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Meta-Analysis

[A SYSTEMATIC REVIEW AND NETWORK META- ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

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[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

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This report is based on research conducted by the Canadian Collaboration for Drug Safety, Effectiveness and Network Meta-Analysis (ccNMA).

The report contains a comprehensive review of the existing public literature, studies, materials, and other information and documentation (collectively, the source documentation) available at the time of report preparation, and was guided by expert input and advice throughout its preparation.

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EXECUTIVE SUMMARY

OBJECTIVES

To determine the effectiveness and safety of pharmacological agents, with or without behavioural interventions, to assist smoking cessation among smokers compared to usual care, or placebo.

METHODS

The strategy for building and analyzing the evidence base for pharmacotherapy smoking cessation included two fundamental steps:

1. A broad systematic review of the available randomized evidence in the published literature for the outcomes specified in this protocol was conducted, following the methods and procedures outlined in the Cochrane Handbook for Systematic Reviews for Interventions.
2. A pair-wise meta-analysis and Bayesian network meta-analysis of randomized evidence was conducted connecting the pharmacologic interventions in a network for each of the outcomes specified a priori. The methods and procedures to be followed are those developed by the Canadian Collaboration for Drug Safety, Effectiveness and Network Meta-Analysis (ccNMA), funded by the Drug Safety and Effectiveness Network (DSEN) of the Canadian Institutes of Health Research.

KEY FINDINGS

- For the selected pharmacotherapies that correspond to those that are covered, or provided with no cost access, under the BC Smoking Cessation Program
 - The continuous abstinence rate at 12 months was significantly better for the pharmacotherapies considered (namely: bupropion 150 mg bid, varenicline 1 mg bid and nicotine gum 2mg) compared to placebo
 - The continuous abstinence rate at 12 months was significantly better for the pharmacotherapies considered (namely: bupropion 150 mg bid, varenicline 1 mg bid, nicotine gum 2mg and nicotine patch 21 mg) plus an active behavior support program compared to an active behavior support program on its own.
 - The continuous abstinence rate at 12 months was significantly better for varenicline 1 mg bid with an active behavior support program then for the other pharmacotherapies considered (namely: bupropion 150 mg bid, nicotine gum 2 and nicotine patch 21 mg) with an active behavior support program.
- No safety signal for cardiovascular events or suicides was identified, however, results should be interpreted with caution given the small number of trials reporting these outcomes and the low number of events available for analysis.

1. PURPOSE

Results in this technical report represent the second installment of the broader DSEN-funded smoking cessation research program being conducted in three distinct phases of research.

The first phase resulted in a scientific report describing a preliminary synthesis of evidence for pharmacotherapies (nicotine replacement, bupropion, varenicline) for smoking cessation in selected outcomes (October 2013). The focus of the report was new evidence published after a 2010 report on smoking cessation by the Canadian Agency for Drugs and Technologies in Health (CADTH) (1). The goal of the first phase was to determine how the addition of new evidence would compare to the findings in the CADTH report, and to determine if results for each outcome would change based on updated analyses. Results were reported for the efficacy outcome (12 month biochemically-verified smoking cessation) and the adverse event (suicidal ideation). To decrease the heterogeneity, we did not include anti-smoking interventions for pregnant women, or those of smoking reduction, alternative approaches, mass media (campus), aversion, and multiple health behaviour.

This document reports results for the second stage of the smoking cessation research program. The focus of this detailed scientific report will be the results of a de novo evidence review of all randomized controlled studies (RCT) comparing varenicline, bupropion, nicotine replacement therapies (NRT), and combinations of these pharmacotherapies with behavioural interventions. Analysis is based on a Bayesian network meta-analysis of efficacy and safety outcomes specified in the protocol, including biochemically-verified smoking cessation (continuous abstinence rate) at 12 and > 12 months, suicidal ideation, cardiovascular death and cardio-cerebrovascular events such as myocardial infarction and stroke.

The third phase of the research program will focus on behavioural intervention RCTs for smoking cessation. These additional studies will be incorporated into the evidence networks for each of the outcomes of interest with the existing RCTs of pharmacotherapies/behavioural combinations. This will allow for a more fulsome analysis of drugs alone, drugs in combination, and behavioural interventions alone with the goal of being able to provide recommendations on which drug, behavioural intervention or combination is most effective and safe. The results of the third and final analysis stage are expected by the end of August 2014. The final analyses will likely involve over 400 randomized clinical trials, and will include analysis for each of the population subgroups described in the study protocol. Results from the final Bayesian network meta-analyses will also be used to inform economic analyses and results for cost-effectiveness will be presented in the third and final technical report

2. CLINICAL AND ECONOMIC CONTEXT

The province of British Columbia (BC) offers a program (BC Smoking Cessation Program) designed to assist residents who wish to stop smoking or using other tobacco products (<http://www.health.gov.bc.ca/pharmacare/stop-smoking/>) with the cost of smoking cessation aids. Conducted under the province's PharmaCare program, the BC Smoking Cessation Program entitles eligible residents to covered benefits for prescription smoking cessation drugs [bupropion (Zyban® version only), varenicline] or no cost access to non-prescription NRT in the form of chewing gum (Thrive™) or patches (Habitrol®) in multiple strengths. Coverage for eligible participants begins each calendar year, and entitles individuals to either one drug or one NRT for up to 12 continuous weeks (84 continuous days). Prescription medication costs are covered differently according to the type of PharmaCare coverage plan of the individual.

Recent concerns over neuropsychiatric and cardiovascular adverse events of prescription medications, coupled with a practical need to appraise the currency of the provincial program against current evidence led to a query request from the province of BC to the CIHR-DSEN program. Following a period of query refinement, topic prioritization and funding approval by the CIHR-DSEN program, a project plan was finalized with the goal of assessing the comparative effectiveness and cost-effectiveness of available drugs and NRT products for smoking cessation by way of a systematic review, network meta-

analysis and economic evaluation. In addition, a broader DSEN-funded smoking cessation research program will study behavioural support interventions and will examine, in a more granular way and using the same methodology, which behavioural support interventions combined with which pharmacological therapy are most clinically efficacious/cost-effective.

3. INTRODUCTION

Tobacco smoking is a causative factor in the development of cancer, respiratory disease, and cardiovascular disease. While the prevalence of smoking has declined dramatically over the past three decades, there are still over 5 million smokers in Canada (approximately 19% of Canadians 15 years of age and older). Quitting smoking can definitively improve health and health outcomes for the vast majority of current smokers, and most smokers express the desire and intent to quit smoking.

Up to 40% of smokers attempt to quit smoking each year; most attempts to quit (over 70%) are unaided and less than 5% of smokers who try to quit without assistance are successful at maintaining their abstinence for more than a few months. Medications and various forms of behavioural support, either alone or in combination, are effective in helping smokers to quit compared to no assistance.(2)

Pharmacotherapy: Nicotine replacement therapy (NRT), bupropion (Zyban), or as prescribed for depression, Wellbutrin) and varenicline (Chantix, Chantix) are first-line smoking cessation medications available in Canada with proven efficacy in helping smokers to quit smoking. Systematic reviews and meta-analyses of their effectiveness indicate that they increase the odds of long-term abstinence 2.0 to 3.5 times compared to control (1-5). Nicotine replacement therapy includes nicotine transdermal patches, gum, lozenges, inhalers, sublingual tablets and nasal spray.

Behavioural Support Programs: Numerous behavioural treatments for smoking cessation were developed in the 1970s, '80s and '90s prior to the introduction of medications for smoking cessation. These treatments include techniques such as aversive conditioning, contingency contracting, rapid smoking, self-monitoring, stimulus control, and relapse prevention (6). More recently, however, the focus of behavioural support has been on more brief interventions such as self-help materials (7), health professional advice (8, 9), and motivational counselling techniques (10). These interventions are intended for face-to-face individual or group counselling settings (11), or can be delivered over the telephone (12) or the internet (13).

Combining Pharmacotherapy with Behavioural Support Programs: The combination of pharmacotherapy and behavioural support may have synergistic effects on quitting outcomes because smoking behaviour itself is maintained by addictive, behavioural, and social factors. Pharmacotherapy appears to be important to help people manage symptoms of nicotine withdrawal. Counselling interventions can assist people to manage behavioural and social cues to smoke, help people identify alternatives to smoking, and assist smokers to develop strategies to avoid relapse using problem solving techniques.

The comparative effectiveness, safety and cost-effectiveness of varenicline, bupropion, and nicotine replacement therapy for smoking cessation have been assessed in different reviews. In particular, the 2010 technology report by the Canadian Agency for Drugs and Technologies in Health (CADTH) (revised October 2011) provided the following results: (a) efficacy - varenicline is better than bupropion which is better than NRT; (b) cost-effectiveness - varenicline is better than bupropion which is equal to NRT; and (c) safety - nicotine patch, varenicline, and bupropion had more withdrawals due to adverse events compared to placebo (1). A Cochrane Review of combined pharmacotherapy and behavioural interventions for smoking cessation compared to usual care, brief advice or less intensive behavioural support was recently published (September 2012). Authors concluded through meta-analysis that there was a beneficial treatment effect from the combined interventions (RR 1.82, 95% CI 1.66 to 2.00) but did not assess which pharmacologic agent combined with which behavioural intervention was best. Our reviews will update these previous reviews, as well as considering a network meta-analysis combining direct and indirect evidence in making head-to-head comparisons of therapies.

Questions remain as to the effect of behavioural support programs added to pharmacotherapy and, more specifically, which programs with which drug. Our research team will focus on addressing this knowledge gap using systematic review methodology and a network meta-analysis following a Bayesian mixed treatment comparison (MTC) approach.

OBJECTIVES

To determine the effectiveness and safety of pharmacological agents, with or without behavioural interventions, to assist smoking cessation among smokers compared to usual care, or placebo.

RESEARCH QUESTIONS

1. What is the clinical effectiveness and safety of pharmacologic agents compared to no treatment to assist in smoking cessation in the population of smokers?
2. What is the clinical effectiveness and safety of combining pharmacologic agents and behavioural support programs compared to behavioural support programs to assist in smoking cessation in the populations of smokers?

4. METHODS

The strategy for building and analyzing the evidence base for pharmacotherapy smoking cessation included two fundamental steps:

1. A broad systematic review of the available randomized evidence in the published literature for the outcomes specified in this protocol was conducted, following the methods and procedures outlined in the Cochrane Handbook for Systematic Reviews for Interventions.(14)
2. A pair-wise meta-analysis and Bayesian network meta-analysis of randomized evidence was conducted connecting the pharmacologic interventions in a network for each of the outcomes specified a priori. The methods and procedures to be followed are those developed by the Canadian Collaboration for Drug Safety, Effectiveness and Network Meta-Analysis (ccNMA), funded by the Drug Safety and Effectiveness Network (DSEN) of the Canadian Institutes of Health Research.

POPULATION, INTERVENTION, COMPARATOR, OUTCOMES (PICO) STATEMENT

Studies were included if the following PICO criteria and type of study were considered:

POPULATION: Smokers of either general populations* or specific populations:

The general population of smokers was defined as all smokers in different age groups, groups of males or females, groups with different ethnicities (e.g., First Nations and Inuit), and those undergoing initial treatment (naive) or those undergoing re-treatment (treatment-failure).

The specific populations of smokers of interest are those smokers with: co morbidities; mental illness (including those with an opioid dependence with or without methadone treatment, alcohol problems, depression, schizophrenia, and bipolar disorder); cardiovascular disease (including peripheral vascular disease, acute coronary syndromes and post-myocardial infarction); chronic obstructive pulmonary disease; diabetes; pregnant women; and heavy smokers (e.g., those who smoke more than 20 cigarettes a day). Note that specific populations will be fully analyzed in the network meta-analyses during the third phase of this research program (End of August 2014).

INTERVENTION: Pharmacologic agents and behavioural support programs in combination or alone.

Pharmacologic agents (NRT, Bupropion, and varenicline) with or without behavioural support programs. NRT includes nicotine transdermal patches, nicotine gum, nicotine inhaler, nicotine lozenge, nicotine spray (mouth and nasal) and nicotine sublingual tablets.

Behavioural support programs (BSP) were counselling interventions offered to patients who were ready to quit smoking. Categories* of BSP were defined according to the most recent (2008) evidence-based Clinical Practice Guidelines and will focus on intensity of person-to-person clinical contact, format, and total contact time.[16] Note that these categories will be fully implemented in the network meta-analyses during the third phase of this research program. For the purposes of this report, behavioural interventions administered in addition to pharmacological interventions were classified into two categories – those with a duration of less than 60 minutes total or those with 60 minutes or longer duration.

COMPARATORS: Placebo, no therapy or standard care, monotherapy (behavioural or pharmacologic) or head-to-head of interventions stated above.

OUTCOMES: Biochemically verified smoking abstinence (at 12 months or longer than 12 months)

ADVERSE EVENTS: Cardiovascular death, myocardial infarction, stroke, transient ischemic attack, suicidal ideation, completed suicides, treatment-associated aggressive behaviour.

STUDY DESIGN: Systematic reviews and randomized controlled trials (RCTs) of 6 months or longer duration.

Crossover study designs are considered to be at high risk of bias for this combined intervention because it is likely that there is carryover of treatment effect from one or both of the interventions under study. We also cannot rule out a systematic difference in the time-periods under study. Therefore, crossover studies were included only when period one results were reported independently from the end-of-study results (period two or later).

Systematic reviews were used to check reference lists for eligible studies that met the PICO criteria.

SYSTEMATIC REVIEW

A systematic review of all available evidence in the published literature for the clinical effectiveness and safety outcomes specified in the PICO statement was conducted, following the methods and procedures outlined in the Cochrane Handbook for Systematic Reviews of Interventions (14).

ELECTRONIC SEARCH STRATEGY

The literature search was conducted by a professional medical librarian with knowledge of systematic reviews and the specific analysis techniques required for mixed treatment comparisons. The strategies were divided into two components. During phase one of this research program, searches pertaining to the pharmacotherapy component of smoking cessation were updated as per the strategies listed in the CADTH smoking cessation report on February 18, 2013. A separate search covering a broad range of behavioural therapy interventions was developed and tested through an iterative process by an experienced medical information specialist in consultation with the review team. This strategy was reviewed by another senior information specialist using the Peer Review for Electronic Search Strategies template Available: [http://ejournals.library.ualberta.ca/index.php/EBLIP/article/view/7402/Eligibility/study selection](http://ejournals.library.ualberta.ca/index.php/EBLIP/article/view/7402/Eligibility/study%20selection)).

Using the OVID platform, we searched Ovid MEDLINE®, Ovid MEDLINE® In-Process & Other Non-Indexed Citations, Embase Classic+Embase, and PsycINFO on February 18, 2013. We also searched the Cochrane Library on Wiley (including CENTRAL, Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects (DARE), Health Technology

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Assessment, and National Health Service Economic Evaluation Database (EED) databases) on February 24, 2013. Strategies utilized a combination of controlled vocabulary (e.g., Smoking Cessation, Behavior Therapy, Counselling) and keywords (e.g., brief advice, motivation, self-help). Vocabulary and syntax were adjusted across databases. We used research design filters to identify systematic reviews and meta-analyses, randomized, non-randomized and controlled clinical trials. There were no language or date restrictions on any of the behavioural searches. Additional references were also sought through hand-searching the bibliographies of relevant articles.

A grey literature search of relevant databases and web sites was performed using resources listed in CADTH's Grey Matters (<http://cadth.ca/resources/grey-matters>).

During the second research phase, search strategies were re-run to emulate the February 2013 search, but to return records from database inception to November 17, 2013. The updated search strategy can be found in Appendix A.

ELIGIBILITY/STUDY SELECTION

Studies were included if the PICO criteria and type of study were appropriate. Selection eligibility criteria were applied to each title and abstract identified in the literature search by two independent review authors in a standardized manner. Any uncertainties were resolved by discussion and consensus with a third review author. Any study passing the selection criteria was obtained in full-text format. The eligibility criteria were then applied to the full-text article and a final decision made for inclusion.

DATA EXTRACTION AND MANAGEMENT

All information was extracted using a standardized data abstraction form, which was developed, piloted and modified as necessary for this systematic review. Abstraction included the characteristics of study participants and the study itself, along with the relevant outcomes. All extracted data were extracted and checked for accuracy by two independent review authors.

RISK OF BIAS ASSESSMENT

Quality assessment was conducted using the Cochrane Collaboration's tool for assessing risk of bias (ROB).(14)

ASSESSMENT OF HETEROGENEITY

Studies were assessed for both clinical and methodological diversity. Clinical diversity was assessed by checking that the patients, exposures, and settings are not too different across studies that combining them would not be appropriate. Methodological diversity was assessed by checking that the studies were similar in terms of study design and risk of bias.

Once satisfied that the studies were minimally diverse and that it made sense to pool them together in a meta-analysis, an assessment of the statistical heterogeneity was undertaken by examining the forest plot and result of the I^2 statistic; the forest plots provided a visual sense of heterogeneity and the I^2 statistic indicated the presence of statistical heterogeneity. If the effects observed across studies were inconsistent, and vary to a large extent (say $I^2 > 50\%$), the results were again explored to assess whether the differences can be explained by some clinical or methodological feature.

ASSESSMENT OF REPORTING BIASES

Reporting bias was assessed by constructing funnel plots, as well as bias indicators (e.g. Egger, Harbord-Egger) for each outcome.

ENDPOINT DEFINITIONS

Continuous abstinence rate (CAR): Abstinent from smoking continually since the commencement of a cessation intervention.

Completed Suicide: An act of intentionally causing one's own death.

Suicidal Ideation: Any self-reported thoughts of engaging in suicide-related behavior.

Aggressive Behaviour: Any reported treatment emergent aggressive behaviour .

Cardiovascular Event: Stroke, myocardial infarction or TIA.

Cardiovascular Death: Death resulting from an acute myocardial infarction, sudden cardiac death, death due to heart failure, death due to stroke, and death due to other cardiovascular causes.

META-ANALYSIS AND NETWORK META-ANALYSIS

Both traditional meta-analysis and network meta-analysis require studies to be sufficiently similar in order to pool their results. As a result, heterogeneity across trials in terms of patient characteristics, trial methodologies, and treatment protocols across trials was carefully assessed (15, 16).

Meta-analyses were undertaken using fixed or random-effects models when data were available, sufficiently similar and of sufficient quality. The effect sizes for the identified dichotomous outcomes were expressed in terms of the relative risk (RR) and/or odds ratio (OR). In cases when events were rare, the Peto odds ratio was used.

WinBUGS software (MRC Biostatistics Unit, Cambridge, UK) was used to conduct Bayesian mixed treatment comparison (MTC) meta-analysis using a binomial likelihood model which allows for the use of multi-arm trials (16, 17). Both fixed and random-effects network meta-analyses were conducted; assessment of model fit and choice of model was based on assessment of the Deviance Information Criterion (DIC) and comparison of residual deviance to number of unconstrained data points (15, 17). Trials with zero cells in both arms were excluded from evidence networks because they do not contribute information (17). Continuity corrections were considered for zero numerators in the network meta-analyses, using the adjusted formula of Sweeting.

We modeled point estimates and 95% credible intervals for odds ratios (OR) using Markov Chain Monte Carlo (MCMC) methods. We also assessed the probability that each drug was the most efficacious regimen, the second best, the third best, and so on, by calculating the OR for each drug compared with control group, and counting the proportion of iterations of the Markov chain in which each drug had the highest OR, the second highest, and so on. Vague or flat priors, such as $N(0, 100^2)$ were assigned for basic parameters throughout (17). Informative priors for variance was determined using the following the method of Turner. To ensure convergence was reached, trace plots and the Brooks-Gelman-Rubin statistic were assessed (18). Three chains were fit in WinBUGS for each analysis, with at least 20,000 iterations, and a burn-in of at least 20,000 iterations. Although many trials consider a comparison of a pharmacotherapy versus a placebo or no treatment, behavioural support programs are sometimes administered along with pharmacotherapies. This results in a comparison of the pharmacotherapy plus the behavioural support program versus placebo/no treatment plus the behavioural support program. In some cases, the behavioural support program is only a simple low-intensity level intervention that is considered to ensure that both sides of the comparison have a similar exposure to behavioural interventions and so reduce the background noise when considering the treatment signal associated with the pharmacotherapy. Behavioural support programs shorter than 60 minutes were considered to be low-intensity level interventions as per the recommendation of our ccNMA smoking experts. In this case, the comparison of pharmacotherapy

plus the behavioural support program versus placebo/no treatment plus the behavioural support program will be considered similar to and analyzed with the comparison of a pharmacotherapy versus a placebo/no treatment. This comparative analysis will be the '**Placebo Index Node**'. Behavioural support programs longer than 60 minutes are considered 'active behavioural interventions', and are analyzed separately from the comparison of a pharmacotherapy versus a placebo/ no treatment. In this instance, we consider the comparison of a pharmacotherapy plus active behavioural support program versus active behavioural support program. This comparative analysis will be the '**Active Behaviour Index Node**'. In considering the comparisons and analysis this way, the assumption is made that the behavioural interventions are all similar. Individual behavioural interventions and combinations of these interventions with drug therapy will be explored in much more detail during phase three of this research program.

For each outcome, the odds ratios based on the network meta-analysis, as well as relative risks and absolute risks estimated using these odds ratios and the mean proportion of patients who experience the outcome in the reference group, are provided comparing pharmacotherapies (with or without active behavioural intervention). For outcomes where data was insufficient to construct a robust evidence network, a fixed effects meta-analyses using the Peto odds ratio estimate were considered. For outcomes where data were not sufficient to conduct meta-analyses, a narrative discussion of results is provided.

STAIRCASE DIAGRAMS

Staircase diagrams have been assembled to present results for relative risk and absolute risk difference generated by the indirect comparisons of the various treatment strategies. Figure 1 provides a guide to the interpretation of the results in each staircase diagram presented in the results section.

Figure 1: Interpretation of Results Presented in a Staircase Diagram of Relative Risk and Risk Difference

Treatment 1	Absolute Risk Difference of treatment 2 compared to treatment 1	Absolute Risk Difference of treatment 3 compared to treatment 1	Absolute Risk Difference of treatment 2 compared to treatment 1
Relative Risk of treatment 2 compared to treatment 1	Treatment 2	Absolute Risk Difference of treatment 3 compared to treatment 2	Absolute Risk Difference of treatment 4 compared to treatment 2
Relative Risk of treatment 3 compared to treatment 1	Relative Risk of treatment 3 compared to treatment 2	Treatment 3	Absolute Risk Difference of treatment 4 compared to treatment 1
Relative Risk of treatment 4 compared to treatment 1	Relative Risk of treatment 2 compared to treatment 4	Relative Risk of treatment 3 compared to treatment 4	Treatment 4

Relative Risk = RR (95% Credible Interval), Absolute Risk Difference = RR (95% Credible Interval)
 Note: Bolded numbers in the table indicate statistical significance.

5. RESULTS – SYSTEMATIC REVIEW

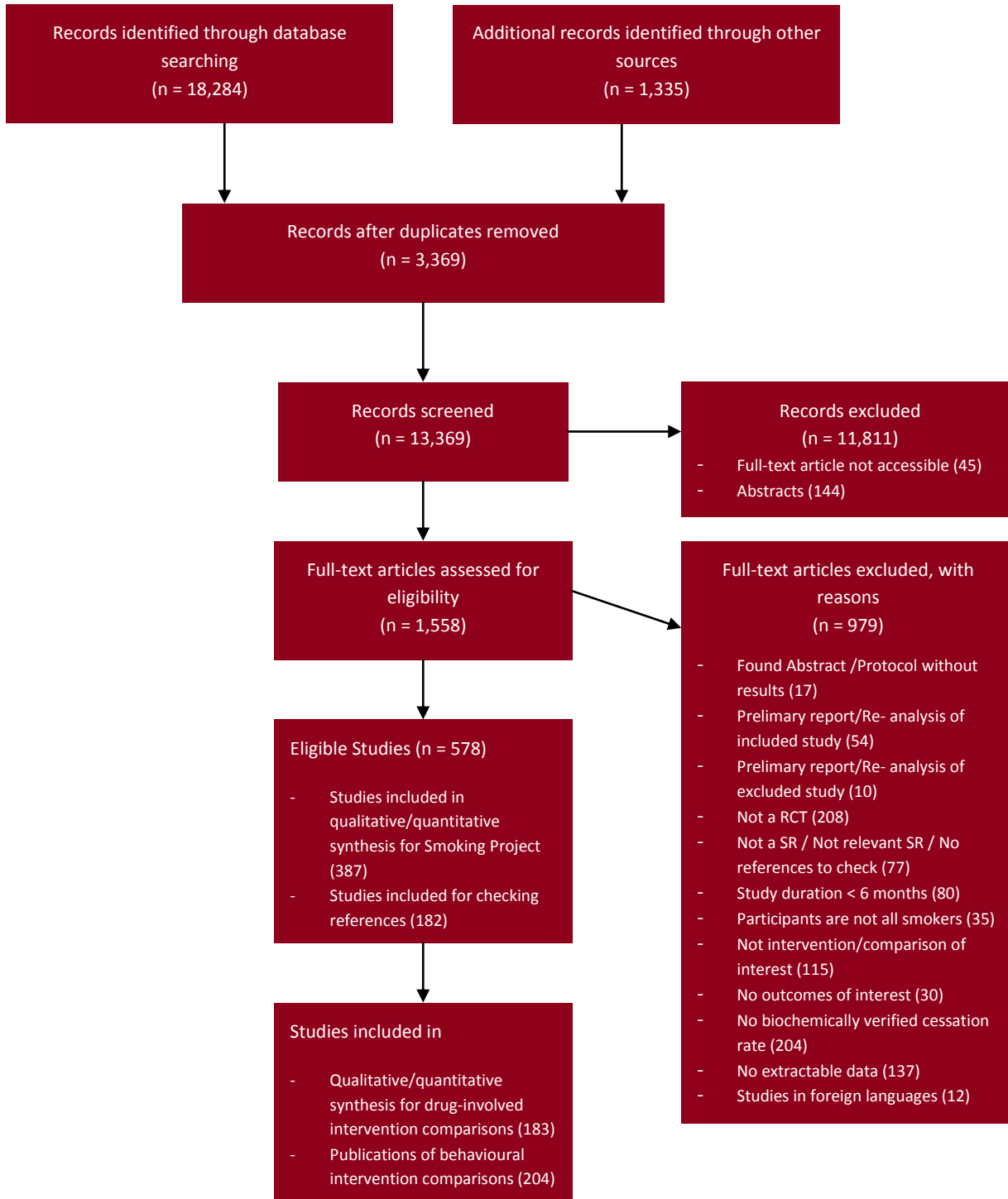
In this section, the results of the literature review, critical appraisal of the studies identified and comparability of the studies are provided.

