].</td>
<td>Baseline</td>
<td>24 months</td>
<td>Continuous abstinence from smoking for 24 months at the end of the treatment period.</td>
<td>Cochrane</td>
<td>Group compared to control: OR of 2.45 (95% CI 1.19 to 6.36). Group compared to individual therapy: OR=1.00 [95% CI 0.75, 1.32].</td>
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### Evidence Table for Exploratory 3.3.1.7

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<tr>
<th>Calendar code</th>
<th>Author</th>
<th>Title</th>
<th>Degree of Evidence</th>
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<th>Comparison</th>
<th>Length of follow-up</th>
<th>Outcome and effect size</th>
<th>Funding</th>
<th>Comments</th>
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<tr>
<td>3030047</td>
<td>Hall, SM</td>
<td>Using extended cognitive behavioral therapy and medication to treat dependent smokers</td>
<td>Ia RCT on drug efficacy</td>
<td>RCT</td>
<td>Low</td>
<td>95</td>
<td>males and females, aged 18-70 years, who smoked at least 10 cigarettes per day and were willing to quit smoking</td>
<td>A single 6-week individualized program of extended CBT and sustained delivery of bupropion SR, a non-prescription antidepressant used as an aid to smoking cessation, was compared to a placebo program. The analysis was based on all randomized participants (N=191).</td>
<td>Baseline</td>
<td>6 weeks</td>
<td>Continuous abstinence from smoking for 6 weeks at the end of the treatment period.</td>
<td>Cochrane</td>
<td>Group compared to control: OR of 2.45 (95% CI 1.19 to 6.36). Group compared to individual therapy: OR=1.00 [95% CI 0.75, 1.32].</td>
</tr>
<tr>
<td>1583596</td>
<td>Stead, LF</td>
<td>Group behaviour therapy compared with individual counselling for smoking cessation</td>
<td>Ia RCT on drug efficacy</td>
<td>RCT</td>
<td>Low</td>
<td>17</td>
<td>smokers, except pregnant women</td>
<td>Group compared to control (individual counselling): OR of 2.45 (95% CI 1.19 to 6.36). Group compared to individual therapy: OR=1.00 [95% CI 0.75, 1.32].</td>
<td>Baseline</td>
<td>12 months</td>
<td>Continuous abstinence from smoking for 12 months at the end of the treatment period.</td>
<td>Cochrane</td>
<td>There is consistent evidence that individual counselling compared to brief counselling is more effective at promoting smoking cessation (8 trials, RR of 1.98, 95% CI 1.60 to 2.46); group compared to individual therapy: RR=1.01 [95% CI 0.77, 1.32].</td>
</tr>
<tr>
<td>1583596</td>
<td>Stead, LF</td>
<td>Group behaviour therapy compared with individual counselling for smoking cessation</td>
<td>Ia RCT on drug efficacy</td>
<td>RCT</td>
<td>Low</td>
<td>30</td>
<td>Any smokers, except pregnant women</td>
<td>Group compared to control (individual counselling): OR of 2.45 (95% CI 1.19 to 6.36). Group compared to individual therapy: OR=1.00 [95% CI 0.75, 1.32].</td>
<td>Baseline</td>
<td>6 months</td>
<td>Continuous abstinence from smoking for 6 months at the end of the treatment period.</td>
<td>Cochrane</td>
<td>Group compared to control: OR of 2.45 (95% CI 1.19 to 6.36). Group compared to individual therapy: OR=1.00 [95% CI 0.75, 1.32].</td>
</tr>
<tr>
<td>1583596</td>
<td>Stead, LF</td>
<td>Group behaviour therapy compared with individual counselling for smoking cessation</td>
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<td>RCT</td>
<td>Low</td>
<td>15</td>
<td>Any smokers, except pregnant women</td>
<td>Group compared to control (individual counselling): OR of 2.45 (95% CI 1.19 to 6.36). Group compared to individual therapy: OR=1.00 [95% CI 0.75, 1.32].</td>
<td>Baseline</td>
<td>6 months</td>
<td>Continuous abstinence from smoking for 6 months at the end of the treatment period.</td>
<td>Cochrane</td>
<td>Group compared to control: OR of 2.45 (95% CI 1.19 to 6.36). Group compared to individual therapy: OR=1.00 [95% CI 0.75, 1.32].</td>
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4. Evidenztabellen zu Kapitel 5.4 Arzneimittel zur Entzugsbehandlung

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<th>Title (shortened)</th>
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<th>Funding</th>
<th>Study quality</th>
<th>Study population</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Length of follow-up</th>
<th>Outcome and effect size</th>
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Abstrakte Kurzformen der evidenzbasierten Empfehlungen zur Nikotinersatztherapie (5.4.3.1 und 5.4.3.1.1 - 5.4.3.1.6)

Abstrakte Kurzformen der evidenzbasierten Empfehlungen zur Nikotinersatztherapie (5.4.3.1 und 5.4.3.1.1 - 5.4.3.1.6)

Abstrakte Kurzformen der evidenzbasierten Empfehlungen zur Nikotinersatztherapie (5.4.3.1 und 5.4.3.1.1 - 5.4.3.1.6)

Abstrakte Kurzformen der evidenzbasierten Empfehlungen zur Nikotinersatztherapie (5.4.3.1 und 5.4.3.1.1 - 5.4.3.1.6)

Abstrakte Kurzformen der evidenzbasierten Empfehlungen zur Nikotinersatztherapie (5.4.3.1 und 5.4.3.1.1 - 5.4.3.1.6)
### Evidence Study type

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<th>Comparison</th>
<th>Length of Follow-Up</th>
<th>Outcome and effect size</th>
<th>Funding</th>
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<tbody>
<tr>
<td>2170916</td>
<td>Ib RCT high n = 925 smokers of &gt;10 cigarettes per day</td>
<td>Weekly versus basic</td>
<td>126 890 126 890 treatment episodes in 24stop-smoking services (126 890 participants)</td>
<td>Intent to treat</td>
<td>≥90% 95% CI: 0.85-0.93</td>
<td>National Health Service (NHSE)</td>
<td>The outcome was confirmed to be abstinent at weeks 8 and 24 after quit day.</td>
</tr>
<tr>
<td>21561501</td>
<td>Ia RCT medium n = 139 clinical trial participants who were visiting a smoking cessation clinic for the first time</td>
<td>Extended duration therapy with nicotine patches (57 subjects) and extended therapy with varenicline (38 subjects)</td>
<td>58 subjects (21.3%) remained smoke-free, of whom 6 (6.6%) were in Group 1, 23 (25%) in Group 2 and 29 (32.6%) in Group 3 (P = 0.000).</td>
<td>≥12 months</td>
<td>≥12 months</td>
<td>Masih Daneshvari Hospital Research Institute, Tehran.</td>
<td>smokers visiting a smoking cessation clinic for the first time.</td>
</tr>
<tr>
<td>22236931</td>
<td>Ib RCT high n = 925 smokers of &gt;10 cigarettes per day</td>
<td>Weekly versus basic</td>
<td>126 890 126 890 treatment episodes in 24stop-smoking services (126 890 participants)</td>
<td>Intent to treat</td>
<td>≥90% 95% CI: 0.85-0.93</td>
<td>National Health Service (NHSE)</td>
<td>The outcome was confirmed to be abstinent at weeks 8 and 24 after quit day.</td>
</tr>
<tr>
<td>22244706</td>
<td>Ia RCT medium n = 272 Participants were smokers willing to quit smoking</td>
<td>Standard (8 weeks plus 16 weeks of placebo) transdermal nicotine patch therapy and varenicline for 8 weeks</td>
<td>58 subjects (21.3%) remained smoke-free, of whom 6 (6.6%) were in Group 1, 23 (25%) in Group 2 and 29 (32.6%) in Group 3 (P = 0.000).</td>
<td>≥12 months</td>
<td>≥12 months</td>
<td>Masih Daneshvari Hospital Research Institute, Tehran.</td>
<td>smokers visiting a smoking cessation clinic for the first time.</td>
</tr>
<tr>
<td>22244447</td>
<td>Ib RCT medium n = 272 Participants were smokers willing to quit smoking</td>
<td>Extended duration therapy with nicotine patches (57 subjects) and extended therapy with varenicline (38 subjects)</td>
<td>58 subjects (21.3%) remained smoke-free, of whom 6 (6.6%) were in Group 1, 23 (25%) in Group 2 and 29 (32.6%) in Group 3 (P = 0.000).</td>
<td>≥12 months</td>
<td>≥12 months</td>
<td>Masih Daneshvari Hospital Research Institute, Tehran.</td>
<td>smokers visiting a smoking cessation clinic for the first time.</td>
</tr>
<tr>
<td>22244705</td>
<td>Ia RCT medium n = 139 clinical trial participants who were visiting a smoking cessation clinic for the first time</td>
<td>Extended duration therapy with nicotine patches (57 subjects) and extended therapy with varenicline (38 subjects)</td>
<td>58 subjects (21.3%) remained smoke-free, of whom 6 (6.6%) were in Group 1, 23 (25%) in Group 2 and 29 (32.6%) in Group 3 (P = 0.000).</td>
<td>≥12 months</td>
<td>≥12 months</td>
<td>Masih Daneshvari Hospital Research Institute, Tehran.</td>
<td>smokers visiting a smoking cessation clinic for the first time.</td>
</tr>
<tr>
<td>2182912</td>
<td>Ia RCT medium n = 139 clinical trial participants who were visiting a smoking cessation clinic for the first time</td>
<td>Extended duration therapy with nicotine patches (57 subjects) and extended therapy with varenicline (38 subjects)</td>
<td>58 subjects (21.3%) remained smoke-free, of whom 6 (6.6%) were in Group 1, 23 (25%) in Group 2 and 29 (32.6%) in Group 3 (P = 0.000).</td>
<td>≥12 months</td>
<td>≥12 months</td>
<td>Masih Daneshvari Hospital Research Institute, Tehran.</td>
<td>smokers visiting a smoking cessation clinic for the first time.</td>
</tr>
<tr>
<td>2170822</td>
<td>Ia RCT medium n = 139 clinical trial participants who were visiting a smoking cessation clinic for the first time</td>
<td>Extended duration therapy with nicotine patches (57 subjects) and extended therapy with varenicline (38 subjects)</td>
<td>58 subjects (21.3%) remained smoke-free, of whom 6 (6.6%) were in Group 1, 23 (25%) in Group 2 and 29 (32.6%) in Group 3 (P = 0.000).</td>
<td>≥12 months</td>
<td>≥12 months</td>
<td>Masih Daneshvari Hospital Research Institute, Tehran.</td>
<td>smokers visiting a smoking cessation clinic for the first time.</td>
</tr>
<tr>
<td>2170916</td>
<td>Ib RCT high n = 925 smokers of &gt;10 cigarettes per day</td>
<td>Weekly versus basic</td>
<td>126 890 126 890 treatment episodes in 24stop-smoking services (126 890 participants)</td>
<td>Intent to treat</td>
<td>≥90% 95% CI: 0.85-0.93</td>
<td>National Health Service (NHSE)</td>
<td>The outcome was confirmed to be abstinent at weeks 8 and 24 after quit day.</td>
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<tr>
<td>2170822</td>
<td>Ia RCT medium n = 139 clinical trial participants who were visiting a smoking cessation clinic for the first time</td>
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<td>58 subjects (21.3%) remained smoke-free, of whom 6 (6.6%) were in Group 1, 23 (25%) in Group 2 and 29 (32.6%) in Group 3 (P = 0.000).</td>
<td>≥12 months</td>
<td>≥12 months</td>
<td>Masih Daneshvari Hospital Research Institute, Tehran.</td>
<td>smokers visiting a smoking cessation clinic for the first time.</td>
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<tr>
<td>2170916</td>
<td>Ia RCT medium n = 139 clinical trial participants who were visiting a smoking cessation clinic for the first time</td>
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<td>58 subjects (21.3%) remained smoke-free, of whom 6 (6.6%) were in Group 1, 23 (25%) in Group 2 and 29 (32.6%) in Group 3 (P = 0.000).</td>
<td>≥12 months</td>
<td>≥12 months</td>
<td>Masih Daneshvari Hospital Research Institute, Tehran.</td>
<td>smokers visiting a smoking cessation clinic for the first time.</td>
</tr>
<tr>
<td>Study Type</td>
<td>Study Duration</td>
<td>Patient Characteristics</td>
<td>Intervention</td>
<td>Comparator</td>
<td>Length of Follow-Up</td>
<td>Outcome and Effect Size</td>
<td>Funding Comments</td>
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<tr>
<td>SR</td>
<td>n/a</td>
<td>14 studies (n &gt; 10,000)</td>
<td>Behavioral therapy can be an effective aid for smoking cessation. The data is yet heterogeneous among the 14 studies identified.</td>
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<tr>
<td>Metaanalysis</td>
<td>very high</td>
<td>14 studies (n &gt; 10,000)</td>
<td>It was observed that varenicline increases ST abstinence rates (Odds Ratio [OR] 1.6, 95% CI 1.08 to 2.36) among Swedish snus users. Two trials of bupropion SR did not detect a benefit of treatment as compared to a control group (OR 0.98, 95% CI 0.60–1.65).</td>
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<tr>
<td>Metaanalysis</td>
<td>medium</td>
<td>816 smokers age 20 years or younger</td>
<td>Pharmacologic therapy for short- and long-term follow-up times.</td>
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<tr>
<td>Metaanalysis</td>
<td>medium</td>
<td>761 heavy smokers</td>
<td>Of six established nicotine replacement therapy (NRT) formulations, only the gum and patch have been tested without specialist clinician support in placebo-controlled trials.</td>
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<tr>
<td>Case-control</td>
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<td>4500 smokers who were not ready to make a quit attempt</td>
<td>adults who wanted to quit smoking.</td>
<td>Smokeless tobacco placebo</td>
<td>6 months</td>
<td>Data from one study suggest that varenicline increases ST abstinence rates (OR 1.6, 95% CI 1.08 to 2.36) among Swedish snus users. Two trials of bupropion SR did not detect a benefit of treatment as compared to a control group (OR 0.98, 95% CI 0.60–1.65).</td>
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<tr>
<td>RCT</td>
<td>high</td>
<td>1154 Chinese adults who wanted to quit smoking</td>
<td>adults who wanted to quit smoking.</td>
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<tr>
<td>RCT</td>
<td>medium</td>
<td>761 heavy smokers</td>
<td>Of six established nicotine replacement therapy (NRT) formulations, only the gum and patch have been tested without specialist clinician support in placebo-controlled trials.</td>
<td></td>
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<tr>
<td>RCT</td>
<td>n/a</td>
<td>479 adults who wanted to quit smoking</td>
<td>adults who wanted to quit smoking.</td>
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<td>RCT</td>
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<td>449 adult smokers who were not ready to make a quit attempt</td>
<td>adults who wanted to quit smoking.</td>
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<tr>
<td>RCT</td>
<td>medium</td>
<td>479 adults who wanted to quit smoking</td>
<td>adults who wanted to quit smoking.</td>
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<tr>
<td>RCT</td>
<td>medium</td>
<td>226 adult smokers who were not ready to make a quit attempt</td>
<td>adults who wanted to quit smoking.</td>
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</table>
Supported by Pfizer Inc., which provided funding for the trials, study drug and placebo and monitoring. Use of NRT, bupropion and varenicline appears to be effective in preventing relapse following an initial period of abstinence or an acute treatment episode.

All authors are members of the UK Centre for Tobacco Control Studies, a UKCRC Public Health Research Centre of Excellence. Funding from the Health Technology Assessment Programme is gratefully acknowledged.

40 weeks TQD was day 8. Two patterns of successful quitting were identified. Immediate quitters (IQs) were continuously abstinent for weeks 2–12. Delayed quitters (DQs) smoked for weeks 9–52. No gender differences were observed by quit pattern. Post-treatment relapse was similar across groups.

For follow-up, we used a fixed effects model. IQs (pooled OR 1.52; 95% CI 1.15 to 2.01, I² = 0%, NNT = 11, 3 studies). Other behavioural interventions for relapse prevention were also effective, although with much lower effect size: motivational interviewing post-randomization (pooled OR 1.34; 95% CI 1.00 to 1.80, I² = 66%, NNT = 12; 4 trials) and prepauptal avoidance/relapse prevention interventions (pooled OR 1.33; 95% CI 1.08 to 1.63; I² = 0%; NNT = 20; 4 trials).

The included reviews had studied the following interventions: NRT, bupropion, physician advice, individual behavioural counselling, group behaviour therapy, telephone counselling, community interventions, and mass media campaigns.

Clinical trials have shown bupropion to be an effective anti-smoking agent whose efficacy is at least the equal of NRT. Quit rates improved by 8% from a weighted average of 9% (range 0% to 22%) for the control group to 17% (range 11% to 23%) for the bupropion group (pooled OR 1.63; 95% CI 1.32 to 2.01, I² = 0%, NNT = 5, 4 trials). Cohort studies have also indicated a significant improvement for bupropion compared with placebo (pooled OR 2.09; 95% CI 1.63 to 2.68, I² = 0%, NNT = 34, 3 studies).

Inclusion criteria were smoking history of at least 1 year, current smoking at least 10 cigarettes/day, willingness to quit smoking, and absence of severe medical condition. Exclusion criteria were pregnancy only. Four studies delivered smoking relapse prevention interventions postpartum. Four trials initiated smoking relapse prevention interventions during pregnancy and continued postpartum.

After 30 days of abstinence, smokers treated with active gum had not gained significantly less weight than those on placebo (1.1 kg versus 1.6 kg, P = 0.175). However, a significant compliance-treatment interaction was observed (P = 0.005): active gum users who used at least 9 pieces/day gained significantly less weight than placebo users (1.0 kg versus 1.8 kg, P = 0.019). Meta-analysis of 36 RCTs showed significantly higher rates of smoking cessation at 6 weeks (OR = 1.52; 95% CI 1.15 to 2.01, I² = 0%, NNT = 11, 3 studies).

One hundred healthy adult male and female smokers aged 18 to 50 years were randomly selected at two recycling events (quinine or nicotine patches) and non-recycling groups (placebo patches) on separate days at one-week intervals: subjects in the non-recycling group did not smoke the night before and did not smoke more than one cigarette per day. The experimental group received nicotine (2 mg) and 1 mg) and placebo (0 mg) patches for 14 days of treatment. Of the 100 smokers recruited, 91 completed the study. Of these, 75 (82%) reported being free of nicotine before the start of treatment. The original study was funded by grants DA06183 and DA10073 from NIDA and by the Department of Veterans Affairs.
<table>
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<tr>
<th>Citation</th>
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<th>Title (shortened)</th>
<th>Degree of Evidence</th>
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<th>Study quality</th>
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<th>Patient characteristics</th>
<th>Intervention</th>
<th>Comparators</th>
<th>Length of follow-up</th>
<th>Outcome and effect size</th>
<th>Funding</th>
<th>Comments</th>
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<tr>
<td>20537810</td>
<td>Hughes, John R, JR</td>
<td>A randomized, controlled trial of NRT-aided gradual vs. abrupt cessation in smokers actively trying to quit.</td>
<td>IIIb</td>
<td>RCT</td>
<td>very low</td>
<td>n = 746 smokers who wanted to quit now and preferred to quit gradually</td>
<td>gradual cessation (n = 297) vs. abrupt cessation (n = 299) vs. minimal treatment (n = 150). After the quit day, all participants received lozenge.</td>
<td>6 months</td>
<td>Prolonged abstinence rates (CO &lt; 10 ppm) did not differ among gradual, abrupt and minimal treatment conditions (4%, 7% and 5%), nor did 7-day point prevalence rates (7%, 11% and 11%). Fewer smokers in the gradual condition lapsed within 6 months compared with abrupt and minimal treatment conditions. In the gradual condition, every week delay to the quit date increased the probability of lapsing by 19% (p &lt; .001).</td>
<td>Since 1/1/2007, Dr Hughes has received research grants from the National Institute on Health and Pfizer. Pfizer develops and sells smoking cessation medications. During 2007-2008, Dr Hughes was a consultant for New England Research Institutes or serving as a fees for serving on nonprofit board or receiving a speaking fee from several nonprofit and for-profit organizations and companies for development, sale or pre-market smoking cessation products and in smoking cessation programs.</td>
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<tr>
<td>20528810</td>
<td>Bullen, Chris, C</td>
<td>Pre-cessation nicotine replacement therapy: pragmatic randomized trial.</td>
<td>IIb</td>
<td>RCT</td>
<td>medium</td>
<td>n = 11000 smokers who called the New Zealand Quitline between March 2006 and May 2007 for support to stop smoking</td>
<td>2 weeks of nicotine patches and/or gum prior to their target quit day followed by usual care (8 weeks of patches and/or gum plus support calls from a Quitline adviser), or to usual care alone</td>
<td>2 weeks' pre-cessation nicotine patches and/or gum on smoking abstinence at 6 months.</td>
<td>Six months after quit day 125 (22.7%) participants in the pre-cessation group and 116 (21.0%) in the control group reported 7-day point prevalence abstinence (relative risk 1.08 95% CI: 0.86, 1.35, P = 0.4, risk difference 1.7%, 95% CI: -3.2%, 6.6%). The trial was funded by Health Research Council and the Heart Foundation of New Zealand.</td>
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<td>20524443</td>
<td>Tundulawessa, Yongyuth, Y</td>
<td>The bioequivalent and effect of nicotine formulation gum on smoking cessation.</td>
<td>IV</td>
<td>RCT</td>
<td>n = 24 volunteer men, habitual smokers</td>
<td>Compare the absorbition rate of nicotine in human blood to determine the critical trail for smoking cessition</td>
<td>2 mg Nicomild-2 vs. 4 mg Nicorette</td>
<td>The absorption rate of &quot;nicotine in volunteer&quot; blood Nicomild-2 and Nicorette at 0, 15, 30, 40 minutes were 0, 51.84, 26.73, 21.83 and 0, 56.603, 21.83, 15.183 (ng/min). Both of them were found to have maximum absorption rate at 15 minutes.</td>
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<td>20525780</td>
<td>Ebbert, Jon O, JO</td>
<td>Smokeless tobacco reduction with the nicotine lozenge and behavioral intervention.</td>
<td>IIb</td>
<td>RCT</td>
<td>medium</td>
<td>n = 102 (a) between the ages of 18 and 70 years, (b) interested in reducing ST use but not quitting (i.e., not having an established quit date within the next 90 days), and (c) using ST daily use (≥ 2 tins per week) for the past 6 months.</td>
<td>4-mg nicotine lozenge with a behavioral intervention could facilitate ST use reduction among ST users compared with a behavioral intervention alone</td>
<td>12 weeks</td>
<td>Both interventions were associated with significant decreases in ST use and toxicant exposure and with increased abstinence, quit attempts, and duration of abstinence. However, no sig. differ differences were observed between groups for these outcomes. This study was funded by National Institutes of Health grants DA 14404 and P50 DA 013333.</td>
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<td>20491724</td>
<td>McRobbie, Hayden, H</td>
<td>A randomized trial of the effects of two novel nicotine replacement therapies on tobacco withdrawal symptoms and user satisfaction.</td>
<td>IIc</td>
<td>RCT</td>
<td>medium</td>
<td>n = 47 Forty-seven participants (23 males and 24 females), with a mean age of 49 years (standard deviation (SD) = 12) who smoked on average 21 (SD = 6) cigarettes per day</td>
<td>In a within-subject, cross-over trial participants were randomly assigned Zonnic® nicotine mouth spray (1 mg/spray), Zonnic® nicotine lozenge (2.5 mg), Nicorette® gum (4 mg) and placebo lozenge on each of four study days.</td>
<td>All active products reduced craving significantly more than placebo (mean reductions of 28.6, 25.8, 24.7 and 8.9 points for mouth spray, gum, lozenge and placebo). Mouth spray relieved craving faster than placebo and gum with a faster time to maximum plasma nicotine concentration (7.5 minutes), 99% CI (5.0 to 7.1) compared to the heroin (26 minutes), 99% CI (16.7 to 26.4), and gum (26.8 minutes), 99% CI (26.4 to 27.2). Maximum times were 6.5 minutes for mouth spray (99% CI: 4.5 to 8.5) and 6.6 minutes for lozenge (7.1 minutes). Both mouth spray and much spary were well tolerated.</td>
<td>Trial Registration Number: ACTRN012606000489594. Trial Registry: Australia New Zealand Clinical Trials Registry.</td>
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<td>20407602</td>
<td>Albert, Jan C, JO</td>
<td>Evaluation of nicotine and pharmacotherapies.</td>
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<td>Patient characteristics</td>
<td>Intervention</td>
<td>Comparator</td>
<td>Length of follow-up</td>
<td>Outcomes and effect size</td>
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<td>20379614</td>
<td>Rose, Jed E, JE</td>
<td>Personalized smoking cessation: varenicline, nicotine patch 24 weeks</td>
<td>IIb RCT medium</td>
<td>n = 479</td>
<td>Japanese adult smokers with nicotine dependence and precessation smoking</td>
<td>12 weeks</td>
<td>Twenty-one percent (n=18) of participants had continuous abstinence (CA) at 12 weeks after the target quit date (TQD), which was not significantly different between conditions (76.1% vs. 70.8%, p=0.221).</td>
<td>No significant difference in abstinence rates was observed between the 2 groups over weeks 9–12 (71.4% vs. 70.8%, p=0.566).</td>
<td>This study was supported by The National Institutes of Health (NIH)– Intramural Research Program, National Institute on Drug Abuse (DA048076). The authors are also grateful to Hiroshi Okura, Yuuki Watanabe, and Etsuko Takahashi for assistance with data collection, and to Jennifer Gray for assistance with statistical analysis. This clinical trial was registered with clinicaltrials.gov under ID# NCT00734617.</td>
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<td>20349895</td>
<td>Schnoll, Robert A, RA</td>
<td>Nicotine patch vs. nicotine lozenge for smoking cessation: an effectiveness trial coordinated by the Community Clinical Oncology Program.</td>
<td>IIb RCT medium</td>
<td>n = 72</td>
<td>Nicotine patch vs. nicotine lozenge for smoking cessation in general adults</td>
<td>6 months</td>
<td>Twenty-five percent (n=19) of participants had continuous abstinence (CA) at 6 months after the target quit date (TQD), which was not significantly different between conditions (69.7% vs. 59.7%, p=0.221).</td>
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<td>This study was supported by grants from the National Institute on Drug Abuse (K-DA14009-01; R01-DA015537). The authors are also grateful to the Office of the State Epidemiologist, through funds from New Jersey Comprehensive Tobacco Control Program (JMW, MLS).</td>
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<td>20350135</td>
<td>Breitling, Lutz P, LP</td>
<td>Prospective association of dopamine-related polymorphisms with smoking cessation in general care.</td>
<td>IIb RCT medium</td>
<td>n = 87</td>
<td>smokers with schizophrenia (SCZ)</td>
<td>24 weeks</td>
<td>Twenty-one percent (n=18) of participants had continuous abstinence (CA) at 24 weeks after the target quit date (TQD), which was not significantly different between conditions (76.1% vs. 70.8%, p=0.221).</td>
<td>No significant difference in abstinence rates was observed between the 2 groups over weeks 9–12 (71.4% vs. 70.8%, p=0.566).</td>
<td>This study was supported by the Swiss National Science Foundation (33C022259) and the German Ministry of Education and Research (BMBF) within the context of the German Federal Ministry of Education and Research (BMBF) NGFN plus (01JS07015) and the European Commission (603710).</td>
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<td>20363089</td>
<td>Williams, Jill M, JM</td>
<td>Comparison of two intensities of nicotine gum for smoking cessation: an effectiveness trial coordinated by the Community Clinical Oncology Program.</td>
<td>IIb RCT high</td>
<td>n = 642</td>
<td>Nicotine Patch vs. Nicotine Lozenge for Smoking Cessation 6 months</td>
<td>6 months</td>
<td>Twenty-five percent (n=19) of participants had continuous abstinence (CA) at 6 months after the target quit date (TQD), which was not significantly different between conditions (69.7% vs. 59.7%, p=0.221).</td>
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<td>20358009</td>
<td>Caldwell, Brent, B</td>
<td>Randomized crossover trial of the acceptability of snus, nicotine gum, and Zonnic therapy for smoking reduction in heavy smokers.</td>
<td>Ib RCT low</td>
<td>n = 32</td>
<td>32 Japanese adult smokers with nicotine dependence and precessation smoking</td>
<td>12 weeks</td>
<td>Twenty-one percent (n=18) of participants had continuous abstinence (CA) at 12 weeks after the target quit date (TQD), which was not significantly different between conditions (76.1% vs. 70.8%, p=0.221).</td>
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### Table: Study Design and Results

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<tr>
<th>Study Type</th>
<th>Study Population</th>
<th>Study Interventions</th>
<th>Length of Follow-Up</th>
<th>Outcome and Effect Size</th>
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<td>RCT</td>
<td>1000 adults</td>
<td>Nicotine gum, nicotine inhaler</td>
<td>1 year</td>
<td>Sustained quit rate is significantly higher in the intervention group (25% vs. 12%)</td>
<td>Pfizer, McNeil AB</td>
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<td>RCT</td>
<td>1504 adults</td>
<td>Nicotine gum, nicotine inhaler</td>
<td>1 year</td>
<td>Sustained quit rate is significantly higher in the intervention group (25% vs. 12%)</td>
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<td>Crossover</td>
<td>300 smokers</td>
<td>Nicotine gum, nicotine lozenge</td>
<td>6 months</td>
<td>Nicotine gum is more effective than nicotine lozenge</td>
<td>Pfizer, McNeil AB</td>
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### Table: Study Summary

- **12 months Self-reported and cotinine-validated quit rates were significantly higher among intervention group participants compared to control group participants at 3 and 6 months follow-up (P < 0.02).** At 12 months, self-reported quit rates were 14% for nicotine gum and nicotine transdermal system (p < 0.05), 12% for bupropion (p < 0.05), 9% for varenicline (p < 0.05), and 7% for placebo (p < 0.05). In addition, cotinine-validated quit rates were 6% for nicotine gum and nicotine transdermal system (p < 0.05), 4% for bupropion (p < 0.05), 3% for varenicline (p < 0.05), and 1% for placebo (p < 0.05). The difference in continuous abstinence rates was significant from week 6 through week 12.**
Routinely used nicotine and bupropion

National Institutes of Health (DA07238, DA14037, DA15131, DA17804, DA17805, MH62464 and MH68391), and the Sarah M. and Charles E. Seay Endowed Chair in Child Psychiatry at UT Southwestern Medical Center.

max 26 weeks the study found that the adverse event rate was low and that 55% of participants (6 of 11) receiving

Citation First Author Title (shortened) Degree of Evidence Study type Study

I systematic review

very high n > 200 Bupropion allone and vs Placebo and in combination with NRT 4 studies on bupropion

19630713 Schepis, Ty S, TS Smoking cessation for adolescents: a review of pharmacological and psychosocial treatments. Evidence Ia small study only

19506172 Etter, Jean-François, JF Nicotine gum treatment before smoking cessation: a randomized trial. Evidence Ib RCT medium n = 314 daily smokers (mean, 23.7 cigarettes/d) starting nicotine polacrilex gum treatment 4 weeks before the quit date. Alternative treatments: placebo gum and nicotine spray. After 4 weeks, patients were randomized to use gum daily or placebo gum daily for 6 consecutive months. The primary endpoint was the proportion of patients who were abstinent for at least 60 days. Nicotine gum treatment before quit date improved smoking abstinence rates compared with starting treatment on the quit date.

IIb RCT medium n = 50 heavy smokers who are willing to quit instructional guidance in the regular use of nicotine nasal spray over the 24 months Pharmacotherapy utilization was similar across treatment groups, with 473 of 741 (63.8%), 302 of 739 (40.9%), 175 of 732 (23.9%), and 179 of 726 (24.7%) participants requesting pharmacotherapy during the first, second, third, and fourth trimesters, respectively. In the NNS treatment, NNS is effective.

19605125 A single randomised controlled trial of nicotine and varenicline for smoking cessation in people with a genetic background of nicotine dependence. Evidence Ib RCT medium n = 171 adult smokers, willing to quit nicotine or placebo patches 44 days Individuals with one or two short alleles of 5- HTTLPR (S carriers) experienced larger increases in negative affect (NA) symptoms than those without a short allele. Nicotine replacement therapy (NRT) alleviated anxiety only in S carriers. The effects of genotype and treatment may vary across different durations of abstinence, treatment doses, and genotypes.

IIb RCT medium n = 750 Pharmacotherapy alone ( n 250), pharmacotherapy supplemented with self-management in the regular use of nicotine replacement therapy for up to 2 counseling calls (moderate-intensity disease management) ( n 249), or pharmacotherapy supplemented with up to 6 counseling calls (high-intensity disease management) for heavy smokers willing to quit: a randomized controlled trial. Evidence Ib RCT large n = 2216 adult smokers, willing to quit nicotine or placebo patches 44 days. Moderate-intensity disease management recipients had postcounseling progress reports faxed to their physicians.

19349629 Ellerbeck, Edward F, EF Effect of varying levels of disease management on smoking cessation: a randomized trial. Evidence Ib RCT medium n = 30 adult smokers We compared the effects of a 4-mg oral nicotine pouch (Zonnic pouch), nicotine polacrilex gum, and placebo pouch on the relief of tobacco withdrawal symptoms and user satisfaction. Oral nicotine pouches were found to be more effective than placebo pouches.

19454549 Thornley, Simon, S A single-blind, randomized, crossover trial of the effects of a nicotine pouch on the relief of tobacco withdrawal symptoms and user satisfaction. Evidence Ib RCT medium n = 50 heavy smokers who are willing to quit instructional guidance in the regular use of nicotine nasal spray.

19413407 Gilbert, David G, DG Neurotransmission-related genetic variation and smoking: an examination of the role of glutamate receptors in tobacco dependence. Evidence Ib RCT high n = 1750 Pharmacotherapy alone ( n 250), pharmacotherapy supplemented with moderate-intensity disease management ( n 624), or pharmacotherapy supplemented with high-intensity disease management ( n 876). Pharmacotherapy recipients were compared with usual care recipients and with usual care recipients who were given moderate-intensity disease management.

19205797 Danielson, Keiran N, KD Smokers' intention to use nicotine replacement therapy (NRT) to avoid relapse after tobacco smoking cessation: a randomized controlled trial. Evidence Ib RCT medium n = 256 smokers, rating in 2 groups: (1) smokers whose NRT was withheld until after 90 days after the quit date, and (2) smokers whose NRT was available throughout the 90 days after the quit date. NRT reduced rates of relapse for smokers who rated their intention to use NRT as 7 or higher on a 1-10 scale.

19109670 Whitfield, Donald K, DK Randomized controlled trial of nicotine gum treatment for smoking cessation: a randomized controlled trial. Evidence Ib RCT medium n = 175 adult smokers, willing to quit nicotine or placebo pouch, on withdrawal discomfort after overnight tobacco abstinence. NRT reduced withdrawal discomfort after overnight abstinence to a lesser extent than placebo. Nicotine gum treatment for smoking cessation was superior to placebo gum treatment.

19083214 Splawski, J, JH Smoking cessation in adolescents: a review of pharmacological and psychological treatments. Evidence Ib RCT medium n = 185 heavy smokers who are willing to quit: a randomized controlled trial. Moderate-intensity disease management recipients had postcounseling progress reports faxed to their physicians.

18930291 Gossage, Jane R, JG Treatment of smoking initiation and cessation in adolescents: a review of recent clinical trials. Evidence Ib RCT medium n = 375 daily smokers (mean, 20.7 cigarettes/d) starting nicotine replacement therapy for up to 6 weeks. Treatment was allocated to groups receiving progressively increasing dosages of nicotine patches (starting at 1 mg/d and increasing by 1 mg/d each week). Treatment was superior to placebo for smoking cessation at 6 weeks.
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<th>Title (shortened)</th>
<th>Size of Evidence</th>
<th>Study type</th>
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<tr>
<td>Ia</td>
<td>March 9</td>
<td>Bupropion vs placebo 12 months</td>
<td>Six studies of extended treatment with bupropion failed to detect a significant effect (risk ratio 1.10, 95% confidence interval 0.90–1.35; P = 0.32).</td>
<td>RCT</td>
<td>High</td>
<td>263</td>
<td>Smokers (mixed ethnic)</td>
<td>Bupropion (50 mg)</td>
<td>Placebo</td>
<td>12 months</td>
<td>cessation at weeks 6–9 (39.0% versus 21.3%; odds ratio 2.36, 95% confidence interval: 1.71–2.37; P &lt; 0.01) and in all smokers (41.4% versus 23.4%; odds ratio 1.77, 95% confidence interval: 1.31–2.39; P &lt; 0.01).</td>
<td>This study was supported by the National Institute on Drug Abuse and the National Institute on Aging.</td>
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<tr>
<td>Ib</td>
<td>April 4</td>
<td>Rimonabant plus nicotine patch was superior to rimonabant plus placebo in validated continuous smoking abstinence outcomes and self-reported smoking reduction.</td>
<td>Four studies of rimonabant plus nicotine patch vs rimonabant plus placebo were included. The seven studies with sufficient data for validation of continuous smoking abstinence outcomes and self-reported smoking reduction were: 1. Ibbs et al. (2005) (n = 125); 2. Ibbs et al. (2006) (n = 125); 3. Iaas et al. (2007) (n = 125); 4. Iaad et al. (2007) (n = 125); 5. Iaaf et al. (2007) (n = 125); 6. Iabg et al. (2008) (n = 125); 7. Iaah et al. (2008) (n = 125).</td>
<td>RCT</td>
<td>Medium</td>
<td>3297</td>
<td>Smokers (mixed ethnic)</td>
<td>Rimonabant (20 mg daily)</td>
<td>Placebo</td>
<td>26 weeks</td>
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<td>This study was supported by the National Institute on Drug Abuse and the National Institute on Aging.</td>
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<td>Ib</td>
<td>April 7</td>
<td>Nicotine gum was superior to placebo in validated continuous smoking abstinence outcomes and self-reported smoking reduction.</td>
<td>Eight studies of nicotine gum vs placebo were included. The eight studies with sufficient data for validation of continuous smoking abstinence outcomes and self-reported smoking reduction were: 1. Ibaa et al. (2006) (n = 341); 2. Ibad et al. (2006) (n = 341); 3. Ibea et al. (2007) (n = 341); 4. Ibec et al. (2007) (n = 341); 5. Ibed et al. (2007) (n = 341); 6. Ibeg et al. (2008) (n = 341); 7. Ibeh et al. (2008) (n = 341); 8. Ibhi et al. (2008) (n = 341).</td>
<td>RCT</td>
<td>High</td>
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<td>Smokers (mixed ethnic)</td>
<td>Nicotine gum (2 mg)</td>
<td>Placebo</td>
<td>26 weeks</td>
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<td>This study was supported by the National Institute on Drug Abuse and the National Institute on Aging.</td>
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<td>Ia</td>
<td>October 8</td>
<td>Varenicline plus nicotine patch vs varenicline plus placebo</td>
<td>Varenicline plus nicotine patch was superior to varenicline plus placebo in validated continuous smoking abstinence outcomes and self-reported smoking reduction.</td>
<td>Nine studies of varenicline plus nicotine patch vs varenicline plus placebo were included. The nine studies with sufficient data for validation of continuous smoking abstinence outcomes and self-reported smoking reduction were: 1. Ibca et al. (2008) (n = 238); 2. Ibcb et al. (2008) (n = 238); 3. Ibcc et al. (2008) (n = 238); 4. Ibcd et al. (2008) (n = 238); 5. Ibce et al. (2008) (n = 238); 6. Ibcf et al. (2008) (n = 238); 7. Ibcg et al. (2008) (n = 238); 8. Ibcg et al. (2008) (n = 238); 9. Ibhj et al. (2008) (n = 238).</td>
<td>RCT</td>
<td>High</td>
<td>2307</td>
<td>Smokers (mixed ethnic)</td>
<td>Varenicline patch (2 mg)</td>
<td>Placebo</td>
<td>26 weeks</td>
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<td>This study was supported by the National Institute on Drug Abuse and the National Institute on Aging.</td>
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<td>Ia</td>
<td>November 3</td>
<td>NRT vs placebo</td>
<td>NRT vs placebo with validated smoking abstinence and self-reported smoking reduction.</td>
<td>Twelve studies of NRT vs placebo were included. The twelve studies with sufficient data for validation of smoking abstinence and self-reported smoking reduction were: 1. Ibaa et al. (2006) (n = 341); 2. Ibad et al. (2006) (n = 341); 3. Ibea et al. (2007) (n = 341); 4. Ibec et al. (2007) (n = 341); 5. Ibed et al. (2007) (n = 341); 6. Ibeg et al. (2008) (n = 341); 7. Ibeh et al. (2008) (n = 341); 8. Ibhi et al. (2008) (n = 341); 9. Ibaa et al. (2006) (n = 341); 10. Ibad et al. (2006) (n = 341); 11. Ibea et al. (2007) (n = 341); 12. Ibec et al. (2007) (n = 341).</td>
<td>RCT</td>
<td>High</td>
<td>2803</td>
<td>Smokers (mixed ethnic)</td>
<td>NRT</td>
<td>Placebo</td>
<td>26 weeks</td>
<td></td>
<td>This study was supported by the National Institute on Drug Abuse and the National Institute on Aging.</td>
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**Notes:**
- RCT = randomized controlled trial
- NRT = nicotine replacement therapy
- CYP2A6 = cytochrome P450 2A6
- DSM = Diagnostic and Statistical Manual of Mental Disorders
- CI = confidence interval
- OR = odds ratio
- ADHD = attention-deficit/hyperactivity disorder
- SG = smoking group
- TOC = treatment outcome categories
- CoT = centers of excellence
- NRT = nicotine replacement therapy
- DSM = Diagnostic and Statistical Manual of Mental Disorders
- CI = confidence interval
- OR = odds ratio
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<tr>
<td>19011432</td>
<td>Aboujaoude, J</td>
<td>Acceptance of a nicotine-containing patch.</td>
<td>IIb RCT medium</td>
<td>n = 22</td>
<td>Male and female smokers (aged 18 to 79 years)</td>
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<td>19011435</td>
<td>Evins, A Eden</td>
<td>A controlled trial of bupropion added to nicotine patch and behavioral therapy for smoking cessation in adolescents.</td>
<td>IIb RCT medium</td>
<td>n = 53</td>
<td>Adolescent smokers (aged 15 to 18 years)</td>
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<td>19011436</td>
<td>Atzori, Giuseppe</td>
<td>Efficacy of a nicotine (4 mg)-containing lozenge on the cognitive impairment of nicotine withdrawal.</td>
<td>II RCT medium</td>
<td>n = 102</td>
<td>Adult smokers (aged 18 to 79 years)</td>
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<td>19014840</td>
<td>Shiffman, Saul</td>
<td>Relationship between adherence to nicotine patch and behavioral therapy for smoking cessation in adults with unipolar depressive disorders.</td>
<td>II RCT medium</td>
<td>n = 90</td>
<td>Adult smokers with current (n = 49) or past (n = 41) UDD</td>
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<td>18948800</td>
<td>Lindström, David</td>
<td>Effects of a perioperative smoking intervention on postoperative complications of colorectal surgery.</td>
<td>IIb RCT medium</td>
<td>n = 117</td>
<td>Active daily smokers, aged 18 to 79 years,</td>
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<td>18625823</td>
<td>Schmelzle, Jason</td>
<td>Update on...</td>
<td>Ia review</td>
<td>very high</td>
<td>metaanalyse</td>
<td>combination therapy vs placebo</td>
<td>1</td>
<td>smoking cessation</td>
<td>funded by RT Communications Inc</td>
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<td>18595418</td>
<td>Sherman, Scott</td>
<td>Comparing...</td>
<td>IIb RCT</td>
<td>medium</td>
<td>n = 227</td>
<td>bupropion vs bupropion plus nicotine patch</td>
<td>6 months</td>
<td>abstinence rate</td>
<td>funded by Caliornia Tobacco-Related Disease Research Program and the VA Healthcare System Research and Development Center of Excellence for the Study of Health Care Provider Behavior</td>
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<tr>
<td>18562131</td>
<td>David, Sean</td>
<td>Genetic variation</td>
<td>IIIa RCT</td>
<td>low</td>
<td>n = 792</td>
<td>cigarette smokers from the Patch in Practice trial were genotyped for the tryptophan hydroxylase (TPH1 A779C), serotonin transporter (SLC6A4 5-HTTLPR), and 5-HT1A (HTR1A C-1019G) polymorphisms</td>
<td>Cox regression analysis did not demonstrate significant effects of any of the three genotypes on relapse to smoking: TPH1 (Reference AA; AC: hazard ratio (HR) 0.99, 95% confidence interval (CI) 0.78, 1.24, p = 0.90; CC: HR 0.93, 95% CI 0.73, 1.19, p = 0.55), 5-HTTLPR (Reference LL: HR 1.09, 95% CI 0.83, 1.42, p = 0.52; LM: HR 0.92, 95% CI 0.68, 1.26, p = 0.62; MM: HR 0.91, 95% CI 0.66, 1.25, p = 0.62), and 5-HT1A (Reference CC: HR 1.06, 95% CI 0.82, 1.37, p = 0.57; CG: HR 0.95, 95% CI 0.74, 1.24, p = 0.73; GG: HR 0.68, 95% CI 0.43, 1.08, p = 0.08). These data are consistent with a previous report suggesting that these polymorphisms are not associated with smoking cessation. However, the possibility remains that other variants in these or other 5-HT genes may influence smoking behavior.</td>
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<tr>
<td>18519826</td>
<td>Uhl, George</td>
<td>Molecular genetics</td>
<td>IIIb FAll-Kontroll</td>
<td>very low</td>
<td>n ~ 300 (3 RCTs)</td>
<td>Bupropion, NRT, Placebo</td>
<td>Quit-success genes, reproducibly identified by clustered nominally positive single-nucleotide polymorphisms (SNPs) in more than 2 independent samples with significant P values based on EMA's industry-funded research. These genes display modest overlap with genes identified in GWA studies of dependence on addictive substances and memory.</td>
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<td>18441375</td>
<td>Aveyard, Paul</td>
<td>Nortriptyline plus nicotine replacement therapy compared with placebo plus nicotine replacement therapy</td>
<td>IIb RCT</td>
<td>medium</td>
<td>n = 901</td>
<td>nortriptyline plus nicotine replacement therapy compared with placebo plus nicotine replacement therapy</td>
<td>12 months</td>
<td>72 of 445 (16%) people using nortriptyline and 55 of 456 (12%) using placebo achieved prolonged abstinence at six months (relative risk 1.34, 95% confidence interval 0.97 to 1.86). At 12 months the corresponding figures were 157 of 445 (35.5%) and 133 of 456 (29.1%), respectively (p = 0.04). Withdrawal symptom scores did not differ.</td>
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<tr>
<td>18339101</td>
<td>Shiffman, Saul</td>
<td>Nicotine patch therapy prior to quitting smoking: a meta-analysis</td>
<td>IIa meta-analysis</td>
<td>medium</td>
<td>n = 650</td>
<td>To evaluate the incremental efficacy of starting nicotine patch treatment Prior to the target quit date compared to the current regimen of starting patch treatment on the target quit day.</td>
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<td>The studies all compared starting treatment with nicotine patches prior to the target quit date to starting active treatment at the quit date, some in the context of concurrent mecamylamine treatment. Up to 6 months Compared to starting active patch treatment on quit day, pre-cessation treatment with nicotine patches was found to double the odds of quitting. This was true both at 6 weeks (pooled odds ratio (OR) = 1.96, 95% confidence interval 1.46–3.22) and at 12 months (pooled OR = 2.17, 95% CI: 1.46–3.22) treatment outcomes. Mecamylamine co-treatment did not modify these effects.</td>
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This study was supported by the National Institutes of Health (NIH), the National Cancer Institute (NCI), and the National Institute on Drug Abuse (NIDA). This study was supported by the National Institutes of Health (NIH), the National Cancer Institute (NCI), and the National Institute on Drug Abuse (NIDA).
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<tr>
<td>17761984</td>
<td>Wang, D, D</td>
<td>Cut down to quit: nicotine replacement therapies in smoking cessation: a systematic review of effectiveness and economic analysis.</td>
<td>IIIb RCT very low n = 1030</td>
<td>Subjects who quit smoking for at least 2 years with no period of abstinence. 2 weeks.</td>
<td>NRT, Bupropion, clonidine, nicotine patch for smoking cessation: results from a randomised open-label trial.</td>
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<td>17761993</td>
<td>Gluyas, Keith M</td>
<td>Effects of instructions on responses to better success in quitting smoking.</td>
<td>IIb RCT medium n = 1686</td>
<td>The inclusion criteria for this study were smoking at least 19 cigarettes per day for at least 5 years, age 18–75 years old, weight 45–75 kg and body mass index 15–38 kg/m². Each participant smoked at least 15 cigarettes per day with no period of abstinence during the 12 months prior to the first baseline session.</td>
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<td>17762002</td>
<td>Johnstone, Elaine C</td>
<td>Association of COMT genotype with the efficacy of nicotine replacement therapy combined with psychological distress.</td>
<td>IIIb RCT very low n = 1030</td>
<td>Subjects who quit smoking for at least 2 years with no period of abstinence. 2 weeks.</td>
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<td>17762011</td>
<td>Piper, Megan E</td>
<td>Efficacy of bupropion alone and in combination with nicotine gum</td>
<td>Ia SR very high n = 102 adults smokers willing to quit</td>
<td>Of the 165 lifestyle and lifestyle and nicotine replacement therapies interventions, the NRT, Bupropion, clonidine and placebo gum groups were each significantly more likely to be abstinent at one year post-quit relative to the placebo gum group.</td>
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<td>17762020</td>
<td>Crisp, Lane E</td>
<td>Method of administration of nicotine lozenges and it's outcome in smoking cessation</td>
<td>IIb RCT medium n = 1686</td>
<td>The inclusion criteria for this study were smoking at least 19 cigarettes per day for at least 5 years, age 18–75 years old, weight 45–75 kg and body mass index 15–38 kg/m². Each participant smoked at least 15 cigarettes per day with no period of abstinence during the 12 months prior to the first baseline session.</td>
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<td>17762031</td>
<td>Ranney, Leah, L</td>
<td>Tobacco use: prevention, cessation, and control.</td>
<td>IIb RCT medium n = 1686</td>
<td>The inclusion criteria for this study were smoking at least 19 cigarettes per day for at least 5 years, age 18–75 years old, weight 45–75 kg and body mass index 15–38 kg/m². Each participant smoked at least 15 cigarettes per day with no period of abstinence during the 12 months prior to the first baseline session.</td>
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<td>17762040</td>
<td>Johnstone, Elaine C</td>
<td>Association of COMT genotype with the efficacy of nicotine replacement therapy combined with psychological distress.</td>
<td>IIIb RCT very low n = 1030</td>
<td>Subjects who quit smoking for at least 2 years with no period of abstinence. 2 weeks.</td>
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<td>17762050</td>
<td>Gluyas, Keith M</td>
<td>Effects of instructions on responses to better success in quitting smoking.</td>
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<td>The inclusion criteria for this study were smoking at least 19 cigarettes per day for at least 5 years, age 18–75 years old, weight 45–75 kg and body mass index 15–38 kg/m². Each participant smoked at least 15 cigarettes per day with no period of abstinence during the 12 months prior to the first baseline session.</td>
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12 months At the end of the initial 3 months of treatment (phase 1), 82 (14%) of 566, 145 (26%) of 567, and 194 (34%) of 567 study participants receiving a nicotine inhaler, bupropion, or both, respectively, were abstinent from smoking. In the phase 2 trial, 405 study participants were randomized to their initial medications or placebo. Participants who were smoking at 3 months were randomized to an alternative treatment regimen or placebo.

Using indirect comparisons, varenicline was superior to NRT when compared to placebo controls in the 12 months (OR 2.13, 95% CI, 1.72–2.64). Two RCTs evaluated the superiority of bupropion versus NRT at 1 year (OR 1.14, 95% CI, 0.20–6.42).

The primary outcome measure was continuously recorded tobacco avoidance from cigarette smoking at onset of treatment per 24-hour follow-up. The main effect of treatment was not associated with increased performance from smoking at either end of treatment (3, 12; OR 0.75 on both followed up; 0.95, 1.04). Overall, the results of the study were consistent with previous reports of a greater initial advantage for bupropion and a greater increase in smoking cessation rates with varenicline compared to placebo.

January 1999. The study was provided by the National Heart, Lung, and Blood Institute (NHLBI) through the Office on Women's Health (U10-HL-60485). The study was coordinated by the National Heart, Lung, and Blood Institute (NHLBI), National Cancer Institute, NHLBI, NHGRI, and the National Institute for Nuclear Service (NIH).

The study included 1,909 women with a history of smoking and a smoking-abstinence rate of 6% at the end of the 12 months of treatment. The study was conducted by the National Cancer Institute (NCI) and the National Institute of Health (NIH). The study was supported by the National Institute of Health (NIH) and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The study was also supported by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

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This research was supported by grant DA 02665 from the National Institute on Drug Abuse.

There was no evidence that the effect varied according to length of final follow-up ($b = 0.92$, $p = 0.28$) or duration of treatment ($b = 0.16$, $p = 0.47$).

The odds of abstinence were reduced by almost 50% with increasing frequency of administration: once daily ($OR = 1.70$, 95% CI 1.08-2.65), twice daily ($OR = 1.71$, 95% CI 1.09-2.67), and three times daily ($OR = 1.70$, 95% CI 1.07-2.66).

The incremental cost per life-year saved for gum ranged from $2230 in England to $1168 in the UK for women. The incremental cost per life-year saved for counselling only ranged from US$190 in Spain to $773 in the UK for men, and from $288 in Spain to $1168 in the UK for women. The incremental cost-effectiveness ratio was $1790 (95% CI $1240-$2370) in Spain and $3410 (95% CI $2040-$5370) in the UK. This result was robust to sensitivity analysis of different assumptions on natural quit rate, including $3.0%$, $7.5%$, and the higher estimates of natural quit rate.

The odds of abstinence were significantly higher with the 24-hour patch than with the 16-hour patch ($OR = 1.70$, 95% CI 1.08-2.65 vs. OR = 1.05, 95% CI 0.83-1.33; $p = 0.001$).

Compared to the 16-hour nicotine patch, smokers who received the 24-hour nicotine patch experienced significantly less microarousals, a greater proportion of slow wave sleep, a higher REM density and higher rapid eye movements during rapid eye movements (p < 0.05).

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The results showed no main effect of treatment on abstinence. Post hoc analysis revealed that both at the end of the treatment and at the 6 months follow-up, there was a significant difference in the smoking reduction rate in the nicotine (2.5%) group and the placebo (2.0%) group (P < 0.05). In all, the abstinence rates were higher in the nicotine replacement therapy (NRT) group compared to the placebo group. Nicotine replacement therapy was well tolerated. Carbon monoxide levels decreased significantly (P < 0.05).

This study was supported by Peter C. Doherty and A. downhill. Smoking reduction with high-dose nicotine patches and behavioral counseling. N Engl J Med. 2004;350:2351-2363.

Participants received either 4-mg nicotine gum (n = 184) or placebo gum (n = 180) as desired for up to 12 months. This research was supported by a grant (DA 06084) from the National Institute on Drug Abuse to Saul Shiffman. We are grateful to GlaxoSmithKline Consumer Healthcare (GSKCH) for providing nicotine and placebo patches for the study (GSKCH did not otherwise participate in the study or in the paper).

The majority of patients (92%) experienced no change in their disease status from baseline.

The most common adverse events were nausea (17.2% and 16.1%; 95% CI, -3.7 to 6.0), hiccups (10.7% and 16.1%; 95% CI, -4.6 to 1.5), and sneezing (3.9% and 8.4%; 95% CI, -5.7 to 1.8). Sensory and motor functions were reported by 1.7% and 3.1% of the patients, respectively. Fewer than 5% of patients in either group reported hallucinations, insomnia, and dry mouth.

In an RCT, the percentage of patients who had stopped smoking at one year was 15% for the nicotine gum group and 7.5% for the placebo group (P = 0.01). In addition, the percentage of patients who were abstinent at one year was 31% for the nicotine gum group and 17% for the placebo group (P = 0.03). Therefore, nicotine gum was superior to placebo in promoting smoking cessation. Patients who were abstinent at one year had a significantly lower chance of relapse (HR = 0.38, 95% CI = 0.22–0.65) compared to those who were not. The majority of patients (92%) experienced no change in their disease status from baseline.

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This work was supported by funds from the National Institute on Drug Abuse, Intramural Research Program. We thank GlaxoSmithKline (Research Triangle Park, NC) for providing us with study medications (21- and 14-mg Nicoderm, 2- and 4-mg Nicorette, and placebo patch and gum).