LITERATURE SEARCH RESULTS

The literature search identified a total of 18,284 references. Once duplicates were removed, 13,369 remained. The titles and abstracts of the search results were independently reviewed by two review authors and 1,561 full-text articles were assessed for eligibility.

For this report on phase two of the research program on smoking cessation, 578 studies met the inclusion criteria. Of the included studies, 183 unique RCTs reported on pharmacotherapies alone or in combination with behavioural interventions in 192 publications that had outcome data required for quantitative analysis of outcomes (19-68)(69-118)(119-167)(168-210). Figure 1 (PRISMA flow diagram) outlines the literature search and article selection process. A list of included studies is provided in Appendix B.

Figure 2. PRISMA Flow Diagram of Article Selection



SUMMARY OF INCLUDED STUDIES

Study and characteristics of the 183 included studies are summarized in Table 1. This review included 183 unique RCTs (reported in 192 publications) evaluating the effects of smoking cessation interventions.

Table 1: Summary of Selected Trial and Patient Characteristics

Trial Characteristics	Categories	Number Of Included Studies/Range
Publication Status	Literature Sources	192
	Unique RCTs	183
Publication Year		Range: 1982 to 2013
Follow-up		Range: 6 months to 6 years
Sample Size		Range: 15 to 3,575
Treatment Arms	2 arms	129
	3 arms	28
	4 arms	21
	≥ 5 arms	5
Patient Characteristics		
% Female		Range: 0% to 100%
Fagerstrom Test for Nicotine Dependence (FTND)		Range: 3.2 to 7.3
Previous Quit Attempts		52% of studies did not report

Detailed study and trial characteristics are provided in Appendix G.

Smoking cessation interventions were administered in a number of different ways in the included studies (Table 2). Combinations of the various interventions were also used and analysed. Many RCTs administered some type of behavioural intervention in addition to the pharmacotherapy interventions. Individual behavioural interventions and combinations of these interventions with drug therapy will be explored in more detail during phase three of this research program.

Table 2: Summary of Doses Available in the Included Studies

Treatment	Lower	Standard	Higher
Bupropion	<150 mg bid	150 mg bid	<150 mg bid
Varenicline	<1 mg bid	1 mg bid	>1 mg bid
Nicotine Replacement Therapy			
Patch (16 hours)	<15 mg	15 mg	>15 mg
Patch (24 hours)	<21 mg	21 mg	>21 mg
Gum	--	2 mg	4 mg
Nasal Spray	--	1mg/dose, 1-2mg/hr	--
Mouth Spray	--	1 mg/spray	--
Lozenge	--	1-2 mg	4 mg
Sublingual Tablet	--	2 mg	--
Inhaler	--	4 mg (~6-16 cartridges/day)	--

qd=once a day, bid=twice a day

RISK OF BIAS ASSESSMENT

A summary of risk of bias assessments of the 183 included trials and their companion publications is provided in Appendix D. A detailed comprehensive assessment of risk of bias by individual trial can be found in Supplemental Appendix A.

The overall risk of bias varied as assessed across the majority of included studies, however, transparency of methods and analysis populations resulted in many assessments rated 'unclear'. For the domain of randomization, although we only included randomized trials in our review, some studies did not provide detailed information. Therefore, we were unable to provide a judgment on 60% and 75% of included studies in terms of random sequence generation and allocation concealment, respectively. For the blinding domain, we categorized our outcome of interest into two sub-types, objective and subjective outcomes. As expected, the blinding of objective outcomes assessment consistently received low risk of bias assessments across studies due to the fact that objective outcomes were based on biochemically verified evidence, which should not be biased by either ineffective blinding approach or the lack of blinding. However, the blinding of subjective outcomes assessment varied across studies (60% low/21% high/19% unclear). In judgment, we only considered the studies which provided appropriate blinding approach as 'low' risk of bias, for example, those described 'matched/identical placebo' with/without details. For those mentioned about 'blind study' in the text but not described the blinding approach, the unclear information would result in the judgment as 'unclear' risk of bias. We were most concerned about the open label studies or studies which did not mention blinding and blinding approach. In our review, 21% of included studies fell in the 'high' risk of bias in this domain.

To judge the domain of "incomplete outcome data addressed", we separate efficacy and safety outcomes because in general, trials have different statistical strategies for those 2 types of outcomes. We also followed a decision hierarchy to make the judgment: firstly, the overall completion rate at endpoint efficacy/outcome assessment (either 6 or 12 months) must be greater than 80%, above which the amount of missing data was considered not to significantly bias the outcome estimate. If the overall completion rate was around 80%, further information about the distributions of the missing data across arms and the approach to handling the missing data were required. However, if the overall completion rate was less than 80%, the outcome estimate would very likely be biased by the missing data and risk level was judged as 'high'. Among all included studies, 13 did not report any efficacy outcome of interest and 38 did not report any efficacy outcome of interest. For the studies where efficacy outcomes of interest were reported, 13% had limited information so we were unable to provide a judgment; 44% and 44% of the studies fell in 'low' and 'high' risk of bias. For those with extractable or inferred safety data, 12% did not provide sufficient information and were judged to be 'unclear' risk of bias; 40% and 48% were respectively considered as 'low' and 'high' risk of bias.

Within the individual studies, 60.6% reported a high risk of bias for one or more key domains. Almost 85% had an unclear risk of bias for one or more key domains, and a large proportion had an unclear risk of bias across 2 domains or more.

Based on the risk of bias assessments, there is a plausible potential for bias in the included studies that needs to be considered when interpreting the results of this report.

6. RESULTS: EFFICACY

The results of the network meta-analysis random effects model for the efficacy outcomes continuous abstinence rate at 12 months and for greater than 12 months are presented below.

CONTINUOUS ABSTINENCE RATE AT 12 MONTHS

Thirty-two studies reported CAR at 12 months involving a total of 16,068 patients. Overall, 20 different treatment strategies were considered, providing for 49 indirect treatment comparisons. Twenty-five studies had 2 treatment arms, six studies had three treatment arms, and one study had four treatment arms. An evidence network diagram could not be generated

due to the complexity of the number of possible treatment comparisons. Detailed results of the network meta-analysis are presented in Appendix E for both the comparison of pharmacotherapy versus placebo (Placebo Index Node) and the comparison of pharmacotherapy plus active behavioural support program versus active behavioural support program (Active Behaviour Index Node). Odds ratios, relative risks and absolute risks are provided for CAR at 12 months comparing each of the treatments. The consistency plots, provided in Appendix F, indicate that both the placebo index node and the active behavior index node networks are consistent.

Results are presented below for selected pharmacotherapies, that correspond to those that are covered, or provided with no cost access, under the BC Smoking Cessation Program, namely: bupropion 150 mg bid, varenicline 1 mg bid, nicotine gum (2 and 4 mg) and nicotine patch (14 and 21 mg). The results of the indirect comparison across the selected treatment strategies are provided in Table 3 and Table 4 for the placebo and active behaviour index nodes respectively.

For CAR 12 months, all pharmacotherapies are significantly better than placebo except for nicotine patch 21 mg. (Table 3)

Table 3: Continuous Abstinence Rate at 12 Months: Relative Risks and Risk Difference for Selected Treatment Comparisons – Network Meta-analysis, Random Effects Model, Placebo Index Node

Placebo	8.00 (3.89,12.89)	8.95 (2.31,19.94)	4.87 (-0.74,14.12)	14.75 (8.06,24.11)
2.01 (1.49,2.65)	bupropion 150 mg bid	0.89 (-7.51,12.93)	-3.06 (-10.81,7.08)	6.74 (-0.43,15.81)
2.13 (1.29,3.63)	1.06 (0.60,1.96)	Nicotine gum 2 mg	-4.00 (-16.42,7.50)	5.87 (-7.18,17.16)
1.61 (0.91,2.81)	0.81 (0.42,1.52)	0.76 (0.35,1.61)	Nicotine Patch 21 mg	6.47 (-6.93,18.71)
2.85 (2.01,4.10)	1.43 (0.98,2.12)	1.35 (0.72,2.44)	1.40 (0.73,2.82)	varenicline 1 mg bid

For pharmacotherapies with an active behaviour support program , 37 studies reported CAR at 12 months involving a total of 15,481 patients. Thirty studies had 2 treatment arms, five studies had three treatment arms, and two study had four treatment arms.

For CAR 12 months, all pharmacotherapies with an active behaviour support program are significantly better than an active behavior support program on its own. Also, varenicline 1 mg bid with active behavior is significantly better than the other pharmacotherapies with active behavior.

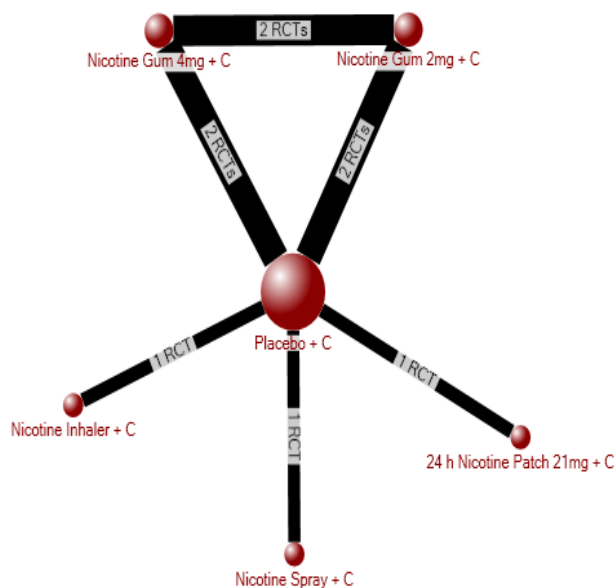
Table 4: Continuous Abstinence Rate at 12 Months: Relative Risks and Risk Difference for Selected Treatment Comparisons – Network Meta-Analysis, Random Effects Model, Active Behaviour Index Node

Placebo	6.22 (3.22,9.84)	5.46 (1.87,9.53)	6.92 (2.28,12.95)	15.36 (10.96,20.53)	11.98 (5.23,20.50)
1.60 (1.30,1.97)	bupropion 150 mg bid	-0.76 (-6.07,4.36)	0.71 (-4.63,6.77)	9.13 (3.98,14.65)	5.75 (-2.16,14.83)
1.52 (1.18,1.95)	0.95 (0.68,1.30)	Nicotine gum 2 mg	1.47 (-4.81,8.66)	9.89 (3.74,16.51)	6.52 (-0.45,14.89)
1.66 (1.22,2.27)	1.04 (0.75,1.44)	1.09 (0.74,1.64)	Nicotine Patch 21 mg	8.37 (2.09,14.52)	5.04 (-4.31,14.83)
2.48 (2.04,3.02)	1.55 (1.21,1.98)	1.62 (1.20,2.25)	1.49 (1.10,2.05)	varenicline 1 mg bid	-3.34 (-12.20,6.13)
2.15 (1.50,3.00)	1.35 (0.88,1.98)	1.41 (0.97,2.02)	1.29 (0.80,2.04)	0.87 (0.57,1.26)	Nicotine gum 4 mg

CONTINUOUS ABSTINENCE RATE > 12 MONTHS

Five studies reported CAR for longer than 12 months involving a total of 1,365 patients. Overall, 6 different treatment strategies were considered, providing for 9 indirect comparisons. Three studies had 2 treatment arms and two studies had three treatment arms. The network consisted of various NRT formats (2 and 4 mg gum, inhaler, nasal spray and 24h patch 21 mg) each with or without active counselling. No studies of varenicline or bupropion were available for analysis in this network.

Figure 3. Evidence diagram for Continuous Abstinence Rate > 12 months



When compared to active behaviour support programs, there was no significant difference between treatment strategies when compared indirectly. The consistency plot, provided in Appendix F, indicate that both the placebo index node and the active behavior index node networks are consistent.

Table 5: Continuous Abstinence Rate > 12 Months: Odds Ratios, Relative Risks and Risk Difference for All Treatment Comparisons – Network Meta-Analysis, Random Effects Model, Active Behaviour Index Node

Treatment	Reference	OR (95% CrI)	RR (95% CrI)	RD% (95% CrI)
NICOTINE GUM 2 MG	ACTIVE BEHAVIOUR	0.93 (0.39,2.60)	0.93 (0.41,2.37)	-0.43 (-4.27,8.22)
24H NICOTINE PATCH 21 MG		2.92 (0.75,11.77)	2.59 (0.77,7.31)	10.19 (-1.45,36.82)
NICOTINE SPRAY		1.43 (0.37,5.57)	1.39 (0.39,4.39)	2.42 (-4.18,20.20)
NICOTINE INHALER		5.17 (0.50,173.80)	4.04 (0.52,23.92)	20.02 (-3.86,83.18)
NICOTINE GUM 4 MG		1.96 (0.86,5.74)	1.84 (0.87,4.49)	5.31 (-0.86,21.08)
24H NICOTINE PATCH 21 MG	NICOTINE GUM 2 MG	3.17 (0.56,15.93)	2.78 (0.59,10.30)	10.44 (-4.21,36.81)
NICOTINE SPRAY		1.54 (0.27,7.37)	1.49 (0.30,5.86)	2.77 (-7.85,20.46)
NICOTINE INHALER		5.62 (0.42,200.50)	4.32 (0.45,31.25)	20.16 (-5.73,82.98)
NICOTINE GUM 4 MG		2.12 (0.85,5.67)	1.98 (0.87,4.71)	5.62 (-1.22,18.58)
NICOTINE SPRAY	24H NICOTINE PATCH 21 MG	0.49 (0.07,3.26)	0.54 (0.10,2.74)	-7.25 (-34.16,13.19)
NICOTINE INHALER		1.78 (0.12,77.19)	1.55 (0.17,13.50)	9.04 (-28.65,76.81)
NICOTINE GUM 4 MG		0.67 (0.14,3.90)	0.72 (0.20,3.24)	-4.54 (-30.98,14.80)
NICOTINE INHALER	NICOTINE SPRAY	3.63 (0.24,159.00)	2.87 (0.29,25.97)	16.74 (-13.85,81.35)
NICOTINE GUM 4 MG		1.37 (0.29,8.09)	1.32 (0.35,6.57)	2.74 (-14.91,19.93)
NICOTINE GUM 4 MG	NICOTINE INHALER	0.38 (0.01,4.99)	0.46 (0.07,4.12)	-14.02 (-79.11,16.22)
Random-Effect Model	Residual Deviance	13.57 vs. 12 data points		
	Deviance Information Criteria	73.332		
Fixed-Effect Model	Residual Deviance	16.77 vs. 12 data points		
	Deviance Information Criteria	75.167		

7. RESULTS: SAFETY

For the safety outcomes, network meta-analysis was conducted for two outcomes, namely: suicidal ideation and myocardial infarction. The choice of these outcomes for network meta-analysis was based on their importance and the sufficiency of the data available to construct a robust evidence network. For outcomes where data were insufficient for a network meta-analysis, a fixed effect meta-analyses using the Peto odds ratio were conducted. This analysis approach was considered for cardiovascular mortality, stroke transient ischemic attack, and treatment emergent aggression. Data was not sufficient to conduct meta-analysis for completed suicides resulting from treatment, and a narrative description of the results is provided.

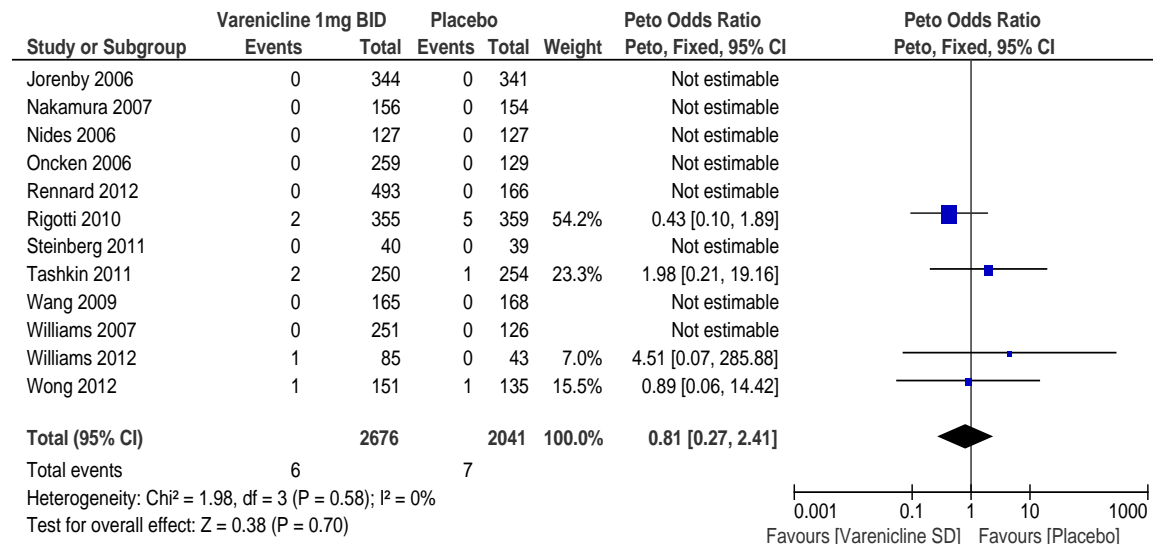
CARDIOVASCULAR MORTALITY

Twelve RCTs (100, 123, 127, 131, 146, 176, 182, 200, 205, 206, 208, 211) reported CV death comparing varenicline 1 mg bid to placebo in 4,588 patients. Eleven RCTs (44, 95, 100, 127, 137, 170, 193, 194, 198, 212, 213) reported CV deaths in comparisons of bupropion 150 mg bid to placebo (n=4,525 patients). Event rates in all trials were low.

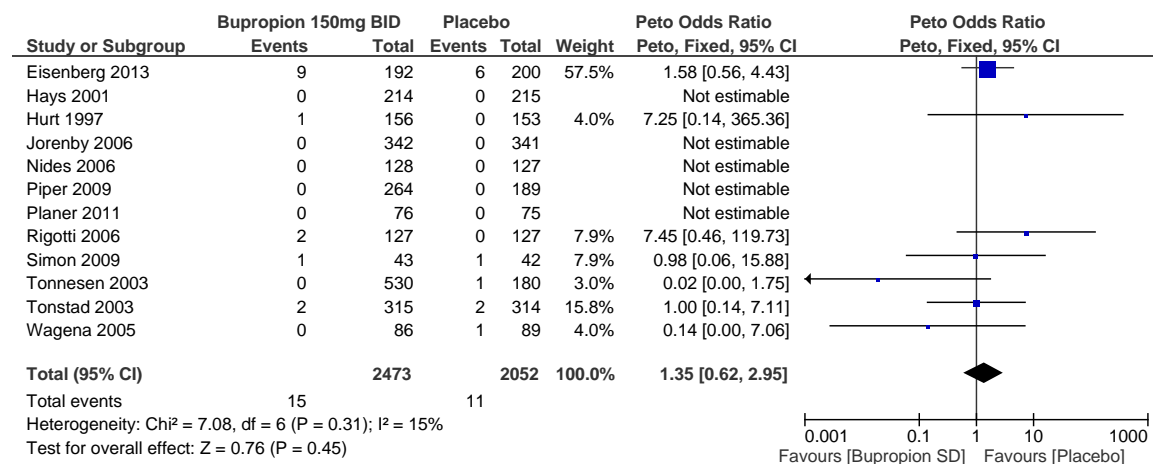
A Bayesian NMA could not be conducted for stroke due to the limited data available for analysis. CV deaths were reported in five RCTs comparing varenicline versus placebo, and 7 RCTs comparing bupropion versus placebo. Fixed effects meta-analyses was conducted for a Peto odds ratio estimate. Results, based on the available evidence, show there is not an increase in CV death risk with standard doses of varenicline (OR 1.06, 95% CI 0.37 to 3.04) and bupropion (OR 1.35, 95% CI 0.62 to 2.95) when compared to placebo (Figure 4); however, results should be interpreted with caution given the small number of trials reporting this outcome and the low number of events available for analysis.

Figure 4: Cardiovascular Death: Peto’s Odds Ratios for Selected Treatment Comparisons – Meta-Analysis, Fixed Effects Model, Placebo Index Node

Varenicline vs. Placebo



Bupropion vs. Placebo



Three, multi-arm studies(123, 127, 131) that reported cardiovascular death as an outcome were excluded from the varenicline versus placebo meta-analysis due to the doses of varenicline used in the treatment arms. No cardiovascular deaths were reported in any treatment arms. A four-arm bupropion dose-ranging study(95) could not be included in the meta-analysis due to the range of doses (n=615). A single case of cardiovascular death was reported the bupropion 300 mg (150 mg bid) plus an active behaviour treatment arm.

CARDIOVASCULAR EVENTS

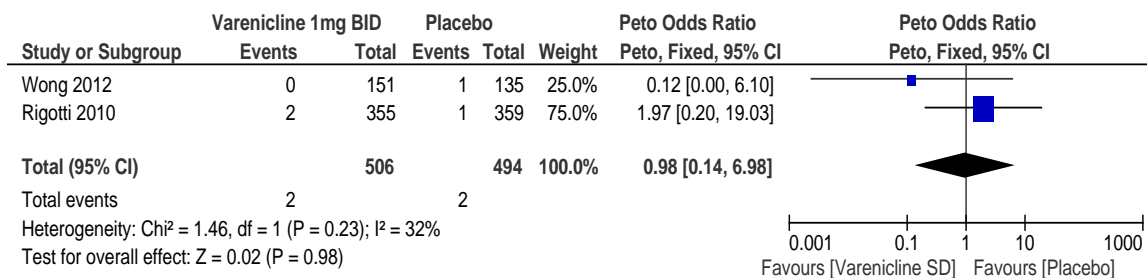
STROKE

Two RCTs (153, 208) reported stroke outcomes. Both RCTs compared varenicline 1 mg bid to placebo (with active behavioural support program in both treatment arms) in 1,000 patients. No data was available to make a comparison of bupropion 150 mg bid to placebo. Event rates in both trials of varenicline were low.

A Bayesian NMA could not be conducted for stroke due to the limited data available for analysis. A fixed effects meta-analysis was conducted for a Peto odds ratio estimate. Results based on the available evidence show there is not an increase in stroke risk with varenicline (OR 0.98, 95% CI 0.14 to 6.98) when compared to placebo (Figure 5); however, results should be interpreted with caution given the small number of trials reporting this outcome and the low number of events available for analysis.

Figure 5: Stroke Events: Peto’s Odds Ratio for Treatment Comparisons to Placebo – Meta-Analysis, Fixed Effects Model

Varenicline 1 mg bid vs. Placebo



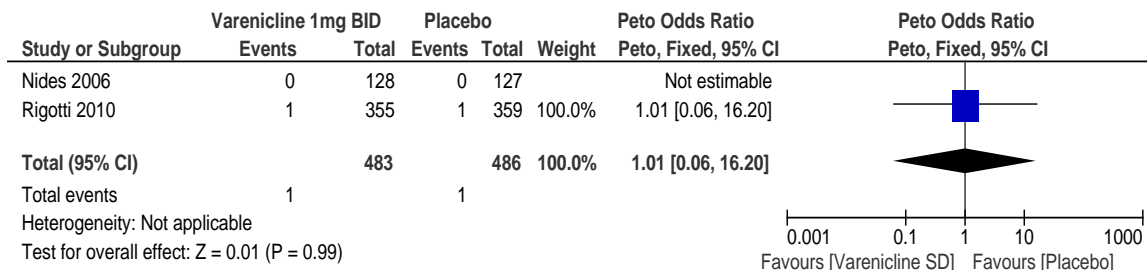
TRANSIENT ISCHEMIC ATTACK (TIA)

Four RCTs reported TIA for two treatment strategies: bupropion 150 mg bid compared to placebo (181, 209) and varenicline 1 mg bid (127, 153) compared to placebo. Event rates were low or null in all four studies. A Bayesian NMA could not be conducted due to the limited data available. Therefore a fixed meta-analyses was conducted for a Peto odds ratio estimate. Results in this limited data showed that the available evidence does not support an increase in risk of TIA with varenicline (OR 1.01, 95% CI 0.06 to 16.20) or bupropion (OR 0.06, 95% CI 0.00 to 1.10) when compared to placebo (

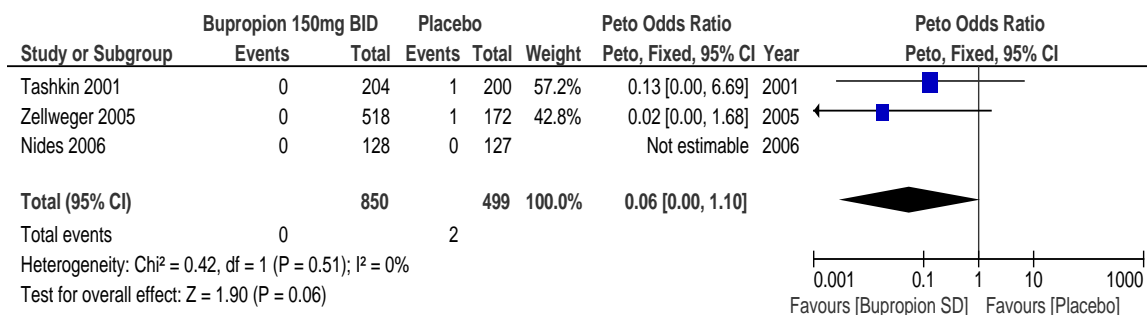
Figure 6); however, results should be interpreted with caution given the small number of trials reporting this outcome and the low number of events available for analysis.

Figure 6: Transient Ischemic Attack: Peto’s Odds Ratios for Treatment Comparisons to Placebo – Meta-Analysis, Fixed Effects Model

Varenicline 1 mg bid vs. Placebo



Bupropion 150 mg bid vs. Placebo



MYOCARDIAL INFARCTION

Four studies (44, 54, 64, 77, 126, 137, 139, 144, 153, 162, 206, 208) reported data for myocardial infarction (MI) involving a total of 2,547 patients. Overall, 4 different treatment strategies were considered, providing for 6? indirect comparisons. Three studies were 2-arm RCTs, and one had three-arms.

Data for only a few pharmacotherapy comparisons were available. Considered without an active behavior support program (Table 6), no significant differences were found but the results should be interpreted with caution given the small number of trials reporting this outcome and the low number of events available for analysis. Insufficient data was available to consider a network for pharmacotherapies with an active behavior support program.

Table 6: Myocardial Infarction: Odds Ratios, Relative Risks and Risk Difference for All Treatment Comparisons – Network Meta-Analysis, Random Effects Model, Placebo Index Node

Treatment	Reference	OR (95% CrI)	RR (95% CrI)	RD% (95% CrI)
BUPROPION 150 MG BID	PLACEBO	1.39 (0.21,11.79)	1.39 (0.21,11.71)	0.08 (-0.39,0.93)
24 H NICOTINE PATCH 21 MG		0.99 (0.02,46.03)	0.99 (0.02,43.46)	0.00 (-0.47,5.23)
VARENICLINE 1 MG BID		0.20 (0.00,11.78)	0.20 (0.00,11.59)	-0.13 (-0.58,1.43)
24 H NICOTINE PATCH 21 MG	BUPROPION 150 MG BID	0.68 (0.01,47.72)	0.68 (0.01,45.16)	-0.08 (-1.01,5.25)
VARENICLINE 1 MG BID		0.14 (0.00,7.74)	0.14 (0.00,7.61)	-0.20 (-1.01,1.30)
VARENICLINE 1 MG BID	24 H NICOTINE PATCH 21 MG	0.16 (0.00,50.38)	0.16 (0.00,49.91)	-0.12 (-5.31,1.44)
Random-Effect Model	Residual Deviance	5.979 vs. 9 data points		
	Deviance Information Criteria	31.556		

Fixed-Effect Model	Residual Deviance	6.041 vs. 9 data points
	Deviance Information Criteria	31.282

COMPLETED SUICIDES

Twenty-three RCTs referred to completed suicide events in their study publications. (23, 28, 46, 77, 78, 123, 127, 131, 139, 144, 146, 153, 162, 164, 175, 176, 180, 182, 198, 200, 205, 206, 214) Event rates were zero in all treatment arms in all 23 studies.

SUICIDAL IDEATION

Data was available to consider a network meta-analysis for suicidal ideation. Seven studies reported suicidal ideation as an outcome involving a total of 2,966 patients. Overall, 4 different treatment strategies were considered, providing for 7 indirect comparisons. All studies had 2 treatment arms. Event rates were low or zero in all studies. No data for suicidal ideation was inferred for this outcome. Only studies directly reporting this outcome in their publication were included in this analysis.

Given the available data, no significant differences in the risk of suicidal ideation between varenicline, bupropion, nicotine patch and placebo were found. This held true across effect estimates (OR, RR and RD). Results must be interpreted with caution given the small number of patients who had experienced this outcome. Consistency could not be evaluated for this network as there were no closed loops in the evidence network.

Table 7: Suicidal Ideation: Odds Ratios, Relative Risks and Risk Difference for All Treatment Comparisons – Network Meta-Analysis, Random Effects Model, Active Behaviour Index Node

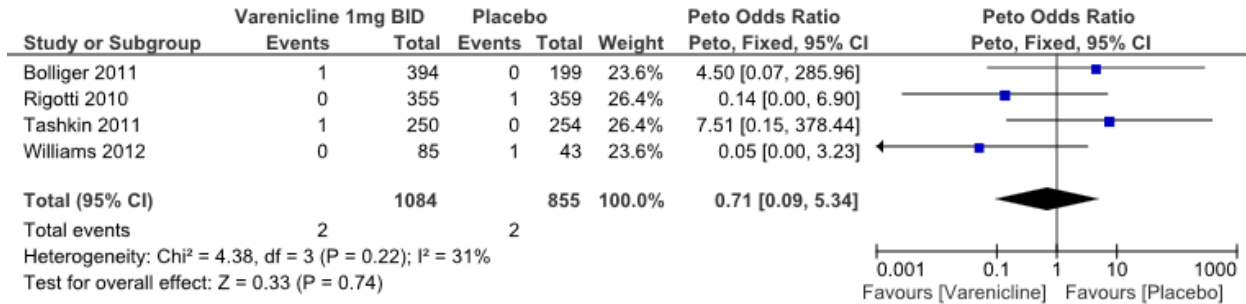
Treatment	Reference	OR (95% CrI)	RR (95% CrI)	RD% (95% CrI)
BUPROPION 150 MG BID	ACTIVE BEHAVIOUR	0.25 (0.01,2.55)	0.26 (0.01,2.49)	-1.26 (-2.99,2.25)
24H NICOTINE PATCH 21 MG		0.11 (0.00,4.46)	0.11 (0.00,4.19)	-1.46 (-3.15,5.46)
VARENICLINE 1 MG BID		0.51 (0.15,1.72)	0.51 (0.15,1.70)	-0.86 (-2.48,0.93)
24H NICOTINE PATCH 21 MG	BUPROPION 150 MG BID	0.42 (0.00,68.75)	0.42 (0.00,64.25)	-0.16 (-3.69,6.76)
VARENICLINE 1 MG BID		2.03 (0.15,84.64)	2.02 (0.15,83.16)	0.41 (-3.15,2.32)
VARENICLINE 1 MG BID	24H NICOTINE PATCH 21 MG	4.80 (0.15,3842.00)	4.76 (0.16,3786.00)	0.57 (-5.77,2.20)
Random-Effect Model	Residual Deviance	9.752 vs. 14 data points		
	Deviance Information Criteria	50.479		
Fixed-Effect Model	Residual Deviance	9.860 vs. 14 data points		
	Deviance Information Criteria	50.403		

TREATMENT-EMERGENT AGGRESSION

Data was insufficient to conduct a network meta-analysis. Four RCTs (5 publications) that reported 3 aggression outcomes in 1,939 study participants (28, 153, 182, 205, 214). All four RCTs compared varenicline to placebo. Bolliger 2011 focused on efficacy and tolerability in Latin America, Africa, and the Middle East participants. One participant in the varenicline group (n=390) had treatment-emergent aggression during the study. No events were reported in the placebo group (n=198). Rigotti 2010 studied participants with cardiovascular disease and closely monitored psychiatric and other treatment emergent serious adverse events. One participant in the placebo group reported aggression in the study. Tashkin

2011 found 1 case of behaviour disturbance in the form of aggression in the varenicline group and none in the placebo group in their study in patients with mild to moderate chronic obstructive pulmonary disorder. In participants with schizophrenia or schizoaffective disorder, Williams 2012 found a single aggression event in the placebo arm of the study.

Figure 7: Treatment-Emergent Aggression: Odds Ratios for Treatment Comparisons to Placebo – Meta-Analysis, Fixed Effects Model



8. DISCUSSION

In the previous report, it was found that the addition of 29 studies available since the CADTH report was published to the CADTH data for the assessment of pharmacotherapies in smoking cessation resulted in similar findings as the CADTH conclusions. This report, which involved a systematic review and analysis of all RCTs using a single search strategy and uniform study selection, considered 183 studies and yielded results consistent with our previous review.

However, as noted in our previous report, this provides a limited assessment of the evidence in smoking cessation. A gap remains in determining which treatment approach is most clinically efficacious/cost effective. This requires a clear analysis of all treatment modalities (in combination and alone) such as pharmacologic and behavioral therapies. While there are reports that have addressed this topic, there is an information gap in assessing which specific behavioral therapies in combination with specific pharmacotherapies are most efficacious/cost effective. Behavioral therapies vary greatly in the literature, making it important to ensure the analysis reflects appropriate categorization of the approaches. An analysis such as this is not possible by simply updating an existing report because the data has not been captured, reported or analyzed with enough detail on the interventions. This would require an entirely new analysis of the evidence base. Our final report will consider these issues in greater detail.

As mentioned in the results section, information on harms data is limited when considering only randomized controlled trials (RCT). To assess the important issue related to harms, both RCT and non RCT data should be considered in subsequent assessments.

Different treatment approaches are needed for different populations, such as those with substance abuse, mental health and other concomitant disorders. There is limited trial evidence in these populations, however, tailoring treatment approaches to best serve these populations is worthy of investigation.

LIMITATIONS

- Heterogeneity of the results across studies is always an issue when considering these types of analyses.
- Based on the risk of bias assessments, there is a plausible potential for bias in the included studies that needs to be considered when interpreting the results of this report.
- For the adverse events, results should be interpreted with caution given the small number of trials reporting these events and the small number of events available for analysis.
- The focus of this report was on pharmacotherapies which may be given with or without an active behavior support program; these behaviour support programs were broadly divided into those that were considered not active (< 60 minutes contact time) and those considered active (> 60 min contact time).
- When considering active behavioural support programs, all these programs were considered the same; in the next report a more detailed assessment of the structure of these programs will be considered in the analysis.

NEXT STEPS

This is the second report in the series, in which a systematic review was conducted from the first pharmacological therapy study, and so replacing the results from the CADTH report of the earlier studies. The third report will include the behavioural programs and the combination of behaviour and pharmacological therapies. The final report will investigate the availability now and in the future of real world data and strategies for incorporating these data into the network analysis.

KEY MESSAGES

- For the selected pharmacotherapies that correspond to those that are covered, or provided with no cost access, under the BC Smoking Cessation Program
 - The continuous abstinence rate at 12 months was significantly better for the pharmacotherapies considered (namely: bupropion 150 mg bid, varenicline 1 mg bid and nicotine gum 2) compared to placebo
 - The continuous abstinence rate at 12 months was significantly better for the pharmacotherapies considered (namely: bupropion 150 mg bid, varenicline 1 mg bid, nicotine gum 2 and nicotine patch 21 mg) plus an active behavior support program compared to an active behavior support program on its own.
 - The continuous abstinence rate at 12 months was significantly better for varenicline 1 mg bid with an active behavior support program than for the other pharmacotherapies considered (namely: bupropion 150 mg bid, nicotine gum 2 and nicotine patch 21 mg) with an active behavior support program.
- No safety signal for cardiovascular events or suicides was identified, however, results should be interpreted with caution given the small number of trials reporting these outcomes and the low number of events available for analysis.

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APPENDIX A: RESEARCH PHASE 2 LITERATURE SEARCH STRATEGY

Database: Embase Classic+Embase <1947 to 2013 November 15>, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1946 to Present> Search Strategy:

- 1 Smoking Cessation/ (57316)
- 2 ((smoking or smokers or smoker or smoke or tobacco or nicotine or cigarette*) adj5 (stop* or ceas* or cessation* or discontinu* or abandon* or desist* or end or "give up" or halt* or quit or quits or quitting or terminat*)).tw. (57684)
- 3 Smoking/pc, th [Prevention & Control, Therapy] (24972)
- 4 or/1-3 (94309)
- 5 Smoking Cessation/px [Psychology] (4563)
- 6 Smoking/px [Psychology] (10288)
- 7 exp Behavior Therapy/ (90667)
- 8 (behavio?r* adj3 (chang* or modif* or therap* or psychotherap* or psycho-therap* or intervention* or treatment*)).tw. (176687)
- 9 ((cognitive or cognition) adj3 (therap* or psychotherap* or psycho-therap* or intervention* or treatment*)).tw. (44006)
- 10 CBT.tw. (12249)
- 11 applied behavio?r* analy*.tw. (688)
- 12 ((acceptance* or commitment) adj therap*).tw. (549)
- 13 ((feedback or biofeedback or bio-feedback) adj3 (psycholog* or psychophysiologic* or psycho-physiologic*)).tw. (217)
- 14 counselling/ or directive counselling/ (70755)
- 15 counsel*.tw. (161687)
- 16 Health Behavior/ (77330)
- 17 health behavio?r*.tw. (25695)
- 18 Self Care/ (53367)
- 19 Self Efficacy/ (67078)
- 20 (self adj (care or control* or efficac* or help* or manag* or monitor* or restrain* or support*)).tw. (97558)
- 21 Self-Help Groups/ (19309)
- 22 social support/ (108319)
- 23 ((social* or behavio?r* or community or family) adj3 support*).tw. (86990)
- 24 support network*.tw. (3892)
- 25 Motivation/ (120623)
- 26 (motivat* or quitline* or quit line\$1).tw. (167112)
- 27 exp Exercise Therapy/ (79922)
- 28 ((exercis* or motion or movement or physical activit* or CPM or resistance or stretching) adj3 (program* or therap* or train*)).tw. (99945)
- 29 (relax* adj3 (program* or technic or technics or technique* or therap* or train*)).tw. (9761)
- 30 Patient Education as Topic/ (157731)
- 31 (patient* adj3 (educat* or booklet* or pamphlet*)).tw. (56719)
- 32 (education* adj3 (advic* or class\$2 or intervention* or program* or project* or train*)).tw. (131175)
- 33 ((professional* or clinician* or doctor* or medical or nurs* or patient* or physician* or therapist*) adj3 (advic* or advis* or encourag* or messag* or warn*)).tw. (59374)
- 34 exp Health promotion/ (124187)
- 35 ((health* or wellness or smoke or smoker* or smoking or anti-smok* or antismok* or tobacco or anti-tobacco or antitobacco or nicotine or anti-nicotine or antinicotine or cigarette* or anti-cigarette* or anticigarette*) adj3 (educat* or booklet* or pamphlet* or advic* or advis* or messag* or warn*)).tw. (115748)
- 36 ((health* or wellness or smoke or smoker* or smoking or anti-smok* or antismok* or tobacco or anti-tobacco or antitobacco or nicotine or anti-nicotine or antinicotine or cigarette* or anti-cigarette* or anticigarette*) adj3 (ad or ads or advertisement* or campaign*)).tw. (12038)
- 37 ((health* or wellness*) adj3 promot*).tw. (76563)
- 38 (brief adj (advic* or intervention*)).tw. (5392)
- 39 ((aversive or aversion) adj3 (conditioning or smoking or therap*)).tw. (2884)
- 40 ("rapid smoking" or "rapid cigarette smoking").tw. (143)
- 41 (stimul* adj1 control*).tw. (8451)
- 42 contingency contracting.tw. (196)
- 43 Avoidance Learning/ (42041)
- 44 Reversal Learning/ (129612)
- 45 ((avoid* or reverse or reversal) adj3 (learn* or train*)).tw. (12051)
- 46 "Conditioning (Psychology)"/ (50603)
- 47 conditioning.tw. (105214)
- 48 ((operant or instrumental) adj learning).tw. (1267)
- 49 "Practice (Psychology)"/ (132330)
- 50 (practice adj1 psycholog*).tw. (448)
- 51 exp "Reinforcement (Psychology)"/ (73599)
- 52 (reinforc* or reward* or penalt* or penali* or punish* or incentive*).tw. (273654)
- 53 "Set (Psychology)"/ (132555)
- 54 (set adj1 psycholog*).tw. (73)
- 55 (desensiti* or de-sensiti*).tw. (57122)
- 56 exp Mind-Body Therapies/ (75138)

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- 57 ((mind-body or body-mind) adj (medicine or therap*)).tw. (812)
58 (breathing exercise* or "Ch'i Kung" or "Qi Gong" or Qigong or respiratory muscle training or respiratory muscle exercis*).tw. (3315)
59 (hypnosis or hypnotic* or hypnotherap* or hypno-therap*).tw. (15332)
60 (guided image* or directed revery therap* or laughter therap* or meditation or psychodrama* or psycho-drama* or role playing or psychophysiolog* or psycho-physiolog*).tw. (29203)
61 (aromatherap* or aroma therap*).tw. (1627)
62 ("Tai Ji" or "Tai Chi" or "Tai Chi" or Taiji or Taijiquan or meditat* or yoga or yogic).tw. (12518)
63 "Extinction, Psychological"/ (38351)
64 (extinction adj1 psycholog*).tw. (1)
65 (relaps* adj3 prevent*).tw. (16864)
66 (game or games or boardgame* or board-game*).tw. (38771)
67 or/5-66 (2270222)
68 4 and 67 (44759)
69 meta-analysis.pt. (51772)
70 meta-analysis/ (129113)
71 meta-analysis as topic/ (24270)
72 exp technology assessment, biomedical/ (20987)
73 ((systematic* adj3 (review* or overview*)) or (methodologic* adj3 (review* or overview*))).tw. (132941)
74 ((quantitative adj3 (review* or overview* or synthes*)) or (research adj3 (integrati* or overview*))).tw. (12150)
75 ((integrative adj3 (review* or overview*)) or (collaborative adj3 (review* or overview*)) or (pool* adj3 analy*)).tw. (25434)
76 (data synthes* or data extraction* or data abstraction*).tw. (30477)
77 (handsearch* or hand search*).tw. (13290)
78 (mantel haenszel or peto or der simonian or dersimonian or fixed effect* or latin square*).tw. (30365)
79 (met analy* or metanaly* or health technology assessment* or HTA or HTAs).tw. (7141)
80 (meta-analy* or metaanaly* or systematic review* or biomedical technology assessment* or bio-medical technology assessment*).mp. (303303)
81 (medline or Cochrane or pubmed or medlars).tw. (195391)
82 (cochrane or health technology assessment or evidence report).jw. (33972)
83 or/69-82 (475192)
84 68 and 83 (2181)
85 limit 84 to human (2075)
86 (in process or publisher or pubmed-not-medline or in-data-review).st. (1675448)
87 84 and 86 (58)
88 85 or 87 (2133)
89 (Randomized Controlled Trial or Controlled Clinical Trial).pt. (475293)
90 Randomized Controlled Trial/ (752782)
91 Randomized Controlled Trials as Topic/ (144124)
92 Controlled Clinical Trial/ or Controlled Clinical Trials as Topic/ (504178)
93 Random Allocation/ (145916)
94 Double-Blind Method/ or Single-Blind Method/ or Placebos/ (504924)
95 (random* or RCT\$1 or sham or shams or placebo*).tw. (1886408)
96 ((singl* or doubl* or trebl* or tripl*) adj (mask* or blind* or dumm*)).tw. (303294)
97 exp Control Groups/ (64720)
98 exp Case-Control Studies/ (757164)
99 ((control* adj2 stud*) or (control* adj2 trial*) or case-control*).tw. (689387)
100 (nonrandom* or non random* or non-random* or quasi-random*).tw. (64541)
101 (control* adj3 ("before and after" or "before after" or "time series")).tw. (6620)
102 interrupted time series.tw. (2328)
103 trial.ti. (296478)
104 or/89-103 (3525079)
105 68 and 104 (11481)
106 limit 105 to human (11038)
107 105 and 86 (223)
108 106 or 107 (11261)
109 88 or 108 (12146)
110 109 use prnz (6617)
111 smoking cessation/ or smoking cessation program/ (58223)
112 ((smoking or smokers or smoker or smoke or tobacco or nicotine or cigarette*) adj5 (stop* or ceas* or cessation* or discontinu* or abandon* or desist* or end or "give up" or halt* or quit or quits or quitting or terminat*)).tw. (57684)
113 smoking/th [Therapy] (1503)
114 or/111-113 (80844)
115 exp behavior therapy/ (90667)
116 (behavio?r* adj3 (chang* or modif* or therap* or psychotherap* or psycho-therap* or intervention* or treatment*)).tw. (176687)
117 ((cognitive or cognition) adj3 (therap* or psychotherap* or psycho-therap* or intervention* or treatment*)).tw. (44006)
118 CBT.tw. (12249)
119 applied behavio?r* analy*.tw. (688)
120 ((acceptance* or commitment) adj therap*).tw. (549)
121 ((feedback or biofeedback or bio-feedback) adj3 (psycholog* or psychophysiologic* or psycho-physiologic*)).tw. (217)

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- 122 counselling/ or directive counselling/ (70755)
- 123 counsel*.tw. (161687)
- 124 health behavior/ (77330)
- 125 health behavior*.tw. (25695)
- 126 self care/ or self help/ (64343)
- 127 self control/ (3628)
- 128 (self adj (care or control* or efficac* or help* or manag* or monitor* or restrain* or support*)).tw. (97558)
- 129 social support/ (108319)
- 130 ((social* or behavior* or community or family) adj3 support*).tw. (86990)
- 131 support network*.tw. (3892)
- 132 motivation/ or motivational interviewing/ (121209)
- 133 (motivat* or quitline* or quit line\$.tw. (167112)
- 134 exp kinesiotherapy/ (49577)
- 135 ((exercis* or motion or movement or physical activit* or CPM or resistance or stretching) adj3 (program* or therap* or train*)).tw. (99945)
- 136 relaxation training/ (8409)
- 137 (relax* adj3 (program* or technic or technics or technique* or therap* or train*)).tw. (9761)
- 138 patient education/ (157731)
- 139 (patient* adj3 (educat* or booklet* or pamphlet*)).tw. (56719)
- 140 (education* adj3 (advice or class\$2 or intervention* or program* or project* or train*)).tw. (131175)
- 141 ((professional* or clinician* or doctor* or medical or nurs* or patient* or physician* or therapist*) adj3 (advice or advis* or encourag* or messag* or warn*)).tw. (59374)
- 142 health promotion/ (122955)
- 143 ((health* or wellness or smoke or smoker* or smoking or anti-smok* or antimok* or tobacco or anti-tobacco or antitobacco or nicotine or anti-nicotine or antinicotine or cigarette* or anti-cigarette* or anticigarette*) adj3 (educat* or booklet* or pamphlet* or advice or advis* or messag* or warn*)).tw. (115748)
- 144 ((health* or wellness or smoke or smoker* or smoking or anti-smok* or antimok* or tobacco or anti-tobacco or antitobacco or nicotine or anti-nicotine or antinicotine or cigarette* or anti-cigarette* or anticigarette*) adj3 (ad or ads or advertisement* or campaign*)).tw. (12038)
- 145 ((health* or wellness*) adj3 promot*).tw. (76563)
- 146 (brief adj (advice or intervention*)).tw. (5392)
- 147 aversion therapy/ (1502)
- 148 ((aversive or aversion) adj3 (conditioning or smoking or therap*)).tw. (2884)
- 149 ("rapid smoking" or "rapid cigarette smoking").tw. (143)
- 150 (stimul* adj1 control*).tw. (8451)
- 151 contingency contracting.tw. (196)
- 152 avoidance behavior/ (22598)
- 153 ((avoid* or reverse or reversal) adj3 (learn* or train*)).tw. (12051)
- 154 conditioning/ (50603)
- 155 conditioning.tw. (105214)
- 156 ((operant or instrumental) adj learning).tw. (1267)
- 157 (practice adj1 psycholog*).tw. (448)
- 158 reinforcement/ (45487)
- 159 (reinforc* or reward* or penal* or penali* or punish* or incentive*).tw. (273654)
- 160 (set adj1 psycholog*).tw. (73)
- 161 (desensiti* or de-sensiti*).tw. (57122)
- 162 ((mind-body or body-mind) adj (medicine or therap*)).tw. (812)
- 163 (breathing exercise* or "Ch'i Kung" or "Qi Gong" or Qigong or respiratory muscle training or respiratory muscle exercis*).tw. (3315)
- 164 hypnosis/ (23882)
- 165 (hypnosis or hypnotic* or hypnotherap* or hypno-therap*).tw. (15332)
- 166 meditation/ (5254)
- 167 psychodrama/ (2271)
- 168 role playing/ (17759)
- 169 psychophysiology/ (26175)
- 170 (guided image* or directed revery therap* or laughter therap* or meditation or psychodrama* or psycho-drama* or role playing or psychophysiol* or psycho-physiol*).tw. (29203)
- 171 aromatherapy/ (1658)
- 172 (aromatherap* or aroma therap*).tw. (1627)
- 173 ("Tai Ji" or "T'ai Chi" or "Tai Chi" or Taiji or Taijiquan or meditat* or yoga or yogic).tw. (12518)
- 174 (extinction adj1 psycholog*).tw. (1)
- 175 (relaps* adj3 prevent*).tw. (16864)
- 176 (game or games or boardgame* or board-game*).tw. (38771)
- 177 or/115-176 (2094159)
- 178 114 and 177 (36908)
- 179 meta analysis/ (129113)
- 180 "meta analysis (topic)"/ (10111)
- 181 biomedical technology assessment/ (19882)
- 182 "systematic review"/ (66372)
- 183 ((systematic* adj3 (review* or overview*)) or (methodologic* adj3 (review* or overview*))).tw. (132941)

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184 ((quantitative adj3 (review* or overview* or synthes*)) or (research adj3 (integrati* or overview*))).tw. (12150)
185 ((integrative adj3 (review* or overview*)) or (collaborative adj3 (review* or overview*)) or (pool* adj3 analy*)).tw. (25434)
186 (data synthes* or data extraction* or data abstraction*).tw. (30477)
187 (handsearch* or hand search*).tw. (13290)
188 (mantel haenszel or peto or der simonian or dersimonian or fixed effect* or latin square*).tw. (30365)
189 (met analy* or metanaly* or health technology assessment* or HTA or HTAs).tw. (7141)
190 (meta-analy* or metaanaly* or systematic review* or biomedical technology assessment* or bio-medical technology assessment*).mp. (303303)
191 (medline or Cochrane or pubmed or medlars).tw. (195391)
192 (cochrane or health technology assessment or evidence report).jx. (14255)
193 or/179-192 (473500)
194 178 and 193 (2017)
195 (exp animal/ or animal.hw. or nonhuman/) not (exp human/ or human cell/ or (human or humans).ti.) (9938056)
196 194 not 195 (2010)
197 randomized controlled trial/ (752782)
198 "randomized controlled trial (topic)"/ (41544)
199 controlled clinical trial/ (496826)
200 "controlled clinical trial (topic)"/ (2215)
201 Randomization/ (145916)
202 double blind procedure/ or single blind procedure/ or placebo/ (333758)
203 (random* or RCT\$1 or sham or shams or placebo*).tw. (1886408)
204 ((singl* or doubl* or trebl* or tripl*) adj (mask* or blind* or dumm*)).tw. (303294)
205 control group/ (64720)
206 exp case control study/ (757164)
207 ((control* adj2 stud* or (control* adj2 trial*) or case-control*).tw. (689387)
208 (nonrandom* or non random* or non-random* or quasi-random*).tw. (64541)
209 (control* adj3 ("before and after" or "before after" or "time series")).tw. (6620)
210 interrupted time series.tw. (2328)
211 trial.ti. (296478)
212 or/197-211 (3473141)
213 178 and 212 (10053)
214 213 not 195 (10033)
215 196 or 214 (10868)
216 215 use emczd (5560)
217 196 use emczd (1112)
218 214 use emczd (5071)
219 exp controlled study/ (4357724) ADDED TO RCT/CCT FILTER
220 212 or 219 (6914676)
221 178 and 220 (12039)
222 221 not 195 (11836)
223 222 use emczd (6874)
224 223 not (110 or 216) (1787)
225 ("201309" or "201310" or 20131* or 20132* or 20133* or 20134*).em. (1297689)
226 224 not 225 (1696) TO EMULATE ORIGINAL SEARCH DATE
227 remove duplicates from 226 (1696) UNIQUE EMBASE RECORDS NOT PART OF ORIGINAL SEARCH