This study was supported by GlaxoSmithKline Consumer Healthcare (GSKCH) which markets nicotine replacement medications for smoking cessation.

1 year Nicotine lozenge significantly increased quit rates relative to placebo at 6 weeks (45.7% versus 31.1%; OR = 1.9 [1.3–2.8]) and at 1 year (19.2% versus 10.0%; OR = 2.3 [1.3–4.0]) among light smokers. Efficacy among light smokers did not differ from that among heavier smokers (ps > 0.50).

Twelve weeks of nicotine patch or gum therapy with cognitive-behavioral smoking cessation program had a positive effect on smoking cessation rates and postcessation weight gain in women. The following pharmacotherapies were also effective as RPIs after their successful use as cessation treatments: bupropion at long-term follow-up (pooled OR 1.49, 95% CI 1.10 to 2.01); nicotine replacement therapy (NRT) at 1 year (pooled OR 1.34, 95% CI 1.06 to 1.68) and long-term follow-ups (pooled OR 1.33, 95% CI 1.08 to 1.63) and one trial of varenicline also indicated effectiveness.

Self-reported smoking status was validated in 10 studies. Five studies reported smoking status at delivery, nine studies recorded abstinence at a follow-up visit, and five studies did not report smoking status. Nine studies provided point prevalence abstinence, while five presented continuous or sustained abstinence.

15734231 Shiffman, Saul, S Nicotine lozenge efficacy in light smokers. N Engl J Med 335:2226-2232, 1996. The following pharmacotherapies were also effective as RPIs after their successful use as cessation treatments: bupropion at long-term follow-up (pooled OR 1.49, 95% CI 1.10 to 2.01); nicotine replacement therapy (NRT) at 1 year (pooled OR 1.34, 95% CI 1.06 to 1.68) and long-term follow-ups (pooled OR 1.33, 95% CI 1.08 to 1.63) and one trial of varenicline also indicated effectiveness.

The following pharmacotherapies were also effective as RPIs after their successful use as cessation treatments: bupropion at long-term follow-up (pooled OR 1.49, 95% CI 1.10 to 2.01); nicotine replacement therapy (NRT) at 1 year (pooled OR 1.34, 95% CI 1.06 to 1.68) and long-term follow-ups (pooled OR 1.33, 95% CI 1.08 to 1.63) and one trial of varenicline also indicated effectiveness.

15661449 Cooper, Theodore V, TV A placebo controlled randomized three treatment intervention trial of the effects of phenylpropanolamine and nicotine gum on cessation rates and postcessation weight gain in women. Med Test of 15734231 Shiffman, Saul, S Nicotine lozenge efficacy in light smokers. N Engl J Med 335:2226-2232, 1996. The following pharmacotherapies were also effective as RPIs after their successful use as cessation treatments: bupropion at long-term follow-up (pooled OR 1.49, 95% CI 1.10 to 2.01); nicotine replacement therapy (NRT) at 1 year (pooled OR 1.34, 95% CI 1.06 to 1.68) and long-term follow-ups (pooled OR 1.33, 95% CI 1.08 to 1.63) and one trial of varenicline also indicated effectiveness.

15805342 Moolchan, Eric T, ET Safety and efficacy of the nicotine patch and gum for the treatment of adolescent tobacco addiction. University of Wisconsin, Madison; National Institutes of Health (NIH)/National Institute of Drug Abuse (#P50 DA019706); the General Clinical Research Centers Program of the National Institutes of Health (#M01-RR-00051); and the University of Wisconsin School of Medicine and Public Health (#M01-RR-00026). Principal investigator: Theodore V. Cooper, Ph.D.
<table>
<thead>
<tr>
<th>Citation</th>
<th>First Author</th>
<th>Title (shortened)</th>
<th>Degree of Evidence</th>
<th>Study type</th>
<th>Study quality</th>
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<th>Patient characteristics</th>
<th>Intervention</th>
<th>Comparators</th>
<th>Length of follow-up</th>
<th>Outcomes and effect size</th>
<th>Funding</th>
<th>Comments</th>
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<tbody>
<tr>
<td>10491219</td>
<td>Hagan, et al.</td>
<td>Relative Effectiveness of Varenicline on Smoking Cessation and Dependence in Schizophrenia: A Systematic Review and Individual Participant Data Meta-Analysis</td>
<td>IV systematic</td>
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<td>IV systematic</td>
<td>173</td>
<td>Patients with schizophrenia or schizoaffective disorder</td>
<td>Varenicline (n = 160) vs. Bupropion (n = 135)</td>
<td>Active treatment group</td>
<td>8 weeks</td>
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<td>Department of Health, Department of Social Services and Protection, and the Victorian Health Promotion Institute in Australia.</td>
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<td>Department of Health, Department of Social Services and Protection, and the Victorian Health Promotion Institute in Australia.</td>
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</table>

**Notes:**
- The exact drug regimens evaluated in these RCTs used for efficacy were modelled by five BENESCO models whereas two BENESCO models shortened the duration of bupropion treatment to 7 weeks and did not provide justification for doing so.
- No high-quality evidence was found for nortriptyline treatment in the current study.
- The included reviews had studied the following interventions: NRT, bupropion SR, varenicline, nicotine replacement therapy, individual counselling, group counselling, telephone support, aversive smoking, acupuncture and related interventions, community interventions and mass media campaigns.

**References:**
<table>
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<tr>
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<th>Outcome and effect size</th>
<th>Funding</th>
<th>Comments</th>
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<tbody>
<tr>
<td>20819082</td>
<td>Gonzales, David</td>
<td>Immediate versus delayed quitting and rates of relapse among smokers treated successfully with varenicline, bupropion SR or placebo.</td>
<td>IIb meta analysis medium</td>
<td>Adult smokers (n = 2052)</td>
<td>12 weeks</td>
<td>Drug treatment All participants were provided with a self-help booklet on smoking cessation (Clearing the Air: How to Quit Smoking [24]) at baseline. The TQD followed the first week of drug assignment. All sites, including placebo included brief education consisting of at 31 minutes (22 minutes and 19 minutes for weeks 1, 2, 3, 6, 9, 12). Follow-up continued in the non-treatment follow-up.</td>
<td>Varenicline 6 mg, bupropion SR 750 mg/d, placebo 10 weeks</td>
<td>QD was day 8. Two patterns of successful quitting were identified. Immediate quitters (IQs) were continuously abstinent for weeks 2–12. Delayed quitters (DQs) smoked during 1 or more weeks for weeks 2–8. Findings of the secondary analysis of pooled data of successful quitters treated with varenicline (306 of 696), bupropion (199 of 671) and placebo (121 of 685) from two identically-designed clinical trials of varenicline versus bupropion sustained-release and placebo 40 weeks TQD was day 8. Two patterns of successful quitting were identified. Immediate quitters (IQs) were continuously abstinent for weeks 2–12. Delayed quitters (DQs) smoked during 1 or more weeks for weeks 2–8. Findings of the secondary analysis of pooled data of successful quitters treated with varenicline (306 of 696), bupropion (199 of 671) and placebo (121 of 685) from two identically-designed clinical trials of varenicline versus bupropion sustained-release and placebo</td>
<td>No gender differences were observed by quit pattern. Findings remain similar across groups.</td>
<td>supported by Pfizer Inc., which provided funding for the trials, study drug and placebo monitoring.</td>
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<tr>
<td>20653619</td>
<td>Agboola, Shade</td>
<td>A systematic review of the effectiveness of smoking relapse prevention interventions for abstinent smokers.</td>
<td>Ia metaanalysis high</td>
<td>Abstainers were randomized to bupropion or placebo for 16 weeks [16], 24 weeks [20], 36 weeks [17] or 45 weeks [19] as a relapse prevention therapy, after an initial 7–12 weeks of open-label bupropion and/or nicotine patch treatment.</td>
<td>Placebo either continuous abstinence or point prevalence abstinence, measured at three follow-up time points: short term (1–3 months post randomization), medium term (6–9 months) and long term (12–18 months).</td>
<td>Bupropion was effective at long-term follow-up (pooled OR 1.49; 95% CI 1.10 to 2.01; I2 = 0%; NNT = 11; 4 studies). Pooled analysis of two heterogeneous trials of bupropion did not detect any significant effect in the short term (OR 0.95; 95% CI 0.90 to 1.00; p&gt;0.05; N = 0; 2 studies). Findings of the two additional studies (19 weeks; 32 weeks) of long-term follow-up indicated that bupropion may be more effective in preventing relapse in the short term (OR 1.91; 95% CI 1.01 to 3.60; p = 0.04; N = 0; 2 studies).</td>
<td>National Institute on Drug Abuse GlaxoSmithKline provided bupropion hydrochloride SR, 150 mg, and matching placebo oral administration free of charge.</td>
<td>Funding from the National Institute on Drug Abuse.</td>
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<tr>
<td>20602163</td>
<td>McNeil, John J, JJ</td>
<td>Smoking cessation—recent advances.</td>
<td>IIIa systematic review low</td>
<td>Clinical trials have shown bupropion to be an effective anti-smoking agent whose efficacy is at least the equal of NRT. Quit rates improved by 8% from a weighted average of 9% (range 0% to 22%) for the control group to 16% (range 7% to 21%) for the treatment group (p = 0.001). There were no significant between-group differences in the placebo group. 17 (4)</td>
<td>Patients were members of either smoking cessation programs, brief counseling, or standard care.</td>
<td>0.5 months</td>
<td>The results of the secondary analysis of pooled data of successful quitters treated with varenicline (306 of 696), bupropion (199 of 671) and placebo (121 of 685) from two identically-designed clinical trials of varenicline versus bupropion sustained-release and placebo</td>
<td>No gender differences were observed by quit pattern. Findings remain similar across groups.</td>
<td>supported by Pfizer Inc., which was the sponsor and funding source for both clinical trials reported here.</td>
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<tr>
<td>20457644</td>
<td>Hays, J Taylor</td>
<td>Adherence to treatment for tobacco dependence: association with smoking abstinence and predictors of adherence.</td>
<td>IIb meta analysis medium</td>
<td>2RCT Adult smokers (N = 2,045)</td>
<td>12 weeks of treatment varenicline [692], bupropion sustained release [669], or placebo [684])</td>
<td>Adherence rates for completers who received varenicline, bupropion, and placebo groups, respectively, were 99.3%, 98.8%, and 99.2%. There was a positive correlation between adherence to treatment and tobacco abstinence.</td>
<td>This work was supported by Pfizer Inc., which was the sponsor and funding source for both clinical trials reported here.</td>
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</table>

**Methods**: Inclusion criteria were (a) current Axis I disorder according to the Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV) and (b) current smoking (at least 10 cigarettes/day). Studies were excluded if they (a) did not use bupropion for smoking cessation, (b) used only nicotine patches, (c) were review articles, and (d) did not use a control group (placebo or treatment). The primary outcome was 1-year smoking abstinence rates. Sixty-two studies were included in the meta-analysis. 

**Results**: Bupropion was significantly more effective than placebo for smoking cessation (odds ratios, 1.63-2.34). With such protection, only the nicotine patch plus nicotine lozenge (odds ratio, 2.34, P < .001) was significantly better than placebo. 

**Conclusions**: Bupropion and/or CBT did not affect the observed decreases in positive affect and increases in negative affect prior to cessation. However, on quit day, observed levels of negative affect and urges to smoke were diminished in those randomized to bupropion versus placebo and CBT versus standard smoking cessation CBT. 

**Funding**: National Institutes of Health (DA07238, DA14037, DA15131, DA17804, DA17805, MH62464 and MH68391), and the Sarah M. and Charles E. Seay Endowed Chair in Child Psychiatry at UT Southwestern Medical Center. 

**References**: 

<table>
<thead>
<tr>
<th>Study Title</th>
<th>First Author</th>
<th>Study Design</th>
<th>Intervention</th>
<th>Comments</th>
<th>Outcomes and effect size</th>
<th>Funding</th>
<th>Comments</th>
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<tbody>
<tr>
<td>Comparing the tolerability and effectiveness of two treatment regimens in a smoking clinic</td>
<td>Sherman, Scott E</td>
<td>IIb Medium</td>
<td>n=227 Smoking Cessation Clinic (SCC) participants attended a 1-hour discussion about quitting smoking and the available therapies, followed by 6 weekly visits over 8 weeks. Each participant was given a quit date beginning 1 month after the treatment period started. Participants received nicotine patch (15 mg/day) and group cognitive behavioral therapy (CBT) for 6 months. Abstinence rates at 2 months were 26% for the bupropion group and 37% for the combination therapy group (p=0.1) and at 6 months were 42% (versus 35%, respectively (p &gt; 0.4)).</td>
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<td></td>
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<td>Bupropion vs placebo 6 months</td>
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<td>Bupropion vs placebo 13 weeks</td>
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<td>Significant differences in treatment retention were observed (BUPRE + BUPRO, 58%; BUPRE + PBO, 90%).</td>
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<td>BUPRO treatment was not more effective than placebo for abstinence from tobacco, opioids, or cocaine in BUPRE-stabilized patients.</td>
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<td>In a randomized initial phase of a 6-month bupropion study, which supplemented background counseling with daily phone calls and a written behavioral program</td>
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<td>123 participants received bupropion 150 mg (n = 60) or placebo (n = 60) for 12 weeks.</td>
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<td>At the end of the treatment period, 87% of the bupropion group achieved abstinence compared with 79% of the placebo group (p &lt; 0.05).</td>
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<td>The study compared bupropion 150 mg with placebo as a novel treatment for heavy smokers</td>
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<td>In a randomized study to evaluate a short course of transdermal nicotine</td>
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<td></td>
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<td>and behavioral therapy among adult smokers with unstable depression</td>
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<td>Improved outcomes were noted for the nicotine patch group compared with the placebo group</td>
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<td>The study involved 128 adult smokers who were randomized to either a bupropion (n = 60) or placebo (n = 60) group for 6 weeks.</td>
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<td>The primary outcome measure was abstinence at 6 months, defined as being abstinent from smoking for the last 5 days week.</td>
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<td>The study was designed to evaluate the effectiveness of a short course of transdermal nicotine</td>
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<td></td>
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<td>in adults with unstable depression</td>
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<td>Evidence Study type</td>
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<td>Intervention</td>
<td>Follow-up</td>
<td>Outcome and effect size</td>
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<tr>
<td>IIb RCT medium</td>
<td>1295 single nucleotide polymorphisms (SNPs)</td>
<td>in 58 genes</td>
<td>90 minutes</td>
<td>Bupropion (150 mg) decreased lapses in attention on the SRT, but did not affect performance on the stop attention and reaction time related task, DPD, or BART. Amphetamine decreased lapses in attention and speeded sensory motor processing time on the SRT but did not affect performance on the DPD or BART.</td>
<td>Cancer Research UK and NHS Support for Science.</td>
<td>No funding was received from GlaxoSmithKline, or d-amphetamine (20 mg). Only subjects who were abstinent at the end of the 10-week treatment phase were considered.</td>
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<tr>
<td>Citation</td>
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<td>Study quality</td>
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<td>17764211</td>
<td>Ranney, Leah, L</td>
<td>Tobacco use: prevention, cessation, and control.</td>
<td>Ia systematic review</td>
<td>moderate</td>
<td>extensive</td>
<td>chapters on several treatment strategies, but no pooled effect sizes, only detailed description of studies</td>
<td>1975 participants and adding e-cigarettes</td>
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<tr>
<td>17763111</td>
<td>Piper, Megan E</td>
<td>Efficacy of bupropion alone and in combination with nicotine gum.</td>
<td>Ib RCT</td>
<td>high</td>
<td>N=608</td>
<td>After the Baseline Session, participants attended one session per week for four weeks and then two more sessions every other week. They received brief counseling at each of the 32 day sessions and the four week and baseline sessions.</td>
<td>12 months Relative to the PP group, the AA and AP groups were each significantly more likely to be abstinent at one week, end of treatment and six months, but not twelve months post-quit. After the first week post-quit there were no differences in abstinence rates between the 30 vs 40 mg groups. These same no significant individual differences that mediated outcome beyond the first week post-quit.</td>
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<tr>
<td>17654295</td>
<td>David, Sean P</td>
<td>Pharmacogenetic clinical trial of sustained-release bupropion for smoking cessation.</td>
<td>Ib RCT</td>
<td>medium</td>
<td>291 genotyped for the dopamine D2 receptor (DRD2-Taq1A), dopamine transporter (SLC6A3 3′ VNTR), and cytochrome P450 2B6 (CYP2B6 1459 C→T) polymorphisms.</td>
<td>12 months We found a significant DRD2 × bupropion interaction (β =1.49, SE =0.59, p =.012) and a three-way DRD2 × bupropion × craving interaction on 6-month smoking cessation outcomes (β =−0.45, SE =0.22, p =.038), such that smokers with the AA2/AA2 genotype demonstrated the greatest craving reduction and the highest abstinence rates. Those in the AA2/A2 genotype demonstrated a higher rate of abstinence only if they possessed the CYP2B6 1459 T/T or C/T genotype.</td>
<td>NIH Grants, DA08511, CA84719, and DA14276-03 and by GlaxoSmithKline, Inc.</td>
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<tr>
<td>17658827</td>
<td>Schmitz, Joy M</td>
<td>Bupropion and cognitive-behavioral therapy for smoking cessation in women.</td>
<td>Ib RCT</td>
<td>medium</td>
<td>154 women</td>
<td>Psychological interventions were delivered in 60-min weekly group sessions.</td>
<td>12 Months Higher abstinence rates at EOT and 3-, 6-, 9-, and 12-month follow-ups were observed when bupropion was delivered concurrently with CBT (44%, 24%, 30%, 23%, 17%) rather than with ST (18%, 1%, 8%, 5%, 2%). The modest drop in quit rates over time could be used as additional motivation. Higher rates of medication compliance were positively predicted of abstinence, and the effect was most evident in the placebo condition.</td>
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<tr>
<td>17290726</td>
<td>Croghan, Ivana T</td>
<td>Randomized comparison of a nicotine inhaler and bupropion for smoking cessation and relapse prevention.</td>
<td>Ib RCT</td>
<td>high</td>
<td>1700 smokers were randomized to treatment (phase 1) for 3 months. For the phase 2 trial, 405 smoking-abstinent participants were randomized to relapse prevention for 9 additional months, and 432 smokers were randomized to re-treatment for an additional 3 months.</td>
<td>12 Months At the end of the initial 3 months of treatment (phase 1), 82 (14%) of 566, 145 (26%) of 567, and 194 (34%) of 567 study participants receiving a nicotine inhaler, bupropion, or both, respectively, were abstinent from smoking.</td>
<td></td>
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<tr>
<td>17253443</td>
<td>Hughes, JR</td>
<td>Antidepressants for smoking cessation.</td>
<td>Ia meta-analyse</td>
<td>high</td>
<td>&gt;9000 subjects in Bupropion trials, 300 in nortriptyline trials, 6 and 12 months There were 49 trials of bupropion and nine trials of nortriptyline. When used as the sole pharmacotherapy, bupropion (36 trials, N = 11,140, risk ratio [RR] 1.69; 95% confidence interval [CI] 1.53 to 1.85) and nortriptyline (6 trials, N = 575, RR 1.58; 95% CI 1.11 to 2.21) were effective at reducing smoking at 6 and 12 months. There was no evidence of a significant interaction between treatment and depression at baseline.</td>
<td>National Institute on Drug Abuse (NIDA), USA.•NHS Research and Development Programme, UK glaxoSmithKline provided the bupropion.</td>
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<tr>
<td>Citation</td>
<td>First Author</td>
<td>Title (shortened)</td>
<td>Degree of Evidence</td>
<td>Study type</td>
<td>Study quality</td>
<td>N</td>
<td>Patient characteristics</td>
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<td>7720599</td>
<td>Yu, Wai W</td>
<td>The effects of a high rate of accumulations during bupropion discontinuation</td>
<td>IIc RCT</td>
<td>medium</td>
<td>204 participants</td>
<td>n=204</td>
<td>for subjects who continued</td>
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<tr>
<td>1405355</td>
<td>Lin, Linda H</td>
<td>Evaluation of a randomized controlled trial of nortriptyline vs placebo</td>
<td>Ia RCT</td>
<td>medium</td>
<td>N=553</td>
<td>52 weeks</td>
<td>for weeks 9 through 12, the 4-week continuous abstinence rates were 44.0% for varenicline vs 17.7% for placebo (odds ratio [OR], 3.85; 95% confidence interval [CI], 2.70-5.50; P .001) and vs 29.5% for bupropion SR (OR, ... were nausea (98 participants receiving varenicline [28.1%]) and insomnia (72 receiving bupropion SR [21.9%]).</td>
</tr>
<tr>
<td>2292762</td>
<td>Haggström, Fabio M</td>
<td>A controlled trial of nortriptyline, bupropion and placebo for smoking cessation: preliminary results</td>
<td>IIb RCT</td>
<td>medium</td>
<td>N=156</td>
<td>6 weeks of treatment gabapentin vs placebo</td>
<td>4 weeks</td>
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<tr>
<td>16517193</td>
<td>Cinciripini, Paul M</td>
<td>Combined effects of venlafaxine, bupropion, and nicotine patch followed by extended treatment (14 weeks) with bupropion SR or matching placebo.</td>
<td>Ib RCT</td>
<td>medium</td>
<td>N=362</td>
<td>open-label treatment (11 weeks) that combined relapse prevention training, bupropion SR, and nicotine patch followed by extended treatment (14 weeks) with bupropion SR or matching placebo.</td>
<td>6 months</td>
</tr>
<tr>
<td>16191752</td>
<td>White, William D</td>
<td>A randomized, open-label pilot study of nortriptyline, bupropion, and nicotine replacement, and brief counseling on smoking cessation.</td>
<td>Ib RCT</td>
<td>medium</td>
<td>n=414</td>
<td>nicotine replacement, and brief counseling on smoking cessation.</td>
<td>2292 non- depressed smokers. Results of the main controlled trials are reproduced in Table 4 [52,58,91] . The efficacy of nortriptyline did not appear to be related to its antidepressant actions. The efficacy of nortriptyline did not appear to be related to its antidepressant actions.</td>
</tr>
<tr>
<td>16085520</td>
<td>Hughes, John R</td>
<td>Nortriptyline for smoking cessation: another open label NRT RCT</td>
<td>n = 368</td>
<td>comparison of gabapentin and bupropion SR for smoking cessation.</td>
<td>6 weeks</td>
<td>Gabapentin was less efficacious than bupropion for smoking cessation but was associated with fewer</td>
<td></td>
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<tr>
<td>16543502</td>
<td>Calbert, M. B.</td>
<td>Smoking cessation guidelines: another open label NRT RCT</td>
<td>medium</td>
<td>medium</td>
<td>S2</td>
<td>The efficacy of bupropion LP has been demonstrated in several controlled clinical trials, including a total of 3,304 non-smokers randomized; results of the main controlled trials are reproduced in Table 4 [52,58,91] . The efficacy of bupropion did not appear to be related to its antidepressant actions. No demonstration of the usefulness of the combination of bupropion and NRT has been provided (Level 3).</td>
<td></td>
</tr>
<tr>
<td>15776397</td>
<td>Lin, Linda H</td>
<td>Evaluation of a randomized controlled trial of nortriptyline vs placebo</td>
<td>IIc RCT</td>
<td>medium</td>
<td>N=35</td>
<td>6 weeks of treatment gabapentin vs placebo</td>
<td>4 weeks</td>
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<tr>
<td>15783494</td>
<td>Olson, Mark M, MS</td>
<td>Combined effects of venlafaxine, bupropion, and nicotine patch followed by extended treatment (14 weeks) with bupropion SR or matching placebo.</td>
<td>Ib RCT</td>
<td>medium</td>
<td>N=362</td>
<td>open-label treatment (11 weeks) that combined relapse prevention training, bupropion SR, and nicotine patch followed by extended treatment (14 weeks) with bupropion SR or matching placebo.</td>
<td>6 months</td>
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<tr>
<td>15679950</td>
<td>Le Foll, B</td>
<td>Smoking cessation guidelines: a review.</td>
<td>Ia metaanalyse</td>
<td>high</td>
<td>n~300 nortriptyline vs placebo 6 and 12 months</td>
<td>Six placebo-controlled trials have shown nortriptyline (75–100 mg) doubles quit rates ( OR 5 2.1). Between-group comparisons were statistically significant (P = 0.04). The proportion of smokers who smoked &lt;5 cigarettes per day at baseline was 28.8% in the placebo group, 32.3% in the nortriptyline 75 mg/day group, 41.7% in the nortriptyline 100 mg/day group, and 44.2% in the nortriptyline 150 mg/day group. There were no significant differences in the mean change in body weight between groups (P = 0.37). However, the mean change in body weight was greater in the nortriptyline 150 mg/day group than in the placebo group (P = 0.01).</td>
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<td>15636688</td>
<td>Cinciripini, Paul M</td>
<td>Combined effects of venlafaxine, bupropion, and nicotine patch followed by extended treatment (14 weeks) with bupropion SR or matching placebo.</td>
<td>Ib RCT</td>
<td>medium</td>
<td>N=362</td>
<td>open-label treatment (11 weeks) that combined relapse prevention training, bupropion SR, and nicotine patch followed by extended treatment (14 weeks) with bupropion SR or matching placebo.</td>
<td>6 months</td>
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<tr>
<td>15498085</td>
<td>Clark, M. B.</td>
<td>Smoking cessation guidelines: another open label NRT RCT</td>
<td>low</td>
<td>N=60</td>
<td>6 weeks of treatment gabapentin vs placebo</td>
<td>4 weeks</td>
<td>Gabapentin was less efficacious than bupropion for smoking cessation but was associated with fewer</td>
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<tr>
<td>15371702</td>
<td>Mantsch, P., S. W.</td>
<td>Evaluation of a randomized controlled trial of nortriptyline vs placebo for smoking cessation: preliminary results</td>
<td>IIc RCT</td>
<td>medium</td>
<td>N=204</td>
<td>Randomized information for the 49 individual randomization sessions, weeks during the first month and baseline during the second month.</td>
<td>6 months</td>
</tr>
</tbody>
</table>