APPENDIX B: LIST OF INCLUDED STUDIES

1. Abelin T, Ehrensam R, Imhof PR, al. e. Clinical experience with a transdermal nicotine system in healthy nicotine-dependent smokers. In: Wilhelmsen L, editor. Smoking as a cardiovascular risk factor - new strategies for smoking cessation. Lewiston NY: Hogrefe & Huber; 1991. p. 35-46.
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APPENDIX C: LIST OF EXCLUDED STUDIES

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APPENDIX D: SUMMARY OF INCLUDED STUDY RISK OF BIAS ASSESSMENTS

Study Code	Adequate sequence generation?	Allocation concealment?	Blinding of objective outcomes' assessment?	Blinding of subjective outcomes' assessment?	Incomplete outcome data addressed – for efficacy outcomes?	Incomplete outcome data addressed – for safety outcomes?
Abelin 1991-35	Unclear	Unclear	Low	Unclear	High	Low
Ahluwalia 1998-1	Low	Unclear	Low	Low	Low	High
Ahluwalia 2002 -468	Unclear	Low	Low	Low	High	High
Ahluwalia 2006 - 883	Unclear	Low	Low	Low	Low	Low
Aubin 2004-1206	Low	Low	Low	Low	High	High
Aubin 2008 - 717	Low	Unclear	Low	High	High	High
Blondal 1997-1585	Low	Unclear	Low	Low	Low	Low
Blondal 1999-285	Low	Low	Low	Low	Low	Low
Bohadana 2000-3128	Low	Low	Low	Low	High	High
Bolliger 2000 - 329	Unclear	Unclear	Low	Low	High	High
Bolliger 2007 - 196	Unclear	Unclear	Low	High	High	High
Bollinger 2011-465	Unclear	Low	Low	Low	Low	Low
BTS 1983 - 595	Unclear	Unclear	Low	Low	Low	Low
Bullen 2010-1474	Low	Low	Low	High	High	High
Campbell 1991 -155	Unclear	Unclear	Low	Low	Low	Low
Campbell 1996 - 47	Unclear	Unclear	Low	Unclear	High	High
Cinciripini 1996 - 314	Unclear	Unclear	Low	High	Low	Low
Cooney 2009 - 1588	Low	Unclear	Low	Low	Low	High
Cooper 2005 - 61	Unclear	Unclear	Low	Unclear	Low	Low
Cox 2012-290	Low	Unclear	Low	Low	High	High
Croghan 2003-181	Low	Low	Low	High	High	High
Dalsgaro 2004 - 55	Low	Unclear	Low	Low	High	High
Daughton 1991- 749	Unclear	Unclear	Low	Low	Unclear	Unclear
Daughton 1998 - 425	Unclear	Unclear	Low	Unclear	Low	Low
Davidson 1998 - 569	Low	Unclear	Low	Unclear	Low	High
de Dios 2012- 322	Unclear	Unclear	Low	Low	High	Low
Eisenberg 2013 - 524	Low	Low	Low	Low	High	High
Etter 2002-487	Low	Unclear	Low	Low	Low	Low
Etter 2009-1028	Low	Unclear	Low	High	Low	Low
Evins 2001-397, 2004-307	Unclear	Unclear	Low	Low	Low	Low
Evins 2005-218	Unclear	Unclear	Low	Low	Low	Low
Evins 2007- 380	Unclear	Unclear	Low	Low	Low	High
Fagerstrom 1982 - 343	Unclear	Unclear	Low	Low	Unclear	Unclear
Fiore 1994 - 524-S1	Low	Unclear	Low	Unclear	High	High
Fiore 1994 - 524-S2	Low	Unclear	Low	Unclear	High	High
Fortmann 1995 - 460	Unclear	Unclear	Low	Unclear	Low	Low
Fossati 2007-1791	Unclear	Unclear	Low	Low	Unclear	Unclear
Gallagher 2007-487	Unclear	Unclear	Low	High	High	Low

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Study Code	Adequate sequence generation?	Allocation concealment?	Blinding of objective outcomes' assessment?	Blinding of subjective outcomes' assessment?	Incomplete outcome data addressed – for efficacy outcomes?	Incomplete outcome data addressed – for safety outcomes?
Garvey 2000-53+ Kinnunen 2008-373	Unclear	Unclear	Low	Unclear	Low	Low
George 2002 - 53	Unclear	Unclear	Low	Low	Low	Low
George 2008 - 1092	Unclear	Unclear	Low	Low	High	High
Gifford 2004-689	Unclear	Unclear	Low	Low	Unclear	Low
Gilbert 1989-49	Unclear	Low	Low	Low	Low	Low
Glavas 2003 - 219	Unclear	Low	Low	Low	Low	Low
Glover 2002 - 441	Low	Unclear	Low	Low	Low	Low
Goldstein 1989-56	Unclear	Unclear	Low	Low	Low	Low
Gonzales 2001 - 438	Unclear	Unclear	Low	Low	Low	Low
Gonzales 2006 - 47	Low	Unclear	Low	Low	High	High
Gourlay 1995 - 363	Low	Low	Low	Low	Low	Low
Grant 2007-381	Unclear	Unclear	Low	Low	High	High
Haggstram 2006 - 205	Unclear	Unclear	Low	Low	Low	Low
Hall 2002 -930	Unclear	Unclear	Low	Low	Low	Low
Hand 2002 - 715	High	Unclear	Low	Low	Low	Low
Hanioka 2010-66	Unclear	Unclear	Low	High	High	High
Hanson 2002-thesis	Unclear	Unclear	Low	Low	Low	High
Harackiewicz 1987-372	Unclear	Unclear	Low	High	High	Low
Harackiewicz 1988 - 319	Unclear	Unclear	Low	Low	Low	Low
Hatsukami 2004 - 151	Low	Unclear	Low	Low	Low	Low
Hays 1999-1701	Low	Low	Low	Low	Low	Low
Hays 2001 - 423	Low	Low	Low	Low	Unclear	Unclear
Herrera 1995-447	Unclear	Unclear	Low	Low	Low	Low
Hertzberg 2001 - 94	Unclear	Unclear	Low	Low	Low	Low
Heydari 2012-268	Unclear	Unclear	Low	Low	Unclear	Unclear
Hilberink 2011 - 120	Unclear	Unclear	Low	Low	Low	Low
Hill 1993 - 321	Unclear	Unclear	Low	Low	Unclear	Unclear
Hilleman 1994-222	Unclear	Unclear	Low	Low	Low	Low
Hjalmarson 1984 - 2835	Unclear	Unclear	Low	Low	Low	Low
Hjalmarson 1994 - 2567	Unclear	Unclear	Low	Low	Unclear	Low
Hjalmarson 1997-1721	Unclear	Unclear	Low	Low	Low	Low
Holt 2005 - 120	Low	Unclear	Low	Low	High	High
Hughes 1989 - 1300	Unclear	Unclear	Low	Low	Unclear	Unclear
Hughes 1990-1175	Unclear	Unclear	Low	Low	Low	Unclear
Hughes 2003 - 946	Unclear	Unclear	Low	Low	Unclear	Unclear
Hughes 2011-955	Unclear	Unclear	Unclear	Low	High	High
Hurt 1994-595	Unclear	Unclear	Unclear	Low	Unclear	Unclear
Hurt 1997 - 1195	Unclear	Unclear	Low	Low	High	High
Hurt 1990 - 1529	High	Unclear	Low	Low	Low	Low
Jamrozik 1984-794	High	Unclear	Low	Low	Low	Low
Jarvik 1984-790	Unclear	Unclear	Low	Low	Low	Low
Jarvis 1982 - 537	High	Unclear	Low	Low	Low	Low

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Study Code	Adequate sequence generation?	Allocation concealment?	Blinding of objective outcomes' assessment?	Blinding of subjective outcomes' assessment?	Incomplete outcome data addressed – for efficacy outcomes?	Incomplete outcome data addressed – for safety outcomes?
Jensen 1990-831	Unclear	Unclear	Low	High	Low	Low
Jorenby 1999 - 685	Unclear	Unclear	Low	Unclear	High	High
Jorenby 2006 - 56	Low	Low	Low	Low	High	Low
Joseph 1996 - 1792	Low	Unclear	Low	Low	High	High
Kalman 2011-111	Low	Unclear	Low	Low	High	Low
Killen 1997 - 663	Unclear	Unclear	Low	Unclear	High	Low
Killen 1999-226	Unclear	Unclear	Low	High	Low	Low
Killen 2004 - 729	Unclear	Unclear	Low	Low	High	Low
Kornitzer 1995 p41	Low	Low	Low	Low	High	Low
Kralikova 2009 - 433	Unclear	Unclear	Low	High	High	Low
Lacasse 2008-1215	Unclear	Unclear	Low	Unclear	Low	Low
Leischow 1996 - 364	Low	Unclear	Low	High	High	High
Lerman 2004 - 426	Low	High	Low	High	Low	Low
Levine 2010-543	High	Unclear	Low	Low	High	Low
Lewis 1998 - 296	Low	Unclear	Low	Low	Low	Low
Malcolm 1980-295	Unclear	Unclear	Low	Low	Low	Low
Marshall 1985-1395	Unclear	Unclear	Low	High	Low	Low
McCarthy 2008 - 717	Low	Unclear	Low	Low	High	High
Molyneux 2003-484	Low	Unclear	Low	Unclear	High	Low
Moolchan 2005-e407	Low	Low	Low	Low	High	High
Muramoto 2007 - 1068	Low	Low	Low	Low	High	High
Myung 2007-1065	Low	Low	Low	Low	Low	Low
Nakamura 2007-1040	Low	Low	Low	Unclear	High	High
Niaura 1994 - 70	Unclear	Unclear	Low	High	Low	Low
Niaura 1999 - 685	Unclear	Unclear	Low	High	Low	Low
Niaura 2008 - 1931	Low	Low	Low	Unclear	Unclear	Low
Nides 2006 - 1561	Low	Low	Low	Low	High	High
Nollen 2007 - 911	Low	Low	Low	Unclear	High	High
Okuyemi 2007 - 43	Unclear	Low	Low	High	High	Low
Oncken 2007-296 + Oncken 2006- 1141	Unclear	Unclear	Low	High	Unclear	Unclear
Oncken 2006-1571	Unclear	Unclear	Low	Unclear	High	High
Ortega 2011-3	Low	Unclear	Low	High	Low	Low
Pack 2008 - 237	Unclear	Unclear	Low	High	Low	Low
Paoletti 1996 - 643	Unclear	Unclear	Low	Low	High	High
Piper 2007 - 947	Unclear	Unclear	Low	Unclear	High	High
Piper 2009 - 1253	Unclear	Unclear	Low	Unclear	Low	High
Pirie 1992 - 1238	Unclear	Unclear	Low	Unclear	Low	Low
Planer 2011-1055	Unclear	Low	Low	Low	Low	Low
Puska 1995 - 231	Unclear	Unclear	Low	Low	High	High
Puska 1979-141	Unclear	Unclear	Low	Low	Low	High
Prapavessis 2007-1416	Unclear	Unclear	Low	High	High	Low
Ray 2007-1237	Unclear	Unclear	Low	High	Low	Low
Registered (GSK) 2001	Unclear	Unclear	Low	Low	Unclear	Unclear
Reid 2008 - 68	Low	Low	Low	Low	Low	Low

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Study Code	Adequate sequence generation?	Allocation concealment?	Blinding of objective outcomes' assessment?	Blinding of subjective outcomes' assessment?	Incomplete outcome data addressed – for efficacy outcomes?	Incomplete outcome data addressed – for safety outcomes?
Rennard 2006-555	Unclear	Unclear	Low	Low	High	High
Rennard 2012- 343	Low	Low	Low	Low	Low	Low
Richmond 1993-187	Unclear	Unclear	Low	High	High	Low
Richmond 1994-130, Richmond 1997-27, Richmond 1997-617& Richmond 2007-282	Unclear	Low	Low	Low	High	High
Rigotti 2006-1080	Low	Low	Low	Low	High	High
Rigotti 2010-221	Low	Low	Low	Low	Low	Low
Rovina 2009-279	Unclear	Unclear	Low	High	Low	Low
Russel 1993-1308 & Stapleton 1995-31	Unclear	Unclear	Low	Low	Unclear	Unclear
Sachs 1993-1881	Unclear	Unclear	Low	Unclear	Unclear	Unclear
Schmitz 2007-699	Unclear	Low	Low	Low	High	Low
Schneider 1983- 253	Unclear	Unclear	Low	Low	Unclear	Unclear
Schneider 1995 - 1671	Unclear	Unclear	Low	Low	Unclear	Unclear
Schneider 1996 - 1293	Low	Low	Low	Low	Unclear	Unclear
Schnoll 2010-144	Low	Low	Low	High	High	Unclear
Schnoll 2010-237	Unclear	Unclear	Low	High	High	High
Schnoll 2010-811	Unclear	Unclear	Low	Unclear	High	High
Schuermans 2004 - 634	Low	Low	Low	Unclear	High	High
Segnan 1991 - 239	Unclear	Low	Low	High	Low	Low
Shiffman 2002-1267	Unclear	Unclear	Low	Unclear	Low	High
Shiffman 2009-96	Low	Unclear	Low	Unclear	Low	High
Simon 2004-1797	Low	Unclear	Low	Unclear	Low	Low
Simon 2009 - 663	Low	Unclear	Low	Low	Low	Low
Sonderskov 1997-309	Unclear	Unclear	Low	Low	Low	Low
Stein 2006-599	Unclear	Unclear	Low	Unclear	Low	Low
Steinberg 2009 - 447	Low	Low	Low	High	High	High
Steinberg 2011 - 1127	Low	Unclear	Low	Low	High	High
Sutherland 1992-324	Low	Unclear	Low	Low	Low	Low
Sutton 1987-1210	Unclear	Unclear	Low	High	Low	Low
Swan 2003 - 2337	Low	Unclear	Low	High	Low	Low
Tashkin 2001-1571	Low	Low	Low	Low	High	High
Tashkin 2011 – 591	Unclear	Unclear	Low	Unclear	High	High
TNS Group 1991 - 3133	Unclear	Unclear	Low	Unclear	High	High
Tonnesen 1988 - 15	Unclear	Unclear	Low	Low	High	High
Tonnesen 1988 - 17	Unclear	Unclear	Low	High	Low	Low
Tonnesen 1991 - 311+Tonnesen 1992- 241+Mikkelsen 1994 95	Low	Unclear	Low	Low	Low	Low
Tonnesen 1993-1268	Low	Unclear	Low	Low	Low	Low
Tonnesen 1996-1169	Unclear	Unclear	Low	High	High	High
Tonnesen 1999 - 238	Low	Low	Low	Low	High	High

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Study Code	Adequate sequence generation?	Allocation concealment?	Blinding of objective outcomes' assessment?	Blinding of subjective outcomes' assessment?	Incomplete outcome data addressed – for efficacy outcomes?	Incomplete outcome data addressed – for safety outcomes?
Tonnesen 2000 - 717	Low	Unclear	Low	High	High	Low
Tonnesen 2003-184	Low	Low	Low	Low	High	High
Tonnesen 2006 - 334	Unclear	Unclear	Low	Low	High	High
Tonnesen 2012 - 548	Low	Low	Low	Low	High	High
Tonstad 2003 - 946	Unclear	Unclear	Low	Unclear	High	High
Tsai 2007 - 1027	Low	Low	Low	Unclear	Low	Low
Tsukahara 2010 - 771	Low	Unclear	Low	High	Low	Low
Uyar 2007 - 922	Unclear	Unclear	Low	High	Low	Low
Wagena 2005-2286	Low	Unclear	Low	Low	Low	Low
Wallstrom 2000 - 1161	Low	Unclear	Low	High	Low	Low
Wang 2009 - 384	Unclear	Unclear	Low	Unclear	Low	Low
Ward 2012 – 394	Low	Low	Low	Low	High	High
Warner 2005-1138	Low	Low	Low	Low	Low	Low
Wennike 2003-1395	Unclear	Unclear	Low	Low	High	High
Westman 1993 - 1917	Unclear	Unclear	Low	Low	Unclear	High
Williams 2007-793	Unclear	Unclear	Low	Unclear	Unclear	High
Williams 2012 - 654+Pfizer 2011	Unclear	Unclear	Low	Unclear	Unclear	High
Wittchen 2011 -28	Low	High	Low	High	Low	High
Wong 2012- 755	Low	Low	Low	Low	Low	Low
Zellweger 2005 - 240	Unclear	Unclear	Low	Unclear	High	High
Zernig 2008-2024	Unclear	Low	Low	High	High	High

APPENDIX E: DETAILED NETWORK META-ANALYSIS RESULTS

CAR AT 12 MONTHS

Table 8: Continuous Abstinence Rate at 12 Months: Odds Ratios, Relative Risks and Risk Difference for All Treatment Comparisons – Network Meta-Analysis, Random Effects Model, Placebo Index Node

TREATMENT	REFERENCE	OR (95% CRI)	RR (95% CRI)	RD% (95% CRI)
BUPROPION 150 MG BID	PLACEBO	2.20 (1.55,3.07)	2.01 (1.49,2.65)	8.00 (3.89,12.89)
NICOTINE GUM 2 MG		2.36 (1.32,4.63)	2.13 (1.29,3.63)	8.95 (2.31,19.94)
NICOTINE INHALER		2.04 (1.21,3.42)	1.88 (1.19,2.89)	7.01 (1.51,14.52)
NICOTINE INHALER+16 HR NICOTINE PATCH 15 MG		3.04 (1.27,7.45)	2.62 (1.24,4.95)	12.82 (1.91,30.83)
NICOTINE LOZENGE 1-2 MG		2.54 (1.41,4.69)	2.26 (1.37,3.64)	10.06 (2.89,20.79)
NICOTINE MOUTH SPRAY 1 MG		2.78 (1.18,6.92)	2.43 (1.17,4.74)	11.41 (1.34,29.22)
16 HR NICOTINE PATCH 15 MG		2.06 (1.55,2.95)	1.90 (1.48,2.57)	7.13 (3.97,11.92)
16 HR NICOTINE PATCH 15 MG+NICOTINE GUM 2 MG		3.39 (1.76,7.05)	2.84 (1.65,4.81)	14.66 (5.32,29.18)
16 HR NICOTINE PATCH 15 MG+NICOTINE INHALER		0.94 (0.23,3.14)	0.95 (0.24,2.69)	-0.41 (-6.08,13.24)
24 HR NICOTINE PATCH 21 MG		1.70 (0.90,3.32)	1.61 (0.91,2.81)	4.87 (-0.74,14.12)
NRT		2.25 (1.14,4.50)	2.04 (1.13,3.55)	8.29 (1.01,19.69)
NICOTINE SPRAY		2.65 (1.06,6.74)	2.34 (1.05,4.66)	10.65 (0.40,28.54)
NICOTINE SPRAY+16 HR NICOTINE PATCH 15 MG		6.21 (2.60,16.59)	4.38 (2.30,7.52)	26.97 (10.42,50.65)
NICOTINE SUBLINGUAL 2 MG		1.83 (1.01,3.38)	1.72 (1.01,2.85)	5.68 (0.09,14.43)
VARENICLINE 1 MG BID		3.40 (2.21,5.54)	2.85 (2.01,4.10)	14.75 (8.06,24.11)
16 HR NICOTINE PATCH <15 MG		0.44 (0.07,2.03)	0.46 (0.07,1.87)	-4.28 (-7.57,6.92)
NICOTINE GUM 4 MG		1.68 (0.78,3.70)	1.59 (0.79,3.06)	4.69 (-1.71,15.93)
NICOTINE LOZENGE 4 MG		2.03 (1.12,3.74)	1.88 (1.11,3.08)	6.99 (0.87,16.44)
16 H NICOTINE PATCH 15 MG		1.91 (1.17,2.92)	1.78 (1.15,2.55)	6.20 (1.23,11.94)
24 HR NICOTINE PATCH >21 MG		1.48 (0.39,5.53)	1.43 (0.41,4.09)	3.40 (-4.78,24.01)
NICOTINE GUM 2 MG	BUPROPION 150 MG BID	1.07 (0.55,2.30)	1.06 (0.60,1.96)	0.89 (-7.51,12.93)
NICOTINE INHALER		0.93 (0.50,1.74)	0.94 (0.55,1.58)	-0.98 (-8.52,7.79)
NICOTINE INHALER+16 HR NICOTINE PATCH 15 MG		1.38 (0.54,3.60)	1.30 (0.59,2.64)	4.74 (-7.44,23.26)
NICOTINE LOZENGE 1-2 MG		1.16 (0.59,2.34)	1.13 (0.64,1.98)	2.03 (-6.60,13.48)
NICOTINE MOUTH SPRAY 1 MG		1.26 (0.51,3.38)	1.21 (0.56,2.53)	3.39 (-7.87,21.75)
16 HR NICOTINE PATCH 15 MG		0.94 (0.61,1.56)	0.95 (0.66,1.45)	-0.88 (-6.66,5.74)
16 HR NICOTINE PATCH 15 MG+NICOTINE GUM 2 MG		1.54 (0.74,3.50)	1.42 (0.77,2.61)	6.64 (-4.11,21.95)
16 HR NICOTINE PATCH 15 MG+NICOTINE INHALER		0.43 (0.10,1.51)	0.47 (0.11,1.40)	-8.32 (-16.28,5.81)
24 HR NICOTINE PATCH 21 MG		0.78 (0.38,1.65)	0.81 (0.42,1.52)	-3.06 (-10.81,7.08)
NRT		1.02 (0.48,2.21)	1.02 (0.53,1.90)	0.29 (-8.67,12.53)
NICOTINE SPRAY		1.20 (0.45,3.22)	1.16 (0.50,2.45)	2.60 (-8.83,20.86)
NICOTINE SPRAY+16 HR NICOTINE PATCH 15 MG		2.82 (1.12,8.04)	2.18 (1.10,4.07)	18.83 (1.65,43.13)

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NICOTINE SUBLINGUAL 2 MG		0.83 (0.42,1.68)	0.85 (0.47,1.53)	-2.31 (-9.88,7.31)
VARENICLINE 1 MG BID		1.55 (0.97,2.59)	1.43 (0.98,2.12)	6.74 (-0.43,15.81)
16 HR NICOTINE PATCH <15 MG		0.20 (0.03,0.96)	0.23 (0.04,0.96)	-12.02 (-18.37,-0.54)
NICOTINE GUM 4 MG		0.76 (0.33,1.81)	0.79 (0.38,1.63)	-3.27 (-11.63,8.82)
NICOTINE LOZENGE 4 MG		0.93 (0.47,1.87)	0.94 (0.52,1.67)	-1.00 (-8.90,9.30)
16 HR NICOTINE PATCH >15 MG		0.87 (0.48,1.49)	0.89 (0.53,1.40)	-1.79 (-8.85,5.27)
24 HR NICOTINE PATCH >21 MG		0.68 (0.17,2.66)	0.71 (0.20,2.15)	-4.56 (-14.47,16.45)
NICOTINE INHALER	NICOTINE GUM 2 MG	0.87 (0.37,1.85)	0.89 (0.43,1.68)	-1.82 (-14.56,8.06)
NICOTINE INHALER+16 HR NICOTINE PATCH 15 MG		1.29 (0.41,3.64)	1.23 (0.48,2.71)	3.77 (-12.21,22.62)
NICOTINE LOZENGE 1-2 MG		1.08 (0.43,2.49)	1.07 (0.51,2.10)	1.13 (-12.17,13.74)
NICOTINE MOUTH SPRAY 1 MG		1.19 (0.40,3.41)	1.15 (0.47,2.58)	2.47 (-12.61,21.33)
16 HR NICOTINE PATCH 15 MG		0.88 (0.46,1.61)	0.90 (0.54,1.51)	-1.75 (-12.24,5.70)
16 HR NICOTINE PATCH 15 MG+NICOTINE GUM 2 MG		1.44 (0.84,2.48)	1.34 (0.87,2.04)	5.59 (-2.59,16.03)
16 HR NICOTINE PATCH 15 MG+NICOTINE INHALER		0.40 (0.08,1.49)	0.45 (0.10,1.40)	-9.07 (-21.80,5.48)
24 HR NICOTINE PATCH 21 MG		0.72 (0.29,1.76)	0.76 (0.35,1.61)	-4.00 (-16.42,7.50)
NRT		0.95 (0.36,2.37)	0.96 (0.43,2.03)	-0.67 (-13.99,12.69)
NICOTINE SPRAY		1.12 (0.36,3.47)	1.10 (0.43,2.64)	1.61 (-13.47,21.24)
NICOTINE SPRAY+16 HR NICOTINE PATCH 15 MG		2.65 (0.91,7.77)	2.06 (0.93,4.13)	17.84 (-1.72,41.81)
NICOTINE SUBLINGUAL 2 MG		0.78 (0.32,1.79)	0.81 (0.38,1.63)	-3.19 (-15.71,7.75)
VARENICLINE 1 MG BID		1.45 (0.66,3.00)	1.35 (0.72,2.44)	5.87 (-7.18,17.16)
16 HR NICOTINE PATCH <15 MG		0.18 (0.03,0.93)	0.22 (0.03,0.94)	-12.80 (-24.34,-0.80)
NICOTINE GUM 4 MG		0.71 (0.26,1.91)	0.75 (0.31,1.72)	-4.17 (-16.84,8.92)
NICOTINE LOZENGE 4 MG		0.87 (0.35,2.00)	0.89 (0.41,1.77)	-1.83 (-14.57,9.65)
16 HR NICOTINE PATCH >15 MG		0.81 (0.36,1.59)	0.84 (0.43,1.49)	-2.74 (-14.69,5.67)
24 HR NICOTINE PATCH >21 MG		0.63 (0.15,2.61)	0.67 (0.18,2.15)	-5.44 (-19.42,16.05)
NICOTINE INHALER+16 HR NICOTINE PATCH 15 MG	NICOTINE INHALER	1.49 (0.73,3.08)	1.39 (0.76,2.36)	5.71 (-3.48,20.57)
NICOTINE LOZENGE 1-2 MG		1.25 (0.57,2.76)	1.21 (0.63,2.30)	3.06 (-7.27,15.04)
NICOTINE MOUTH SPRAY 1 MG		1.38 (0.50,3.94)	1.30 (0.55,2.93)	4.45 (-8.47,23.17)
16 HR NICOTINE PATCH 15 MG		1.01 (0.59,1.86)	1.01 (0.64,1.71)	0.11 (-7.64,7.25)
16 HR NICOTINE PATCH 15 MG+NICOTINE GUM 2 MG		1.66 (0.74,4.06)	1.50 (0.78,3.02)	7.53 (-4.26,23.32)
16 HR NICOTINE PATCH 15 MG+NICOTINE INHALER		0.46 (0.11,1.54)	0.51 (0.13,1.44)	-7.22 (-15.87,5.91)
24 HR NICOTINE PATCH 21 MG		0.84 (0.37,1.96)	0.86 (0.42,1.76)	-2.05 (-11.50,8.69)
NRT		1.10 (0.48,2.62)	1.09 (0.53,2.20)	1.28 (-9.26,14.11)
NICOTINE SPRAY		1.31 (0.46,3.79)	1.25 (0.51,2.82)	3.68 (-9.28,22.42)
NICOTINE SPRAY+16 HR NICOTINE PATCH 15 MG		3.06 (1.12,9.16)	2.33 (1.10,4.66)	19.81 (1.76,44.00)
NICOTINE SUBLINGUAL 2 MG		0.90 (0.41,1.96)	0.92 (0.46,1.76)	-1.26 (-10.84,8.70)
VARENICLINE 1 MG BID		1.67 (0.86,3.38)	1.52 (0.88,2.70)	7.72 (-2.39,18.65)
16 HR NICOTINE PATCH <15 MG		0.22 (0.03,0.98)	0.25 (0.04,0.98)	-10.84 (-18.75,-0.25)
NICOTINE GUM 4 MG		0.82 (0.32,2.12)	0.85 (0.37,1.87)	-2.25 (-12.50,10.26)
NICOTINE LOZENGE 4 MG		1.01 (0.45,2.22)	1.01 (0.51,1.96)	0.07 (-9.77,10.95)