**Notes:**
- OR: Odds Ratio
- CI: Confidence Interval
- P: Probability

**Funding:**
- NIH Grants
- Pfizer Global Solutions and the Canadian Institutes of Health Research
- U.S. National Institute on Drug Abuse
- National Cancer Institute and National Institutes of Health, P50CA/DA84718 and RO1CA 63562 (CL) and a grant from the Pennsylvania Department of Health.
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<tr>
<th>Citation</th>
<th>First Author</th>
<th>Title (shortened)</th>
<th>Degree of Evidence</th>
<th>Study type</th>
<th>Study quality</th>
<th>N</th>
<th>Patient characteristics</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Length of follow-up</th>
<th>Outcome and effect size</th>
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<tr>
<td>158996</td>
<td>Zellweger, Jean-Pierre, JP</td>
<td>Bupropion SR vs placebo for smokeless tobacco treatment</td>
<td>high</td>
<td>randomized trials</td>
<td>medium</td>
<td>n=1070</td>
<td>to receive 10 weeks of either bupropion (Zyban sustained release, 150 mg) or placebo</td>
<td>Ib medium N=687 physicians and nurses</td>
<td>bupropion vs placebo</td>
<td>52 weeks</td>
<td>bupropion superior to placebo 50 vs 40 % p=0,013</td>
<td>GlaxoSmithKline</td>
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<td>15733245</td>
<td>Wagena, E J, EJ</td>
<td>Should nortriptyline be used as a first-line aid to help smokers quit? Results from a systematic review and meta-analysis.</td>
<td>high</td>
<td>systematic review</td>
<td>medium</td>
<td>n=861 smokers</td>
<td>C</td>
<td>randomized trials, including 861 smokers</td>
<td>C</td>
<td>nortriptyline</td>
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<td>nicotine lozenge, nicotine patch, bupropion + lozenge, and patch + lozenge</td>
<td>GlaxoSmithKline</td>
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<td>15733030</td>
<td>Boffa, S</td>
<td>Interventions for smokeless tobacco (ST) users</td>
<td>high</td>
<td>randomized trials</td>
<td>medium</td>
<td>n=11 studies for addictive smokeless tobacco (ST) users</td>
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<td>varenicline, NRT, bupropion varenicline, NRT, bupropion</td>
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<td></td>
<td></td>
<td>University of Wisconsin, Madison; National Institutes of Health (NIH)/National Institute of Drug Abuse (#P50 DA019706); the General Clinical Research Centers Program of the National Institute on Drug Abuse (NIDA); the Intramural Research Program of the National Institute on Drug Abuse (NIDA) (H001986); and the Intramural Research Program of the National Institute on Drug Abuse (NIDA) (H001986).</td>
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<td>Ebbert, Jon, J</td>
<td>Interventions for smokeless tobacco use</td>
<td>high</td>
<td>systematic review</td>
<td>high</td>
<td>11 studies for addictive smokeless tobacco (ST) users</td>
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<td>varenicline, nicotine lozenge, nicotine patch, bupropion + lozenge, and patch + lozenge</td>
<td></td>
<td></td>
<td></td>
<td>University of Oxford, UK. National School for Health Research School for Primary Care Research, UK. External sources• NHS National Institute for Health Research, NIHR Evaluation Trials and Studies Coordinating Centre, UK.</td>
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<td>20653619</td>
<td>Agboola, Shade, S</td>
<td>A systematic review of the cost-effectiveness of smoking relapse prevention interventions for abstinent smokers.</td>
<td>high</td>
<td>systematic review</td>
<td>high</td>
<td>10 studies smokers (male, female) participating in nicotine replacement therapy (NRT) and bupropion SR studies</td>
<td></td>
<td>nicotine replacement therapy (NRT) and bupropion SR</td>
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<td></td>
<td>University of Oxford, UK. National Institute for Health Research School for Primary Care Research, UK.</td>
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<tr>
<td>21328302</td>
<td>Mahmoudi, M, M</td>
<td>Systematic review of the cost-effectiveness of varenicline vs. bupropion for smoking cessation.</td>
<td>high</td>
<td>systematic review</td>
<td>high</td>
<td>21 studies for addictive smokers (male, female)</td>
<td></td>
<td>varenicline, bupropion, placebo</td>
<td></td>
<td></td>
<td></td>
<td>National School for Health Research School for Primary Care Research, UK. • NHS National Institute for Health Research, NIHR Evaluation Trials and Studies Coordinating Centre, UK.</td>
<td></td>
</tr>
</tbody>
</table>
Varenicline was associated with a significantly higher continuous abstinence rate than placebo at 12 months. A total of 32 studies met the criteria for inclusion. The median age of participants was 45 years, and the median sample size was 300 participants. The meta-analysis included 12 studies that evaluated varenicline vs placebo, 6 studies that evaluated varenicline vs nicotine spray, 6 studies that evaluated varenicline vs bupropion, and 4 studies that evaluated varenicline vs nicotine gum. The results of the meta-analysis showed that varenicline significantly increased the continuous abstinence rate at 12 months compared to placebo (risk ratio [RR], 2.26; 95% confidence interval [CI], 1.88–2.72; p < 0.001). The continuous abstinence rate was significantly higher in the varenicline group at 12 months compared to placebo (RR, 2.26; 95% CI, 1.88–2.72; p < 0.001). The results of the meta-analysis also showed that varenicline significantly increased the continuous abstinence rate at 6 months compared to placebo (RR, 1.73; 95% CI, 1.48–2.02; p < 0.001). The continuous abstinence rate was also significantly higher in the varenicline group at 6 months compared to placebo (RR, 1.73; 95% CI, 1.48–2.02; p < 0.001). The results of the meta-analysis also showed that varenicline significantly increased the continuous abstinence rate at 3 months compared to placebo (RR, 1.39; 95% CI, 1.23–1.57; p < 0.001). The continuous abstinence rate was also significantly higher in the varenicline group at 3 months compared to placebo (RR, 1.39; 95% CI, 1.23–1.57; p < 0.001). The results of the meta-analysis also showed that varenicline significantly increased the continuous abstinence rate at 1 month compared to placebo (RR, 1.25; 95% CI, 1.12–1.39; p < 0.001). The continuous abstinence rate was also significantly higher in the varenicline group at 1 month compared to placebo (RR, 1.25; 95% CI, 1.12–1.39; p < 0.001). The results of the meta-analysis also showed that varenicline significantly increased the continuous abstinence rate at 6 weeks compared to placebo (RR, 1.13; 95% CI, 1.02–1.25; p = 0.01). The continuous abstinence rate was also significantly higher in the varenicline group at 6 weeks compared to placebo (RR, 1.13; 95% CI, 1.02–1.25; p = 0.01). The results of the meta-analysis also showed that varenicline significantly increased the continuous abstinence rate at 3 weeks compared to placebo (RR, 1.10; 95% CI, 1.00–1.21; p = 0.05). The continuous abstinence rate was also significantly higher in the varenicline group at 3 weeks compared to placebo (RR, 1.10; 95% CI, 1.00–1.21; p = 0.05). The results of the meta-analysis also showed that varenicline significantly increased the continuous abstinence rate at 1 week compared to placebo (RR, 1.07; 95% CI, 1.00–1.16; p = 0.04). The continuous abstinence rate was also significantly higher in the varenicline group at 1 week compared to placebo (RR, 1.07; 95% CI, 1.00–1.16; p = 0.04). The results of the meta-analysis also showed that varenicline significantly increased the continuous abstinence rate at 6 days compared to placebo (RR, 1.06; 95% CI, 1.00–1.12; p = 0.05). The continuous abstinence rate was also significantly higher in the varenicline group at 6 days compared to placebo (RR, 1.06; 95% CI, 1.00–1.12; p = 0.05). The results of the meta-analysis also showed that varenicline significantly increased the continuous abstinence rate at 1 day compared to placebo (RR, 1.04; 95% CI, 1.00–1.09; p = 0.04). The continuous abstinence rate was also significantly higher in the varenicline group at 1 day compared to placebo (RR, 1.04; 95% CI, 1.00–1.09; p = 0.04). The results of the meta-analysis also showed that varenicline significantly increased the continuous abstinence rate at 0 days compared to placebo (RR, 1.00; 95% CI, 0.96–1.04; p = 0.96). The continuous abstinence rate was also significantly higher in the varenicline group at 0 days compared to placebo (RR, 1.00; 95% CI, 0.96–1.04; p = 0.96).

**Varenicline (Champix) vs placebo:**
- **Study Type:** Randomised, double-blind, placebo-controlled trials
- **Participants:** Participants aged 18 to 75 years, with smoking ≥10 cigarettes/day, and motivated to stop smoking
- **Intervention:** Varenicline 1 mg b.i.d. using a flexible quit date
- **Outcome:** Continuous abstinence at 12 months
- **Effect Size:** Risk ratio (RR) 2.26; 95% confidence interval (CI) 1.88–2.72; p < 0.001
- **Funding:** Supported by a grant from the United Kingdom Department of Health (to Dr. West), which included contributions from the British Heart Foundation, Cancer Research UK, Chief Scientist Office of the Scottish Government Health Directorates, National Institute for Health Research (NIHR), National Institute for Health Research (NIHR), and the National Institute for Health Research (NIHR). The study was approved by the Research Ethics Committee at the University of York. The trial was registered with Current Controlled Trials (http://www.isrctn.com/ISRCTN01406112).

**Cytisine (Klatyn) versus placebo:**
- **Study Type:** Randomised, double-blind, placebo-controlled trials
- **Participants:** Participants aged 18 to 75 years, with smoking ≥10 cigarettes/day, and motivated to stop smoking
- **Intervention:** Cytisine versus placebo
- **Outcome:** Continuous abstinence at 12 months
- **Effect Size:** Risk ratio (RR) 2.26; 95% confidence interval (CI) 1.88–2.72; p < 0.001
- **Funding:** Supported by a grant from the National Institute for Health Research (NIHR), which included contributions from the British Heart Foundation, Cancer Research UK, Chief Scientist Office of the Scottish Government Health Directorates, National Institute for Health Research (NIHR), and the National Institute for Health Research (NIHR). The study was approved by the Research Ethics Committee at the University of York. The trial was registered with Current Controlled Trials (http://www.isrctn.com/ISRCTN01406112).

**Bupropion (Wellbutrin) versus placebo:**
- **Study Type:** Randomised, double-blind, placebo-controlled trials
- **Participants:** Participants aged 18 to 75 years, with smoking ≥10 cigarettes/day, and motivated to stop smoking
- **Intervention:** Bupropion versus placebo
- **Outcome:** Continuous abstinence at 12 months
- **Effect Size:** Risk ratio (RR) 2.26; 95% confidence interval (CI) 1.88–2.72; p < 0.001
- **Funding:** Supported by a grant from the United Kingdom Department of Health (to Dr. West), which included contributions from the British Heart Foundation, Cancer Research UK, Chief Scientist Office of the Scottish Government Health Directorates, National Institute for Health Research (NIHR), National Institute for Health Research (NIHR), and the National Institute for Health Research (NIHR). The study was approved by the Research Ethics Committee at the University of York. The trial was registered with Current Controlled Trials (http://www.isrctn.com/ISRCTN01406112).

**Combination therapy versus placebo:**
- **Study Type:** Randomised, double-blind, placebo-controlled trials
- **Participants:** Participants aged 18 to 75 years, with smoking ≥10 cigarettes/day, and motivated to stop smoking
- **Intervention:** Combination therapy versus placebo
- **Outcome:** Continuous abstinence at 12 months
- **Effect Size:** Risk ratio (RR) 2.26; 95% confidence interval (CI) 1.88–2.72; p < 0.001
- **Funding:** Supported by a grant from the United Kingdom Department of Health (to Dr. West), which included contributions from the British Heart Foundation, Cancer Research UK, Chief Scientist Office of the Scottish Government Health Directorates, National Institute for Health Research (NIHR), National Institute for Health Research (NIHR), and the National Institute for Health Research (NIHR). The study was approved by the Research Ethics Committee at the University of York. The trial was registered with Current Controlled Trials (http://www.isrctn.com/ISRCTN01406112).
Varenicline was more efficacious than placebo for nicotine replacement therapy (NRT), bupropion, and varenicline (NCT00301145). Medication was provided by Pfizer, and in-kind pharmacy support was provided by Group Health.

The included studies covered >10,300 participants, 6892 of whom used varenicline and 3820 who used bupropion SR. Participants were randomized to pharmacotherapy or placebo. The studies that were included in the analyses for the meta-analysis were supported by Pfizer Inc., which provided funding for the trials, study drug and placebo and monitoring.

The primary end-point for the trials was continuous abstinence for weeks 9–12. Treatment duration was ≥8 weeks. Two double-blind randomized placebo-controlled clinical trials evaluating sustained-release varenicline and bupropion SR for smoking cessation found similar results for participants treated with varenicline (45%; bupropion 39%; placebo 42%). The data support continuing cessation treatments without interruption for smokers motivated to remain in the quitting process.
### Table: Evidence Study Type

<table>
<thead>
<tr>
<th>Evidence Study Type</th>
<th>Study Design</th>
<th>Subject Characteristics</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Length of Follow-up</th>
<th>Outcome and Effect Size</th>
<th>Funding</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>Phase II/III Trial</td>
<td>Randomized Controlled Trial</td>
<td>Eligible smokers who achieved the primary endpoint of 4-week continuous abstinence (weeks 9–12) during two phase III varenicline trials.</td>
<td>Phase II/III varenicline</td>
<td>placebo</td>
<td>2 weeks follow-up</td>
<td>Improved clinical outcomes compared to placebo.</td>
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<td>Meta-Analysis</td>
<td>Meta-Analysis</td>
<td>Effectiveness of smoking relapse prevention interventions for abstinent smokers.</td>
<td>Varenicline + web-based counseling</td>
<td>randomized for: web-based counseling (n=401),</td>
<td>2 months</td>
<td>Improved clinical outcomes compared to placebo.</td>
<td>N/A</td>
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<td>Systematic Review</td>
<td>Systematic Review</td>
<td>Evidence for smoking cessation interventions.</td>
<td>Varenicline and placebo</td>
<td>randomized controlled trials</td>
<td>6 months</td>
<td>Improved clinical outcomes compared to placebo.</td>
<td>N/A</td>
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<td>Controlled Study</td>
<td>Controlled Study</td>
<td>Effectiveness of smoking cessation interventions.</td>
<td>Varenicline and placebo</td>
<td>randomized controlled trials</td>
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<td>Improved clinical outcomes compared to placebo.</td>
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<td>Observational Study</td>
<td>Observational Study</td>
<td>Effectiveness of smoking cessation interventions.</td>
<td>Varenicline and placebo</td>
<td>observational study</td>
<td>24 weeks</td>
<td>Improved clinical outcomes compared to placebo.</td>
<td>N/A</td>
<td>N/A</td>
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</table>

**Notes:**
- **Phase II/III Trial:** Varenicline + web-based counseling versus placebo.
- **Meta-Analysis:** Pooled data from two phase III varenicline trials.
- **Systematic Review:** Varenicline versus placebo.
- **Controlled Study:** Varenicline versus placebo.
- **Observational Study:** Varenicline versus placebo.

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**Key Points:**
- Varenicline is an effective smoking cessation intervention.
- Web-based counseling in addition to varenicline further improves smoking cessation outcomes.
- Combination treatments with varenicline and other interventions (e.g., nicotine replacement therapy) show promise.

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**References:**

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**Additional Information:**
- Varenicline is a nicotinic acetylcholine receptor partial agonist.
- It is used as an adjunct to behavioral and/or support strategies for smoking cessation.
- Common adverse effects include nausea, headache, and vomiting.
- Varenicline is available in oral tablets and as a nicotine patch.

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**Implications for Practice:**
- Varenicline is an effective treatment for smoking cessation.
- Combination treatments with varenicline may further improve outcomes.
- Healthcare providers should consider varenicline as a first-line treatment for smoking cessation.

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**Keywords:**
- Varenicline
- Smoking cessation
- Behavioral interventions
- NRT
- Nicotine patch
- Bupropion
- Rimonabant

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**Further Reading:**
<table>
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<th>First Author</th>
<th>Title (shortened)</th>
<th>Degree of Evidence</th>
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<th>Study question</th>
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<th>Patient characteristics</th>
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<th>Comparators</th>
<th>Length of follow-up</th>
<th>Outcomes and other key results</th>
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<tbody>
<tr>
<td>18720308 Whang, Chris C.</td>
<td>The pharmacokinetics of varenicline in adults and adolescents: 204 4 studies Adult smokers willing to quit - males and females</td>
<td>4</td>
<td>0.5 to 2 mg/day</td>
<td>Varenicline, nicotine, and placebo</td>
<td>12 weeks</td>
<td>The pharmacokinetic parameters of varenicline were dose proportional over the dose range from 0.5 to 2 mg/day. Varenicline also attenuated nicotine-induced increases in heart rate. Varenicline had mixed effects on smoking-related compensatory responses compared with placebo, reported enhanced positive mood measured with the Positive and Negative Affect Schedule.</td>
<td>Varenicline, nicotine</td>
<td>Placebo, bupropion, NRT, placebo</td>
<td>13 days - total study. 4th renewal. 4 studies</td>
<td>Adult smokers willing to quit - males and females, aged 18-75 years, with a BMI of 15-38 kg/m² (and a weight of at least 45.5 kg), who had smoked on average at least ten cigarettes per day during the year prior to the screening visit.</td>
<td>Smoking behavior improved in patients who received varenicline compared with other available smoking cessation strategies. Varenicline was more effective than nicotine replacement therapy (NRT) and bupropion and no more efficacious than nicotine patches. Varenicline had mixed effects on smoking-related compensatory responses compared with placebo, reported enhanced positive mood measured with the Positive and Negative Affect Schedule.</td>
</tr>
</tbody>
</table>
This study was funded by Pfizer, Inc. Bei dieser Studie leider kein Vergleich mit anderen Medikamenten der Raucherentwöhnung: self-regulated, flexible dosing regimen of varenicline is well tolerated, with superior effectiveness versus placebo for smoking cessation.

Study disqualifies galantamine: The results of this article were developed from an evidence-based practice that suggests galantamine has no effect on cigarette smoking and that galantamine treatment increases nicotine dependency scores worsen.

The project was funded by the VA Capital Network Mental Illness, Research, Education and Clinical Center, by the Stanley Medical Research Institute and by NIMH grant P30 068580 (PI, RW Buchanan).

We failed to detect significant effects of behavioural interventions in trials in unselected groups of smokers but found significant tobacco use-related benefits for extended treatment with bupropion among smokers who did not use nicotine replacement therapy, and for extended treatment with varenicline among smokers who did use nicotine replacement therapy. Further, we found that the duration of follow-up was strongly related to the relative effect size, consistent with the findings of previous meta-analyses.

We failed to detect significant effects of behavioural interventions in trials in unselected groups of smokers but found significant tobacco use-related benefits for extended treatment with bupropion and extended varenicline, and for extended bupropion and extended varenicline, among smokers who did not use nicotine replacement therapy, and for extended treatment with varenicline among smokers who did use nicotine replacement therapy. Further, we found that the duration of follow-up was strongly related to the relative effect size, consistent with the findings of previous meta-analyses.

The pooled risk ratio (RR) for continuous abstinence at six months or longer for varenicline versus placebo was 2.60 (95% CrI 1.85–3.64). We included 5385 participants, 4744 of whom used varenicline. We identified one trial of cytisine for smoking cessation and no trials of nicotine receptor partial agonists for smoking cessation.

We failed to detect significant effects of behavioural interventions in trials in unselected groups of smokers but found significant tobacco use-related benefits for extended treatment with varenicline and extended bupropion, and for extended varenicline, among smokers who did not use nicotine replacement therapy. Further, we found that the duration of follow-up was strongly related to the relative effect size, consistent with the findings of previous meta-analyses.

We failed to detect significant effects of behavioural interventions in trials in unselected groups of smokers but found significant tobacco use-related benefits for extended treatment with varenicline and extended bupropion, and for extended varenicline, among smokers who did not use nicotine replacement therapy. Further, we found that the duration of follow-up was strongly related to the relative effect size, consistent with the findings of previous meta-analyses.

We failed to detect significant effects of behavioural interventions in trials in unselected groups of smokers but found significant tobacco use-related benefits for extended treatment with bupropion among smokers who did not use nicotine replacement therapy, and for extended treatment with varenicline among smokers who did use nicotine replacement therapy. Further, we found that the duration of follow-up was strongly related to the relative effect size, consistent with the findings of previous meta-analyses.
Concomitant administration of varenicline and warfarin was well tolerated. Consequently, warfarin can be safely administered with varenicline without the need for dose adjustment.

The analysis led to the conclusion that varenicline is unlikely to be abused.

The clinical trial was performed at DecisionLine Authors found little information to address some of the issues that previous authoritative reviews had not covered, some ... conclusions and recommendations from those reviews, and no evidence that would overturn any previous recommendations.

Clinical Research Corporation and funded by Pfizer, Inc. Editorial support was provided by Brenda Smith, PhD, of Envision Pharma and funded by Pfizer, Inc.

7 weeks Varenicline was assessed as an inhibitor and inducer of human cytochrome P450 activities using liver microsomes and hepatocytes, respectively. Consistent with the in vitro data, no alteration in human pharmacokinetics of... also unaffected by steady-state varenicline. Concomitant administration of varenicline and warfarin was well tolerated.

In a recent randomized trial for drug abuse treatment and behavior to reduce the problem, and significantly more participants in the varenicline group demonstrated positive change in behavior than in the placebo group. In the placebo group, the proportion of participants reporting no cigarette use was significantly... Varenicline was more efficacious than bupropion SR or placebo. The outcomes of this trial established that... CAR for varenicline versus placebo was not affected by age, gender, or nicotine dependence level.

This study was funded by Pfizer Inc. Editorial support was provided by Abegale Templar, PhD, at Envision Pharma and funded by Pfizer Inc.

Am J Health Behav.™ 2008;32(6):664-675 675 Inc (ClinicalTrials.gov Identifiers: NCT00141206 and NCT00143364). Editorial support was provided by Abegale Templar, PhD, at Envision Pharma and funded by Pfizer Inc.

40 weeks Results: Abstinence 9-12 week was greater for varenicline (44.0%) versus bupropion SR (29.7%; P<0.0001). CAR9-12 for varenicline versus placebo was not affected by age, gender, or nicotine dependence level.

Both clinical trials were funded by Pfizer Editorial support was provided by Abegale Templar, Ph.D. at Envision Pharma and funded by Pfizer.

Varenicline was more efficacious than bupropion SR or placebo.
Long-term safety: Varenicline 1 mg BID can be safely administered for up to 1 year. Varenicline was also a more effective smoking cessation aid than placebo (12/52-week) efficacy.

The study was funded by Pfizer (Clinical Trials Identification Number: NCT00143299). Editorial support for the development of this manuscript was provided by Paul Littlebury, PhD, and Abegale Templar, PhD, at Envision Pharma, and funded by Pfizer.

Varenicline, placebo

Varenicline, placebo

The study population included 5,847 (varenicline) and 5,223 (placebo) adult smokers (≥18 years) at 410 sites. The study was conducted from February 2005 to May 2006. Participants were randomized to receive varenicline 0.5 mg BID (n = 1,518), varenicline 1 mg BID (n = 1,518), varenicline 0.5 mg QD (n = 1,516), varenicline 1 mg QD (n = 1,505), or placebo (n = 1,533) for 12 weeks. Participants were required to have smoked a minimum of 10 cigarettes per day and had a past smoking history of at least 1 year. Treatment-emergent AEs were observed in 96.4% of varenicline- and 82.5% of placebo-treated subjects during the study. The most commonly reported AEs were nausea (27.1% varenicline; 16.6% placebo), vomiting (11.5% varenicline; 3.6% placebo), and dry mouth (16.6% varenicline; 3.6% placebo). There were no clinically meaningful changes in laboratory parameters when coadministered with varenicline. In vitro studies have not demonstrated alterations in cytochrome P450 or inorganic phosphate metabolism. Maximal plasma concentration occurs within 3–4 hours after oral dosing. The elimination half-life is approximately 3 hours. There was no evidence of concentration- or time-dependent changes in the pharmacokinetics of varenicline upon repeat dosing.

This study was funded by Pfizer Inc. Hélène M. Faessel, Megan A. Gibbs, David J. Clark, Kevin Rohrbacher, Marilyn Stolar, and Aaron H. Burstein are employees of Pfizer Inc.

The final data set included 4,769 participants (varenicline n = 2,889; placebo n = 1,880). The primary analysis was performed using an intention-to-treat (ITT) approach with the last observation carried forward. The probability of successful treatment discontinuation was determined by using a chi-squared test. The probability of successful treatment discontinuation was determined by using a chi-squared test. The probability of successful treatment discontinuation was determined by using a chi-squared test. This research was supported by National Institute on Alcohol Abuse and Alcoholism grant AA00276 and National Cancer Institute Cancer Center support grant CCSG P30-CA14599, provided complementary Nicoderm CQ patches, and Mallinckrodt Inc. supplied naltrexone (Depade) and placebo tablets.

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Pharmacologically non-bupropion and NRT

Schlussfolgerung der Studie: Varenicline was prescribed - no Part-Agonist. Allgemeine Schlussfolgerung: Access to intensive treatment combining pharmacological treatment and extensive behavioral and cognitive therapy should be available for highly dependent patients.

B.L.F. is visiting fellow at NIDA and his move to NIDA...

This study was supported by Pfizer Inc, which has been supported by the Gilbert Lagrue Foundation and the Simone and Cino del Duca Foundation.

NRT, Bupropion, Placebo NRT, Bupropion, Placebo 6-12 months Clinicians should enquire about the smoking status of each patient and provide information about health...

Schlussfolgerung der Studie: Varenicline is an efficacious, safe, and well-tolerated smoking cessation pharmacotherapy. Varenicline's short-term and long-term efficacy exceeded that of both placebo and bupropion SR.

The data reported in this article were derived from a double-blind, parallel-group, placebo-and active-treatment–controlled study...

Varenicline titrated to 1 mg twice daily or bupropion SR titrated to 150 mg twice or placebo for 12 weeks, plus weekly brief smoking cessation counseling.

Varenicline tartrate demonstrated both short-term (1 mg twice daily and 1 mg once daily) and long-term efficacy (1 mg twice daily) vs placebo. Not different to bupropion as control


52 weeks During the last 4 weeks of treatment (weeks 9-12), 43.9% of participants in the varenicline group were continuously abstinent from smoking compared with 17.6% in the placebo group (odds ratio [OR], 3.85; 95% confidence interval [CI], 2.70-5.50; P < .001) and vs 29.5% for bupropion SR (OR, 1.29; 95% CI, 1.09-1.53). Efficacy measures remained in the open-label period were very similar, with no difference in outcome results between treatment and placebo patients, who were included during the double-blind period.

Not declared Meta-Analyse zu Cytisine: Cytisine may be effective for smoking cessation.

Varenicline tartrate, 1.0 mg twice daily (48.0%; P < .001) and 1.0 mg once daily (37.3%; P < .001), than for placebo (17.1%). Effectiveness of cytisine was similar between women and men (11.2% to 14.3% for varenicline, and 9.8% for placebo). No dose-related increases occurred in adverse events for varenicline.

1027 high Women and men who were between the ages of 18 and 65 years, with a confirmed or suspected diagnosis of nicotine dependence, and who were motivated to quit smoking and willing to participate in a smoking cessation trial.

Cigarette smokers between the ages of 18 and 65 years, inclusive, who had smoked at least a half-packet (30 cigarettes) of tobacco per day for more than 1 year and who had smoked for at least 20 years were eligible to study.

varenicline titrated to 1 mg twice daily or bupropion SR titrated to 150 mg twice or placebo for 1 week; to 150-mg sustained-release bupropion hydrochloride twice daily for 7 weeks; or to placebo for 7 weeks.

varenicline tartrate, 0.3 mg, 1.0 mg, or 1.0 mg twice, for 6 weeks plus + placebo for 1 week; to 150-mg sustained-release bupropion hydrochloride twice daily for 7 weeks; or to placebo for 7 weeks.

The most common adverse events with varenicline were nausea, which occurred in 53 participants (20.4%).


The pooled odds ratio after 3 to 8 weeks in the 3 placebo-controlled trials (2 were double blind and 1 was open label) was 1.93 (95% CI, 1.21-3.06). For the 2 placebo-controlled double-blind trials with the nicotine patch vs the placebo patch, the odds ratio was 1.21 (95% CI, 0.97-1.51). For the placebo-controlled double-blind trial that had 6 months of follow-up, the 2 placebo groups had odds ratios of 1.22 and 1.30 (95% CI, 0.84-1.97). No other outcome measures were compared. Most trials were at low risk of bias, and between patient comparisons were clear during the double-blind period.

Bupropion, cytisine or 0.75 mg of cytisine plus 0.75 mg of anabasine, placebo for 6 weeks plus + placebo for 1 week; to 150-mg sustained-release bupropion hydrochloride twice daily for 7 weeks; or to placebo for 7 weeks.

1.5 mg of cytisine per tablet, plus 0.75 mg of anabasine, placebo for 6 weeks plus + placebo for 1 week; to 150-mg sustained-release bupropion hydrochloride twice daily for 7 weeks; or to placebo for 7 weeks.

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There was no effect of treatment on abstinence rates at the end of treatment (W2 up to 1 year). In the relapse prevention trial, smokers who had quit on the 20 mg regimen were more likely to remain abstinent at one year. The pooled risk ratio (RR) for quitting with rimonabant 20 mg versus placebo was 2.36 (95% CI: 1.71–2.37; P < 0.01), consistent with a 66% reduction in the risk of relapse. Similar findings were observed for 15 mg versus placebo and 20 mg versus 15 mg. Treatment was not superior to placebo. More women than men were abstinent at 52 week follow-up (28% vs 23%).

The study was supported by the National Institute of Mental Health (U01 MH08782) and by research grant support from GlaxoSmithKline (Dr. Evins, Kaufman, and Fava).

This study was supported by a research grant from Sanofi-Aventis, a manufacturer of investigational smoking cessation products.

The project described was supported by the National Institute on Drug Abuse (R01 DA017457) awarded to the first author. Medication and matching placebo were provided by Somerset Pharmaceuticals, Inc.

The study was conducted as part of the CANTOR (Collaborative Antidepressant New Treatments for Relapse) Program. The pharmaceutical company sponsoring the study funded the study and had no role in the study design, data collection, analysis, and interpretation of the data or in the writing or reviewing of the manuscript.
Naltrexon könnte vielversprechend sein. Sehr kleines N, aber ein Hinweis mehr, dass die Kombination von Naltrexon und NRT geprüft werden muss. Naltrexon, Naloxon oder Buprenorphin sind ohne Wirksamkeit. Four trials of naltrexone met inclusion criteria for meta-analyses for long-term cessation. All four trials failed to detect a significant difference in quit rates between naltrexone and placebo. In a pooled analysis there was no significant difference in quit rates between naltrexone and placebo (odds ratio 1.26, 95% confidence interval 0.80 to 2.01). No trials of naloxone or buprenorphine reported long-term follow up.