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16 HR NICOTINE PATCH >15 MG		0.94 (0.46,1.80)	0.95 (0.52,1.66)	-0.78 (-9.81,7.08)
24 HR NICOTINE PATCH >21 MG		0.73 (0.18,3.00)	0.76 (0.21,2.40)	-3.48 (-14.87,17.76)
NICOTINE LOZENGE 1-2 MG	NICOTINE INHALER+16 HR NICOTINE PATCH 15 MG	0.84 (0.29,2.42)	0.87 (0.38,2.09)	-2.72 (-21.89,12.37)
NICOTINE MOUTH SPRAY 1 MG		0.93 (0.26,3.28)	0.94 (0.35,2.57)	-1.24 (-22.07,19.42)
16 HR NICOTINE PATCH 15 MG		0.68 (0.28,1.73)	0.73 (0.38,1.61)	-5.62 (-23.53,6.31)
16 HR NICOTINE PATCH 15 MG+NICOTINE GUM 2 MG		1.12 (0.38,3.54)	1.09 (0.48,2.74)	1.93 (-18.05,20.31)
16 HR NICOTINE PATCH 15 MG+NICOTINE INHALER		0.31 (0.06,1.30)	0.36 (0.09,1.25)	-12.83 (-30.87,3.26)
24 HR NICOTINE PATCH 21 MG		0.56 (0.19,1.67)	0.62 (0.27,1.55)	-7.74 (-26.26,6.33)
NRT		0.74 (0.24,2.31)	0.78 (0.33,2.01)	-4.51 (-24.02,11.82)
NICOTINE SPRAY		0.88 (0.24,3.19)	0.90 (0.32,2.49)	-1.97 (-23.32,19.00)
NICOTINE SPRAY+16 HR NICOTINE PATCH 15 MG		2.06 (0.60,7.57)	1.67 (0.69,4.19)	13.82 (-10.04,40.22)
NICOTINE SUBLINGUAL 2 MG		0.60 (0.21,1.77)	0.66 (0.28,1.63)	-7.03 (-25.83,7.12)
VARENICLINE 1 MG BID		1.12 (0.42,3.08)	1.09 (0.53,2.51)	1.91 (-16.94,16.53)
16 HR NICOTINE PATCH <15 MG		0.14 (0.02,0.77)	0.18 (0.03,0.80)	-16.45 (-34.45,-2.82)
NICOTINE GUM 4 MG		0.55 (0.17,1.84)	0.61 (0.24,1.67)	-7.97 (-27.05,7.90)
NICOTINE LOZENGE 4 MG		0.67 (0.23,1.98)	0.72 (0.31,1.77)	-5.74 (-24.67,8.76)
16 HR NICOTINE PATCH >15 MG		0.63 (0.23,1.64)	0.68 (0.31,1.54)	-6.60 (-25.39,5.70)
24 HR NICOTINE PATCH >21 MG		0.49 (0.10,2.37)	0.55 (0.14,1.98)	-8.92 (-29.35,13.59)
NICOTINE MOUTH SPRAY 1 MG	NICOTINE LOZENGE 1-2 MG	1.10 (0.38,3.30)	1.08 (0.45,2.52)	1.43 (-13.60,20.74)
16 HR NICOTINE PATCH 15 MG		0.81 (0.43,1.66)	0.84 (0.51,1.55)	-2.93 (-13.65,6.15)
16 HR NICOTINE PATCH 15 MG+NICOTINE GUM 2 MG		1.33 (0.55,3.47)	1.26 (0.62,2.63)	4.61 (-9.34,21.07)
16 HR NICOTINE PATCH 15 MG+NICOTINE INHALER		0.37 (0.08,1.41)	0.42 (0.10,1.33)	-10.23 (-22.67,4.69)
24 HR NICOTINE PATCH 21 MG		0.67 (0.28,1.64)	0.71 (0.34,1.51)	-5.09 (-17.15,6.65)
NRT		0.88 (0.36,2.19)	0.90 (0.42,1.90)	-1.75 (-14.71,11.53)
NICOTINE SPRAY		1.04 (0.35,3.15)	1.03 (0.41,2.43)	0.60 (-14.23,19.76)
NICOTINE SPRAY+16 HR NICOTINE PATCH 15 MG		2.44 (0.86,7.59)	1.93 (0.89,4.05)	16.64 (-2.55,41.20)
NICOTINE SUBLINGUAL 2 MG		0.72 (0.30,1.68)	0.76 (0.37,1.54)	-4.29 (-16.60,6.96)
VARENICLINE 1 MG BID		1.34 (0.64,2.93)	1.26 (0.71,2.37)	4.64 (-7.65,16.57)
16 HR NICOTINE PATCH <15 MG		0.17 (0.02,0.90)	0.20 (0.03,0.92)	-13.97 (-25.35,-1.23)
NICOTINE GUM 4 MG		0.66 (0.24,1.78)	0.70 (0.30,1.62)	-5.23 (-17.87,8.11)
NICOTINE LOZENGE 4 MG		0.80 (0.44,1.46)	0.83 (0.50,1.37)	-2.97 (-11.89,5.28)
16 HR NICOTINE PATCH >15 MG		0.75 (0.34,1.54)	0.79 (0.41,1.44)	-3.81 (-15.78,5.26)
24 HR NICOTINE PATCH >21 MG		0.58 (0.14,2.50)	0.63 (0.17,2.04)	-6.57 (-20.40,15.26)
16 HR NICOTINE PATCH 15 MG	NICOTINE MOUTH SPRAY 1 MG	0.74 (0.29,1.90)	0.78 (0.39,1.74)	-4.24 (-22.22,7.30)
16 HR NICOTINE PATCH 15 MG+NICOTINE GUM 2 MG		1.21 (0.40,3.73)	1.17 (0.50,2.89)	3.13 (-16.80,21.09)
16 HR NICOTINE PATCH 15 MG+NICOTINE INHALER		0.33 (0.06,1.50)	0.38 (0.09,1.40)	-11.57 (-30.42,5.10)
24 HR NICOTINE PATCH 21 MG		0.61 (0.20,1.85)	0.66 (0.27,1.69)	-6.53 (-25.21,7.47)
NRT		0.81 (0.26,2.40)	0.84 (0.34,2.07)	-3.04 (-22.56,12.24)

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NICOTINE SPRAY		0.95 (0.25,3.38)	0.96 (0.33,2.63)	-0.76 (-21.74,19.89)
NICOTINE SPRAY+16 HR NICOTINE PATCH 15 MG		2.25 (0.63,8.17)	1.80 (0.72,4.48)	15.19 (-8.97,41.33)
NICOTINE SUBLINGUAL 2 MG		0.66 (0.22,1.90)	0.70 (0.30,1.72)	-5.60 (-24.48,7.75)
VARENICLINE 1 MG BID		1.23 (0.45,3.26)	1.17 (0.55,2.65)	3.33 (-15.46,17.38)
16 HR NICOTINE PATCH <15 MG		0.15 (0.02,0.92)	0.19 (0.03,0.93)	-15.10 (-33.58,-0.85)
NICOTINE GUM 4 MG		0.60 (0.19,1.90)	0.65 (0.25,1.73)	-6.62 (-25.48,8.27)
NICOTINE LOZENGE 4 MG		0.73 (0.24,2.11)	0.77 (0.33,1.88)	-4.39 (-23.15,9.62)
16 HR NICOTINE PATCH >15 MG		0.68 (0.25,1.77)	0.73 (0.33,1.64)	-5.20 (-23.80,6.50)
24 HR NICOTINE PATCH >21 MG		0.53 (0.10,2.66)	0.58 (0.14,2.19)	-7.80 (-27.87,15.20)
16 HR NICOTINE PATCH 15 MG+NICOTINE GUM 2 MG	16 HR NICOTINE PATCH 15 MG	1.64 (0.85,3.22)	1.50 (0.87,2.42)	7.48 (-2.06,21.16)
16 HR NICOTINE PATCH 15 MG+NICOTINE INHALER		0.45 (0.11,1.50)	0.50 (0.12,1.40)	-7.58 (-14.72,5.80)
24 HR NICOTINE PATCH 21 MG		0.83 (0.40,1.70)	0.85 (0.44,1.55)	-2.23 (-9.87,7.58)
NRT		1.08 (0.50,2.30)	1.07 (0.55,1.96)	1.05 (-7.81,13.12)
NICOTINE SPRAY		1.28 (0.47,3.38)	1.23 (0.52,2.53)	3.46 (-8.17,21.53)
NICOTINE SPRAY+16 HR NICOTINE PATCH 15 MG		3.02 (1.30,7.38)	2.31 (1.24,3.75)	19.79 (3.62,41.93)
NICOTINE SUBLINGUAL 2 MG		0.89 (0.44,1.70)	0.90 (0.49,1.55)	-1.45 (-9.07,7.61)
VARENICLINE 1 MG BID		1.65 (0.98,2.76)	1.50 (0.99,2.23)	7.57 (-0.24,16.82)
16 HR NICOTINE PATCH <15 MG		0.21 (0.03,0.95)	0.24 (0.04,0.96)	-11.24 (-16.87,-0.59)
NICOTINE GUM 4 MG		0.81 (0.34,1.86)	0.84 (0.39,1.67)	-2.46 (-10.77,9.21)
NICOTINE LOZENGE 4 MG		0.99 (0.48,1.90)	0.99 (0.53,1.69)	-0.10 (-8.23,9.62)
16 HR NICOTINE PATCH >15 MG		0.93 (0.55,1.35)	0.94 (0.59,1.29)	-0.88 (-6.93,4.04)
24 HR NICOTINE PATCH >21 MG		0.72 (0.18,2.76)	0.75 (0.21,2.21)	-3.76 (-13.61,17.14)
16 HR NICOTINE PATCH 15 MG+NICOTINE INHALER	16 HR NICOTINE PATCH 15 MG+NICOTINE GUM 2 MG	0.28 (0.06,1.10)	0.33 (0.08,1.08)	-14.67 (-30.60,1.34)
24 HR NICOTINE PATCH 21 MG		0.50 (0.19,1.28)	0.57 (0.26,1.23)	-9.72 (-25.24,3.47)
NRT		0.67 (0.24,1.72)	0.72 (0.32,1.54)	-6.27 (-22.99,8.49)
NICOTINE SPRAY		0.78 (0.24,2.50)	0.82 (0.32,1.99)	-3.97 (-22.17,16.77)
NICOTINE SPRAY+16 HR NICOTINE PATCH 15 MG		1.85 (0.61,5.66)	1.54 (0.69,3.18)	12.12 (-9.41,36.67)
NICOTINE SUBLINGUAL 2 MG		0.54 (0.21,1.30)	0.60 (0.28,1.24)	-8.83 (-24.56,3.74)
VARENICLINE 1 MG BID		1.01 (0.44,2.22)	1.01 (0.55,1.88)	0.14 (-15.75,13.26)
16 HR NICOTINE PATCH <15 MG		0.13 (0.02,0.67)	0.16 (0.02,0.72)	-18.36 (-33.69,-4.97)
NICOTINE GUM 4 MG		0.49 (0.17,1.41)	0.56 (0.23,1.32)	-9.80 (-25.88,5.09)
NICOTINE LOZENGE 4 MG		0.60 (0.23,1.45)	0.66 (0.31,1.36)	-7.54 (-23.35,5.54)
16 HR NICOTINE PATCH >15 MG		0.56 (0.24,1.17)	0.63 (0.32,1.14)	-8.40 (-23.61,2.02)
24 HR NICOTINE PATCH >21 MG		0.44 (0.10,1.88)	0.50 (0.13,1.62)	-10.94 (-28.44,11.10)
24 HR NICOTINE PATCH 21 MG	16 HR NICOTINE PATCH 15 MG+NICOTINE INHALER	1.84 (0.44,8.83)	1.72 (0.50,7.52)	5.21 (-9.67,16.21)
NRT		2.38 (0.62,11.83)	2.15 (0.67,9.53)	8.47 (-6.12,21.30)
NICOTINE SPRAY		2.82 (0.62,15.91)	2.46 (0.67,11.67)	10.65 (-5.63,29.84)
NICOTINE SPRAY+16 HR NICOTINE PATCH 15		6.72 (1.56,36.82)	4.61 (1.42,20.15)	26.80 (6.69,51.07)

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MG				
NICOTINE SUBLINGUAL 2 MG		1.95 (0.52,9.30)	1.82 (0.57,7.91)	5.95 (-8.25,16.44)
VARENICLINE 1 MG BID		3.64 (1.00,16.78)	3.03 (1.00,12.75)	14.92 (0.00,26.19)
16 HR NICOTINE PATCH <15 MG		0.48 (0.06,2.96)	0.50 (0.06,2.75)	-3.45 (-16.65,6.77)
NICOTINE GUM 4 MG		1.81 (0.42,8.84)	1.70 (0.47,7.48)	5.00 (-9.96,17.60)
NICOTINE LOZENGE 4 MG		2.19 (0.57,10.44)	2.01 (0.62,8.68)	7.29 (-7.27,18.54)
16 HR NICOTINE PATCH >15 MG		2.02 (0.56,8.73)	1.87 (0.62,7.56)	6.47 (-7.46,14.51)
24 HR NICOTINE PATCH >21 MG		1.59 (0.27,10.47)	1.52 (0.30,8.10)	3.64 (-12.12,24.84)
NRT	24 HR NICOTINE PATCH 21 MG	1.32 (0.51,3.44)	1.27 (0.56,2.83)	3.36 (-8.46,16.34)
NICOTINE SPRAY		1.55 (0.50,4.72)	1.45 (0.55,3.49)	5.67 (-8.36,24.38)
NICOTINE SPRAY+16 HR NICOTINE PATCH 15 MG		3.64 (1.21,11.76)	2.71 (1.17,6.02)	21.80 (2.92,46.60)
NICOTINE SUBLINGUAL 2 MG		1.07 (0.44,2.58)	1.06 (0.49,2.28)	0.77 (-10.06,11.08)
VARENICLINE 1 MG BID		2.00 (0.90,4.47)	1.77 (0.92,3.50)	9.78 (-1.68,20.92)
16 HR NICOTINE PATCH <15 MG		0.25 (0.03,1.38)	0.28 (0.04,1.34)	-8.87 (-19.01,3.29)
NICOTINE GUM 4 MG		0.98 (0.35,2.76)	0.98 (0.40,2.38)	-0.21 (-11.82,12.65)
NICOTINE LOZENGE 4 MG		1.20 (0.49,2.88)	1.17 (0.54,2.47)	2.12 (-8.85,13.14)
16 HR NICOTINE PATCH >15 MG		1.12 (0.49,2.37)	1.10 (0.54,2.14)	1.27 (-9.43,9.33)
24 HR NICOTINE PATCH >21 MG		0.87 (0.20,3.65)	0.88 (0.23,2.87)	-1.47 (-14.21,19.30)
NICOTINE SPRAY	NRT	1.18 (0.38,3.70)	1.15 (0.44,2.82)	2.35 (-12.94,21.65)
NICOTINE SPRAY+16 HR NICOTINE PATCH 15 MG		2.77 (0.91,9.19)	2.14 (0.93,4.82)	18.39 (-1.49,43.57)
NICOTINE SUBLINGUAL 2 MG		0.81 (0.33,2.05)	0.84 (0.39,1.85)	-2.57 (-15.48,9.12)
VARENICLINE 1 MG BID		1.52 (0.67,3.54)	1.40 (0.73,2.82)	6.47 (-6.93,18.71)
16 HR NICOTINE PATCH <15 MG		0.20 (0.03,0.99)	0.23 (0.03,0.99)	-12.02 (-24.37,-0.08)
NICOTINE GUM 4 MG		0.75 (0.27,2.11)	0.78 (0.32,1.88)	-3.55 (-16.65,9.80)
NICOTINE LOZENGE 4 MG		0.91 (0.37,2.29)	0.92 (0.43,2.01)	-1.28 (-14.08,10.87)
16 HR NICOTINE PATCH >15 MG		0.85 (0.37,1.86)	0.87 (0.44,1.71)	-2.11 (-14.50,7.17)
24 HR NICOTINE PATCH >21 MG		0.66 (0.15,2.94)	0.70 (0.18,2.37)	-4.71 (-18.92,17.20)
NICOTINE SPRAY+16 HR NICOTINE PATCH 15 MG	NICOTINE SPRAY	2.38 (0.66,8.68)	1.88 (0.74,4.82)	16.03 (-7.90,42.00)
NICOTINE SUBLINGUAL 2 MG		0.69 (0.23,2.08)	0.74 (0.31,1.88)	-4.86 (-23.53,8.65)
VARENICLINE 1 MG BID		1.29 (0.47,3.65)	1.22 (0.57,2.94)	4.07 (-14.56,18.15)
16 HR NICOTINE PATCH <15 MG		0.16 (0.02,0.99)	0.20 (0.03,0.99)	-14.35 (-32.46,-0.10)
NICOTINE GUM 4 MG		0.63 (0.19,2.13)	0.68 (0.26,1.89)	-5.78 (-24.81,9.58)
NICOTINE LOZENGE 4 MG		0.77 (0.25,2.30)	0.81 (0.34,2.04)	-3.57 (-22.27,10.37)
16 HR NICOTINE PATCH >15 MG		0.72 (0.25,1.97)	0.76 (0.34,1.81)	-4.45 (-23.05,7.45)
24 HR NICOTINE PATCH >21 MG		0.56 (0.11,2.73)	0.61 (0.15,2.25)	-6.87 (-26.84,15.30)
NICOTINE SUBLINGUAL 2 MG	NICOTINE SPRAY+16 HR NICOTINE PATCH 15 MG	0.29 (0.09,0.83)	0.39 (0.18,0.86)	-21.10 (-45.38,-2.80)
VARENICLINE 1 MG BID		0.55 (0.19,1.44)	0.65 (0.35,1.33)	-12.03 (-36.23,6.49)
16 HR NICOTINE PATCH <15 MG		0.07 (0.01,0.40)	0.11 (0.02,0.48)	-30.56 (-54.66,-11.63)
NICOTINE GUM 4 MG		0.27 (0.08,0.88)	0.36 (0.15,0.90)	-21.87 (-46.93,-2.12)
NICOTINE LOZENGE 4 MG		0.33 (0.10,0.93)	0.43 (0.20,0.95)	-19.67 (-44.21,-1.09)

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16 HR NICOTINE PATCH >15 MG		0.31 (0.11,0.75)	0.41 (0.21,0.79)	-20.72 (-44.54,-4.06)
24 HR NICOTINE PATCH >21 MG		0.24 (0.04,1.17)	0.33 (0.08,1.12)	-22.72 (-49.21,2.77)
VARENICLINE 1 MG BID	NICOTINE SUBLINGUAL 2 MG	1.87 (0.89,4.00)	1.67 (0.91,3.14)	8.98 (-1.87,20.14)
16 HR NICOTINE PATCH <15 MG		0.24 (0.03,1.24)	0.27 (0.04,1.20)	-9.63 (-19.09,2.22)
NICOTINE GUM 4 MG		0.92 (0.34,2.48)	0.93 (0.39,2.16)	-0.96 (-12.08,11.61)
NICOTINE LOZENGE 4 MG		1.11 (0.48,2.64)	1.10 (0.53,2.28)	1.26 (-9.32,12.49)
16 HR NICOTINE PATCH >15 MG		1.04 (0.48,2.15)	1.04 (0.53,1.95)	0.49 (-9.63,8.63)
24 HR NICOTINE PATCH >21 MG		0.81 (0.18,3.50)	0.84 (0.21,2.76)	-2.19 (-14.84,19.21)
16 HR NICOTINE PATCH <15 MG	VARENICLINE 1 MG BID	0.13 (0.02,0.62)	0.16 (0.02,0.67)	-18.55 (-28.69,-6.48)
NICOTINE GUM 4 MG		0.49 (0.20,1.22)	0.55 (0.25,1.17)	-9.98 (-21.50,3.28)
NICOTINE LOZENGE 4 MG		0.60 (0.27,1.26)	0.66 (0.34,1.20)	-7.65 (-18.97,3.76)
16 HR NICOTINE PATCH >15 MG		0.56 (0.28,0.99)	0.63 (0.36,0.99)	-8.46 (-19.19,-0.17)
24 HR NICOTINE PATCH >21 MG		0.43 (0.11,1.73)	0.50 (0.14,1.51)	-11.19 (-24.07,10.17)
NICOTINE GUM 4 MG	16 HR NICOTINE PATCH <15 MG	3.86 (0.67,29.65)	3.48 (0.70,24.85)	8.59 (-3.97,20.40)
NICOTINE LOZENGE 4 MG		4.69 (0.88,34.16)	4.12 (0.90,28.29)	11.02 (-1.32,21.17)
16 HR NICOTINE PATCH >15 MG		4.32 (0.87,30.03)	3.85 (0.89,25.64)	10.14 (-1.60,16.96)
24 HR NICOTINE PATCH >21 MG		3.39 (0.45,35.23)	3.08 (0.48,27.65)	7.17 (-5.96,28.24)
NICOTINE LOZENGE 4 MG	NICOTINE GUM 4 MG	1.21 (0.45,3.29)	1.18 (0.51,2.82)	2.25 (-10.40,13.90)
16 HR NICOTINE PATCH >15 MG		1.13 (0.45,2.74)	1.11 (0.51,2.44)	1.43 (-10.82,10.39)
24 HR NICOTINE PATCH >21 MG		0.88 (0.19,4.20)	0.89 (0.23,3.24)	-1.34 (-15.21,20.35)
16 HR NICOTINE PATCH >15 MG	NICOTINE LOZENGE 4 MG	0.93 (0.42,1.93)	0.94 (0.48,1.77)	-0.84 (-11.67,7.48)
24 HR NICOTINE PATCH >21 MG		0.72 (0.17,3.13)	0.75 (0.20,2.49)	-3.58 (-16.20,17.81)
24 HR NICOTINE PATCH >21 MG	16 HR NICOTINE PATCH >15 MG	0.78 (0.19,3.26)	0.80 (0.22,2.56)	-2.73 (-13.03,18.77)
RANDOM-EFFECT MODEL	RESIDUAL DEVIANCE	71.7 VS. 72 DATA POINTS		
	DEVIANCE INFORMATION CRITERIA	459.226		
FIXED-EFFECT MODEL	RESIDUAL DEVIANCE	81.08 VS. 72 DATA POINTS		
	DEVIANCE INFORMATION CRITERIA	462.74		

Table 9: Continuous Abstinence Rate at 12 Months: Odds Ratios, Relative Risks and Risk Difference for All Treatment Comparisons – Network Meta-Analysis, Random Effects Model, Active Behaviour Index Node

TREATMENT	REFERENCE	OR (95% CRI)	RR (95% CRI)	RD% (95% CRI)
BUPROPION 150 MG BID	PLACEBO	1.72 (1.35,2.21)	1.60 (1.30,1.97)	6.22 (3.22,9.84)
BUPROPION 150 MG BID+24 HR NICOTINE PATCH 21 MG		2.53 (1.53,4.19)	2.18 (1.45,3.16)	12.33 (4.74,22.20)
BUPROPION 150 MG BID+NRT		1.85 (0.25,18.61)	1.70 (0.27,6.74)	7.30 (-7.84,57.38)
NICOTINE GUM 2 MG		1.62 (1.20,2.18)	1.52 (1.18,1.95)	5.46 (1.87,9.53)
NICOTINE INHALER SD		2.05 (1.02,4.19)	1.85 (1.02,3.16)	8.84 (0.16,22.12)
24 HR NICOTINE PATCH 21 MG+COUNSELING		1.80 (1.25,2.65)	1.66 (1.22,2.27)	6.92 (2.28,12.95)
NRT		1.66 (1.03,2.48)	1.55 (1.03,2.15)	5.73 (0.28,11.90)
NICOTINE SPRAY		2.29 (1.41,3.72)	2.02 (1.36,2.91)	10.61 (3.72,19.68)

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NICOTINE SUBLINGUAL 2 MG		2.88 (1.23,7.05)	2.41 (1.20,4.35)	14.67 (2.09,34.44)
VARENICLINE 1 MG BID		2.99 (2.33,3.91)	2.48 (2.04,3.02)	15.36 (10.96,20.53)
VARENICLINE <2 MG/D		1.98 (1.36,2.94)	1.79 (1.31,2.45)	8.26 (3.25,14.85)
NICOTINE GUM 4 MG		2.48 (1.59,3.88)	2.15 (1.50,3.00)	11.98 (5.23,20.50)
BUPROPION 150 MG BID+24 HR NICOTINE PATCH 21 MG	BUPROPION 150 MG BID	1.48 (0.89,2.43)	1.37 (0.90,1.98)	6.10 (-1.68,15.69)
BUPROPION 150 MG BID+NRT		1.08 (0.14,10.89)	1.06 (0.17,4.25)	1.07 (-14.68,51.34)
NICOTINE GUM 2 MG		0.95 (0.64,1.37)	0.95 (0.68,1.30)	-0.76 (-6.07,4.36)
NICOTINE INHALER SD		1.19 (0.56,2.55)	1.16 (0.61,2.06)	2.57 (-6.99,16.36)
24 HR NICOTINE PATCH 21 MG+COUNSELING		1.05 (0.71,1.57)	1.04 (0.75,1.44)	0.71 (-4.63,6.77)
NRT		0.96 (0.56,1.53)	0.97 (0.61,1.41)	-0.51 (-7.17,6.33)
NICOTINE SPRAY		1.33 (0.78,2.28)	1.26 (0.81,1.91)	4.36 (-3.48,13.88)
NICOTINE SUBLINGUAL 2 MG		1.68 (0.69,4.21)	1.51 (0.73,2.79)	8.44 (-4.72,28.37)
VARENICLINE 1 MG BID		1.74 (1.28,2.39)	1.55 (1.21,1.98)	9.13 (3.98,14.65)
VARENICLINE <2 MG/D		1.15 (0.75,1.77)	1.12 (0.79,1.58)	2.05 (-3.83,8.89)
NICOTINE GUM 4 MG		1.45 (0.86,2.40)	1.35 (0.88,1.98)	5.75 (-2.16,14.83)
BUPROPION 150 MG BID+NRT	BUPROPION 150 MG BID+24 HR NICOTINE PATCH 21 MG	0.73 (0.09,7.71)	0.78 (0.12,3.25)	-4.97 (-23.80,45.57)
NICOTINE GUM 2 MG		0.64 (0.36,1.15)	0.70 (0.44,1.12)	-6.85 (-17.56,1.89)
NICOTINE INHALER SD		0.81 (0.34,1.96)	0.85 (0.42,1.67)	-3.43 (-16.83,12.11)
24 HR NICOTINE PATCH 21 MG+COUNSELING		0.71 (0.45,1.14)	0.76 (0.54,1.11)	-5.36 (-13.92,1.94)
NRT		0.65 (0.33,1.24)	0.71 (0.41,1.19)	-6.61 (-17.97,3.17)
NICOTINE SPRAY		0.90 (0.45,1.82)	0.92 (0.54,1.60)	-1.70 (-13.78,10.20)
NICOTINE SUBLINGUAL 2 MG		1.14 (0.42,3.18)	1.10 (0.50,2.26)	2.31 (-13.87,23.65)
VARENICLINE 1 MG BID		1.18 (0.70,2.03)	1.13 (0.78,1.74)	3.02 (-7.06,11.90)
VARENICLINE <2 MG/D		0.78 (0.43,1.45)	0.82 (0.52,1.35)	-4.02 (-14.81,5.82)
NICOTINE GUM 4 MG		0.98 (0.49,1.93)	0.99 (0.58,1.67)	-0.30 (-12.73,11.24)
NICOTINE GUM 2 MG	BUPROPION 150 MG BID+NRT	0.88 (0.09,6.75)	0.90 (0.22,5.81)	-1.81 (-52.30,14.10)
NICOTINE INHALER SD		1.11 (0.10,9.37)	1.09 (0.24,7.34)	1.54 (-49.07,22.67)
24 HR NICOTINE PATCH 21 MG+COUNSELING		0.98 (0.10,7.50)	0.98 (0.24,6.29)	-0.28 (-50.70,16.23)
NRT		0.89 (0.08,6.92)	0.91 (0.21,5.86)	-1.61 (-52.03,15.07)
NICOTINE SPRAY		1.24 (0.12,9.97)	1.19 (0.28,7.82)	3.24 (-47.16,21.89)
NICOTINE SUBLINGUAL 2 MG		1.57 (0.13,13.84)	1.42 (0.30,9.68)	7.06 (-44.40,32.91)
VARENICLINE 1 MG BID		1.61 (0.16,12.40)	1.46 (0.37,9.33)	8.02 (-42.26,24.62)
VARENICLINE <2 MG/D		1.07 (0.10,8.43)	1.05 (0.26,6.90)	0.95 (-49.23,18.07)
NICOTINE GUM 4 MG		1.34 (0.13,10.74)	1.26 (0.31,8.38)	4.52 (-46.11,23.11)
NICOTINE INHALER SD	NICOTINE GUM 2 MG	1.26 (0.59,2.73)	1.21 (0.64,2.19)	3.35 (-6.30,17.19)
24 HR NICOTINE PATCH 21 MG		1.11 (0.70,1.82)	1.09 (0.74,1.64)	1.47 (-4.81,8.66)
NRT		1.02 (0.59,1.69)	1.01 (0.63,1.54)	0.21 (-6.60,7.57)
NICOTINE SPRAY		1.41 (0.80,2.51)	1.33 (0.83,2.08)	5.17 (-3.18,14.96)
NICOTINE SUBLINGUAL 2 MG		1.78 (0.72,4.58)	1.58 (0.76,3.01)	9.17 (-4.12,29.42)
VARENICLINE 1 MG BID		1.84 (1.26,2.78)	1.62 (1.20,2.25)	9.89 (3.74,16.51)
VARENICLINE <2 MG/D		1.22 (0.76,2.01)	1.18 (0.80,1.77)	2.78 (-3.75,10.48)

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NICOTINE GUM 4 MG		1.53 (0.97,2.43)	1.41 (0.97,2.02)	6.52 (-0.45,14.89)
24 HR NICOTINE PATCH 21 MG+COUNSELING	NICOTINE INHALER SD	0.88 (0.39,1.96)	0.90 (0.48,1.77)	-1.84 (-16.13,8.81)
NRT		0.80 (0.34,1.80)	0.83 (0.42,1.65)	-3.17 (-17.69,7.63)
NICOTINE SPRAY		1.12 (0.47,2.64)	1.09 (0.56,2.21)	1.81 (-13.37,14.53)
NICOTINE SUBLINGUAL 2 MG		1.41 (0.46,4.37)	1.31 (0.54,3.02)	5.77 (-12.83,27.40)
VARENICLINE 1 MG BID		1.46 (0.68,3.12)	1.34 (0.76,2.53)	6.52 (-7.65,17.10)
VARENICLINE <2 MG/D		0.96 (0.43,2.17)	0.97 (0.52,1.92)	-0.59 (-14.81,10.64)
NICOTINE GUM 4 MG		1.21 (0.52,2.80)	1.16 (0.61,2.32)	3.12 (-11.93,15.57)
NRT	24 HR NICOTINE PATCH 21 MG+COUNSELING	0.92 (0.49,1.58)	0.93 (0.55,1.46)	-1.23 (-9.51,6.55)
NICOTINE SPRAY		1.27 (0.69,2.35)	1.21 (0.74,1.97)	3.64 (-5.53,13.95)
NICOTINE SUBLINGUAL 2 MG		1.59 (0.62,4.19)	1.44 (0.67,2.81)	7.67 (-6.46,28.08)
VARENICLINE 1 MG BID		1.65 (1.13,2.45)	1.49 (1.10,2.05)	8.37 (2.09,14.52)
VARENICLINE <2 MG/D		1.10 (0.67,1.80)	1.08 (0.72,1.62)	1.34 (-6.01,8.87)
NICOTINE GUM 4 MG		1.38 (0.76,2.45)	1.29 (0.80,2.04)	5.04 (-4.31,14.83)
NICOTINE SPRAY	NRT	1.39 (0.74,2.78)	1.31 (0.78,2.29)	4.90 (-4.36,15.68)
NICOTINE SUBLINGUAL 2 MG		1.76 (0.68,4.77)	1.56 (0.73,3.18)	9.01 (-5.08,29.42)
VARENICLINE 1 MG BID		1.81 (1.13,3.16)	1.60 (1.10,2.55)	9.62 (2.09,17.43)
VARENICLINE <2 MG/D		1.20 (0.69,2.23)	1.16 (0.74,1.95)	2.55 (-5.43,11.26)
NICOTINE GUM 4 MG		1.50 (0.83,2.87)	1.39 (0.86,2.35)	6.26 (-2.85,16.44)
NICOTINE SUBLINGUAL 2 MG	NICOTINE SPRAY	1.26 (0.48,3.45)	1.20 (0.55,2.42)	4.08 (-11.46,24.83)
VARENICLINE 1 MG BID		1.31 (0.75,2.26)	1.23 (0.81,1.91)	4.76 (-5.40,13.56)
VARENICLINE <2 MG/D		0.86 (0.47,1.61)	0.89 (0.55,1.47)	-2.30 (-12.83,7.28)
NICOTINE GUM 4 MG		1.08 (0.56,2.09)	1.06 (0.64,1.78)	1.35 (-10.09,12.42)
VARENICLINE 1 MG BID	NICOTINE SUBLINGUAL 2 MG	1.04 (0.41,2.55)	1.03 (0.55,2.13)	0.68 (-19.57,14.61)
VARENICLINE <2 MG/D		0.69 (0.26,1.75)	0.75 (0.38,1.60)	-6.37 (-26.82,7.92)
NICOTINE GUM 4 MG		0.86 (0.32,2.27)	0.89 (0.45,1.93)	-2.68 (-23.76,12.73)
VARENICLINE <2 MG/D	VARENICLINE 1 MG BID	0.66 (0.46,0.95)	0.73 (0.54,0.96)	-7.05 (-12.83,-0.98)
NICOTINE GUM 4 MG		0.83 (0.49,1.37)	0.87 (0.57,1.26)	-3.34 (-12.20,6.13)
NICOTINE GUM 4 MG	VARENICLINE <2 MG/D	1.26 (0.69,2.23)	1.20 (0.74,1.88)	3.69 (-5.91,13.61)
RANDOM-EFFECT MODEL	RESIDUAL DEVIANCE	84.35 VS. 83 DATA POINTS		
	DEVIANCE INFORMATION CRITERIA	532.348		
FIXED-EFFECT MODEL	RESIDUAL DEVIANCE	99.67 VS. 83 DATA POINTS		
	DEVIANCE INFORMATION CRITERIA	537.31		

APPENDIX F: CONSISTENCY PLOTS FOR CONTINUOUS ABSTINENCE RATES

Figure 8: Continuous abstinence rate at 12 Months: Plot of Posterior Mean Deviance of the Individual Data Points in the Inconsistency Model against Their Posterior Mean Deviance in the Consistency Model – Placebo Index Node

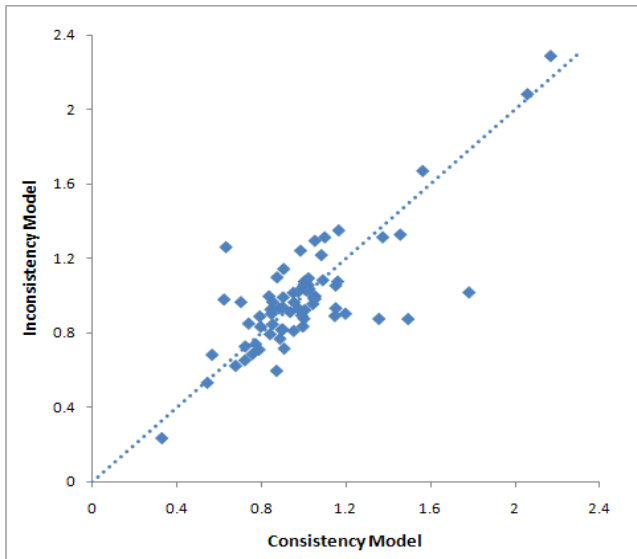


Figure 9: Continuous abstinence rate at 12 Months: Plot of Posterior Mean Deviance of the Individual Data Points in the Inconsistency Model against Their Posterior Mean Deviance in the Consistency Model – Active Behaviour Index Node

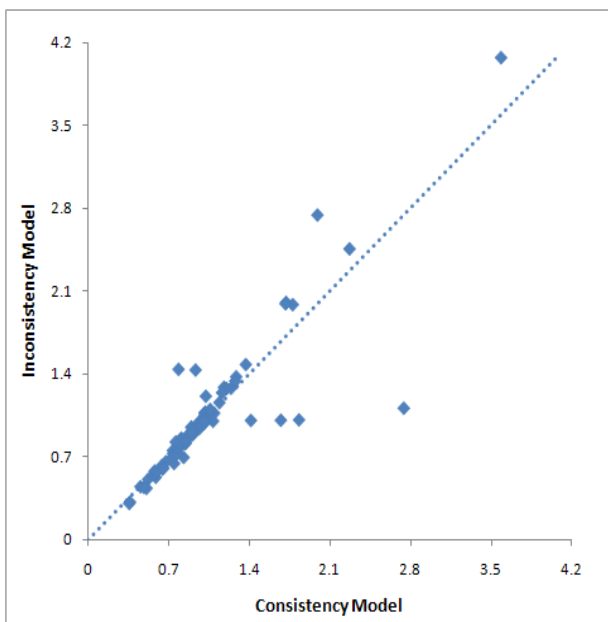
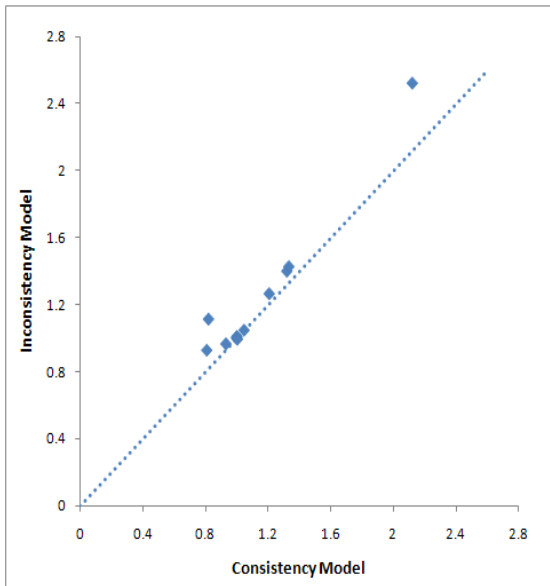


Figure 10: Continuous abstinence rate > 12 Months: Plot of Posterior Mean Deviance of the Individual Data Points in the Inconsistency Model against Their Posterior Mean Deviance in the Consistency Model – Active Behaviour I Index Node



APPENDIX G: DETAILED STUDY CHARACTERISTICS

Reference	Study Details	Patients	Intervention	Outcomes
Aubin 2004-1206	<p>Study Design: Parallel</p> <p>Group 1 (N): 341</p> <p>Group 2 (N): 165</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: GlaxoSmithKline (GSK) France</p> <p>Protocol availability: NR</p>	<p>Bupropion 300 mg/d</p> <p>Age: 41</p> <p>Female: 56%</p> <p>FTND Score: 5.8</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: NR</p> <p>Placebo</p> <p>Age: 41</p> <p>Female: 55%</p> <p>FTND Score: 5.4</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: NR</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Bupropion 300 mg/d, started at 150 mg once daily and then increased to 150 mg twice daily from day 7 to the end of 7 weeks</p> <p>Group 2: Placebo, same regimen as above</p> <p>Mutual interventions:</p> <ul style="list-style-type: none"> - Brief individual counseling*4 sessions - Four telephone contacts 	<p>Efficacy:</p> <ul style="list-style-type: none"> o CAR 6 Months o PPA 6 M - exhaled carbon monoxide < 10 ppm <p>Safety:</p> <ul style="list-style-type: none"> o DEATH - inferred 0 o SAE o CV DEATH- inferred 0 o COMPLETED SUICIDE- inferred 0
Abelin 1991 - 35	<p>Study Design: Parallel</p> <p>NP24 14 mg-21mg (N): 156</p> <p>Placebo (N): 155</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: NR</p> <p>Protocol availability: NR</p>	<p>NP24 14 mg-21 mg</p> <p>Age: 35.3</p> <p>Female: 54</p> <p>FTND Score: 6.2</p> <p>Years Smoked: 16.3</p> <p>Cigarettes per day: 25.6</p> <p>Placebo</p> <p>Age: 36.7</p> <p>Female: 56</p> <p>FTND Score: 6.1</p> <p>Years Smoked: 17.9</p> <p>Cigarettes per day: 26.1</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: NP24 14 mg-21 mg</p> <p>NP24 14 mg-21 mg: The 24hr nicotine patch was given for 4 weeks at 21mg/d for those smoking >20 cigarettes/d and 14 mg/d for those smoking <20 cigarettes/d. Next, they were reduced to the next step down at 7mg/d. Tx duration was 3 months.</p> <p>Group 2: Placebo</p> <p>Placebo: The placebo patch was given at the same dosage and duration as those in the NP24 14 MG-HD group.</p> <p>Mutual interventions: None</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> o PPA 6 months o PPA 12 M - BV: NR <p>Safety:</p> <ul style="list-style-type: none"> o NR
Ahluwalia 1998 - 1	<p>Study Design: Parallel</p> <p>NP24 21 mg (N): 205</p> <p>Placebo (N): 205</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: American Cancer Society Career Development Award</p> <p>Protocol availability: NR</p>	<p>NP24 21 mg:</p> <p>Age: 48.7</p> <p>Female: 70</p> <p>FTND Score: 5.87</p> <p>Years Smoked: 31</p> <p>Cigarettes per day: 20.4</p> <p>Placebo:</p> <p>Age: 46.4</p> <p>Female: 73</p> <p>FTND Score: 5.68</p> <p>Years Smoked: 28.9</p> <p>Cigarettes per day: 19.8</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: NP24 21 mg</p> <p>NP24 21 mg: Participants were placed on a 10 week Tx of nicotine patch starting at 21 mg/d for 6 weeks, then 14 mg/d for 2 weeks and 7 mg/d for 2 weeks.</p> <p>Group 2: Placebo</p> <p>Placebo: Participants received a placebo patch that gave <1 mg/d to mimic the odor of the active patch. Tx duration was also 10 weeks.</p> <p>Mutual interventions:</p> <p>During treatment period</p> <ul style="list-style-type: none"> - Smoking cessation guide - 34 mins video on smoking cessation - \$5 	<p>Efficacy:</p> <ul style="list-style-type: none"> o CAR 6 M - not BV <p>Safety:</p> <ul style="list-style-type: none"> o DEATH – inferred 0 o SAE – inferred 0 o CV DEATH- inferred 0 o COMPLETED SUICIDE- inferred 0

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
Ahluwalia 2002-468	<p>Study Design: Parallel</p> <p>Bupropion SR 300 mg/d (N): 300</p> <p>Placebo (N): 300</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: The National Cancer Institute (grant R01CA77856)</p> <p>Protocol availability: NR</p>	<p>Bupropion SR 300 mg/d:</p> <p>Age: 44.0</p> <p>Female: 70.7%</p> <p>FTND Score: 4.6</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 16.1</p> <p>Placebo:</p> <p>Age: 44.4</p> <p>Female: 69.3%</p> <p>FTND Score: 4.7</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 17.1</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Sustained release bupropion 150mg once a day for 3 days, then 150mg twice a day for a total of 7 weeks</p> <p>Group 2: Placebo, with same regimen as Group 1 drug.</p> <p>Mutual interventions: During treatment period</p> <ul style="list-style-type: none"> - Smoking cessation guide - 45-min counseling for 8 sessions <p>Post-treatment</p> <ul style="list-style-type: none"> - A brief relapse prevention telephone call - Postcard appointment reminders - Token gifts - \$100 	<p>Efficacy:</p> <ul style="list-style-type: none"> o CAR 6 M o PPA 6 M - expired carbon monoxide ≤ 10 ppm <p>Safety:</p> <ul style="list-style-type: none"> o DEATH - inferred 0 o SAE o CV DEATH- inferred 0 o COMPLETED SUICIDE- inferred 0
Ahluwalia 2006-883	<p>Study Design: 2*2 Parallel</p> <p>Nicotine gum + HE (N): 189</p> <p>Placebo + HE (N): 189</p> <p>Nicotine gum + MI (N): 205</p> <p>Placebo + MI (N): 189</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: The National Institutes of Health (R01CA091912)</p> <p>Protocol availability: NR</p>	<p>Nicotine gum + HE:</p> <p>Age: 43.5</p> <p>Female: 68.3%</p> <p>FTND Score: 4.3</p> <p>Years Smoked: 22.8</p> <p>Cigarettes per day: 7.5</p> <p>Placebo + HE:</p> <p>Age: 45.2</p> <p>Female: 68.1%</p> <p>FTND Score: 4.5</p> <p>Years Smoked: 24.2</p> <p>Cigarettes per day: 7.3</p> <p>Nicotine gum + MI:</p> <p>Age: 45.2</p> <p>Female: 66.1%</p> <p>FTND Score: 4.1</p> <p>Years Smoked: 23.5</p> <p>Cigarettes per day: 7.8</p> <p>Placebo + MI:</p> <p>Age: 46.5</p> <p>Female: 65.1%</p> <p>FTND Score: 4.2</p> <p>Years Smoked: 25.1</p> <p>Cigarettes per day: 7.5</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Nicotine gum + health education (HE)</p> <p>Group 2: Placebo + HE</p> <p>Group 3: Nicotine gum + motivational interviewing (MI)</p> <p>Group 4: Placebo + MI</p> <p>Nicotine gum or Placebo: For 8-10 cigarettes per day (cpd) – Ten pieces for the first 4 weeks, eight pieces for weeks 5 and 6, and six pieces during weeks 7 and 8. For 5-7 cpd – Eight pieces for the first weeks, six pieces for weeks 5 and 6, and four pieces during weeks 7 and 8. For <5 cpd – Six pieces for the first weeks, four pieces for weeks 5 and 6, and two pieces during weeks 7 and 8.</p> <p>Health education (HE) or motivational interviewing (MI): Three in-person visits and three telephone counseling</p> <p>Mutual interventions: - KIS II smoking cessation guide during treatment period</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> o PPA 6 M - salivary cotinine ≤ 20 ng/ml <p>Safety:</p> <ul style="list-style-type: none"> o DEATH - inferred 0 o SAE- inferred 0 o CV DEATH- inferred 0 o COMPLETED SUICIDE- inferred 0
Aubin 2008-717	<p>Study Design: Parallel</p> <p>Varenicline 2 mg/d (N): 378</p> <p>Nicotine patch (N): 379</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: Pfizer Inc.</p> <p>Protocol availability: Y, NCT00143325</p>	<p>Varenicline 2 mg/d:</p> <p>Age: 42.9</p> <p>Female: 51.6%</p> <p>FTND Score: 5.62</p> <p>Years Smoked: 25.9</p> <p>Cigarettes per day: 23.0</p> <p>Nicotine patch:</p> <p>Age: 42.9</p> <p>Female: 50.0%</p> <p>FTND Score: 5.37</p> <p>Years Smoked: 25.2</p> <p>Cigarettes per day: 22.4</p>	<p>Group 1: Varenicline Varenicline were administered 0.5 mg/day for 3 days, 0.5 mg twice daily for 4 days, then 1 mg twice daily for a further 11 weeks</p> <p>Group 2: Transdermal nicotine patches Nicotine patch were administered for 10 weeks. Doses started from 21 mg/day for the first 6 weeks, decreased to 14 mg/day for 2 weeks and then 7 mg/day for the last 2 weeks (as per the manufacturer's recommendation)</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> o CAR 6 Months o CAR 12 M o PPA 6 M o PPA 12 M - exhaled carbon monoxide < 10 ppm <p>Safety:</p> <ul style="list-style-type: none"> o DEATH o SAE o CV DEATH o COMPLETED SUICIDE

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
		Are patients willing to quit or have they set a quit date: Y	Mutual interventions: - During treatment: Education booklet + Brief individual counseling (≤10min) +1 contact telephone call + weekly clinic visit - No- treatment follow up: 7 weekly visits, interspersed with 5 telephone calls	
Blondal 1997-1585	Study Design: Parallel Nasal nicotine spray: (N): 79 Placebo spray (N): 78 Follow-up lengths: 24 Months Sponsor: the Icelandic Ministry of Health and Social Security (grant), and Pharmacia & Upjohn (equipment, drugs) Protocol availability: NR	Nasal nicotine spray: Age: 42 Female: 49.4% FTND Score: 7.1 Years Smoked: NR Cigarettes per day: 26 Placebo spray: Age: 42 Female: 61.5% FTND Score: 7.3 Years Smoked: NR Cigarettes per day: 24 Are patients willing to quit or have they set a quit date: Y	Group 1: Nasal nicotine spray Nasal nicotine spray delivered 0.5mg nicotine per 50 µL squirt for each nostril and used on an <i>ad libitum</i> basis Group 2: Placebo spray Same regimen as above Mutual interventions: - group sessions*6 - instruction booklet - telephone contacts	Efficacy: ○ CAR 6 Months ○ CAR 12 M ○ CAR 2 years - exhaled carbon monoxide < 10 ppm Safety: ○ DEATH- inferred 0 ○ SAE ○ CV DEATH- inferred 0 ○ COMPLETED SUICIDE- inferred 0
Blondal 1999-285	Study Design: Parallel Nicotine nasal spray (N): 120 Placebo spray (N): 119 Follow-up lengths: 6 Years Sponsor: Pharmacia, and Upjohn provided the drugs and placebo Protocol availability: NR	Nicotine nasal spray: Age: 41 Female: 63.6% FTND Score: 5.7 Years Smoked: NR Cigarettes per day: 25.0 g/day Placebo spray: Age: 43 Female: 70.6% FTND Score: 5.7 Years Smoked: NR Cigarettes per day: 25.6 g/day Are patients willing to quit or have they set a quit date: Y	Group 1: Nicotine nasal spray, for 1 year Group 2: Placebo spray , same regimen as group 1 Mutual interventions: - Patch and 4* group meetings (1, 8, 15 and 22 days after stopping smoking)	Efficacy: ○ CAR 6 Months ○ CAR 12 M ○ PPA 6 M ○ PPA 12 M ○ PPA 6 years - exhaled carbon monoxide < 10 ppm Safety: ○ DEATH ○ SAE- inferred 0
Bohadana 2000-3128	Study Design: Parallel Group 1 (N): 200 Group 2 (N): 200 Follow-up lengths: 12 Months Sponsor: Pharmacia & Upjohn Consumer Healthcare, Helsingborg, Sweden Protocol availability: NR	Nicotine inhaler + Nicotine patch: Age: 37.1 Female: 50.5% FTND Score: 6.28 Years Smoked: 20.7 Cigarettes per day: 26.1 Nicotine inhaler + placebo patch: Age: 37.4 Female: 51.5% FTND Score: 6.14 Years Smoked: 20.4 Cigarettes per day: 23.5 Are patients willing to quit or have they set a quit date: Y	Group 1: Nicotine inhaler and Nicotine patch Nicotine inhaler - 6-12 inhaler cartridges per day <i>ad libitum</i> for 6 weeks; then tapered as follows: up to 8 per day during month 4, up to 6 per day during month 5, and up to 3 per day during month 6. Nicotine patch – 15mg per 16 hours, for 6 weeks Group 2: Nicotine inhaler and Placebo patch, with the same regimen as group 1. Mutual interventions: - Nicotine inhaler and placebo patch from weeks 7 to 12; then Nicotine inhaler alone from weeks 13 to 26. - Brief counseling and support at	Efficacy: ○ CAR 6 Months ○ CAR 12 M - exhaled carbon monoxide < 10 ppm Safety: ○ DEATH - inferred 0 ○ SAE ○ CV DEATH- inferred 0 ○ COMPLETED SUICIDE- inferred 0