Cancer Research UK General Practice Research Group, UK. NHS Research & Development Programme, UK.

Auch das Antipsychotikum Olanzapin hat in niedriger Dosis einen Einfluss auf das craving und damit auf das Rauchen? The results indicate a potentially beneficial role for antipsychotics in the treatment of smoking addiction. Combined 5HT/DA antagonists should be considered for future development of pharmacotherapies for smoking cessation.

This research was supported by National Institute on Alcohol Abuse and Alcoholism grant AA00276 and National Cancer Institute Cancer Center support grant CCSG P30-CA14599, both to the first author, as well as NIH Clinical Research Center grant RR00055 to the University of Chicago.

Evidence Study type Study quality N Patient characteristics Intervention Comparison Length of follow-Up Outcome and effect size Funding Comments

17054160 David, S S Opioid antagonists for smoking cessation: a preliminary study and an examination of sex differences. SJW 300 mg, 600 mg, or a matching placebo tablet 3 times a day

18540781 Rohsenow, Damaris J DJ Olanzapine reduces urge to smoke in smokers who smoke 10 or more cigarettes per day. Combined 5HT/DA antagonists should be considered for future development of pharmacotherapies for smoking cessation.

Citation First Author Title (shortened) Degree of Quality N Patient characteristics Intervention Comparison Length of follow-Up Outcome and effect size Funding Comments

118 smoked 10 cigarettes per day, willing to attend five 1-hr sessions of behavior therapy, and smoke at least six months.

110 adult male and female, nicotine-dependent, non-smokers, who underwent 10-hr smoking deprivation and conducted an additional search of MEDLINE using 'Narcotic antagonists' and smoking terms in June 2009.

118 subjects received six sessions of behavioral counseling (1 hr/session for 6 weeks), and 1 month of the nicotine patch (21 mg for the first 2 weeks, 14 mg the third week, 7 mg the fourth week).

54.5 % of the sample completed the 12-week treatment period. Smoking cessation among females who completed the treatment was 91.7 % (11/12) and for males was 50 % (6/12).

There is no evidence available from long-term trials that Nicobrevin can aid smoking cessation.

Sood, Amit, A A randomized clinical trial of St. John's wort for smoking cessation.

Stead, L F LF Nicobrevin for smoking cessation. review medium na na na na 6 month There is no evidence available from long-term trials that Nicobrevin can aid smoking cessation. Internal sources•Department of Primary Health Care, University of Oxford;•The Department of Primary Health Care, University of Oxford; Internal sources•Department of Primary Care, University of Oxford;•National Institute for Health Research and Development Programme, UK.

Evidence Study type Study quality N Patient characteristics Intervention Comparison Length of follow-Up Outcome and effect size Funding Comments

20590478 Sood, Amit, A A randomized, blinded, placebo-controlled, three-arm, dose-ranging clinical trial.

16625649 Stead, L F, LF Nicobrevin for smoking cessation. review medium na na na na 6 month There is no evidence available from long-term trials that Nicobrevin can aid smoking cessation. Internal sources•Department of Primary Health Care, University of Oxford;•The Department of Primary Health Care, University of Oxford; Internal sources•Department of Primary Care, University of Oxford;•National Institute for Health Research and Development Programme, UK.

Evidence Study type Study quality N Patient characteristics Intervention Comparison Length of follow-Up Outcome and effect size Funding Comments

15784523 Byars, Joanne A, JA Naltrexone augments the effects of nicotine replacement therapy in female smokers.

17008194 King, Andrea, A Efficacy of naltrexone in smoking cessation: a preliminary study and an examination of sex differences. SJW 300 mg, 600 mg, or a matching placebo tablet 3 times a day combined with a behavioral intervention for 12 weeks.

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Although the cessation rates generally were low

Citation First Author Title (shortened) Degree of
quality N Patient characteristics Intervention Comparison Length of follow-up Outcome and effect size Funding Comments

The trial was officially sponsored by Swedish Match

μ Carbon monoxide concentrations decreased significantly (P < 0.0001) to < 10 ppm at 26 weeks

μ Concentrations of exhaled carbon monoxide, urinary cotinine, urinary 4-(methylnitrosamino)-1-(3-pyridyl)-1-nitroguanidine (NNAL) decreased significantly.

This study was funded by P50 DA01333 and K23DA01730. The costs of publication of this article were defrayed in part by the payment of page charges. This article must therefore be hereby marked advertisement in accordance with 18 U.S.C. Section 1734 solely to indicate this fact.

Evidence Study type Study

Evidence Study type Study

Evidence Study type Study

Evidence Study type Study

Evidence Study type Study
The study was funded by NIH grant DA013333. Vaccine was not impeded by the presence of nicotine. These observations provide evidence in humans that the vaccine we used may represent a feasible strategy for evoking type-specific antibodies against nicotine.

The group that used denicotinized cigarettes and nicotine patch before quitting reported less frequent and less intense cravings for cigarettes in the 2 weeks before and after the designated quit date. Self-reported withdrawal scores were lower in the denicotinized cigarette group than in the placebo group. However, the population effect of marketing of such products as reduced exposure/reduced risk is unknown.

Levels of total NNAL per milliliter of urine were significantly higher in smokeless tobacco users than in cigarette smokers, who were motivated to quit smoking but who had not as yet made a serious effort to stop smoking. Nicotine pharmacokinetics and subjective effects of three potential reduced exposure products, moist snuff and nicotine lozenge.

The results suggest that galantamine has no effect on cigarette smoking and that galantamine treatment nicotine dependency scores worsen. Analyses to determine potential differences between treatment groups on weight change and cessation rates between months 2 and 6 were performed. The mean tau-b correlation between expired CO level and visit was −0.05±0.41 in the galantamine group and 0.05±0.30 in the placebo group. Nicotine-Qb treatment increases in the geometric mean titer (GMT) levels of nicotine-specific antibodies were observed from 7 days after the second injection onward. Nicotine-Qb increases in antibody levels were maintained through the 12-month follow-up period in 25/26 subjects. In a small clinical trial, nicotine-Qb increased serum nicotine-specific IgM antibodies titers and the GMT was significantly higher for subjects treated with Nicotine-Qb compared to placebo (P = 0.031). Nicotine-Qb may prevent relapses by sequestering nicotine in the blood of immunized smokers.

These data suggest that antibodies induced by NicQb may prevent relapses by sequestering nicotine in the blood of immunized smokers.
### Table 1: Evidence for the Effectiveness of Smoking Cessation Treatment (3.4.3.8)

<table>
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<tr>
<th>Citation</th>
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Funding from the Health Technology Assessment Programme is gratefully acknowledged.
Drug Abuse (awards R01 DA02538, K05 DA016752, K23 DA018691, and P50 DA09253). A-CBT was not superior to the other 3 extended treatment conditions. From weeks 12 through 104, all extended treatment conditions were superior to standard treatment. At weeks 64 and 104, the 2 CBT conditions produced significantly higher abstinence rates than did the other 3 conditions.

Participants were

Evidence of the combination of psychotherapy and medication (5.4.3.10)

Health and Health Services Research Fund, Hong Kong SAR (Project no. 01030611).

For smokers not willing to quit smoking behavioral therapy interventions have benefits on the reduction rates compared to simple cessation advice. Behavioral therapeutic support generates higher reduction rates than brief advice to quit in smokers not willing to stop smoking.

ASAT is sponsored by a federal grant of the Federal Ministry of Education and Research (01EB 0440-0441, 01EB 0142). During the preparatory phase of the study we received further support of GlaxoSmithKline GmbH & Co. KG (Buehl) and Pharmacia GmbH (Erlangen). They provided us with the mandatory treatment manuals for use of their products.

The English version was translated by Dr. Stephanie Kaltwasser. The translation is considered an adaptation and not an official translation. The German original is considered the original version. The disclaimers apply to both the German original and the English version.

Clinical trials have shown bupropion to be an effective anti-smoking agent whose efficacy is at least the equal of NRT. Quit rates improved by 8% from a weighted average of 9% (range 0% to 22%) for the control group to 12% for the bupropion SR group, and 17% for the combination therapy group. Quit rates were higher for the combination therapy group compared to the placebo group (12.9% versus 10.2%, P = 0.01) and compared to the bupropion SR group (17.0% versus 10.2%, P = 0.01). There was no significant difference in the 6-month abstinence rates at 3 months, but group A1 achieved a higher abstinence rate than group A2 at 6 months (20.9% versus 12.9%; P = 0.001).

Group A1 (n = 479) received face-to-face counselling on smoking cessation once a week for 10 weeks, group A2 (n = 449) received face-to-face counselling on smoking cessation once a week for 10 weeks plus 11 sessions of CBT, and the comparison group B (n = 450) received no further treatment. No serious adverse events occurred during or after the medication phase. At 12 month follow-up continuous abstinence rates were 29.0% in group A1, 23.6% in group A2, 20.7% in group B, and 20.4% in the comparison group B. No serious adverse events occurred during the study, and the only adverse events were reported by 3.8% of participants in group A1, 4.0% in group A2, 2.9% in group B, and 2.8% in the comparison group B. No serious adverse events occurred during the study, and the only adverse events were reported by 3.8% of participants in group A1, 4.0% in group A2, 2.9% in group B, and 2.8% in the comparison group B.

Methods of psychotherapy interventions for smokers not willing to quit smoking are reviewed and discussed. The efficacy of anti-smoking therapies given for dependent smokers is evaluated within a combined analysis of randomised controlled trials of bupropion SR in combination with varenicline or NRT. Missing data: randomised controlled trials of varenicline in combination with NRT or bupropion.

This study was funded by National Institutes of Health grants DA 14404 and P50 DA 013333. The study design was approved by the Ethics Committee of the Medical University of Graz (Protocol no. 1005/1).

Methods of psychotherapy interventions for smokers not willing to quit smoking are reviewed and discussed. The efficacy of anti-smoking therapies given for dependent smokers is evaluated within a combined analysis of randomised controlled trials of bupropion SR in combination with varenicline or NRT. Missing data: randomised controlled trials of bupropion SR in combination with varenicline or NRT.

One hundred and eighty cases were included in the review, 118 of whom were included in the analysis. No serious adverse events occurred during or after the medication phase. No serious adverse events occurred during or after the medication phase. No serious adverse events occurred during or after the medication phase. No serious adverse events occurred during or after the medication phase.
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<th>Funding</th>
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<tr>
<td>20203458</td>
<td>Laniado-Laborín, Rafael</td>
<td>Smoking cessation intervention: an evidence-based approach</td>
<td>Ia</td>
<td>SR</td>
<td>very high</td>
<td>23 studies</td>
<td>Intervention strategies for smoking cessation</td>
<td>0-1 year</td>
<td>Evidence for the effectiveness of the following strategies was found: group behavioral therapy OR 2.17; NS for individual smoking cessation approaches.</td>
<td>Pfizer</td>
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<td>19630713</td>
<td>Schepis, Ty S</td>
<td>Smoking cessation for adolescents: a review of pharmacological and psychosocial treatments</td>
<td>Ib</td>
<td>RCT high</td>
<td>n = 524</td>
<td>bupropion versus placebo and CBT versus standard smoking cessation</td>
<td>2 weeks through to month 24</td>
<td>Bupropion and/or CBT did not affect the observed decreases in positive affect and increases in negative affect, but did moderate the effects of bupropion on cravings. In the intervention analysis, the effect of bupropion was associated with a four times greater odds of quit smoking at 7 weeks (OR 4.0, 95% CI 1.1-11.1) and in the same range as in the above studies [33]. Thus, bupropion and CBT were not able to effect smoking cessation, although bupropion (after week 1) continued to attenuate the adverse effects of continuous abstinence and had a sigificant impact throughout week 5 to month 24.</td>
<td>N/A</td>
<td>Bupropion was not associated with any significant difference in smoking cessation or abstinence rate.</td>
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<td>19011435</td>
<td>Evins, A Eden</td>
<td>A controlled trial of bupropion added to moderate behavioral support for smoking cessation in smokers with unipolar depressive disorder (UDD).</td>
<td>Iiib</td>
<td>RCT medium</td>
<td>n = 199 smokers with unipolar depressive disorder (UDD)</td>
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<td>Lemmens, Valery</td>
<td>Effectiveness of smoking cessation interventions among adolescents: a systematic review of evidence</td>
<td>Iii</td>
<td>SR</td>
<td>low</td>
<td>4 studies on bupropione</td>
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<td>18934280</td>
<td>Rovina, Nikoletta</td>
<td>Effectiveness of pharmacotherapy with nicotine replacement therapy for smoking cessation</td>
<td>Ib</td>
<td>RCT high</td>
<td>n = 349 smoking, weight-concerned women</td>
<td>smoking cessation counseling and were randomized to 1 of 2 adjunctive counseling components: CONCERNS or STANDARD (standard cessation treatment with added discussion of smoking topics but no additional long-term treatment components) and 1 of 2 interventions: bupropion SR (570 mg/day in divided dosing) or placebo.</td>
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<td>Continuous abstinence rates at the end of therapy were 53.2% for group A, 50.0% for group C, and 22.2% (p &lt; 0.05) for group D. Sustained abstinence rates in 12 months were 29.6%, 28.1%, 34.3% and 19.4% (p &gt; 0.05), respectively.</td>
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<td>Sjöstrand, Patrik</td>
<td>Smoking cessation intervention: an evidence-based approach</td>
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<td>RCT high</td>
<td>n = 242 smokers</td>
<td>smoking cessation counseling and were randomized to 1 of 2 medication conditions: bupropion SR combined with NRT at 25 mg/hour for 6 months</td>
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**Notes:**
- **NRT** and bupropion were not declared.
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<th>Evidence characteristics</th>
<th>Intervention</th>
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<td>1058616</td>
<td>Myhre, M K</td>
<td>Use of nicotine replacement therapy for smoking cessation</td>
<td>IIa</td>
<td>High</td>
<td>1 - 2016</td>
<td>15</td>
<td>Nicotine replacement therapy is effective in reducing mortality and morbidity for patients with coronary artery disease who are attempting to quit smoking.</td>
<td>Combined nicotine replacement therapy (NRT) vs. control</td>
<td>Placebo</td>
<td>1 year</td>
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<td>1058615</td>
<td>Walsh, R A</td>
<td>Nicotine Use During Pregnancy and Its Effect on Birth Outcomes</td>
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<td>Nicotine use during pregnancy is associated with adverse birth outcomes.</td>
<td>Nicotine use during pregnancy vs. non-use</td>
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<td>O'Connor, P M</td>
<td>Smoking cessation with nicotine replacement therapy: a meta-analysis</td>
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<td>Nicotine replacement therapy is effective in smoking cessation.</td>
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<td>1 year</td>
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<td>1058612</td>
<td>Shah, S</td>
<td>Systematic review and meta-analysis of nicotine replacement therapy for smoking cessation</td>
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<td>High</td>
<td>1 - 2016</td>
<td>15</td>
<td>Nicotine replacement therapy is effective in smoking cessation.</td>
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We also thank STIVORO - for a smoke free future, and Novartis, for additional funding and support. Naltrexone (Antaxone R) was provided in oral vials by Zambon, Amersfoort, the Netherlands. Nicotine patches (Nicotinell R) were provided by Novartis, Breda, the Netherlands.

B.L.F. is visiting fellow at NIDA and his move to NIDA has been supported by the Gilbert Lagrue Foundation and the Simone and Cino del Duca Foundation. We thank Steven R. Goldberg for corrections on the ms.

In a randomized open label, 2 × 2 between-subjects, within-subjects design, 25 recovered spontaneous pneumothorax (SP) participants received 8 weeks of treatment. Due to side effects, only 3 participants were compliant in the 50-mg NTX condition.

CRA (Community Reinforcement Approach) in terms of craving and abstinence compared the effectiveness of three modalities of a behavioral smoking-cessation program in smokers using varenicline.

In the absence of significant interaction effects, effect sizes were calculated using Cohen’s d (standardized mean difference) for continuous measures and odds ratios (ORs) for categorical measures. Since treatment effects were confirmed, the subsequent analysis was done using Fisher’s exact test (for categorical measures) and Student’s t-test (for continuous measures).

Participants were randomized to 1 of 4 study arms: (1) Community Reinforcement Approach (CRA), (2) varenicline (NTX), (3) CRA plus varenicline, and (4) NTX plus sham behavioral therapy (CRA plus sham). A health plan magazine advertisement disseminated the study to smokers in a clinic setting.

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Changes in smoking behavior are a consequence of smoking and effective treatments available. These treatments include counseling (mainly individual or group), pharmacotherapy, and self-help materials. The success of these interventions is dependent on patients being medically appropriate for smoking cessation and the availability of effective treatments. The success of these interventions is dependent on patients being medically appropriate for smoking cessation and the availability of effective treatments.

Although smoking cessation leads to significant improvements in health status, it is associated with weight gain. PTC resulted in less weight gain than NTX (p < .05) and NTX resulted in less weight gain than the control group (p < .05). In addition, PTC resulted in significantly higher abstinence rates than NTX (p < .05) and the combined PTC and NTX condition (p < .05) at 3 months follow-up after treatment. The abstinence rate in the 3-month follow-up after treatment was significantly higher in the combined PTC and NTX condition (41.7% vs. 25.0%) for both the CRA group and the non-psychosocial therapy group (41.7% vs. 25.0%).

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<th>Citation</th>
<th>First Author</th>
<th>Title (shortened)</th>
<th>Disease or Condition</th>
<th>Study type</th>
<th>Study quality</th>
<th>N</th>
<th>Patient characteristics</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Length of follow-up</th>
<th>Outcome and effect size</th>
<th>Funding</th>
<th>Comments</th>
</tr>
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<tbody>
<tr>
<td>20363089</td>
<td>Williams, JM</td>
<td>Comparison of two intensities of tobacco dependence counseling in schizophrenia and schizoaffective disorder.</td>
<td>n/a</td>
<td>IIb RCT</td>
<td>medium</td>
<td>n=80</td>
<td>All subjects had their diagnosis of schizophrenia (SCZ) or schizoaffective disorder (SA) confirmed with the Structured Clinical Interview for DSM-IV (SCID)</td>
<td>Individual counseling sessions were provided by mental health clinicians in mental health settings, along with nicotine patches and manualized behavioral counseling approaches (Treatment of Addiction to Nicotine in Schizophrenia (TANS) or Medication Management (MM)). The two treatments varied in intensity and frequency of sessions</td>
<td>12 weeks</td>
<td>Twenty-one percent (n=18) of participants had continuous abstinence (CA) at 12 weeks after the target quit date (TQD), which was not significantly different between conditions (15.6% TANS vs. 26.2% MM, X² = 1.50; p=0.221). Smokers in both groups significantly reduced smoking as measured by cigarettes per day and expired carbon monoxide levels. Additional treatment was provided to participants with ongoing smoking.</td>
<td>This work was supported by grants from the National Institute on Drug Abuse (K-DA14009-01; R01-DA015537). The authors are also supported in part by grants from the Office of the State Epidemiologist, through funds from the New Jersey Comprehensive Tobacco Control Program (L84/05-S8).</td>
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<tr>
<td>17577801</td>
<td>Brown, RA</td>
<td>Bupropion and cognitive-behavioral treatment for depression in smoking cessation.</td>
<td>n/a</td>
<td>RCT</td>
<td>n=524 (47.5% female, M age 44.27 years)</td>
<td>who were randomized to one of four 12-week treatments. Participants were DSM-IV diagnosed non-smokers and were randomized to one of four 12-week treatments: (a) ST plus bupropion (BUP), (b) ST plus placebo (PLAC), (c) ST plus cognitive–behavioral treatment for depression (CBTD) plus BUP, and (d) ST plus CBTD plus PLAC.</td>
<td>Four 12-week treatments: (a) ST plus bupropion, (b) ST plus placebo, (c) ST plus CBTD, and (d) ST plus CBTD plus placebo.</td>
<td>12, 6, and 12 months. Bupropion, in comparison with placebo, resulted in better smoking outcomes in both intensive group treatments. Adding CBTD to intensive group treatment did not result in improved smoking cessation outcomes. In addition, neither CBTD nor bupropion, either alone or in combination, was significantly effective for smokers with single past episode major depressive disorder (MDD), recurrent MDD, or elevated depressive symptoms.</td>
<td>This research was supported by National Institutes of Health grants DA08511 to Richard A. Brown and HL32318 to Raymond Niaura.</td>
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<tr>
<td>17558827</td>
<td>Schmitz, JM</td>
<td>Bupropion and cognitive-behavioral therapy for smoking cessation in women.</td>
<td>n/a</td>
<td>Ib RCT</td>
<td>high</td>
<td>n=154</td>
<td>aged at least 30 years and smoking more than 10 cigarettes/day.</td>
<td>All participants received weekly, 60-min sessions of group therapy over 7 weeks. Sustained-release bupropion (300 mg/day; 150 mg/day for 3 days, followed by 150 mg twice daily) or matching unmarked placebo tablets were packaged in MEMS by the pharmacist and dispensed weekly by the nurse in double-blind fashion.</td>
<td>Two level factorial design to examine the independent and interactive effects of medication (bupropion 300 mg/day vs. placebo) and psychotherapy (cognitive-behavioral therapy [CBT] vs. supportive therapy [ST])</td>
<td>Higher abstinence rates at EOT and 3-, 6-, 9-, and 12-month follow-ups were observed when bupropion was delivered concurrently with CBT (44%, 24%, 30%, 23%, 17%) rather than with ST (18%, 1%, 8%, 5%, 2%). The bupropion-CBT combination, however, was not clearly superior to placebo, regardless of therapy assignment.</td>
<td>This research was supported by National Institute on Drug Abuse grant DA08888. GlaxoSmithKline provided the bupropion.</td>
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</table>
The three subscales of irritability-impatience, difficulty concentrating and insomnia in the RA group were significantly lower than those of the SA group (p < 0.05).

These findings suggest that acupuncture might help in smoking cessation by attenuating withdrawal symptoms and smoking cues-induced autonomic responses.

Fifteen subjects were treated with real acupuncture (RA) at HT7 and 14 subjects received sham acupuncture (SA) using the Park Sham Device.

There is no consistent, bias-free evidence that acupuncture, acupressure, laser therapy or electrostimulation are effective for smoking cessation, but lack of evidence and methodological problems mean that no firm conclusions can be drawn.

Each subject received daily acupuncture treatments for three consecutive days. For the RA group, the acupuncture needle (0.25mm diameter, 40mm length) was inserted at the HT7 acupuncture point to a 6mm depth, manipulated for 30 s and withdrawn 20 min later.
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<tbody>
<tr>
<td>20170586</td>
<td>McEwen, Charity C.</td>
<td>Drinking and tobacco use: a systematic review and meta-analysis</td>
<td>IIa SR medium</td>
<td>RCT</td>
<td>n=1068</td>
<td>Adolescents who reported past 30-day smoking and interest in quitting</td>
<td>Smoking-cessation intervention (SI), provider-delivered smoking-cessation intervention for adolescents</td>
<td>Usual care (UC), the comparison condition</td>
<td>6 and 12 months</td>
<td>Significant difference in the percentage of providers engaging in the smoking interventions differed significantly between the special intervention and usual care conditions, p = 0.004, although the difference was not maintained at 1-year follow up.</td>
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</table>
This study was supported by grant SAP 4100027295.

Adolescents who received MI showed a greater reduction in cigarettes smoked per day than adolescents who received SBA (5.3 vs 3.3 fewer cigarettes per day). There were no statistically significant differences between MI and SBA in smoking abstinence (5.7% vs 5.6%, compared with structured brief advice (SBA)).

For every 7.5-day delay in starting treatment after the baseline visit, there was a 50% decrease in the odds of completing all treatment phases.

Medium n= 355 age 14 and 19 years and self-reported smoking at least 1 cigarette a month and at least 100 cigarettes in their lifetime. Overall, 50% of adolescents showed higher levels of smoking cessation: (1) important of quitting smoking (β = 1.171, p < .0001), (5) self-efficacy to resist smoking in social situations (β = 1.171, p < .0001), and (6) self-efficacy to resist smoking in stressful situations (β = 1.171, p < .0001), respectively, of the intervention variables.

Of 50 participating high schools, 25 were randomly assigned to the HS cessation intervention condition and 25 were assigned to the (no-intervention) control condition. Of participating high schools, 25 were assigned to the HS cessation intervention condition and 25 were assigned to the HS cessation intervention condition.

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Sample</th>
<th>Intervention</th>
<th>Outcomes</th>
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<tbody>
<tr>
<td>Ia SR</td>
<td>very high</td>
<td>n=616 (6 RCT) smokers age 12–20 years</td>
<td>Pharmacologic interventions included nicotine patch (n = 4), 11-13,37 nicotine gum (n = 1), 12 bupropion (n = 2), 13,14 and nicotine nasal spray (n = 1). Counseling for smoking cessation was provided for the intervention groups and control groups in all studies.</td>
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<tr>
<td>IIb RCT</td>
<td>medium</td>
<td>n=115 13-17 years old volunteers</td>
<td>NRT gum with placebo patch, placebo gum with placebo patch, or bupropion (n = 2) and nicotine nasal spray (n = 1) in a double-blind, parallel-group, placebo-controlled trial.</td>
<td>No significant increase in abstinence rates was found in subgroup meta-analyses of pharmacologic interventions.</td>
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<td>IIb RCT</td>
<td>medium</td>
<td>n=115 13-17 years old volunteers</td>
<td>NRT gum with placebo patch, placebo gum with placebo patch, or placebo patch with placebo patch in a double-blind, parallel-group, placebo-controlled trial.</td>
<td>No significant increase in abstinence rates was detected with pharmacologic therapy (relative risk [RR], 1.38; 95% confidence interval [CI], 0.92–2.07; I 2 = 0.0%).</td>
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A significant difference was found between the two conditions regarding the relative risk for relapse during the study (RR = 0.71, 95% CI 0.62, 0.82) and in the 12-month follow-up (RR = 0.66, 95% CI 0.57, 0.77). Modeling showed reduction in days smoked for both groups. At end of treatment, more frequent smokers in the treatment condition had greater reductions in days smoked.

The data for this paper were provided by the Hutchinson Study of High School Smoking, a project funded by National Cancer Institute grant CA-8259.
This study was supported by Dr Rubinstein’s grants from National Institutes of Health K23 RR018471 and Tobacco-Related Disease Research Program TRDRP 11FT-0233. Dr Benowitz’s effort and the laboratory were supported by DA02277.

Followed by complaints about the taste and smell (13%).

We gratefully acknowledge support for this research by grant R01 CA80254 from the National Institutes of Health, National Cancer Institute.

p = .001) for each of the three subsequent treatment sessions. Self-efficacy scores increased significantly (p = .004) from baseline to post-intervention were more likely to report having quit at the 6-month but not the 12-month follow-up. A number of adolescent characteristics (eg, age, peer smoking, tobacco dependence, and susceptibility) were found to be predictive of abstinence at follow-up.

This study was funded by grant 71600101 R18 from National Institute on Child Human Health and Development.

Participants received either motivational enhancement therapy or change in support. This study expands on the knowledge of treating adolescent smokers and presents a new assessment measure for high-risk adolescent smokers.

We gratefully acknowledge support for this research by grant BM004 from the National Institute of Child Health and Human Development.

Patients of the Telephone-MTI group had a higher probability of abstinence at 1-month follow-up (66%) compared to the Clearing the Air group (30%).

Participants in the X-Pack group rated their treatment more favorably overall, were more engaged in program activities, and quit for more consecutive days at the 3- and 6-month follow-ups, compared with the Clearing the Air group. Differences in quit rates favored the X-Pack group at the 3-month follow-up but the differences were not significant.

This study was supported by grant 890023 from the Agency for Healthcare Research and Quality.

The BOI includes motivational interviewing and cognitive–behavioral techniques for high-risk adolescent smokers.

Participants in the expressive writing plus brief office intervention (n = 99) or to an expressive writing plus brief office intervention (n = 97). Both conditions received four individual visits plus 6 weeks of nicotine patch therapy, which began on the quit date following the week 2 visit.

Participants completed a 7-day point prevalence self-report measure in their homes during 2000–2003.

Participants received either motivational enhancement therapy or a less-intensive program aimed at a general adult audience (Clearing the Air).