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
Bolliger 2000 - 329	<p>Study Design: Parallel</p> <p>Nicotine inhaler (N): 200</p> <p>Placebo inhaler (N): 200</p> <p>Follow-up lengths: 24 Months</p> <p>Sponsor: Pharmacia and Upjohn Consumer Healthcare, Sweden</p> <p>Protocol availability: NR</p>	<p>Nicotine inhaler: Age: 46.4 Female: 57% FTND Score: 5.5 Years Smoked: NR Cigarettes per day: 28.2</p> <p>Placebo inhaler: Age: 45.8 Female: 48% FTND Score: 5.6 Years Smoked: NR Cigarettes per day: 30.3</p> <p>Are patients willing to quit or have they set a quit date: N</p>	<p>every visit</p> <p>Group 1: Nicotine inhaler Used as needed, with the recommendation to use 6-12 cartridges (nicotine 4-5 mg per cartridge) over 24 hours. Participants were encouraged to decrease use of inhaler after four months but were permitted to continue treatment for 18 months.</p> <p>Group 2: Placebo inhaler, same regimen as group 1</p> <p>Mutual interventions: - Counseling on smoking reduction at baseline, months 4, 12, and 24 visits.</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> o CAR 12 M o CAR 2 years o PPA 12 M o PPA 2 years - exhaled carbon monoxide < 10 ppm <p>Safety:</p> <ul style="list-style-type: none"> o DEATH - inferred 0 o SAE o CV DEATH - inferred 0 o COMPLETED SUICIDE - inferred 0
Bolliger 2007 - 196	<p>Study Design: Parallel</p> <p>Nicotine mouth spray (N): 50</p> <p>Nicotine gum (N): 25</p> <p>Nicotine inhaler (N): 25</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: NicoNovum AB</p> <p>Protocol availability: NR</p>	<p>Nicotine mouth spray: Age: 42.5 Female: 48% FTND Score: 5.3 Years Smoked: NR Cigarettes per day: 23.0</p> <p>Nicotine gum: Age: 43.0 Female: 28% FTND Score: 6.0 Years Smoked: NR Cigarettes per day: 23.7</p> <p>Nicotine inhaler: Age: 44.3 Female: 36% FTND Score: 5.8 Years Smoked: NR Cigarettes per day: 23.9</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Nicotine mouth spray One spray at a time (1 mg/spray), used ad libitum, recommended 6-12 actuation/day, for 3 months</p> <p>Group 2: Nicotine gum 2-mg nicotine gum, used ad libitum, recommended 6-12 gums/day, for 3 months</p> <p>Group 3: Nicotine inhaler 10 mg/blister, used ad libitum, recommended 6-12 cartridges/day, for 3 months</p> <p>Mutual interventions: - 1-week try-out according to individual's preference of nicotine products - 8 counseling sessions at the subsequent visits (coping strategies, correct use of NRT, analysis of side effects and withdrawal symptoms), 15-20 minutes/session, by a certified smoking cessation therapist.</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> o CAR 6 Months o CAR 12 M o PPA 6 M o PPA 12 M - exhaled carbon monoxide < 10 ppm <p>Safety:</p> <ul style="list-style-type: none"> o DEATH - inferred 0 o SAE - inferred 0 o CV DEATH - inferred 0 o COMPLETED SUICIDE - inferred 0
Bolliger 2011- 465	<p>Study Design: Parallel</p> <p>Varenicline (N): 394</p> <p>Placebo (N): 199</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: Pfizer Inc</p> <p>Protocol availability: Y, NCT00594204</p>	<p>Varenicline: Age: 43.1 Female: 42.3% FTND Score: 6.0 Years Smoked: 25.0 Cigarettes per day: 23.8</p> <p>Nicotine gum: Age: 43.9 Female: 34.3% FTND Score: 6.1 Years Smoked: 26.8 Cigarettes per day: 23.7</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Varenicline 1 week of dose titration (0.5 mg once daily for 3 days followed by 0.5 mg BID for 4 days) followed by 11 weeks of varenicline 1 mg BID</p> <p>Group 2: Placebo, same regimen as group 1</p> <p>Mutual interventions: - Educational booklet on smoking cessation - Brief 1-on-1 smoking cessation counseling (<10 minutes) at each subsequent visit (14 visits in total)</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> o CAR 6 Months o PPA 6 M o PPA 12 M - exhaled carbon monoxide ≤ 10 ppm <p>Safety:</p> <ul style="list-style-type: none"> o DEATH o SAE o CV DEATH o SUICIDAL IDEATION o COMPLETED SUICIDE o AGGRESSION

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
British Thoracic Society 1983-595	<p>Study Design: Parallel</p> <p>VA (N): 395</p> <p>VA + Booklet (N): 401</p> <p>VA + Booklet + Placebo gum (N): 412</p> <p>VA + Booklet+ Nicotine gum (N): 410</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: British Thoracic Society</p> <p>Protocol availability: NR</p>	<p>Overall:</p> <p>Age: 49</p> <p>Female: 27%</p> <p>FTND Score: NR</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 24</p> <p>Data by groups was not available.</p> <p>Are patients willing to quit or have they set a quit date: N</p>	<p>Group 1: VA</p> <p>Group 2: VA + Booklet</p> <p>Group 3: VA + Booklet + Placebo gum</p> <p>Group 4: VA + Booklet+ Nicotine gum</p> <p>Mutual interventions: None</p> <p>Nicotine or placebo gum: 2 mg, taken when participants had an urge to smoke in 3 months. From months 3 to 6, further nicotine or placebo gum were given only if participants required. No further supplies were issued after month 6.</p> <p>Booklet: Information about the dangers of smoking and advice on how to stop</p> <p>VA: usual advice from the physician about smoking and verbal instructions to stop</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ PPA 6 M ○ PPA 12 M - the levels of carboxyhaemoglobin (<1.6%) and thiocyanate (< 73 µmol/l or 424 µg/100 ml) in venous blood <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH ○ SAE - inferred
Bullen 2010-1474	<p>Study Design: Parallel</p> <p>Pre-cessation NRT (N): 549</p> <p>No treatment (N): 551</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: Health Research Council and the Heart Foundation of New Zealand</p> <p>Protocol availability: Y, ACTRN12605000373673</p>	<p>Pre-cessation NRT:</p> <p>Age: 39.6</p> <p>Female: 60%</p> <p>FTND Score: 6.1</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 19.0</p> <p>No treatment:</p> <p>Age: 39.6</p> <p>Female: 60%</p> <p>FTND Score: 6.0</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 19.0</p> <p>Are patients willing to quit or have they set a quit date: Y/N</p>	<p>Group 1: Pre-cessation NRT Study-specific voucher for 2 weeks' supply of nicotine patches and/or gum,</p> <p>Group 2: Control, no treatment</p> <p>Mutual interventions:</p> <ul style="list-style-type: none"> - 8-week usual, including patches and/or gum plus support calls from a Quitline adviser <p>Nicotine patches and/or gum (pre- or post-quit date): The product and strength were determined after discussion with the Quitline</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ PPA 6 M - salivary cotinine, with cut-off point not being specified <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH ○ SAE ○ CV EVENTS
Campbell 1991- 155	<p>Study Design: Parallel</p> <p>Nicotine gum + Repeated advice: 107</p> <p>Placebo gum + Repeated advice (N): 105</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: Pharmacia LEO</p> <p>Protocol availability: NR</p>	<p>Nicotine gum + Repeated advice:</p> <p>Age: NR</p> <p>Female: 49%</p> <p>FTND Score: NR</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: NR</p> <p>Placebo gum + Repeated advice:</p> <p>Age: NR</p> <p>Female: 39%</p> <p>FTND Score: NR</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: NR</p> <p>Are patients willing to quit or have they set a quit date: N</p>	<p>Group 1: Nicotine gum + Repeated advice</p> <p>Group 2: Placebo gum + Repeated advice</p> <p>Nicotine or placebo gum: Nicotine or placebo gum 2 mg were provided to the participants before they left the hospital. Stronger gum (4 mg N or P) was offered up to 3 months to those still smoking in the follow-up visits.</p> <p>Repeated advice: The patients were asked to attend outpatients to see research assistant at 2, 3 and 5 weeks, and 3 and 6 months, who would further give advice and encouragement of smoking cessation.</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ PAR 12 M - verified by exhaled carbon monoxide, with cut-off point not being specified <p>Safety:</p> <ul style="list-style-type: none"> ○ SAE – inferred 0
Campbell 1996 - 47	<p>Study Design: Parallel</p>	<p>Overall:</p> <p>Age: 49</p>	<p>Group 1: Nicotine patch</p> <p>Group 2: Placebo patch</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ PAR 12 M (from months 3 to 12)

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
	<p>Nicotine patch (N): 115</p> <p>Placebo patch (N): 119</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: Ciba-Geigy Ltd</p> <p>Protocol availability: NR</p>	<p>Nicotine patch: Female: 58%</p> <p>Years Smoked: 31 FTND Score: NR Cigarettes per day: NR</p> <p>Placebo patch: Female: 50%</p> <p>Years Smoked: 31 FTND Score: NR Cigarettes per day: NR</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Nicotine or placebo patch: Outpatients with a high Fagerstrom Score (≥ 7) were randomized to 40 cm² nicotine (TNS) or placebo (P) patches and those who scored < 6 were prescribed a 20 cm² TNS or P patch. Inpatients were randomized to 20 cm² TNS or P patches regardless of their Fagerstrom score. The treatment lasted 12 weeks, within which the dosage was adjusted accordingly in these patients.</p> <p>Mutual interventions: - Repeated advice and encouragement from the smoking cessation counselor at baseline and weeks 2, 4, 8 and 12</p>	<p>- exhaled carbon monoxide ≤ 7 ppm</p> <p>Safety: o DEATH o SAE o CV DEATH o COMPLETED SUICIDE - 12-week treatment</p>
CF				
Cinciripini 1996 - 314	<p>Study Design: Parallel/Crossover</p> <p>Nicotine patch + CBT (N): 32</p> <p>CBT (N): 32</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: Supported by Grant DHHS DA-04520 and by grants from the Ciba Geigy Corporation and Marion Merrell Dow.</p> <p>Protocol availability: NR</p>	<p>Nicotine patch + CBT: Age: 43.9 Female: 78.1%</p> <p>FTND Score: 6.09 Years Smoked: 23.8 Cigarettes per day: NR</p> <p>CBT: Age: 49.9 Female: 62.5%</p> <p>FTND Score: 5.88 Years Smoked: 26.9 Cigarettes per day: NR</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Nicotine patch + Cognitive-behavioral training (CBT)</p> <p>Group 2: CBT</p> <p>Nicotine patch: Recommended for relapse prevention from Weeks 5. A dose titration schedule using 21-, 14-, and 7-mg patches (Habitrol) was implemented, with participants receiving each dose for approximately 4 weeks (i.e., switching to 14 mg at Week 9 and to 7 mg at Week 13). Participants who reduced the dosage early or started on the 14 mg/day patch (e.g., because of side effects of the 21-mg patch) remained at that dose until the next scheduled reduction but were asked to continue using the patch for the full 12 weeks. Patches were dispensed in session, a month's supply at a time, and participants were instructed to use one per morning, applied on alternating sites, for a 24-hr period.</p> <p>CBT: Weekly, 2-hour group (7-11 participants) meeting for 9 weeks. In weeks 1-5, CBT covered physiological and psychological effects of nicotine, deep breathing, use of behaviors incompatible with smoking, or changing the environment in response to a smoking urge. In weeks 5-9, CBT emphasized maintenance for those who quit and cessation for those who did not. Participants would learn to anticipate and cope with high-risk situations for smoking and develop new skills to manipulate affect, reduce tension, increase energy and pleasure and avoid contact with aversive stimuli.</p> <p>Mutual interventions: - Deposit contract system: Smokers</p>	<p>Efficacy: o PPA 6 M - exhaled carbon monoxide < 6 ppm</p> <p>Safety: o NR</p>

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
			provided a \$ 120 deposit, which was returned weekly in \$ 10 increments contingent on attendance, compliance with instructions, completion of homework, and meeting of abstinence criteria.	
Cooney 2009 - 1588	<p>Study Design: Parallel</p> <p>Nicotine patch + Nicotine gum (N): 45</p> <p>Nicotine patch + Placebo gum (N): 51</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: National Institute on Alcohol Abuse and Alcoholism (R01 AA011197 and P50 AA1563) and by a MIRECC award from the Department of Veterans Affairs</p> <p>Protocol availability: Y, NCT00064844</p>	<p>Nicotine patch + Nicotine gum: Age: 45.1 Female: 28.9 FTND Score: 6.47 Years Smoked: NR Cigarettes per day: 26.0</p> <p>Nicotine patch + Placebo gum: Age: 44.8 Female: 29.4 FTND Score: 5.45 Years Smoked: NR Cigarettes per day: 25.0</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Nicotine patch + Nicotine gum</p> <p>Group 2: Nicotine patch + Placebo gum</p> <p>Nicotine patch: one 21 mg (Nicoderm CQ[®]) nicotine patch daily for 8 weeks, followed by one 14 mg patch daily for 2 weeks, then followed by one 7 mg patch daily for 2 weeks, for a total of 12 weeks.</p> <p>Nicotine or placebo gum: Nicotine gum (2 mg uncoated mint Nicorette[®]) or placebo gum (manufactured by Fertin Pharma A/S, Vejle, Denmark, which contained 2.6% cayenne pepper to simulate the taste of Nicotine) was given for ad libitum use, with encouragement to use at least six pieces per day, up to a maximum of twenty pieces per day. Use of the gum was encouraged for 24 weeks.</p> <p>Mutual interventions:</p> <ul style="list-style-type: none"> - Behavioral alcohol and smoking treatment: 60-min cognitive behavioral addiction therapy * 16 sessions (weekly session from months 1 to 3; then monthly session from months 4 to 6). Each session includes approximately 40-45 minutes for alcohol treatment and 15-20 minutes for smoking treatment. - \$75 for each of the four follow-up meetings 	<p>Efficacy:</p> <ul style="list-style-type: none"> o PAR 6 M o PAR 12 M - exhaled carbon monoxide < 10 ppm <p>Safety:</p> <ul style="list-style-type: none"> o DEATH - inferred 0 o SAE - inferred 0 o CV DEATH - inferred 0 o COMPLETED SUICIDE - inferred 0
Cooper 2005 - 61	<p>Study Design: Parallel</p> <p>Nicotine gum (N): 146</p> <p>Placebo gum (N): 148</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: NR</p> <p>Protocol availability: NR</p>	<p>Nicotine gum: Age: 38.4 Female: 100% FTND Score: 5.5 Years Smoked: 19.4 Cigarettes per day: NR</p> <p>Placebo gum: Age: 39.0 Female: 100% FTND Score: 5.8 Years Smoked: 19.5 Cigarettes per day: NR</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Nicotine gum + cognitive-behavioral smoking cessation program (CBSC)</p> <p>Group 2: Placebo gum + CBSC program</p> <p>Nicotine or placebo gum: Each participant was given a weekly supply of chewing gum. Each piece of nicotine gum was 2 mg. The participants were instructed on a gum chewing protocol, which suggested that the participants chew their gum on an as needed basis, with the caveat that they chew 10 to 12 pieces per day and no more than one piece of gum per hour. "Weaning" of gum chewing took place on Weeks 11 through 13 by reducing the amount of gum chewed by 33% each week.</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> o PPA 6 M o PPA 12 M - exhaled carbon monoxide < 10 ppm <p>Safety:</p> <ul style="list-style-type: none"> o NR

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
			<p>Cognitive-behavioral smoking cessation program: Thirteen weekly 1-hour group intervention, including self-monitoring, reduction strategies, problem-solving training, social support identification, tips on how to avoid weight gain, relapse prevention, and development of cohesion among group members).</p> <p>Mutual interventions:</p> <ul style="list-style-type: none"> - Gradual reduction from weeks 1-4 (25% decrease a week), and required to quit at week 5 	
Cox 2012-290	<p>Study Design: Parallel</p> <p>Bupropion SR (N): 270</p> <p>Placebo (N): 270</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: National Cancer Institute (CA 091912), and in part by the National Institute for Minority Health and Disparities (1P60MD003422).</p> <p>Protocol availability: Y, NCT00666978</p>	<p>Bupropion SR:</p> <p>Age: 46.8</p> <p>Female: 64.4%</p> <p>FTND Score: 3.1</p> <p>Years Smoked: 8.0</p> <p>Cigarettes per day: NR</p> <p>Placebo:</p> <p>Age: 46.2</p> <p>Female: 67.8%</p> <p>FTND Score: 3.3</p> <p>Years Smoked: 7.9</p> <p>Cigarettes per day: NR</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Bupropion SR</p> <p>Group 2: Placebo</p> <p>Bupropion SR or Placebo: 150 mg daily for 3 days and then 150 mg twice daily for the remaining 46 days</p> <p>Mutual interventions:</p> <ul style="list-style-type: none"> - 36-page culturally sensitive smoking cessation guide - Health Education Counseling*6 sessions (4 in-person counseling at weeks 0, 1, 3 and 7; 2 via telephone at weeks 5 and 16) 	<p>Efficacy:</p> <ul style="list-style-type: none"> o PPA 6 M - Salivary \leq15 ng/mL <p>Safety:</p> <ul style="list-style-type: none"> o DEATH - inferred 0 o SAE o CV DEATH - inferred 0 o COMPLETED SUICIDE - inferred 0
Croghan 2003-181	<p>Study Design: Parallel</p> <p>Nicotine patch (N): 459</p> <p>Nicotine nasal spray (N): 463</p> <p>Nicotine patch + Nicotine nasal spray (N): 462</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: In part by Public Health Service from the National Cancer Institute, Department of Health and Human Services (Grants CA-25224, CA-37404, CA-63849, CA-35269, CA-52352, CA-37417, CA-63848, CA-35195, and CA-35103)</p> <p>Protocol availability: NR</p>	<p>Overall:</p> <p>Age: 42.0</p> <p>Female: 58%</p> <p>FTND Score: NR</p> <p>Years Smoked: 23.3</p> <p>Cigarettes per day: 26.2</p> <p>Data by groups was not available.</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Nicotine patch</p> <p>Group 2: Nicotine nasal spray</p> <p>Group 3: Nicotine patch + Nicotine nasal spray</p> <p>Nicotine patch: 15-mg transdermal nicotine patch for 16 hours a day. Participants are required to put on a new patch each morning.</p> <p>Nicotine nasal spray: 0.5 mg of nicotine per spray. The recommended dose was one puff per nostril as needed to a maximum of five doses per hour or 40 doses per day.</p> <p>The above treatments were all initiated within 7 days of randomization and was to be continued for 6 weeks.</p> <p>Mutual interventions: No</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> o PPA 6 M - exhaled carbon monoxide < 8 ppm <p>Safety:</p> <ul style="list-style-type: none"> o DEATH - inferred 0 o SAE - inferred 0 o CV DEATH - inferred 0 o COMPLETED SUICIDE - inferred 0
Dalsgarð 2004 - 55	<p>Study Design: Parallel</p> <p>Bupropion SR (N): 222</p> <p>Placebo (N): 114</p> <p>Follow-up lengths: 6 Months</p>	<p>Bupropion SR:</p> <p>Age: 42.5</p> <p>Female: 75%</p> <p>FTND Score: NR</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 18.9</p>	<p>Group 1: Bupropion SR</p> <p>Group 2: Placebo</p> <p>Bupropion SR or placebo: All participants were instructed to take start taking one tablet daily, containing either bupropion 150mg or</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> o CAR 6 Months o PPA 6 M - exhaled carbon monoxide < 10 ppm <p>Safety:</p>

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
	<p>Sponsor: GlaxoSmithKline, Denmark</p> <p>Protocol availability: NR</p>	<p>Placebo:</p> <p>Age: 44.3</p> <p>Female: 75%</p> <p>FTND Score: NR</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 19.3</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>placebo, for the first 3 days and then twice daily for a total of 7 weeks.</p> <p>Mutual interventions:</p> <ul style="list-style-type: none"> - Smoking-related information - Behavioral counseling, based on materials from the Danish Council Against Tobacco 	<ul style="list-style-type: none"> o DEATH o SAE - inferred 0
Daughton 1991 - 749	<p>Study Design: Parallel</p> <p>24-hour Nicotine patch (N): 51</p> <p>16-hour Nicotine patch (N): 55</p> <p>Placebo (N): 52</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor ALZA Corp, Palo Alto, Calif.</p> <p>Protocol availability: NR</p>	<p>Overall:</p> <p>Age: 41.8</p> <p>Female: 53%</p> <p>FTND Score: 7.0</p> <p>Years Smoked: 23.9</p> <p>Cigarettes per day: 32.9</p> <p>Data by groups was not available.</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: 24-hour Nicotine patch</p> <p>Group 2: 16-hour Nicotine patch</p> <p>Group 3: Placebo</p> <p>24-hour or 16-hour Nicotine or Placebo patch: All participants were instructed to apply two 15-cm² transdermal therapeutic systems (TTS) daily for four weeks, as following regimen:</p> <ul style="list-style-type: none"> o For 24-hour Nicotine patch group: Participants would apply one TTS (nicotine) and one TTS (placebo) system each morning and remove the TTS (placebo) patch at bedtime. o For 16-hour Nicotine patch group: Participants would apply one TTS (nicotine) and one TTS (placebo) system each morning, and remove the TTS (nicotine) at bedtime. o Placebo treatment: Participants would apply two TTS (placebo) systems in the morning and removed one patch at bedtime. <p>Mutual interventions:</p> <ul style="list-style-type: none"> - Brief smoking cessation counseling, either by individual counseling or two group lectures during the first 2 weeks of the trial. 	<p>Efficacy:</p> <ul style="list-style-type: none"> o PPA 6 Months - exhaled carbon monoxide ≤ 8 ppm <p>Safety:</p> <ul style="list-style-type: none"> o DEATH - inferred 0 o SAE - inferred 0 o CV DEATH - inferred 0 o COMPLETED SUICIDE - inferred 0
Daughton 1998 - 425	<p>Study Design: Parallel</p> <p>Nicotine patch (N): 184</p> <p>Placebo (N): 185</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: Marion Merrell Dow Inc, Kansas City, Mo.</p> <p>Protocol availability: NR</p>	<p>Nicotine patch:</p> <p>Age: 37.9</p> <p>Female: 61.4%</p> <p>FTND Score: 6.9</p> <p>Years Smoked: 19.3</p> <p>Cigarettes per day: 27.2</p> <p>Placebo:</p> <p>Age: 36.7</p> <p>Female: 58.4%</p> <p>FTND Score: 7.2</p> <p>Years Smoked: 19.8</p> <p>Cigarettes per day: 29.8</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Nicotine patch</p> <p>Group 2: Placebo</p> <p>Nicotine or Placebo patch: 6 weeks of 21-mg, 2 weeks of 14-mg, and, finally, 2 weeks of 7-mg patches.</p> <p>Mutual interventions:</p> <ul style="list-style-type: none"> - \$75 honorarium 	<p>Efficacy:</p> <ul style="list-style-type: none"> o CAR 6 Months o CAR 12 M - exhaled carbon monoxide ≤ 8 ppm at months 6 and 12 - salivary cotinine level < 20 mg/mL at month 12 <p>Safety:</p> <ul style="list-style-type: none"> o NR
Davidson 1998 - 569	<p>Study Design: Parallel</p>	<p>Nicotine patch:</p> <p>Age: 39.3</p>	<p>Group 1: Nicotine patch</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> o NR