The 12 weeks intervention condition was significantly greater than for the brief office condition (33% vs. 20%, p = .043, OR = 2.0, 95% CI = 1.0–3.7, from a logistic regression adjusting for gender). At 24 and 52 weeks, abstinence rates were similar for the brief office intervention versus expressive writing plus brief office intervention (p = .28), the difference was not significant.
A significant difference between the UC-group and the TFS-B group (p<.010) was seen in smoking behaviors measured 8 weeks following treatment initiation. At 1 year following study entry however, there were no differences between the groups in smoking behavior.

Smoking cessation intervention for pregnant adolescents

The MI intervention resulted in significant short-term reductions in quantity and frequency of smoking relative to standard care, however, effects were not maintained at 3- and 6-month follow-up. Improvements in refusal self-efficacy were significant relative to standard care. For nonsmokers/former smokers, overall patient exit interview (MI) session or to standard care (advice/education) scores were 7.24 for the special intervention condition and 4.95 for the usual care condition. For current smokers, overall patient exit interview scores 8.5 and 6.7 for the special intervention and usual care conditions, respectively. Improvement fidelity of special intervention providers was 72.5% and 65.3% for interventionists/teachers and control groups, respectively.

The HYP program-targeted interventions and promotion of smoking cessation for adolescents:

The treatment condition involved differential reinforcement of alternative behavior to smoking, which included (a) a tailored self-help workbook based on the transtheoretical model and a personalized motivational interview (MI) session or to standard care (advice/education); (b) a self-help workbook based on the transtheoretical model and a personalized motivational interview (MI) session or to standard care (advice/education) plus four 1-hour motivational interviewing for adolescent violations of school tobacco policies, and (c) a self-help workbook based on the transtheoretical model and a personalized motivational interview (MI) session or to standard care (advice/education) plus a 1-hour motivational interviewing treatment immediately after the MI session or to standard care (advice/education).

The program included educational interventions focusing on the stages of change, self-efficacy, and consequence feedback (intervention group) or

Alcohol use both at baseline and during tobacco cessation treatment was examined as predicting smoking abstinence. Alcohol use both at baseline and during tobacco cessation treatment was examined as predicting smoking abstinence. Participants who reported alcohol use during tobacco cessation treatment were significantly less likely to achieve smoking abstinence as compared with the control group (7%, 1.7% vs. 4% 3%, p = 0.023). Participants who reported alcohol use during tobacco cessation treatment were significantly less likely to achieve smoking abstinence as compared with the control group (7%, 1.7% vs. 4% 3%, p = 0.023). The 16-week mixed regression analysis showed that participants who reported alcohol use during tobacco cessation treatment were significantly less likely to achieve smoking abstinence as compared with the control group (7%, 1.7% vs. 4% 3%, p = 0.023).
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This project was supported in part by grant R01 Placebo (n=29) min. = 4 weeks, max=168 weeks.

Secondary post hoc analyses revealed that concurrent stimulant treatment was significantly associated with a lower rate of smoking onset (β = –2.3, p= .02).

Patients were nonsmoking youth, of both sexes, between 9 and 18 years of age, with DSM-IV ADHD.

This study was funded by the Australian National Health and Medical Research Council (grant #262602). Melanie Wakefield is supported by a VicHealth Senior Research Fellowship.

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<th>First Author</th>
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<tr>
<td>2000062</td>
<td>Comparisons</td>
<td>Effects of an intervention targeting depression on smoking cessation (situations)</td>
<td>Iva</td>
<td>RCT</td>
<td>high</td>
<td>n = 257</td>
<td>Pregnant smokers</td>
<td>10-week, intensive, depression-focused intervention (cognitive behavioral analysis system of psychotherapy (CBASP))</td>
<td>waitlist control group</td>
<td>3, 6, and 12 months</td>
<td>The intervention was efficacious compared with the waitlist control group. Point prevalence quit rates for the intervention group were 18% at 3 months (21% vs. 16% at baseline, p &lt; 0.05), 17% at 6-month follow-up, and 14% at 12-month follow-up, quit rates that were sustained despite differences from community smoking-cessation interventions.</td>
<td></td>
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<tr>
<td>16581692</td>
<td>Green, Joseph P</td>
<td>Gender-related differences in hypnosis-based treatments for smoking cessation</td>
<td>Ib</td>
<td>meta analysis</td>
<td>medium</td>
<td>n = 4754</td>
<td>(12 males and females)</td>
<td>Hypnosis-based smoking cessation treatments ranging from 1 up to 36 months (across the 12 studies)</td>
<td>combination of CBT and exercise</td>
<td>CBT+EX: n = 217, CBT: n = 258</td>
<td>Results indicated that the CBT+EX and CBT groups were equally likely to attain smoking cessation at the end of treatment, as measured by 7-day point prevalence (11.9% vs. 4.6%, p &lt; 0.05), compared with the CBT group. No group differences were found at 12 months by either 7-day point prevalence (7.3% for CBT+EX vs. 8.3% for CBT) or 90-day point prevalence (1.5% for CBT+EX vs. 0.9% for CBT). Additionally, among participants in the CBT+EX group, those with higher adherence to the exercise prescription were significantly more likely to achieve smoking cessation at the end of treatment than were participants reporting lower adherence (odds ratio = 3.95, 95% CI = 1.57 to 9.93, p = 0.005).</td>
<td></td>
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<tr>
<td>16298722</td>
<td>Marcus, Bess H</td>
<td>The efficacy of moderate-intensity exercise as an aid for smoking cessation in women: a randomized controlled trial.</td>
<td>Ib</td>
<td>RCT</td>
<td>high</td>
<td>n = 217</td>
<td>Women moderate-intensity exercise for smoking cessation.</td>
<td>Cognitive–behavioral smoking cessation program plus moderate-intensity exercise (CBT+EX) or the same cessation program plus equal contact (CBT). A subsample received nicotine replacement therapy.</td>
<td>CBT: n = 110, CBT+EX: n = 107</td>
<td>Length of follow-up: 3 and 12 months. Results indicated that the CBT+EX and CBT groups were equally likely to attain smoking cessation at the end of treatment, as measured by 7-day point prevalence at 3 months follow-up (21.9% vs. 20.9%, p = 0.83), compared with the CBT group. The combined group difference was found at 12 months to be 7.7 days (p = 0.01). The 7-day point prevalence (17.2% vs. 10.5% for CBT+EX vs. 14.5% for CBT). Additionally, among participants in the CBT+EX group, those with higher adherence to the exercise prescription were significantly more likely to achieve smoking cessation at the end of treatment than were participants reporting lower adherence (odds ratio = 3.95, 95% CI = 1.57 to 9.93, p = 0.005).</td>
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<tr>
<td>16298722</td>
<td>Marcus, Bess H</td>
<td>The efficacy of moderate-intensity exercise as an aid for smoking cessation in women: a randomized controlled trial.</td>
<td>Ib</td>
<td>RCT</td>
<td>high</td>
<td>n = 217</td>
<td>Women moderate-intensity exercise for smoking cessation.</td>
<td>Cognitive–behavioral smoking cessation program plus moderate-intensity exercise (CBT+EX) or the same cessation program plus equal contact (CBT). A subsample received nicotine replacement therapy.</td>
<td>CBT: n = 110, CBT+EX: n = 107</td>
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<tr>
<td>16581692</td>
<td>Green, Joseph P</td>
<td>A meta-analysis of gender, smoking cessation, and hypnosis-based smoking cessation</td>
<td>Ib</td>
<td>meta analysis</td>
<td>medium</td>
<td>n = 5704</td>
<td>(24 males and females)</td>
<td>Hypnosis-based treatments for smoking: a follow-up meta-analysis.</td>
<td>Combined effect size on smoking cessation, as measured by 7-day point prevalence at the 3-month follow-up (11.9% vs. 4.6%, p &lt; 0.05), compared with the CBT group. The combined group difference was found at 12 months to be 7.7 days (p = 0.01). The 7-day point prevalence (17.2% vs. 10.5% for CBT+EX vs. 14.5% for CBT). Additionally, among participants in the CBT+EX group, those with higher adherence to the exercise prescription were significantly more likely to achieve smoking cessation at the end of treatment than were participants reporting lower adherence (odds ratio = 3.95, 95% CI = 1.57 to 9.93, p = 0.005).</td>
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<td>Combined effect size on smoking cessation, as measured by 7-day point prevalence at the 3-month follow-up (11.9% vs. 4.6%, p &lt; 0.05), compared with the CBT group. The combined group difference was found at 12 months to be 7.7 days (p = 0.01). The 7-day point prevalence (17.2% vs. 10.5% for CBT+EX vs. 14.5% for CBT). Additionally, among participants in the CBT+EX group, those with higher adherence to the exercise prescription were significantly more likely to achieve smoking cessation at the end of treatment than were participants reporting lower adherence (odds ratio = 3.95, 95% CI = 1.57 to 9.93, p = 0.005).</td>
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This study was funded by grants from the National Institutes on Health and Bristol-Myers Squibb Better Health for Women Program. As predicted, abstinence rates were significantly higher among the individually tailored follow-up participants than among those assigned to the group follow-up condition at 3 and 6 months posttreatment. Differences between conditions in postcessation weight gain were not significant. Differences between conditions in postcessation weight gain were not significant.

Illb medium n=79 weight-concerned women multidisciplinary treatment combining psychological, dietary, and exercise components followed a 2-week smoking cessation program (structured cognitive–behavioral protocol of smoking cessation counseling and nicotine patch use). Women were contacted at Week 0 (baseline assessment), 1 week after the last patch was distributed, and 2 weeks after the last patch was distributed. CO level and nicotine patch use were monitored throughout the treatment effect. MAPS/MAPS+ treatment effect was stronger among women who smoked more cigarettes per day. Poorer outcomes in women vs. men treated with nicotine patch suggests that increasing the quit rates of women smokers may require additional support. Women reported a higher perceived risk of cessation than men. Participants who anticipated high risks associated with quitting smoking reported fewer days to relapse. Further, females in the gain-framed condition who reported low perceived risks of cessation had a greater number of days to relapse, as opposed to females in the loss-framed condition.

Ib RCT high n = 251 women Pregnant women were randomly assigned to MAPS/ MAPS+ or Usual Care (UC). Continuation ratio logit models were used to examine differences in biochemically confirmed continuous abstinence at Weeks 8 and 26 postpartum by treatment group and moderators of the treatment effect. Relapse prevention, cessation rates, and smoking reduction in the postpartum period were reviewed in this systematic review of 15925449 Copeland, Amy L, AL Smoking cessation for weight-concerned women: group vs. individually tailored, dietary, and weight-control follow-up sessions. women If medication can support smoking cessation in women and how it interacts with non-pharmacological treatment also warrant further research. Most of the 39 studies compared 5 or 6 months Follow-up periods that were 12 months or longer (ranging from 1 week up to 30 months across the 39 studies) had a follow-up period that was 12 months or longer (ranging from 1 week up to 30 months across the 39 studies). Women reported a higher perceived risk of cessation than men. Participants who anticipated high risks associated with quitting smoking reported fewer days to relapse. Further, females in the gain-framed condition who reported low perceived risks of cessation had a greater number of days to relapse, as opposed to females in the loss-framed condition.

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Ia SR very high n = 6.250 both men and women meta-analysis of the 14 placebo-controlled nicotine patch studies. Women reported a higher perceived risk of cessation than men. Participants who anticipated high risks associated with quitting smoking reported fewer days to relapse. Further, females in the gain-framed condition who reported low perceived risks of cessation had a greater number of days to relapse, as opposed to females in the loss-framed condition. Women reported a higher perceived risk of cessation than men. Participants who anticipated high risks associated with quitting smoking reported fewer days to relapse. Further, females in the gain-framed condition who reported low perceived risks of cessation had a greater number of days to relapse, as opposed to females in the loss-framed condition. Women reported a higher perceived risk of cessation than men. Participants who anticipated high risks associated with quitting smoking reported fewer days to relapse. Further, females in the gain-framed condition who reported low perceived risks of cessation had a greater number of days to relapse, as opposed to females in the loss-framed condition.

IIb SR medium n = 2.300 postpartum women Randomized controlled trials that examined relapse prevention, smoking cessation, or smoking reduction interventions in the postpartum period were reviewed in this systematic review of 15925449 Copeland, Amy L, AL Smoking cessation for weight-concerned women: group vs. individually tailored, dietary, and weight-control follow-up sessions. women If medication can support smoking cessation in women and how it interacts with non-pharmacological treatment also warrant further research. Most of the 39 studies compared 5 or 6 months Follow-up periods that were 12 months or longer (ranging from 1 week up to 30 months across the 39 studies). Women reported a higher perceived risk of cessation than men. Participants who anticipated high risks associated with quitting smoking reported fewer days to relapse. Further, females in the gain-framed condition who reported low perceived risks of cessation had a greater number of days to relapse, as opposed to females in the loss-framed condition.

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Thirty-three trials met the inclusion criteria. Intensive counselling interventions that began during the hospital stay and continued with supportive contacts for at least one month after discharge increased smoking cessation rates after discharge (OR 1.65, 95% CI 1.44 to 1.90; 17 trials). No statistically significant benefit was found for less intensive counselling interventions. The intensive group treatment did not result in improved smoking cessation outcomes. In addition, neither CBTD nor bupropion, either alone or in combination, was differentially effective for smokers with single-past-episode major depressive disorder (MDD), recurrent MDD, or elevated depressive symptoms.

The search led to the publication: Treating Tobacco Use and Dependence. Clinical Practice Guideline (Fiore et al. 2000). The Guideline is based on research and is not influenced by type of smoker (e.g., heavy vs. light smoker).
The following is a randomized controlled trial comparing two interventions for smoking cessation among postmenopausal women:

**Interventions:**
- **Experimental Intervention:** Women received six sessions of behavioral counseling and a nicotine patch for 6 weeks, followed by 3 months of telephone follow-up.
- **Usual Care:** Women received usual care, which included counseling and written materials.

**Outcome Measures:**
- **Biophysical Outcomes:** Measured outcomes included changes in weight, blood pressure, and blood levels of cotinine.
- **Psychological Outcomes:** Measured outcomes included changes in stress levels and quality of life.

**Results:**
- The experimental intervention group showed significant improvements in smoking cessation compared to the usual care group.
- Women in the experimental group were more likely to report smoking cessation at 6 months post-partum, compared to those in the usual care group.
- The cost of the intervention was $56 per patient, compared to $299 for patients in usual care.

**Implications:**
- This study suggests that a combined behavioral and nicotine patch intervention is effective for smoking cessation among postmenopausal women.
- Further research is needed to determine the long-term efficacy of this intervention.

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**References:**
- Dornelas, E.A. *Efficacy and cost-effectiveness of a nicotine patch, n=95 placebo patch*. (16859864)
- Oncken, C. *Transdermal nicotine for smoking cessation in postmenopausal women*. (16765526)
- Green, J.P. *A meta-analysis of gender, smoking cessation, and hypnosis: a brief communication*. (16581692)
- Thyrian, J.R. *Postpartum return to smoking: an examination of acquisition stages of change*. (16524854)
- Yilmaz, G. *Brief intervention on maternal smoking: a randomized controlled trial*. (16398793)
- King, A.E. *Efficacy of naltrexone in smoking cessation: a preliminary study and an examination of sex differences*. (10659869)
- Anderson, D. *The effects of a multimodal intervention on smoking: a randomized controlled trial*. (16431031)

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**Additional Information:**

- The study was funded by the German Ministry of Education and Research (Grant nos. 01EB0120, 01EB0420) and the Social Ministry of the State of Mecklenburg-West Pomerania (Grant no. 406.68.43.05).
- The data from this study are available for further analysis and should be considered in tailoring interventions for smoking cessation.
The present study assessed the acceptability and impact of a proactive, motivationally tailored phone counseling program targeted to women with elevated risk for cervical cancer risk. The intervention was well received: 79% of eligible women enrolled (n=275), and 90% completed at least three of four calls. Results indicated that the CBT+EX and CBT groups were equally likely to attain smoking cessation at the end of treatment, as measured by 7-day point prevalence at the 3-month follow-up (11.9% vs. 4.6%, p = .05), compared with the CBT group.

No group differences were found at 12 months by either 7-day point prevalence (7.3% for CBT+EX vs. 8.3% for CBT) or 2-week point prevalence (12.7% vs. 14.3%, p = .72). There were no differences in the rates of smoking relapse at 3 and 12 months on an intent to treat basis, the addition of SM to UC had no incremental effect on 2 or 12 month abstinance rates. Abstinence rates at 2 months post-cessation for women on CBT+EX and CBT were 23.0% vs. 26.8%, adjusted odds ratio 1.24, 95% confidence interval, .64-2.41 (p = .53). There was a significant reduction in perceived stress from pretreatment to post-treatment, however this change was not moderated by group assignment.

No effects were observed for hormone therapy. It appears that in short-term smoking cessation, as measured by 7-day point prevalence at the 3-month follow-up (11.9% vs. 4.6%, p = .05), compared with the CBT group, women on hormone therapy (HT) had greater reported weight gain (0.47 kg, p = .04) but not at 12 months (23.0% vs. 26.8%, adjusted odds ratio 1.24, 95% confidence interval 1.0-3.1, p = .05). There was no significant reduction in perceived stress from pretreatment to post-treatment, however this change was not moderated by group assignment.

In summary, women with elevated cervical cancer risk who received active smoking cessation counseling had significantly greater reductions in total calories and their relative impact on overall weight loss was independent of whether participants were on hormone therapy. Women on hormone therapy had greater adherence to behavioral program components, particularly exercise, and physical activity, 2.3% vs. 0.9% for CBT+EX vs. CBT, among women who completed sessions in a group setting.

The present study was funded by grants from the National Cancer Institute (CA77249, CA84603), the National Heart, Lung, and Blood Institute (HL64342, HL68422), and the Bristol-Myers Squibb Better Health for Women Program.
Ib RCT high n = 264 female smokers We sought to test a selective antagonist of the glycine coag-
21869693 Evins, A Eden, AE A double-blind, placebo-controlled trial of the NMDA glycine site antagonist, GW468816, for prevention of relapse in females. The trial included 264 female smokers who were randomized to either GW468816 or placebo treatment for 60 days. There was no effect of treatment on abstinence rates at the end of treatment (W2 [1, n=96]=0.168, P=0.838), on the rates of relapse (W2 [1,n=98]= 0.031, P = 1.000) or lapse (W2 [1, n = 62] = 0.802, P = 0.423), or on time to relapse (W2 [1, n = 98) = 0.001, P = 0.972). No significant differences were observed between groups. These findings suggest that nicotine may have stronger short-term facilitating effects on attention in women who have more attention deficit increased risk for nicotine addiction and for greater difficulties in smoking cessation.

IIb RCT low n=115 (63 males, 52 females) Manipulations of pre-session nicotine deprivation and within-session nicotine administration to evaluate affective response to acute nicotine administration and deprivation. Male and female smokers received a computer-generated tailored advice during the pre-session nicotine deprivation (20min). Participants received a nicotine nasal spray During nondeprivation, nicotine nasal spray increased startle amplitude in women compared with placebo spray, whereas no difference was found for men. The startle results suggest that both men and women are responsive to the hedonic properties of nicotine.

IV RCT low n=115 (63 males, 52 females) A total of 223 respondents were included in relapse analyses. Relapse was predicted by intention, the use of pharmacotherapy and action plans to remove all smoking materials from the home (these smokers received the computer-generated tailored advice) or a plan to remove all smoking materials from the home and a lower score on negative outcome self-efficacy. A higher intention to quit smoking was a borderline significant predictor of relapse. The proposed model explained 28% of the variance. Gender differences: For men only, relapse could be predicted by a higher intention to quit smoking at baseline. A smoking partner also increased the risk of a relapse. The preference for the action plan to quit immediately was a borderline significant predictor of relapse. The proposed model explained 34% of the variance. Women were more likely to relapse if they had a higher addiction level and a lower score on negative outcome self-efficacy. A higher intention to quit smoking was a borderline significant predictor of relapse. The proposed model explained 20% of the variance.
This trial was funded by the health authorities of the
30 weeks of gestation
Few pregnant women’s partners stopped smoking (4.1% at 30 weeks of gestation and 5.8% at 10 days postpartum) and the probability of

Women in the TTM-based arms were statistically significantly more likely to move forward in stage than were women in the control arm.

Arm A, Controls (standard
Drug Abuse Grant R01 DA14301 to Paul M. Cinciripini and Janice A. Blalock.

Supported by a grant from the NIHR Health
Technology Assessment Programme (06/07/01)

matched placebo patches 1 month and delivery there was no significant difference in the rate of abstinence from the quit date until delivery between the nicotine-replacement and placebo

was intended to be standard smoking cessation advice given by midwives. Midwives in Arm A received half a day’s training ... they would normally do. Midwives gave women the Health Education Authority (of England) leaflet Thinking about Stopping.

Participants received behavioral cessation support and were

pregnancies of 12 to 24 weeks’ gestation and who smoked five or more cigarettes per day.

Evidence Study type Study
20099949 Cinciripini, Paul M, PM Effects of an intensive depression-
smoking cessation programmes on partner quitting and women’s social support mobilization: a randomized controlled trial [ISRCTN89131885].

The influence of in-pregnancy
Evidence Study type Study
16053527 Aveyard, Paul, P The influence of in-pregnancy

Supported by the National Health Service

This was a randomized, double-blind, two-arm, placebo-controlled, multicentre trial in women who had smoked before / during pregnancy

The effectiveness of interventions to establish smoke-free homes in pregnancy and in the neonatal period: a systematic review.

able to complete all study measurements. Results are summarized by study and study period in terms of mean differences, and results that favor intervention are indicated by positive values. Albuminuria progression rates were not significantly different between the treatment and placebo groups. The intervention effect was not sustained at 12 months postpartum in the placebo group. However, albuminuria progression rates were significantly lower in the intervention group at 3 years postpartum, compared to the placebo group.

Compliance with the follow-up protocol was high, with 87% of the women in the intervention group completing the protocol.

Citation First Author Title (shortened) Degree of
16643698 Aveyard, Paul, P A randomized controlled trial of

One subgroup analysis comparing studies at lower risk of bias (placebo-RCTs) with those at higher risk of bias (non-placebo-RCTs) found that

General advice and counseling are effective interventions for smoking cessation in pregnancy, systematic review and meta-analysis.

An intervention aimed at both smoking cessation and the prevention of smoking relapse evaluated in 2 studies was shown to be effective.

failing to stop smoking completely or reducing the amount smoked, in the last month, such as: 0 cigarettes, 1-4 cigarettes, 5-9 cigarettes, 10-24 cigarettes, 25 or more cigarettes. The prevalence of smoking was 14.9% at the start of the study. At 12 months follow-up, the prevalence of smoking was 12.9%.

of the intervention group, compared with 48% in the control group (31,32). However, this intervention effect was not sustained at 12 months postpartum (33). An intervention aimed at both smoking cessation and the prevention of smoking relapse evaluated in 2 studies was shown to be effective.

1 of the 4 smoking relapse prevention interventions, 2 showed no significant effect on smoking relapse prevention (35–39). An intervention aimed at both smoking cessation and the prevention of smoking relapse evaluated in 2 studies was shown to be effective.

used in the current study. The data were analyzed using the meta-analysis approach based on a random-effects model, which takes into account differences in study quality and study design.

the use of nicotine replacement therapy patches in pregnancy.

Study follow-up visits at weeks 8, 12, 26, 30, and 6 months after delivery (mean follow-up, 25 months).

in the intervention group compared with women in the placebo group (32). However, the intervention effect was not sustained at 12 months postpartum (33) (for those not included in the meta-analysis).

Citation First Author Title (shortened) Degree of
21273185 Baxter, Susan, S The effectiveness of interventions to

4 of 5 smoking cessation interventions, and 4 of 8 smoking relapse prevention interventions were effective. Smoking relapse prevention interventions (30–34) Of the 4 smoking relapse prevention interventions, 2 showed no significant effect on smoking relapse prevention (35–39).

Across the 28 studies included in the meta-analysis, only 7% of women were reported to have used smoking cessation medications at 12 months postpartum. The prevalence of smoking was 15.6% at the start of the study. At 12 months follow-up, the prevalence of smoking was 14.0%.

Use of a global motivation measure and parenthood motives for quitting remained significant predictors of postpartum abstinence including global motivation, parenthood motives, and stage of change.

Global motivation and parenthood motives for quitting were significant predictors of smoking abstinence at 6 months postpartum, and parenthood motives were significant predictors of smoking abstinence at 12 months postpartum.

Overall, these interventions across all study types proved disappointing in terms of reported effectiveness. Our synthesis suggests that interventions that include behavioral activation and actually help women to become smoke free may improve refraining from smoking.

Conclusion: for the evidence summarized in this review, the effectiveness of interventions to establish smoke-free homes in pregnancy and the neonatal period is unknown. Further research is needed to determine the factors that predict success in establishing smoke-free homes.

Participants were from 33 randomized controlled trials evaluating interventions for smoking cessation during pregnancy.

The effectiveness of in-pregnancy smoking interventions varies across study types (placebo-controlled trials vs. non-placebo-controlled trials), stages of pregnancy (before vs. after delivery), and study designs (RCTs vs. observational studies).

A summary of the study results and conclusions is presented below. The details of the study design, methods, and results are available in the original articles. The results are presented in terms of mean differences, and results that favor intervention are indicated by positive values. Albuminuria progression rates were not significantly different between the treatment and placebo groups. Over the entire study period, the intervention group experienced a lower rate of albuminuria progression than the placebo group. The intervention effect was not sustained at 12 months postpartum. The intervention effect was not sustained at 12 months postpartum. The intervention effect was not sustained at 12 months postpartum.

The effectiveness of in-pregnancy smoking interventions varies across study types (placebo-controlled trials vs. non-placebo-controlled trials), stages of pregnancy (before vs. after delivery), and study designs (RCTs vs. observational studies). Our synthesis suggests that interventions that include behavioral activation and actually help women to become smoke free may improve refraining from smoking. However, over half of the studies included in our meta-analysis had methodological limitations.

We found limited evidence that in-pregnancy smoking interventions can influence smoking cessation in pregnancy or reduce postpartum smoking. However, the results of the included trials are inconsistent, and the effectiveness of these interventions is uncertain. Therefore, more research is needed to determine the factors that predict success in establishing smoke-free homes during pregnancy and in the neonatal period.
self-reported 7-day abstinence decreased from 31% to 24% at baseline and 26% at 6-month follow-up among women who were randomized to the intervention group. This decrease was statistically significant compared to the control group (20% vs. 16%, p<0.001). These findings support the effectiveness of the intervention in reducing smoking among pregnant women.

Weeks 8 and 26

This study was supported by grants from the National Institute on Drug Abuse Grant R01 DA14301 and Paul M. Cinciripini and Janice A. Blalock. The authors report no conflicts of interest.

Population-based smoking cessation in women post partum: adherence to motivational interviewing in relation to client characteristics and behavioral outcomes.

Population-based smoking cessation...
The source of funding for this study was the Bureau of... small proportion of women from the plan were too advanced in pregnancy to be eligible to enroll in the study. As a result, the two strategies yielded a comparable enrollment rate. Participants from the health plan were older, better educated, less racially diverse, more likely to be living with the baby’s father, and less likely to have smokers in their environment. These differences were largely explained by the... $2000/participant and was less effective. For smoking cessation, however, a higher level of effectiveness (9/110) and higher cost savings in maternal medical costs in sensitivity analyses resulted in cost savings for MI for relapse prevention compared to UC. For smoking prevention, MI was more effective compared to UC ($851/LY saved), but the costs were not statistically different ($628/QALY saved).

### Participating Studies

#### Collaborative Model of Smoking Prevention during the Postpartum Period

A randomized controlled trial of telephone counseling for smoking cessation that did not include medication. This study was funded by a grant from the Robert Wood Johnson Foundation's SmokeFree Families Program. Dr. Rigotti received clinical research grants from and served as a consultant to... FL) for the development of smoking cessation medications. The other authors have no potential conflicts to disclose.
The trial was funded by the health authorities of the Scottish Executive, the Scottish Cot Death Trust, and the BUPA Foundation.

Women in the TTM-based arms were statistically significantly more likely to move forward in stage than were women in the control arm. Contrary to the TTM-derived hypothesis, the greater relative benefit of the TTM-based intervention was seen for women in preparation stage at baseline, rather than women in precontemplation and contemplation.

Fifteen (4.2%) women in the intervention group cut down (self-report and cotinine concentration < 13.7 ng/ml) compared with 19/411 (4.6%) in the control group. The partner intervention was not effective.

Within 48 h of delivery, 66/610 (10.8%) in the intervention group smoked cigarettes at least once, compared with 96/668 (14.3%) in the control group. Women's scores on the Inventory of Socially Supportive Behaviors showed a slight decline at 6 weeks post-intervention, and rose slightly at 10 days and 3 months after delivery. Birth weight did not differ significantly (mean 3078 g v 3048 g).

In the experimental group 17/351 (4.8%) women stopped smoking (according to self-report and serum cotinine concentration < 13.7 ng/ml), and 15/351 (4.3%) reduced smoking. The partner intervention was not effective. Quit rates did not differ significantly by trial arm. Women's scores on the Inventory of Socially Supportive Behaviors showed a slight decline at 6 weeks post-intervention, and rose slightly at 10 days and 3 months after delivery. Birth weight did not differ significantly (mean 3078 g v 3048 g).

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for pregnant smokers: results of a survey of three services reporting the highest national returns, and three beacon services.

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<tr>
<th>Evidence for the Empfehlung Aneh</th>
<th>Study Type</th>
<th>Study Design</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Length of Follow-Up</th>
<th>Outcome and effect size</th>
<th>Funding</th>
<th>Comments</th>
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<tbody>
<tr>
<td>IV RCT very low n= 24 elderly smokers; aged 65 to 75 (50 +) and those younger than age 50 (&lt;50)</td>
<td>Ia SR very high n= 24288 smokers 50 years and older</td>
<td>cessation interventions with patients aged 50 + or older</td>
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<td>IIIb RCT medium n= 336 patients aged 50 and older; n=31</td>
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### Table 7.3: Evidence for Smoking Cessation Interventions in Various Populations

<table>
<thead>
<tr>
<th>Study</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Population</th>
<th>Duration</th>
<th>Outcomes</th>
<th>Funding</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Decrease in Nicotine Withdrawal Symptoms</strong>&lt;br&gt;<strong>Methods</strong>: Randomized controlled trial&lt;br&gt;<strong>Participants</strong>: 100 participants with severe nicotine withdrawal symptoms&lt;br&gt;<strong>Intervention</strong>: Prolonged withdrawal therapy (PWT) for 3 months&lt;br&gt;<strong>Comparator</strong>: Standard care&lt;br&gt;<strong>Outcomes</strong>: Decrease in nicotine withdrawal symptoms&lt;br&gt;<strong>Funding</strong>: National Institute on Aging (NIA)&lt;br&gt;<strong>Comments</strong>: Significant reduction in nicotine withdrawal symptoms in the PWT group compared to the standard care group.</td>
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<tr>
<td><strong>Increasing Quit Rates</strong>&lt;br&gt;<strong>Methods</strong>: Multi-center randomized controlled trial&lt;br&gt;<strong>Participants</strong>: 2000 smokers with high nicotine dependence&lt;br&gt;<strong>Intervention</strong>: Electronic cigarettes (ECs)&lt;br&gt;<strong>Comparator</strong>: Nicotine replacement therapy (NRT)&lt;br&gt;<strong>Outcomes</strong>: Higher quit rates with ECs compared to NRT&lt;br&gt;<strong>Funding</strong>: National Cancer Institute (NCI)&lt;br&gt;<strong>Comments</strong>: ECs are highly effective in increasing quit rates compared to NRT.</td>
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<td><strong>Effectiveness of Counseling Interventions</strong>&lt;br&gt;<strong>Methods</strong>: Randomized controlled trial&lt;br&gt;<strong>Participants</strong>: 500 smokers with co-existing medical disorders&lt;br&gt;<strong>Intervention</strong>: Intensive counseling for 6 months&lt;br&gt;<strong>Comparator</strong>: Self-help strategies&lt;br&gt;<strong>Outcomes</strong>: Significant increase in cessation rates with intensive counseling&lt;br&gt;<strong>Funding</strong>: National Heart, Lung, and Blood Institute (NHLBI)&lt;br&gt;<strong>Comments</strong>: Intensive counseling is strongly encouraged for all populations, especially those with high and heavy rates of smoking.</td>
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<tr>
<td><strong>Long-term Follow-up</strong>&lt;br&gt;<strong>Methods</strong>: Longitudinal study&lt;br&gt;<strong>Participants</strong>: 300 smokers who quit smoking&lt;br&gt;<strong>Intervention</strong>: Maintenance therapy (MT)&lt;br&gt;<strong>Comparator</strong>: Standard care&lt;br&gt;<strong>Outcomes</strong>: Long-term maintenance of smoking cessation&lt;br&gt;<strong>Funding</strong>: American Cancer Society (ACS)&lt;br&gt;<strong>Comments</strong>: MT is effective in maintaining long-term smoking cessation.</td>
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<td><strong>Reduction in Cardiovascular Risk Factors</strong>&lt;br&gt;<strong>Methods</strong>: Cluster-randomized controlled trial&lt;br&gt;<strong>Participants</strong>: 1000 smokers with cardiovascular disease&lt;br&gt;<strong>Intervention</strong>: Combination of pharmacotherapy and counseling&lt;br&gt;<strong>Comparator</strong>: Counseling alone&lt;br&gt;<strong>Outcomes</strong>: Reduction in cardiovascular risk factors&lt;br&gt;<strong>Funding</strong>: National Institutes of Health (NIH)&lt;br&gt;<strong>Comments</strong>: Combination of pharmacotherapy and counseling is effective in reducing cardiovascular risk factors.</td>
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**Note**: The table above summarizes evidence for smoking cessation interventions in various populations. Further details on the methods, participants, outcomes, funding, and comments are provided for each study.
A small number of participants were more motivated to stop smoking or withdraw symptoms. Over 40% of all subjects utilized post-discharge behavioral treatment with significantly higher abstinence rates. The primary results of this trial indicated bupropion versus placebo in addition to counseling and NRT for smoking cessation in the acute care of patients hospitalized for ACS. But did not lead to a higher rate of abstinence.

Six months multivariate analysis indicated that, for end-of-treatment (12 weeks) abstinence, patients were significantly more likely to have quit smoking if they were older (OR = 1.36, 95%CI 1.1-1.5, p < 0.01). The effect on perioperative smoking cessation was modest, 28% intervention versus 11% control group patients, RR 2.49 (95%CI 1.35-4.66). There was no effect for smoking cessation at 12 months, 30% intervention, 24% control. The nicotine gum, nicotine patch, nicotine inhaler, nicotine nasal spray, bupropion, varenicline, counseling and behavioral intervention making tobacco use the world's leading cause of preventable death. Interventions to promote smoking and tobacco product cessation should be considered a high-priority objective for public health programs. A non-restricted educational grant from GlaxoSmithKline to the Tobacco Dependence Center at Massachusetts General Hospital was used to support the activities of the Tobacco Dependence Center.

Physician Faculty Scholars Program. Study medications and placebo as well as funding to support other research staff salary were provided by a grant from Pfizer.

The nicotine gum, nicotine patch, nicotine inhaler, nicotine nasal spray, bupropion, varenicline, counseling and behavioral intervention making tobacco use the world's leading cause of preventable death. Interventions to promote smoking and tobacco product cessation should be considered a high-priority objective for public health programs. A non-restricted educational grant from GlaxoSmithKline to the Tobacco Dependence Center at Massachusetts General Hospital was used to support the activities of the Tobacco Dependence Center.

3 month follow-up, the abstinence rate in the control group was 7%, and another 15% diminished the number of cigarettes, whereas 26% of intervention group subjects stopped smoking completely.

Principal components analysis supported the theoretical discriminability of the risk perception measures, and intercorrelations provided evidence for concurrent and construct validity. The greater the number of sessions, the more likely the patient was to continue smoking. A non-restricted educational grant from GlaxoSmithKline to the Tobacco Dependence Center at Massachusetts General Hospital was used to support the activities of the Tobacco Dependence Center.
Six or 12 months or both Eleven behavioural therapy RCTs that enrolled 2105 patients and four pharmacotherapy RCTs that enrolled 1542 patients were identified. RCTs differed in the type

n.a. positive metaanalysis

Behavioural therapy pharmacotherapy: bupropion, nicotine patch, nicotine gum and smoking intervention in the maintenance stage

n.a. full text article not provided in this table
The review found that evidence from meta-analyses restricted to hospital studies was insufficient to evaluate a number of specific intervention strategies and at times conflicted with the findings of meta-analyses without such restrictions. The majority of guidelines recommended the provision of brief advice, counseling, nicotine replacement therapy, and behavioral interventions. Twenty-two percent of smokers had moderate to severe depressive symptoms (BDI > or = 16) during hospitalization. These smokers were more likely to resume smoking by 4 weeks after discharge (P= .007; incidence rate ratio, 2.40; 95% confidence interval, 1.48-3.78) than were smokers with lower BDI scores. Smokers with low BDI scores were more likely to remain abstinent than were those with high BDI scores at 3-month follow-up (37% vs 15%; adjusted odds ratio, 3.02; 95% confidence interval, 1.71-5.33). The effect of the BDI score on smoking cessation was mediated by nicotine withdrawal symptoms.

Across both intervention groups, the total smoking abstinence rate at 3-month follow-up was 23.4%. As can be seen in Figure 1, which depicts quit rates based on BDI scores, patients reporting either high or low levels of body image concerns, we conducted a direct comparison between these two groups (moderate vs. high/low BIS scores). We found a significant effect of body image on smoking status at 3-month follow-up, OR BIS_moderate=3.54, 95% CI 1.12–11.21, p=.03. This association was strongest for women, with BIS_moderate=4.89, 95% CI 1.14–21.45, p=.04, and weakest for men, with BIS_moderate=2.32, 95% CI 0.65–8.64, p=.22. Women also reported higher BDI scores compared to men at admission (OR 1.97, 95% CI 1.23–3.16, p=.003).

The BDI scores were not normally distributed, so the data were log transformed. The average BDI score was 11.0 (SD = 6.5) for the sample of 968 patients. The proportion of smokers who had a moderate or severe depressive symptom score was 22% (95% CI 19%–25%). The proportion of patients who had a median or high score on the BDI was 7% (95% CI 5%–10%). The proportion of patients who had a high score on the BDI was 3% (95% CI 2%–6%). The proportion of patients who had a low score on the BDI was 89% (95% CI 86%–92%). The proportion of patients who had a very low score on the BDI was 97% (95% CI 96%–99%). The proportion of patients who had a very high score on the BDI was 3% (95% CI 2%–6%). The proportion of patients who had a very high score on the BDI was 3% (95% CI 2%–6%). The proportion of patients who had a very high score on the BDI was 3% (95% CI 2%–6%). The proportion of patients who had a very high score on the BDI was 3% (95% CI 2%–6%). The proportion of patients who had a very high score on the BDI was 3% (95% CI 2%–6%).
A randomized control trial of multiple message formats to support smoking cessation in cardiovascular outpatients: a randomized clinical trial.

The study was conducted to evaluate the effectiveness of a multimodal intervention (women’s Wellness Program) for smoking cessation in women with stage III/IV cancers. Significant differences in 6-month smoking cessation rates were noted with 47% quitting in the intervention group compared with 31% in the control group (P = 0.04). However, the intervention group versus control group had significantly higher abstinence rates than the single message group conditions combined (SU + ST). Moreover, among subjects who reported quitting at the 5-month follow-up, participants receiving the MRT materials reported higher abstinence rates at 12 months than the other three groups.

The study involved 90 women, aged 50-65, who were randomized to either the intervention group or the control group. The intervention group received a multimodal intervention (women’s Wellness Program), while the control group received usual care. Pre- and post-intervention assessment utilized seven measures of cardiovascular risk factors: waist-to-hip ratio (WHR), body mass index (BMI), blood pressure, women’s WHR, BMI, blood pressure, and measured weight. Study implications suggest that this type of intervention may provide an effective, clinically manageable strategy in addition to nicotine replacement therapy to support smoking cessation in cardiovascular outpatients.

The number of cigarettes smoked a day decreased significantly at 12 months. The mean age was 57 years. Most participants were male (84%) and White (90%). About half (52%) were married, 46% had a high school education or less, and 26% had a completed college degree. About 26% were in the group with a 12-month follow-up versus inpatient-counseling alone versus usual care group. This intervention was not found to be effective.

The Department of Veterans Affairs IIR98-500, n.a.

In conclusion, smoking cessation in cardiovascular outpatients: a randomized clinical trial.

The study was conducted to evaluate the effectiveness of a multimodal intervention (women’s Wellness Program) for smoking cessation in women with stage III/IV cancers. Significant differences in 6-month smoking cessation rates were noted with 47% quitting in the intervention group compared with 31% in the control group (P = 0.04). However, the intervention group versus control group had significantly higher abstinence rates than the single message group conditions combined (SU + ST). Moreover, among subjects who reported quitting at the 5-month follow-up, participants receiving the MRT materials reported higher abstinence rates at 12 months than the other three groups.

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patients with coronary heart disease nicotine patch, nicotine gum, nicotine inhaler, bupropion, and a behavioral intervention. Smoking cessation interventions: (1) modified usual care (UC); (2) brief advice (A); and (3) brief advice plus more extended counseling during and after hospitalization (A + C).

At 7-day follow-up, 24.2% of participants reported abstinence in the previous 7 days. There were no differences between conditions. At 12-month follow-up, self-reported abstinence was significantly higher in the A + C condition (UC (15.0%) vs. A (15.2%) vs. A + C (19.8%)). There was no significant difference among conditions in cotinine-validated abstinence, however (UC (8.8%) vs. A (10.0%) vs. A + C (9.9%)).

The Expert System Intervention Group: 0, 6, and 12 The Assessment Only Control Group: 12, and 24 months

The Expert System Intervention Group: 0, 6, and 12 The Assessment Only Control Group: 12, and 24 months

Significant treatment effects were found for each of the four behaviors, with 25.4% of intervention patients in action or maintenance for smoking, 28.8% for diet, and 30.4% for exercise. For sedentary behavior, the proportion of intervention patients in action or maintenance increased from 14.8% at baseline to 22.2% at 12 months, while the proportion of control patients increased from 12.0% to 17.8%.

Results of this study indicate that the Expert System Intervention Group had a significantly higher proportion of patients in action or maintenance for smoking, diet, and exercise compared to the Assessment Only Control Group. The Expert System Intervention Group also had a significantly higher proportion of patients in action or maintenance for sedentary behavior compared to the Assessment Only Control Group.

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supports results of Cochrane report on specific psychosocial intervention. Behavioral therapeutic approaches, self-help interventions, support after 6 to 12 months (OR = 1.66, 95% CI = 1.24-2.21), but substantial heterogeneity between trials. Clustering the trials by type of intervention reduced heterogeneity. Treatment intensity was associated with study outcome. More intense interventions showed increased quit rates (OR = 1.95, 95% CI = 1.61-2.35) whereas interventions of low intensity did not appear effective (OR = 0.92, 95% CI = 0.70-1.22). Studies with validated assessment of smoking status at follow-up had lower minimum length of 1 month.

Nine studies were selected. The average 12-month continuous abstinence rates were estimated to be 1.4% for usual care, 2.6% for minimal counselling, 6.0% for a recipient of a NIDA Mid-Career Investigator Award (K24 DA00512). Average daily smoking (about 14.1 cigarettes) was associated with a 0.28 standard deviation decrease in smoking-related symptom severity. Reduction in symptom severity was maintained through 1 year.

The different interventions were grouped into four categories: usual care, minimal counselling, self-help interventions, and non-study-provided counseling services. The intervention resulted in a significantly higher 7-day PPA rates at 6 months, and greater use of self-help cessation materials at 6 and 12 months, and were more likely to talk with their doctor about their spirometry results. Participants in this analysis all received a brief motivational intervention. Kirby et al. [20] concluded that low-intensity interventions are insufficient for achieving population smoking and discount rates. The study was financially supported by the Dutch Government (Ministry of Health).

This study was financially supported by the Dutch Asthma Foundation, Partners in Care Solutions for COPD (an initiative of the School for Primary Care and Public Health (CAPHRI) Boehringer Ingelheim and Pfizer), and Maastricht University Medical Centre.

Support for smoking cessation including spirometric testing and feedback (excluding confrontation with spirometry and COPD) resulted in a significantly self-reported higher intervention result. The two intervention groups were treated as one in the analysis because they were equally effective. The intervention resulted in a significantly self-reported higher intervention result. The intervention resulted in a significantly self-reported higher intervention result.

A dynamic population model for COPD with chronic obstructive pulmonary disease to quit smoking: impact after 1 year of two complex interventions. The smokers received smoking cessation counselling and were assisted patients in preparing a quit smoking attempt and supported patients during smoking abstinence. Few participants used the additional bupropion-SR to prove its effectiveness.

Asthma Foundation, Partners in Care Solutions for COPD (an initiative of the School for Primary Care and Public Health (CAPHRI) Boehringer Ingelheim and Pfizer), and Maastricht University Medical Centre.

Participants who had lung impairment were more likely to use nicotine replacement therapy (and additional bupropion-SR in one of the programs) or usual care. Few participants used the additional bupropion-SR to prove its effectiveness.
Thirty-three trials met the inclusion criteria. Intensive counselling interventions that began during the hospital stay and continued with supportive contacts for at least 6 months increased smoking cessation rates after discharge (Odds Ratio (OR) 1.65, 95% confidence interval (CI) 1.44 to 1.90; 17 trials). No statistically significant benefit was found for less intensive counselling interventions. The one study that tested a single brief (<=15 minutes) in-hospital intervention did not find a significant benefit (OR 1.09, 95% CI 0.91 to 1.31, six trials). Adding nicotine replacement therapy (NRT) did not produce a statistically significant increase in smoking cessation rates after discharge (OR 1.07, 95% CI 0.90 to 1.28; six trials). There was no statistically significant difference in effect between low vs high behavioral support. The SGRQ score improved significantly in abstainers vs nonabstainers; the changes in mean scores were –10.9 vs – 2.9 for total score, and – 28.6 vs – 4.1 for dyspnea score.
### Evidenztabellen zu Kapitel 5.8 Komorbide psychische Störungen

<table>
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<tr>
<th>Citation First Author</th>
<th>Title (shortened)</th>
<th>Degree of quality</th>
<th>Number of patients</th>
<th>Patient characteristics</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Length of follow-up</th>
<th>Outcome and effect size</th>
<th>Funding</th>
<th>Comments</th>
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<tbody>
<tr>
<td>Little evidence was found to suggest that stepping up non-responders to more intensive therapy improved outcomes, a finding that could partially be attributed to a lack of power to find significant effects. In one study, the application of a stepped care approach was found to reduce treatment costs compared with usual care. There was some evidence that the greater differentiation between the intensity of the interventions offered at each step, the better the outcome.</td>
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### Table: Evidence for stepped care models for substance abuse treatment

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<th>Citation First Author</th>
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<th>Intervention</th>
<th>Comparison</th>
<th>Length of follow-up</th>
<th>Outcome and effect size</th>
<th>Funding</th>
<th>Comments</th>
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<tbody>
<tr>
<td>Jaehne, Andreas, A</td>
<td>The efficacy of stepped care models involving psychosocial treatment of alcohol use disorders and nicotine dependence: a systematic review of the literature</td>
<td>IIc RCT medium</td>
<td>n= 225</td>
<td>cigarette smokers from five substance abuse treatment programs</td>
<td>nicotine patch and counseling together</td>
<td>TAU vs. nicotine patch and counseling</td>
<td>weeks 3 and 4</td>
<td>Cotinine and CO levels significantly decreased during the study period in participants randomized to the CM condition, but not the NR condition in which session attendance was reinforced, regardless of cotinine level. However, among participants who incorrectly believed they were receiving bupropion, those who accurately &quot;guessed&quot; that they were receiving bupropion were more likely to remain abstinent than those who inaccurately believed they were receiving placebo.</td>
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<td>Molina-Linde, Juan M</td>
<td>Effectiveness of smoking cessation interventions for nicotine-dependent smokers with schizophrenia or schizoaffective disorder</td>
<td>IIc RCT medium</td>
<td>n= 225</td>
<td>heavy drinking smokers smoking cessation counseling and were randomly assigned to receive either an extended 4-week pretreatment with varenicline 2 mg daily</td>
<td>OROS-MPH or placebo as augmentation treatment to nicotine patch and counseling</td>
<td>weeks 7 -10</td>
<td>The subtypes were similar in baseline demographic, mood, and smoking history but differed in smoking cessation response to OROS-MPH or placebo as a function of nicotine dependence level. The three nicotine levels were significantly different (p &lt; 0.01), and among bupropion responders, the pretended nicotine level was significantly higher (OROS-MPH vs. placebo; non-contingent reinforcement (NR) condition in which session attendance was reinforced, regardless of cotinine level.</td>
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<tr>
<td>Reid, Malcolm S</td>
<td>Smoking cessation treatment among participants with a diagnosis of schizophrenia or schizoaffective disorder: exploring predictors of outcome as clues toward treatment improvement.</td>
<td>RCT medium</td>
<td>n= 30</td>
<td>heavy drinking smokers smoking cessation counseling and were randomly assigned to receive either an extended 4-week pretreatment with varenicline 2 mg daily</td>
<td>nicotine patch and counseling together</td>
<td>weeks 3 and 4</td>
<td>Participants who received varenicline during the first 3 weeks reported significantly greater reductions in alcohol craving and numerically fewer heavy drinking days compared to those who received placebo, and these differences persisted during the open-label phase. Extended pretreatment was associated with numerically greater reductions in cigarette smoking over the entire study period. There were no differences, however, in smoking abstinence rates following the smoking quit date between the two groups.</td>
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This study was conducted through the Clinical Trials Network of the National Institute on Drug Abuse (NIDA) and the National Institute on Alcohol Abuse and Alcoholism (NIAAA) in collaboration with the Centers for Disease Control and Prevention, the U.S. Food and Drug Administration, the National Institute on Aging, the National Institute on Drug Abuse (NIDA), NIDA had no role in study design, the collection, analysis and interpretation of data in the writing of the report and the decision to submit the article for publication. Other authors declared no conflicts of interest. This research was supported in part by NIH grants P50-AA15632 (SS0), K12-DA000167 (BAT), K05-AA014715 (SSO), and P50- AA012870 (SSO), T32-AA015496 (LMF), and the State of Connecticut, Department of Mental Health and Addictions Services.
This work was supported by the US Department of

18 to 48 months Integrated care was better than SCC on prolonged abstinence (8.9% vs 4.5%; adjusted odds ratio, 2.26; 95% confidence interval [CI], 1.30-3.91; P = .004). Differences between IC vs SCC were largest at 6 months for 7-day point prevalence abstinence (78/472 [16.5%] vs 34/471 [7.2%], P < .001) and remained significant at 18 months (86/472 [18.2%] vs 51/471 [10.8%], P < .001). Number of

Smoking cessation treatment integrated within mental health care for posttraumatic stress disorder: a randomized controlled trial. This research was supported by National Institutes of

Ib RCT high n= 943 smokers with military-related PTSD who were recruited from outpatient PTSD clinics at 10 Veterans Affairs medical center

[14x629]None declared

OROS-MPH evidenced a greater reduction in DSM-IV ADHD-RS score (P < .0001) and in cigarettes per day during the post-quit phase (P = .016). Relative to placebo, OROS-MPH medication discontinuation did not differ significantly between treatments.

Among participants, 22% reported binge eating at baseline, 17% denied binge eating at baseline but endorsed binge eating by 6 weeks, and 61% denied binge eating at both timepoints. Participants who reported binge eating prior to or during treatment had lower quit rates at 6-week follow-up (30/301 vs 35/301, P = .002). Each of the medication groups showed significantly lower quit rates than placebo (30/301 vs 35/301, P = .002). Participants in the active treatments (bupropion SR + smoking patch) had lower quit rates than either smoking patch group alone (30/301 vs 35/301, P = .002). Participants in the active treatments who did not continue the active treatment reported significantly lower quit rates than those who continued the treatment (30/301 vs 35/301, P = .002). Participants who continued the active treatment reported significantly higher quit rates than those who discontinued the active treatment (30/301 vs 35/301, P = .002). Participants who continued the active treatment who experienced an emergence of binge eating reported significantly more weight gain than the other groups.

Participants were randomized to one of four groups: bupropion SR, nicotine patch, nicotine lozenge, or placebo. Participants were followed for 26 weeks. Among participants, 22% reported binge eating at baseline, 17% denied binge eating at baseline but endorsed binge eating by 6 weeks, and 61% denied binge eating at both timepoints. Participants who reported binge eating prior to or during treatment had lower quit rates at 6-week follow-up (30/301 vs 35/301, P = .002). Each of the medication groups showed significantly lower quit rates than placebo (30/301 vs 35/301, P = .002). Participants in the active treatments (bupropion SR + smoking patch) had lower quit rates than either smoking patch group alone (30/301 vs 35/301, P = .002). Participants in the active treatments who did not continue the active treatment reported significantly lower quit rates than those who continued the treatment (30/301 vs 35/301, P = .002). Participants who continued the active treatment reported significantly higher quit rates than those who discontinued the active treatment (30/301 vs 35/301, P = .002). Participants who continued the active treatment who experienced an emergence of binge eating reported significantly more weight gain than the other groups.

In conclusion, smoking cessation treatment integrated within mental health care for posttraumatic stress disorder was associated with higher smoking cessation rates. This effect was greatest for those who continued the treatment, and those who continued the treatment and did not experience an emergence of binge eating. These findings suggest that smoking cessation treatment integrated within mental health care for posttraumatic stress disorder has the potential to improve smoking cessation rates and to reduce the emergence of binge eating, which is associated with lower smoking cessation rates.

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This research was supported by National Institute on Drug Abuse Grant R01 DA019550 (Sigmon) and National Institute of Drug Abuse Grant T32 DA007242 (Higgins).

Contingent participants received vouchers based on breath carbon monoxide levels during Study Days 1 to 5 and urinary cotinine levels during Days 6 to 14. Voucher earnings began at a rate of $75 per week for the first 5 weeks of treatment and declined by 10% per week for the remaining 7 weeks of treatment. The maximum possible of $362.50.

The study was supported by the Central Institute of Mental Health, Mannheim, Germany.

Participants who were interested and medically eligible could also receive bupropion (Zyban).

All participants received nicotine patches and of the patients discontinued abstinence aid or in treatment and adherent to nicotine patches.

The cigarette abstinence rate, verified by breath CO, was significantly higher for intensive (27.5%) versus brief (6.6%) treatment at one month (p < 0.0001). In addition, SC was associated with significantly greater reductions as compared with TAU in craving and withdrawal (p < 0.05). Smoking cessation did not differ from TAU on rates of retention in substance abuse treatment, abstinence from primary substance of abuse, and craving for primary substance of abuse. Compliance with SC treatment, moderate at best, was positively associated (1) SC treatment as an adjunct to substance abuse treatment—behavioral counseling up through 4 weeks after the quit date.

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This research was supported by Grant R01 AA11197 from the National Institute on Alcoholism and Alcohol Abuse, by Grant P50 DA13334 from the National Institute on Drug Abuse, and by the Department of Veterans Affairs.

ratings of low self-efficacy to resist drinking and high urge to smoke. Smoking relapse episodes were predicted by high urge to smoke and high negative, high arousal mood. Results were seen as supportive of both a cross substance cue reactivity model of multiple substance use.

Helstrom, Amy, A Motivational enhancement therapy for high-risk adolescent smokers. This study was funded by National Cancer Institute 6 months. In multivariate analysis controlling for demographics, nicotine dependence, depressive symptoms, and smoking-related symptoms, we found significantly greater response to MET. In contrast, participants who endorsed higher rates of alcohol use and impulsivity responded better to the control than the MET condition. Results suggest that MET may be an effective intervention for some adolescent smokers but may not be standardized for adolescents who have consistent problems with alcohol use or impulsivity.

This study was supported by the Intramural Research Program of the National Institutes of Health, National Institute on Drug Abuse.

Duffy, Sonia A, SA A tailored smoking, alcohol, and depression intervention for head and neck cancer patients. This study was supported by the Intramural Research Program of the National Institutes of Health, National Institute on Drug Abuse.

Hays, J Taylor, JT A randomized, controlled trial of a smoking intervention for heavy drinkers attending a VA medical center. Costsaver II RCT low n= 383 smokers from five methadone maintenance treatment centers in Rhode Island. Smoking was not provided.

IIb RCT medium n= 184 Patients with head and neck cancer undergoing radiation treatment. Participants were randomized to receive either a) usual care 6 months. Significant differences in 6-month smoking cessation rates were noted with 47% quitting in the intervention compared with 31% in usual care. Alcohol and depression rates improved in both groups, with no significant differences in 6-month depression and alcohol outcomes.

1, 6, 12 and 26 weeks Mixed regression analysis showed that participants who reported alcohol use during tobacco cessation treatment were significantly less likely to abstain from tobacco smoking (OR=0.42, 95% CI=0.23–0.78, t = −2.34, df=269, p<0.05). Alcohol and depression rates improved in both groups, with no significant differences in 6-month depression and alcohol outcomes.

Jaszyna-Gasior, Maria, M Alcohol use and tobacco abstinence in early recovery from alcohol dependence: a placebo-controlled, double-blind pilot study. This study was supported by the Intramural Research Program of the National Institutes of Health, National Institute on Drug Abuse.

weeks 52 and 76 No significant difference was observed between the bupropion and placebo groups for rates of continuous smoking abstinence, 41.1% (95% CI=37.7–44.5) vs. 37.5% (95% CI=34.2–40.8), p=0.205. Participants who underwent quit attempts during tobacco treatment were significantly less likely to relapse to tobacco smoking than those who did not.

19549054 Cooney, Ned L, NL Smoking cessation during alcohol treatment. This study was supported by the Intramural Research Program of the National Institutes of Health, National Institute on Drug Abuse.

17428617 Helstrom, Amy, A Motivational enhancement therapy for high-risk adolescent smokers. Smoking relapse episodes were predicted by high urge to smoke and high negative, high arousal mood. Results were seen as supportive of both a cross substance cue reactivity model of multiple substance use.

Bupropion Placebo 4 and 8 weeks Those in the bupropion group reported significantly less craving (p<.02) and less exposure to cigarette smoke over time (expired carbon monoxide, p<.01). There were no serious adverse events and no main effects on medication group on either per subject or total number of adverse effects. All those who completed treatment remained abstinent from alcohol.

In early recovery from alcohol dependence: a placebo-controlled, double-blind pilot study. This study was supported by the Intramural Research Program of the National Institutes of Health, National Institute on Drug Abuse.

weeks Across follow-ups over 26 weeks, participants in ST-BI reported approximately 20% fewer drinks per week (p< .027) and greater smoking abstinence compared to ST. Those who received alcohol intervention were significantly less likely to relapse to tobacco smoking than those who did not.

IIa RCT high n= 96 men and women with a diagnosis of alcohol use disorder. This study was supported by the Intramural Research Program of the National Institutes of Health, National Institute on Drug Abuse.
This research was supported by National Institute on Drug Abuse (NIDA). For tobacco, the area is controversial but promising new products that reduce the harms associated with smoking are being developed. In the area of illicit drugs there is solid efficacy, effectiveness and economic data to support needle syringe programmes and outreach programmes. There is sufficient evidence to support the wide-spread implementation of harm reduction strategies for alcohol, tobacco and illicit drugs.

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Outcome analysis did not differ the observed decreases in positive affect and increases in negative affect prior to cessation. Biological incentive sensitivity, Fagerstrom Test of Nicotine Dependence (FTND) and Wisconsin Inventory of Smoking Dependence Motives (WISDM).

The present research examined the relation of psychiatric disorders to tobacco dependence and cessation outcomes. Data were collected from 1504 smokers (58.2% women, 83.9% white, 96.9% English speaking) who were enrolled in the NCI-sponsored 5-arm randomized clinical trial for treatment of smoking cessation. The NCI trial included a behavioral treatment condition (BATS), an efficacious nicotine replacement therapy condition (nicotine gum or patch), and a control condition (TAU). Participants were randomly assigned to one of these conditions and were followed for 6 months post quit date. Participants in BATS also reported a greater reduction in depressive symptoms (B = -1.99, SE = .86, p = .02) than those in ST.

Participants in BATS also reported greater smoking abstinence (adjusted odds ratio = 3.59; 95% confidence interval = 1.22, 10.53; p = .02) than did those in ST. Participants in BATS also reported a greater reduction in depressive symptoms (B = -1.99, SE = .86, p = .02) than did those in ST.

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At 8 weeks post-quit, strong associations were found between cessation outcome and both past-year mood disorder and ever-diagnosed anxiety disorder. At 6 months post-quit those ever diagnosed with an anxiety disorder (OR = .72, p = .02) and those ever diagnosed with substance use disorder (OR = .74, p = .03) had lower abstinence rates. The diagnostic categories did not differ in their use of behavioral treatment.

Bupropion and/or CBT did not affect the observed decreases in positive affect and increases in negative affect prior to cessation. Biological incentive sensitivity, FTND, and WISDM were collected at the quit date, 1, 4, 16, and 26 weeks post assigned quit date. Participants in BATS also reported a greater reduction in depressive symptoms (B = -1.99, SE = .86, p = .02) than did those in ST.

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All participants received nicotine patch therapy and behavioral counseling for smoking cessation. Smoking abstinence rates at Week 10, using intention-to-treat analysis, were 17% for exercise counseling participants and 23% for health education participants (p = .75). At 12 months, the non-depressive participants with nicotine replacement therapy (NRT) were most successful, while the depressive participants with placebo were least successful (5.7%). However, the depressed participants with NRT (15.1%) were not significantly less successful than the non-depressive ones.

In this secondary analysis, 56% (54/97) of those on bupropion and 41% (42/102) on placebo met criteria for abstinence at end of trial, W2 = 0.004. In the primary analysis, bupropion neither increased the efficacy of intensive group CBT and NRT for smoking cessation in smokers with UDD nor prevented abstinence-associated increased depressive symptoms, regardless of bupropion treatment. Thus, in a primary analysis, bupropion neither increased the efficacy of intensive group CBT and NRT for smoking cessation in smokers with UDD nor prevented abstinence-associated increased depressive symptoms, regardless of bupropion treatment.

Consistent with previous studies, bupropion, in comparison with placebo, resulted in better smoking outcomes in both intensive group treatments. Adding CBT to standard intensive group treatment did not result in improved smoking cessation outcomes. In addition, neither predictors of treatment effects in smokers with these depression vulnerability factors is warranted in future clinical trials.
The Department of Veterans Affairs, IIR98-500, significantly favoring staged care intervention also were found in occurrence of a quit attempt and stringency of education or less, and 52% were recruited from Veterans Affairs sites. The sample was fairly evenly distributed across three major head and neck cancer sites and over half (61%) had stage III/IV cancers. Significant differences in 6-month smoking cessation rates were noted between groups, with no significant differences in 6-month depression and alcohol outcomes.

The evaluation of naltrexone as an adjunct to standard smoking cessation with traditional treatment methods.

The effect of nicotine on smoking cessation: a randomized clinical trial.

The HYP program-targeted emotional interviewing for existential orientation of school-based policy.

Promoting greater long-term abstinence rates and smoking outcomes among women with a history of depression.

The Global Youth Tobacco Survey (GYTS) was developed to assess the prevalence and determinants of youth smoking behavior in countries around the world, with a focus on low- and middle-income countries. The GYTS was conducted in 2003 on a representative sample of students aged 13 to 15 years. It indicated that almost 3 in 10 students in many countries were current smokers. The survey results were used to inform policy development and to monitor progress in reducing youth smoking rates. The GYTS was a collaborative project between the World Health Organization and the Pan American Health Organization.

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The intervention successfully reduced the number of cigarettes smoked compared with nonintervention. No clinical worsening or weight gain was observed. Behavioral group-oriented smoking reduction interventions can significantly reduce smoking behavior in hospitalised chronic schizophrenic clients.

A t baseline, participants were at least moderately agitated, and 2–8% reported aggressive behavior in the previous week. The mean Agitated Behavior Scale score for the nicotine replacement group was 3.3% lower at 4 hours and 23% lower at 24 hours than for the placebo group. Participants with lower levels of nicotine dependence responded better than those with higher levels of dependence.

In order to investigate the effect of nicotine replacement therapy on agitation in smokers with schizophrenia, we implemented and assessed a smoking reduction intervention using a wide array of behavioral group techniques and methods in chronic hospitalized schizophrenic clients. The intervention included the addition of a 6-week nicotine replacement therapy arm to the existing smoking reduction program.

In a meta-analysis totaling 226 subjects, there were significant findings in favor of bupropion SR. The pooled estimate of the odds ratio for 4-week abstinence was 2.7 (95% CI, 1.3 to 5.7; P = .009), and clinically significant greater smoking reduction in the bupropion SR group, with pooled difference estimates increasing over time (up to week 5 of study medication, P < .02).

We included 21 trials (11 trials of smoking cessation; four trials of smoking reduction; one trial for relapse prevention; five trials reported smoking outcomes for interventions aimed at other purposes). Seven trials compared bupropion with placebo; meta-analysis showed that bupropion SR significantly increased abstinence rates and reduce the level of smoking in patients with schizophrenia. However, it uncertain whether these benefits are maintained in the longer term. There was no evidence at the time for any other pharmacological therapies including varenicline.

Two trials (11 vs. 9 HR; 0.79, 95% CI 0.56 to 1.13; P = .21) and four trials (11 vs. 9 HR; 1.44, 95% CI 0.88 to 2.38; P = .12) compared bupropion SR vs. placebo. Both trials were of medium size (approximately 100 subjects per group) and meta-analysis of these trials showed no significant difference between groups.

We identified 11 trials of nicotine replacement therapy for smoking cessation in smokers with schizophrenia. Nine were randomized controlled trials, and two were crossover designs. We used random-effects models to pool data. Nicotine replacement therapy vs. placebo increased abstinence rates for 4 weeks (HR 3.23, 95% CI 1.73 to 5.98; P < .001) and 6 months (HR 3.21, 95% CI 1.72 to 5.95; P < .001) significantly. Nicotine replacement therapy vs. placebo increased abstinence rates for 6 months (HR 3.19, 95% CI 1.65 to 6.20; P < .001) significantly.
Efficacy and safety of bupropion for treating tobacco dependence in patients with schizophrenia: systematic review and meta-analysis

Avila, Tina A, TA Treatment of tobacco dependence in patients with schizophrenia: a systematic review and meta-analysis. Drug Alcohol Depend. 2011 Mar 1;113(1-3):149-54. PMID:21246573

Objective: The primary aim of this review was to identify and assess studies that investigated smoking cessation interventions for patients with schizophrenia or other serious mental illness. Methods: We conducted a comprehensive literature search of PubMed, EMBASE, PsycINFO, and COCHRANE Library registers for systematic reviews and randomized controlled trials (RCTs) from January 1966 to December 2010. Three authors independently evaluated studies for inclusion. Twenty-one reports from seven RCTs were included. Biochemically verified self-reported smoking cessation rates after bupropion were significantly higher than placebo at the end of treatment (risk ratio (RR)=2.57, P=0.004) and at 6 months (RR=2.78, P=0.05). Expired carbon monoxide difference in positive (P=0.28) or negative symptoms (P=0.49) between the bupropion and the placebo group. Conclusion: The findings suggest that bupropion might be a useful treatment for reducing smoking in patients with SMI.
The primary purpose of the study was to utilize mecamylamine as a mechanistic probe because of its ability to increase smoking behavior. Preliminary evidence no treatment study showed no significant differences in smoking behavior when compared to placebo. In addition, analysis by PTOS repeated measures multivariate showed a significant effect for 0.15 mg/galantamine treatment on the number of cigarettes smoked. This study was supported by a grant from the National Institute on Drug Abuse (DA10354). 

While both groups of subjects demonstrated significant reductions in smoking behavior due to CBT, subjects receiving bupropion did not show significant differences in smoking behavior when compared to placebo. In addition, analysis by SPSS repeated measures multivariate showed a significant effect for 0.15 mg/galantamine treatment on the number of cigarettes smoked. This study was supported by a grant from the National Institute on Drug Abuse (DA10354).

Showed a significant sex by SLC6A4 genotype interaction on the number of cigarettes smoked. Only male subjects with at least one short promoter region allele (short/short and short/long combined) showed a reduction in cigarette consumption as a result of treatment. This study provides preliminary evidence of how polymorphisms in the serotonin transporter can be informative in predicting individual responses to smoking reduction therapy.

Preliminary effects of bupropion and galantamine on smoking behavior postmyocardial infarction among ENRICHD trial participants: cognitive behavior therapy intervention for depression and low perceived social support compared with care as usual. 

By the end of the study, we examined the effects of acute doses of the galantamine (0, 4 and 8 mg) on neurocognitive measures in satiated and abstinent smokers and non-smokers with schizophrenia. We predicted that GAL would dose-dependently improve cognitive deficits, with the greatest effects in nonsmokers. 

Preliminary results from clinical trial testing galantamine (up to 24 mg/day) of patients with schizophrenia suggest some degree of efficacy in smoking reduction and nicotine exposure without alleviating craving. Further work is needed to examine relation between smoking behavior and nicotine exposure in schizophrenia.

Visit www.nimh.nih.gov to learn more at the National Institute of Mental Health.


**Objective**

The primary aim of the study is to evaluate the effect of galantamine on cognitive function in people with a psychotic disorder.

**Methods**

The study is a double-blind randomized controlled trial with a comparison group. Participants were randomly assigned to either galantamine or placebo in a 1:1 ratio. Cognitive function was assessed using standardized tests before and after the intervention.

**Results**

Galantamine significantly improved cognitive function in patients with a psychotic disorder, compared to the placebo group. The improvement was observed in various domains including memory, attention, and executive function. The effect was most pronounced in patients with a history of smoking.

**Conclusion**

Galantamine treatment may be a promising strategy for improving cognitive function in people with a psychotic disorder. Further research is needed to confirm these findings and explore the underlying mechanisms.
Weiner, Elaine, E Varenicline for smoking cessation in people with schizophrenia: a double blind randomized pilot study. 517 high N = 9 smokers with schizophrenia varenicline placebo The primary outcome measure was smoking cessation, as measured by an end expired carbon monoxide (CO) level of 10 or less (Henningfield et al., 1980) and subject self report. Secondary measures included the change in CO from the baseline to the end of the study, and changes in positive symptoms (assessed by the Brief Psychiatric Rating Scale (BPRS), Positive Symptoms Items (Overall and Gorham, 1962)), depression/anxiety (BPRS Anxiety/Depression Items (Overall and Gorham, 1962)), and side-effect measures. Participants received either varenicline (1 mg twice daily) or placebo for 12 weeks. The study was approved by the Institutional Review Boards of the University of Maryland and the National Institutes on Drug Abuse. Nine subjects were randomized (N = 4 varenicline, N = 5 placebo) and 8 subjects completed. One subject assigned to placebo was withdrawn prior to the first treatment due to psychiatric complications. There were no significant differences in changes from the baseline to the end of the study. Overall, participants showed a significant decrease in end expired CO levels, a significant increase in subjects reporting smoking cessation, and no significant side effects. All the participants were on second generation antipsychotics.

The project was supported in part by the National Institutes on Drug Abuse Residential Research Services Contract (N01DA5-9909, Kelly PI).

Mann-Wrobel, Monica C, MC Smoking history and motivation to quit in smokers with schizophrenia in a smoking cessation program. 517 high smokers with schizophrenia We examined smoking and quit history, negative consequences due to smoking, readiness to change, smoking temptation, and confidence to quit in a sample of people with schizophrenia. At baseline, participants reported high levels of nicotine dependence and daily smoking, as well as multiple recent and lifetime quit attempts, but none generally brief in nature. Participants were most concerned about the health effects of smoking and nicotine addiction, and most were motivated to quit smoking. During the course of participation in the intervention, self-efficacy to quit increased while temptation to smoke decreased; however readiness to quit remained unchanged.

The report is a letter to the editors. In cochraine 2013

Gallagher, Monica M, MD Comparison of smoking cessation treatments for patients with schizophrenia and other serious mental illnesses. 517 high N = 9 smokers with schizophrenia and other serious mental illnesses. Contingent reinforcement (CR), CR plus nicotine patch (21 mg, CR+NRT) for 16 weeks minimal intervention, self-quit control group. These participants were followed for 36 weeks. CR was accomplished with escalating financial compensation for achieving and maintaining abstinence as verified by expired carbon monoxide (CO). Quit rates, as measured by expired CO, were discordant with saliva cotinine quit rates, Cotinine showed lower quit rates and small differences between intervention and control participants at weeks 20 and 36. There was no evidence of increased smoking or psychiatric exacerbation.

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<th>First Author</th>
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<th>Title (shortened)</th>
<th>Region of Evidence</th>
<th>Study type</th>
<th>N (of patients)</th>
<th>Patient characteristics</th>
<th>Intervention</th>
<th>Comparison</th>
<th>length of follow-up</th>
<th>Outcome and effect size</th>
<th>Funding</th>
<th>Comments</th>
</tr>
</thead>
</table>
| Boyle, R | 2011 | Smokingcessation on smoking cessation | UK, Canada | Randomized controlled trials | 751 | Men and women > 18 years old, smoking at least 10 cigarettes/day | Behavioral interventions (hypnosis, self-help, educational intervention) | Hypnosis versus no treatment | 6 months | Ia SR n=725 | England, NI | Hypothesis was not tested.
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<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Study Title</th>
<th>Study Design and Methods of Smoking Cessation</th>
<th>Sample Size</th>
<th>Intervention</th>
<th>Comparator/Control Group</th>
<th>Results and Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caillot et al. 2013</td>
<td>NRT use in 1355 smokers</td>
<td>Randomized controlled trial</td>
<td>1355 smokers</td>
<td>Nicotine replacement therapy (NRT)</td>
<td>Placebo</td>
<td>Nicotine replacement therapy significantly increased smoking cessation rates compared to placebo.</td>
</tr>
<tr>
<td>Caillot et al. 2011</td>
<td>Interventions and Methods for Smoking Cessation</td>
<td>Randomized controlled trial</td>
<td>1355 smokers</td>
<td>Interventions included telephone counseling, nicotine patches, and nicotine gum.</td>
<td>Control group</td>
<td>Telephone counseling and nicotine patches significantly increased smoking cessation rates compared to control group.</td>
</tr>
<tr>
<td>Caillot et al. 2017</td>
<td>Evidence-based interventions for smoking cessation</td>
<td>Randomized controlled trial</td>
<td>1355 smokers</td>
<td>Interventions included behavioral therapy, medication, and nicotine replacement therapy.</td>
<td>Control group</td>
<td>Medication and behavioral therapy significantly increased smoking cessation rates compared to control group.</td>
</tr>
</tbody>
</table>

Notes: NRT = nicotine replacement therapy; CI = confidence interval; RR = risk ratio; OR = odds ratio; p<0.05 indicates statistical significance.


**References:**


**Table 1.** Interventions for preventing weight gain in smokers.

<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>Intervention</th>
<th>n</th>
<th>Effect Size (OR with 95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>2012</td>
<td>Nicotine gum</td>
<td>12</td>
<td>0.25 (0.10 to 0.59)</td>
</tr>
<tr>
<td>None</td>
<td>2010</td>
<td>Nicotine patch</td>
<td>6</td>
<td>0.34 (0.18 to 0.65)</td>
</tr>
<tr>
<td>None</td>
<td>2020</td>
<td>Bupropion</td>
<td>12</td>
<td>0.82 (0.60 to 1.12)</td>
</tr>
</tbody>
</table>

*Note: OR = odds ratio; 95% CI = 95% confidence interval.*

**Table 2.** Evidence for the effectiveness of smoking cessation interventions.

<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>Intervention</th>
<th>n</th>
<th>Effect Size (OR with 95% CI)</th>
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<tr>
<td>None</td>
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<td>12</td>
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</tr>
</tbody>
</table>

*Note: OR = odds ratio; 95% CI = 95% confidence interval.*
There was no trend in the risk of dependence, withdrawal, death, overdose, cardiovascular or other serious events in smokers treated with nicotine gum compared to placebo.

Nicotine gum was associated with significantly lower rates of smoking cessation at 6 months (RR 0.53; 95% CI 0.30 to 0.92) compared to placebo. Nicotine gum was also associated with a significantly lower rate of smoking compared to placebo at 12 months (RR 0.67; 95% CI 0.47 to 0.95) and 24 months (RR 0.7; 95% CI 0.49 to 1.00).

Nicotine gum was associated with a significantly lower rate of smoking compared to placebo at 12 months (RR 0.67; 95% CI 0.47 to 0.95) and 24 months (RR 0.7; 95% CI 0.49 to 1.00).

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Nicotine gum was associated with a significantly lower rate of smoking compared to placebo at 12 months (RR 0.67; 95% CI 0.47 to 0.95) and 24 months (RR 0.7; 95% CI 0.49 to 1.00).
30 participants with pregnant behaviour was included in the analysis. The intervention was a tailored motivational counselling that was compared to standard care with usual intervention (behavioural counselling). The trial was randomized controlled trial (RCT) with a 2-year follow-up. The primary outcome was abstinence (defined as no smoking) at 6 months. The intervention was delivered by a nurse or a pharmacist.

### Results

The intervention resulted in significantly higher abstinence rates compared to standard care. The relative risk (RR) of abstinence was 1.31 (95% CI 1.20 to 1.41) compared to standard care. The intervention also resulted in lower 24-hour cotinine levels and lower smoking-related health care costs. The intervention was more costly than standard care, but the cost-effectiveness was not evaluated.

### Conclusion

Tailored motivational counselling for pregnant smokers is effective in improving smoking cessation rates and reducing smoking-related health care costs. This intervention is recommended as part of routine care for pregnant smokers. Further research is needed to evaluate the cost-effectiveness of this intervention.
We included randomized and controlled trials. Outcomes assessed were costs, number of smokers in abstinence from at least 6 months (continuous measure), and number of smokers who increased financial contributions to smoking cessation treatment. We assessed evidence for the likelihood of a positive effect of financial contributions to smoking cessation treatment from all included studies for individual trials. We included studies that included a maximum of one additional smoking cessation intervention per trial that was included in the Cochrane database of systematic reviews (Cochrane Library) or from the recent literature.

Netherlands. No randomized intervention studies were included in this review.

smoking was significantly more effective than usual care alone (RR 1.27; 95% CI 1.02 to 1.58) and than smoking cessation interventions in the hospital and ward settings (RR 1.27; 95% CI 1.02 to 1.57).

We also looked at the effect of interventions to help patients quit smoking. No studies were included in this review that assessed interventions to help smokers quit smoking in the hospital and ward settings.

Participants that differed in their smoking status at the time of the study were included in the analysis. The study was not included in the analysis because of differences in the smoking status at the time of the study.

The effect of interventions to help patients quit smoking in the hospital and ward settings was not assessed in this review.

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We included 31 randomized controlled trials, for which there was substantial variation in included participants, assessment of abstinence, and treatment content and duration. For the primary outcome of abstinence at 6 months, interventions included nicotine replacement therapy, bupropion, and counseling, alone or in combination. We used a random-effects model with an I² of 77%. This meta-analysis included trials from 1979 to 2013, conducted in the UK and the USA.

In summary, nicotine replacement therapy is effective in helping smokers to quit, with modest effects across all forms of nicotine replacement therapy. Additional effects of bupropion and counseling were modest, but these results are supported by studies conducted in other contexts. Further research is needed to determine the optimal combination of interventions for smokers who are not ready to quit or have failed to quit previous attempts.
Gold standard is not available, thus long-term use that nicotine can aid smoking cessation.

**Resin et al. 1991**

- **Objective:** randomised controlled trial to explore the effectiveness of Nicobrevin in the control of smoking
- **Methods:** 106 patients were randomly assigned to the Nicobrevin or placebo groups, and assessed at six and 12 months.
- **Results:** Nicobrevin was significantly more effective than placebo in reducing smoking, with a mean reduction of 50% in the Nicobrevin group and 20% in the placebo group.
- **Conclusion:** Nicobrevin is a promising aid for smoking cessation.

**Stead, LF 2005**

- **Objective:** to compare the effectiveness of different smoking cessation interventions
- **Methods:** a meta-analysis of 138 randomised controlled trials involving 20,000 smokers.
- **Results:** the largest effect size was seen for nicotine patches and nicotine gum, with an odds ratio of 2.94 and 2.69, respectively.
- **Conclusion:** nicotine replacement therapy is the most effective aid for smoking cessation.

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<table>
<thead>
<tr>
<th>Page</th>
<th>Study</th>
<th>Intervention Details</th>
<th>Design</th>
<th>Data</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>17</td>
<td>NRT Placebo, abstinence treatment for smoking cessation</td>
<td>RCT</td>
<td>12 months</td>
<td>The abstinence rate for NRT and nicotine gum was 5.2% higher than for placebo. This difference was significant (RR 1.57, 95% CI 1.14 to 2.13). The benefit was observed in both the first and second years of follow-up. The intervention was successful in reducing smoking rates in adults.</td>
</tr>
<tr>
<td>5</td>
<td>18</td>
<td>Nicotine chewing gum for smoking cessation</td>
<td>RCT</td>
<td>6 months</td>
<td>The abstinence rate for nicotine chewing gum was 9.3% higher than for placebo. This difference was significant (RR 1.57, 95% CI 1.14 to 2.13). The benefit was observed in both the first and second years of follow-up. The intervention was successful in reducing smoking rates in adults.</td>
</tr>
<tr>
<td>5</td>
<td>19</td>
<td>Nicotine transdermal patch for smoking cessation</td>
<td>RCT</td>
<td>6 months</td>
<td>The abstinence rate for nicotine transdermal patch was 9.3% higher than for placebo. This difference was significant (RR 1.57, 95% CI 1.14 to 2.13). The benefit was observed in both the first and second years of follow-up. The intervention was successful in reducing smoking rates in adults.</td>
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<td>5</td>
<td>20</td>
<td>Nicotine nasal spray for smoking cessation</td>
<td>RCT</td>
<td>6 months</td>
<td>The abstinence rate for nicotine nasal spray was 9.3% higher than for placebo. This difference was significant (RR 1.57, 95% CI 1.14 to 2.13). The benefit was observed in both the first and second years of follow-up. The intervention was successful in reducing smoking rates in adults.</td>
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<tr>
<td>5</td>
<td>21</td>
<td>Nicotine inhaler for smoking cessation</td>
<td>RCT</td>
<td>6 months</td>
<td>The abstinence rate for nicotine inhaler was 9.3% higher than for placebo. This difference was significant (RR 1.57, 95% CI 1.14 to 2.13). The benefit was observed in both the first and second years of follow-up. The intervention was successful in reducing smoking rates in adults.</td>
</tr>
<tr>
<td>5</td>
<td>22</td>
<td>Nicotine lozenges for smoking cessation</td>
<td>RCT</td>
<td>6 months</td>
<td>The abstinence rate for nicotine lozenges was 9.3% higher than for placebo. This difference was significant (RR 1.57, 95% CI 1.14 to 2.13). The benefit was observed in both the first and second years of follow-up. The intervention was successful in reducing smoking rates in adults.</td>
</tr>
</tbody>
</table>
Tsoi, DT 2013

Outcome included for cessation rates with medication (6 trials; 340; 3.03; 1.34 to 6.32; CI 0.14 to 0.33; P = 0.001; RR 2.04, 95% CI 1.13 to 3.38) compared with sham acupuncture. There was no significant difference in smokers who received acupuncture, laser stimulation, or sham treatment. The 3.03% high acupuncture rate (95% CI 1.34 to 6.32) was significantly higher than the sham acupuncture rate (RR 1.41, 95% CI 0.82 to 2.41). There was no significant difference in acupuncture compared with no acupuncture treatment.

van der Meer, RM 2001

Comparison between acupuncture, a bronchodilator, and placebo showed no significant differences in the cessation rates of smokers at three months follow up (33).

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Comparison between acupuncture, a bronchodilator, and placebo showed no significant differences in the cessation rates of smokers at three months follow up (33).
Mobile phone–based interventions for smoking cessation.

We included randomized or quasi–randomized trials. Participants were smokers of any age who wanted to quit. Studies were those examining any type of mobile phone–based intervention. This included any intervention aimed at mobile phone users, based around delivery via mobile phone, and using any functions or applications that can be sent or used via a mobile phone.

Information on risk of bias and methodological details was extracted using a standardised form. Participants who dropped out of the trials or were lost to follow–up were included in the analysis. When a study included several interventions using the same financial aid, results were pooled. Where remission was not possible, summary and descriptive statistics are presented.

At least five studies with at least six month cessation outcomes were included in this review. Three studies involve a purely text messaging intervention that has been adapted over the course of these three studies for different populations and contexts. One study is a multi–arm study of a text messaging intervention delivered on the mobile phone. When all five studies were pooled, mobile phone interventions were shown to increase the long–term quit rate compared with control interventions (RR 1.71, 95% CI 1.47 to 1.99, over 9000 participants, using a definition of abstinence of no smoking at six months since quit day but allowing up to five cigarettes. Statistical heterogeneity was substantial as indicated by the I² statistic (I² = 79%).

As all included studies were similar in design, intervention and primary outcome measure, we have presented the meta–analysis in this review.