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Reference	Study Details	Patients	Intervention	Outcomes
	<p>Nicotine patch (N): 401</p> <p>Placebo patch (N): 401</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: Elan Pharmaceutical Research Corporation, Gainesville, Ga.</p> <p>Protocol availability: NR</p>	<p>Female: 53%</p> <p>FTND Score: NR</p> <p>Years Smoked: 21.5</p> <p>Cigarettes per day: 29.8</p> <p>Placebo patch:</p> <p>Age: 39.6</p> <p>Female: 54%</p> <p>FTND Score: NR</p> <p>Years Smoked: 21.4</p> <p>Cigarettes per day: 29.1</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 2: Placebo patch</p> <p>Nicotine or Placebo patch: 6 weeks treatment. Each nicotine patch contained 30 mg of nicotine to release 22 mg every 24 hours.</p> <p>Mutual interventions:</p> <ul style="list-style-type: none"> - Smoking cessation self-help booklet 	<p>Safety:</p> <ul style="list-style-type: none"> o DEATH - inferred 0 o SAE - inferred 0 o CV DEATH - inferred 0 o COMPLETED SUICIDE - inferred 0
de Dios 2012-322	<p>Study Design: Parallel</p> <p>Varenicline (N): 10</p> <p>Varenicline-placebo (N): 11</p> <p>Nicotine patch (N): 11</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: National Cancer Institute (Supplement grant: R01CA0129226-S1 and K07-CA95623) and National Institute of Drug Abuse (Mid-Career Award K24-DA000512 and R01-DA12344).</p> <p>Protocol availability: NR</p>	<p>Varenicline:</p> <p>Age: 45.7</p> <p>Female: 60%</p> <p>FTND Score: 2.7</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 7.4</p> <p>Varenicline-placebo:</p> <p>Age: 44.2</p> <p>Female: 54.5%</p> <p>FTND Score: 2.3</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 6.9</p> <p>Nicotine patch:</p> <p>Age: 39.1</p> <p>Female: 45.5%</p> <p>FTND Score: 3.6</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 8.6</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Varenicline</p> <p>Group 2: Varenicline-placebo</p> <p>Varenicline or placebo: starting with 0.5 mg (orally) once daily for Days 1 through 3, 0.5 mg twice daily for Days 4 through 7, then 1 mg twice daily thereafter. The total treatment period was 12 weeks.</p> <p>Group 3: Nicotine patch: starting at moderate strength (14 mg) for 4 weeks, followed by tapering to the 7-mg patch for 8 weeks.</p> <p>Mutual interventions:</p> <ul style="list-style-type: none"> - Gift cards + \$120+ transportation voucher 	<p>Efficacy:</p> <ul style="list-style-type: none"> o PPA 6 M - exhaled carbon monoxide < 5 ppm <p>Safety:</p> <ul style="list-style-type: none"> o NR
Eisenberg 2013 - 524	<p>Study Design: Parallel</p> <p>Bupropion (N): 192</p> <p>Placebo (N): 200</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: Canadian Institutes of Health Research (Grant NCT64989) and Heart and Stroke Foundation of Quebec.</p> <p>Protocol availability: Y, NCT00689611</p>	<p>Bupropion:</p> <p>Age: 54.5</p> <p>Female: 16.2%</p> <p>FTND Score:</p> <p>Years Smoked: 33.2</p> <p>Cigarettes per day: 23.2</p> <p>Placebo:</p> <p>Age: 53.4</p> <p>Female: 16.8%</p> <p>FTND Score:</p> <p>Years Smoked: 32.6</p> <p>Cigarettes per day: 23.2</p> <p>Are patients willing to quit or have they set a quit date: N</p>	<p>Group 1: Bupropion SR</p> <p>Group 2: Placebo</p> <p>Bupropion or placebo: bupropion was recommended as 150 mg daily for 3 days, followed by 150 mg twice daily for the remainder of the 9-week treatment period. Patients in the placebo group received a matching placebo administered with the same schedule.</p> <p>Mutual interventions:</p> <ul style="list-style-type: none"> - Behavioral counseling*7 sessions provided by nurse at baseline and each follow-up visits. Every session includes brief advice based on 5-A models (Ask, Advise, Address, Assist and Arrange) for < 20-minutes (averagely 5 minutes), and discussions. 	<p>Efficacy:</p> <ul style="list-style-type: none"> o CAR 6 Months o CAR 12 M o PPA 6 M o PPA 12 M - exhaled carbon monoxide ≤ 10 ppm <p>Safety:</p> <ul style="list-style-type: none"> o DEATH o SAE o CV EVENTS
Etter 2002-487	<p>Study Design: Parallel</p>	<p>Nicotine:</p> <p>Age: 43.2</p> <p>Female: 46%</p>	<p>Group 1: Nicotine</p> <p>Group 2: Placebo</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> o NR

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Reference	Study Details	Patients	Intervention	Outcomes
	<p>Nicotine (N): 265</p> <p>Placebo (N): 269</p> <p>No treatment (N): 389</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: Swiss National Science Foundation (grant 3233-054994.98 and 3200-055141.98) and Swiss Federal Office of Public Health.</p> <p>Protocol availability: NR</p>	<p>FTND Score: 6.0</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 29.8</p> <p>Placebo:</p> <p>Age: 41.7</p> <p>Female: 51%</p> <p>FTND Score: 5.9</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 29.4</p> <p>No treatment:</p> <p>Age: 42.9</p> <p>Female: 56%</p> <p>FTND Score: 6.2</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 30.2</p> <p>Are patients willing to quit or have they set a quit date: Y/N</p> <p>Group 1 or 2: changed to the net comparison</p>	<p>Nicotine or placebo group:</p> <p>Participants can choose among a nicotine transdermal patch (contains 25 mg and delivers 15 mg nicotine over 16 hours), a nicotine gum (contains 4 mg and delivers 2 mg nicotine), and a nicotine inhaler (a plug contains 10 mg and delivers 5 mg nicotine, or a combination of these.</p> <p>Participants in the placebo group could choose among matching placebo patches, gums, and inhalers.</p> <p>Participants in the nicotine and placebo groups could switch between products or use several products at the same time.</p> <p>Group 3: No treatment</p> <p>Mutual interventions:</p> <ul style="list-style-type: none"> - Information booklet 	<p>Safety:</p> <ul style="list-style-type: none"> o DEATH o CV DEATH o COMPLETED SUICIDE
Etter 2009-1028	<p>Study Design: Parallel</p> <p>Pre-cessation nicotine gum (N): 154</p> <p>Precession-no treatment (N): 160</p> <p>Follow-up lengths:12 Months</p> <p>Sponsor: Swiss National Science Foundation (grant 3200-067835)</p> <p>Protocol availability: Y, ISRCTN60585119</p>	<p>Pre-cessation nicotine gum:</p> <p>Age: 42.0</p> <p>Female: 35.1%</p> <p>FTND Score: 5.5</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 24.0</p> <p>Precession-no treatment:</p> <p>Age: 44.1</p> <p>Female: 47.5%</p> <p>FTND Score: 5.4</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 23.4</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Pre-cessation nicotine gum + Smoking reduction</p> <p>Participants received nicotine polacrilex gum (Nicorette [4 mg, unflavored]) by mail for 4 weeks before their quit date. They were also recommended to decrease their cigarette consumption by half before quitting. No particular reduction schedule was specified.</p> <p>Group 2: Precession-no treatment</p> <p>Mutual interventions:</p> <ul style="list-style-type: none"> - Nicotine gum treatment for 8 weeks after the quit date. All participants were instructed to use at least 10 pieces of gum per day before and after cessation. - Booklet (by mail and assess to smoking cessation web site) 	<p>Efficacy:</p> <ul style="list-style-type: none"> o PPA 12 M - salivary cotinine levels ≤ 10 ng/mL or exhaled carbon monoxide ≤ 10 ppm <p>Safety:</p> <ul style="list-style-type: none"> o DEATH
Evins 2001-397 and Evins 2004-307	<p>Study Design: Parallel</p> <p>Bupropion SR + CBT (N): 9</p> <p>Placebo + CBT (N): 9</p> <p>Follow-up lengths: 2 Years</p> <p>Sponsor: National Association for Research on Schizophrenia and Affective Disorders (NARSAD) Young Investigator Award and by NIDA R03 DA12542-01</p> <p>Protocol availability: Y/NR</p>	<p>Bupropion SR + CBT:</p> <p>Age: 45.5</p> <p>Female: 33.3%</p> <p>FTND Score: NR</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 38</p> <p>Placebo + CBT:</p> <p>Age: 42.7</p> <p>Female: 44.4%</p> <p>FTND Score: NR</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 30</p> <p>Are patients willing to quit or have they set a</p>	<p>Group 1: Bupropion SR + CBT</p> <p>Group 2: Placebo + CBT</p> <p>Bupropion SR or placebo: 150 mg/day for 12 weeks</p> <p>CBT: A "Cognitive Behavioral Quit Smoking" group program designed for patients with schizophrenia that consisted of nine weekly 1-hour group sessions co-led by a nurse a cognitive behavioral psychologist.</p> <p>Mutual interventions:</p> <ul style="list-style-type: none"> - Brief advice 	<p>Efficacy:</p> <ul style="list-style-type: none"> o PPA 6 M o PPA 2 Y o PAR 6 M (from weeks 4 through 24) - exhaled carbon monoxide < 9 ppm or serum cotinine < 14 ng/ml <p>Safety:</p> <ul style="list-style-type: none"> o NR

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
Evins 2005-218	<p>Study Design: Parallel</p> <p>Bupropion SR + CBT (N)*: 25</p> <p>Placebo + CBT (N)*: 28</p> <p>*: No. of treated participants</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: NARSAD Young Investigator Award, NIDA (grants RO3 DA12542, K23 DA00510, K24 MH02025 and K24 HL04440).</p> <p>Protocol availability: NR</p>	<p>quit date: Y</p> <p>Bupropion SR + CBT:</p> <p>Age: 46.0</p> <p>Female: 24.0%</p> <p>FTND Score: NR</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 34.2</p> <p>Placebo + CBT:</p> <p>Age: 45.5</p> <p>Female: 28.6%</p> <p>FTND Score: NR</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 25.4</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Bupropion SR + CBT</p> <p>Group 2: Placebo + CBT</p> <p>Bupropion SR or placebo: Subjects initially took 1 tablet (150 mg) daily for 7 days beginning the day of the first group meeting. Subjects were evaluated for change in psychiatric symptoms at the second group meeting, and if they had tolerated study medication for the first week, their dose was increased to 1 tablet twice daily for the remaining 11 weeks of the trial.</p> <p>CBT: A 12-week, 12-session group meeting (≤ 6 subjects per a group) based on a written manual adapted for patients with schizophrenia from American Heart Association and American Lung Association materials and delivered by 1 of 2 psychologists who had completed Tobacco Treatment Specialist certification training.</p> <p>Mutual interventions: None</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ PPA 6 M - exhaled carbon monoxide < 9 ppm <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - inferred 0 ○ SAE ○ CV DEATH- inferred 0 ○ SUICIDAL IDEATION ○ COMPLETED SUICIDE- inferred 0
Evins 2007-380	<p>Study Design: Parallel</p> <p>Bupropion SR + Nicotine patch + Nicotine gum + CBT (N): 25</p> <p>Placebo + Nicotine patch + Nicotine gum + NRT + CBT (N): 26</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: K23 DA00510 and DHHS SAMHSA 05B1MACMHS-04 Massachusetts Department of Mental Health Federal Block Grant.</p> <p>Protocol availability: NR</p>	<p>Bupropion SR + Nicotine patch + Nicotine gum + CBT:</p> <p>Age: 44.8</p> <p>Female: NR</p> <p>FTND Score: 7.2</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 28.1</p> <p>Placebo + Nicotine patch + Nicotine gum + NRT + CBT:</p> <p>Age: 43.6</p> <p>Female: NR</p> <p>FTND Score: 7.1</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 24.7</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Bupropion SR + Nicotine patch + Nicotine gum + CBT</p> <p>Group 2: Placebo + Nicotine patch + Nicotine gum + NRT + CBT</p> <p>Bupropion SR or placebo: Participants started receiving bupropion SR 150 mg or placebo, once daily for 7 days, then twice daily for 11 weeks.</p> <p>Nicotine patch: In the fourth week, participants received Nicotine patches (Habitrol) and nicotine polacrilex gum (Nicorette). Nicotine patch was dosed at 21 mg/d for 4 weeks, 14 mg/d for 2 weeks, and 7 mg/d for 2 weeks, then discontinued.</p> <p>Nicotine gum: In the fourth week, nicotine gum (2 mg) was distributed for use as needed for craving up to 18 mg/d, and for 8 weeks.</p> <p>CBT: A 12-session, 1-hour, weekly smoking cessation group program with 3 to 7 participants led by a psychologist with tobacco treatment specialist training.</p> <p>Mutual interventions: None</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ CAR 6 Months ○ CAR 12 M ○ PPA 6 M ○ PPA 12 M - exhaled carbon monoxide < 8 ppm <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - inferred 0 ○ SAE ○ CV DEATH - inferred 0 ○ CV EVENTS ○ COMPLETED SUICIDE - inferred 0
Fagerstrom 1982 - 343	<p>Study Design: Parallel</p> <p>Group 1 (N): 50</p> <p>Group 2 (N): 50</p>	<p>Overall:</p> <p>Age: NR</p> <p>Female:</p> <p>FTND Score: NR</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: NR</p>	<p>Group 1: Nicotine gum + Psychological treatment (PT)</p> <p>Group 2: Placebo + PT</p> <p>Nicotine or placebo gum: Nicotine</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ PPA 6 M - exhaled carbon monoxide ≤ 4 ppm <p>Safety:</p>

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
	<p>Follow-up lengths: Months</p> <p>Sponsor: NR</p> <p>Protocol availability: Y/NR</p>	<p>Data by groups was not available.</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>gum 2 mg or placebo was administered <i>ad libitum</i> for about 4 weeks, whereafter the patients were encouraged to reduce and, finally, eliminate use.</p> <p>Psychological treatment: individualized, comprehensive smoking cessation program consists of assessment, treatment related components (occasionally and rarely used) and fundamental premises. Participants averagely received 7.7 sessions.</p> <p>Mutual interventions: None</p>	<ul style="list-style-type: none"> ○ DEATH - inferred 0 ○ SAE ○ CV DEATH - inferred 0 ○ COMPLETED SUICIDE - inferred 0
Fiore 1994 – 524-S1	<p>Study Design: Parallel</p> <p>Nicotine patch + Group counseling (N): 44</p> <p>Placebo + Group counseling (N): 44</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: Elan Pharmaceutical Research Corporation, Gainesville, Ga, and Athlone, Ireland</p> <p>Protocol availability: NR</p>	<p>Nicotine patch + Group counseling:</p> <p>Age: 43.3</p> <p>Female: 56.8%</p> <p>FTQ Score: 7.3</p> <p>Years Smoked: 25.2</p> <p>Cigarettes per day: 28.3</p> <p>Placebo + Group counseling:</p> <p>Age: 42.6</p> <p>Female: 55.8%</p> <p>FTQ Score: 6.9</p> <p>Years Smoked: 24.3</p> <p>Cigarettes per day: 30.3</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Nicotine patch + Group counseling</p> <p>Group 2: Placebo + Group counseling</p> <p>Nicotine or placebo patch: For 8 weeks, subjects were instructed to apply a new patch each morning to a nonirritated portion of the arms or torso above the waist and below the neck. Subjects were provided with a “body map” indicating how to roate patch placement sites. Patches were worn for 24 h, and delivered a steady rate total absorbed dose 22 mg of nicotine. Placebo patches did not contain any nicotine.</p> <p>Group counseling: 8 to 10 subjects were assigned per group and groups met for met for approximately 60 minutes once a week for 8 weeks. In each session, group counselors (clinical psychologists or advanced psychology graduate students), working from a standardized treatment manual, introduced topics appropriate to particular phases of the smoking cessation process. Selected group sessions were videotaped for review, and meetings were held with group counselors to ensure that treatment was delivered in a uniform manner.</p> <p>Mutual interventions: None</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ PPA 6 M - exhaled carbon monoxide < 10 ppm <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - inferred 0 ○ SAE - inferred 0 ○ CV DEATH - inferred 0 ○ COMPLETED SUICIDE - inferred 0
Fiore 1994 – 524-S2	<p>Study Design: Parallel</p> <p>Nicotine patch + Individual counseling (N): 57</p> <p>Placebo + Individual counseling (N): 55</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: Elan Pharmaceutical Research Corporation, Gainesville, Ga, and Athlone,</p>	<p>Nicotine patch + Individual counseling:</p> <p>Age: 43.1</p> <p>Female: 68.4%</p> <p>FTQ Score: 7.2</p> <p>Years Smoked: 24.3</p> <p>Cigarettes per day: 29.8</p> <p>Placebo + Individual counseling:</p> <p>Age: 44.2</p> <p>Female: 67.3%</p> <p>FTQ Score: 7.7</p>	<p>Group 1: Nicotine patch + Individual counseling</p> <p>Group 2: Placebo + Individual counseling</p> <p>Nicotine or placebo patch: Subjects were instructed to apply a new patch each morning to a nonirritated portion of the arms or torso above the waist and below the neck. They were recommended to start with 22-mg nicotine patch for 4 weeks, then 11-mg patch for the following 2 weeks.</p> <p>Mutual interventions: None</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ PPA 6 M - exhaled carbon monoxide < 10 ppm <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - inferred 0 ○ SAE - inferred 0 ○ CV DEATH - inferred 0 ○ COMPLETED SUICIDE - inferred 0

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Reference	Study Details	Patients	Intervention	Outcomes
	Ireland Protocol availability: NR	Years Smoked: 25.9 Cigarettes per day: 30.8 Are patients willing to quit or have they set a quit date: Y	Subjects were provided with a "body map" indicating how to rotate patch placement sites. Patches were worn for 24 h, and delivered a steady rate total absorbed dose either 22 or 11 mg of nicotine. Placebo patches did not contain any nicotine. Individual counseling: Clinical psychologists or advanced psychology graduate students would meet with individual subjects for 10 to 20 minutes per week for a total of 8 weeks. Topics for each session were referenced to the stage of the quitting process (specified in a standardized treatment manual), and meetings among counselors were held as in study 1. The individual counseling intervention in this study was intended to approximate the type of adjuvant treatment a smoker could receive a physician's office by a clinician (physician, nurse, etc). Mutual interventions: None	
Fortmann 1995 - 460	Study Design: Parallel NG 2 mg + Materials (N): 260 NG 2 mg (N): 262 Materials (N): 261 No Tx (N): 261 Follow-up lengths: 12 Months Sponsor: Public Health Service from the National Heart, Lung, and Blood Institute Protocol availability: NR	NG 2 mg + Materials: Age: 39.3 Female: 109 FTND Score: NR Years Smoked: NR Cigarettes per day: 20.1 NG 2 mg: Age: 40.6 Female: 110 FTND Score: NR Years Smoked: NR Cigarettes per day: 20.1 Materials: Age: 39.9 Female: 110 FTND Score: NR Years Smoked: NR Cigarettes per day: 20.1 No Tx: Age: 39.8 Female: 109 FTND Score: NR Years Smoked: NR Cigarettes per day: 20.1 Are patients willing to quit or have they set a quit date: Y	Group 1: NG 2 mg + Materials NG 2 mg: Participants were given 2 mg nicotine gum to take a minimum of 10 pieces/day and a maximum of 30/day. No duration was reported. Materials: Participants were provided with written material on smoking cessation. Group 2: NG 2 mg Group 3: Materials Group 4: No Tx Mutual interventions: - Participants were enrolled in a self-help relapse prevention program to help them create new behaviors to replace their smoking habits and to follow up with 12 mail in progress reports.	Efficacy: o PPA 6 M o PPA 12 M - exhaled carbon monoxide < 9 ppm and salivary cotinine <20 ng/ml Safety: o NR
Fossati 2007-1791	Study Design: Parallel Bupropion SR (N): 400	Bupropion SR: Age: 49.4 (median) Female: 38.0% FTND Score: 5.0 Years Smoked: NR	Group 1: Bupropion SR Group 2: Placebo Bupropion SR or placebo: Participants	Efficacy: o CAR 12 M o PPA 6 M o PPA 12 M - exhaled carbon monoxide

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Reference	Study Details	Patients	Intervention	Outcomes
	<p>Placebo (N): 193</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: Mario Negri Institute, Milan, Italy and partly by GlaxoSmithKline's unconditional grant</p> <p>Protocol availability: NR</p>	<p>Cigarettes per day: 21.1</p> <p>Placebo:</p> <p>Age: 48.5 (median)</p> <p>Female: 44.6%</p> <p>FTND Score: 5.2</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 21.6</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>started receiving bupropion SR 150 mg or placebo, once daily for 7 days, then twice daily for 7 weeks.</p> <p>Mutual interventions: - Counseling telephone call*3</p>	<p>< 10 ppm</p> <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - inferred 0 ○ SAE ○ CV DEATH - inferred 0 ○ CV EVENTS ○ COMPLETED SUICIDE
Gallagher 2007-487	<p>Study Design: Parallel</p> <p>CR (N): 60</p> <p>CR + Nicotine patch (N): 60</p> <p>Minimal intervention self-quit (N): 60</p> <p>Follow-up lengths: Months</p> <p>Sponsor: Arizona Biomedical Research Commission (formerly the Arizona Disease Control Research Commission, Grant # 7014)</p> <p>Protocol availability: NR</p>	<p>CR:</p> <p>Age: 42.6</p> <p>Female: 60%</p> <p>FTQ Score: 5.76</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 21.8</p> <p>CR + Nicotine patch:</p> <p>Age: 43.6</p> <p>Female: 40%</p> <p>FTQ Score: 6.15</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 27.0</p> <p>Minimal intervention self-quit:</p> <p>Age: 42.5</p> <p>Female: 43%</p> <p>FTQ Score: 6.43</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 25.5</p> <p>Are patients willing to quit or have they set a quit date: N</p>	<p>Group 1: Contingent reinforcement (CR)</p> <p>Group 2: CR + Nicotine patch</p> <p>Contingent reinforcement (CR): Participants would earn progressively more money for each visit where they demonstrated abstinence. Based on the CR schedule, participants would earn \$20, \$40, \$60 and \$80 per visit if they demonstrated abstinence at the visit of 2 to 4 weeks, 6 to 12 weeks, 16 to 24 weeks and 36 weeks, respectively. The protocol allowed for participants to earn up to a maximum of \$580 (\$480 contingently and \$ 1 00 for participation and completion of measures) over the course of the study, assuming abstinence by the second visit and no relapses.</p> <p>Nicotine patch: 21 mg nicotine patches were provided at each visit for the first 16 weeks.</p> <p>Group 3: Minimal intervention self-quit. Participants were required to make 3 visits to complete the assessments at baseline, week 20 and 36. They were encouraged to use available community resources and received smoking cessation literature.</p> <p>Mutual interventions: None</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ PPA 6 M - exhaled carbon monoxide < 10 ppm <p>Safety:</p> <ul style="list-style-type: none"> ○ NR
Garvey 2000-53 + Kinnunen 2008-373	<p>Study Design: Parallel</p> <p>Nicotine gum 2 gm (N): 202</p> <p>Nicotine gum 4 gm (N): 203</p> <p>Placebo (N): 203</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: National Institute on Drug Abuse and Department of Veterans Affairs (Grants DA06183 and DA10073)</p> <p>Protocol availability: NR</p>	<p>Nicotine gum 2 gm:</p> <p>Age: 41.0</p> <p>Female: 54.0%</p> <p>FTND Score: 5.7</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 23.3</p> <p>Nicotine gum 4 gm:</p> <p>Age: 41.4</p> <p>Female: 48.3%</p> <p>FTND Score: 5.5</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 23.9</p> <p>Placebo:</p>	<p>Group 1: Nicotine gum 2 gm</p> <p>Group 2: Nicotine gum 4 gm</p> <p>Group 3: Placebo</p> <p>Nicotine gum 2 or 4 gm or placebo: Participants were recommended to use 9–15 pieces of gum each day. They were told not to use less than six pieces per day, nor to exceed 20 pieces per day. They were instructed to use the gum at the recommended level of 9–15 pieces per day for 2 months, after which they would begin weaning themselves from the gum. The weaning procedure involved</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ CAR 12 M ○ PPA 12 M - exhaled carbon monoxide < 8 ppm <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - inferred 0 ○ SAE - inferred 0 ○ CV DEATH - inferred 0 ○ COMPLETED SUICIDE - inferred 0

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
		Age: 40.1 Female: 51.7% FTND Score: 5.4 Years Smoked: NR Cigarettes per day: 23.3 Are patients willing to quit or have they set a quit date: Y	reducing gum consumption by one piece per day each week after the 2-month treatment period. Mutual interventions: - Brief behavior counseling: 5-10 minutes commonsense counseling provided by staff members with PhD or MA degrees in psychology or education at every visit (10 visits in total).	
George 2002 - 53	Study Design: Parallel Bupropion SR + schizophrenia smoking cessation group therapy (N): 16 Placebo + schizophrenia smoking cessation group therapy (N): 16 Follow-up lengths: 6 Months Sponsor: National Institute on Drug Abuse (Grant Nos. R01-DA-13672 and R01-DA-14039, P50-DA-12762, P50-DA-13334, and K12-DA-00167), VISN 1 Mental Illness Research, Education and Clinical Center of the U.S. Department of Veterans Affairs, and National Alliance for Research on Schizophrenia and Depression (Wodecroft Foundation Young Investigator Award) Protocol availability: Y/NR	Bupropion SR + schizophrenia smoking cessation group therapy: Age: 45.4 Female: 37.5% FTND Score: 7.1 Years Smoked: NR Cigarettes per day: 25.0 Placebo + schizophrenia smoking cessation group therapy: Age: 40.9 Female: 50% FTND Score: 7.3 Years Smoked: NR Cigarettes per day: 23.3 Are patients willing to quit or have they set a quit date: Y	Group 1: Bupropion SR + schizophrenia smoking cessation group therapy Group 2: Placebo + schizophrenia smoking cessation group therapy Bupropion SR or placebo: Participants were instructed to begin during the medication at 150 mg p.o. daily for the first 3 days, then the dose was increased to 150 mg p.o. twice daily on the fourth day to the rest of 9 weeks. Schizophrenia smoking cessation group therapy: It included motivational enhancement therapy (weeks 1–3) and psychoeducation, social skills training, and relapse prevention strategies (weeks 4–10) for a total of 10 weeks. Sessions were of 60-min duration. Mutual interventions: None	Efficacy: ○ PPA 6 M - exhaled carbon monoxide < 10 ppm Safety: ○ DEATH - inferred 0 ○ SAE - inferred 0 ○ CV DEATH - inferred 0 ○ COMPLETED SUICIDE - inferred 0
George 2008 - 1092	Study Design: Parallel/Crossover Bupropion SR + Nicotine patch + Behavioral group therapy (N): 29 Placebo + Nicotine patch + Behavioral group therapy (N)*:29 * The total randomized participants are 59 Follow-up lengths: 6 Months Sponsor: National Institute on Drug Abuse (NIDA, Grant Nos.R01-DA-13672, R01-DA-14039, K02-DA-16611, and K12-DA-00167), Young Investigator Awards, and National Alliance for Research in Schizophrenia and Depression (NARSAD, an Independent Investigator Award) Protocol availability: Y, NCT00124683	Bupropion SR + Nicotine patch + Behavioral group therapy: Age: 41.2 Female: 41.4% FTND Score: 6.8 Years Smoked: 22.9 Cigarettes per day: 24.3 Placebo + Nicotine patch + Behavioral group therapy: Age: 39.3 Female: 37.9% FTND Score: 6.8 Years Smoked: 22.2 Cigarettes per day: 22.4 Are patients willing to quit or have they set a quit date: Y	Group 1: Bupropion SR + Nicotine patch + Behavioral group therapy Group 2: Placebo + Nicotine patch + Behavioral group therapy Bupropion SR or placebo: Participants were instructed to begin during the medication at 150 mg p.o. daily for the first 3 days, then the dose was increased to 150 mg p.o. twice daily on the fourth day and continued to the end of 10 weeks. Nicotine patch: Participants were instructed to apply Nicoderm CQ TNP (21 mg/24 hours applied at Day 15 concurrent with the target quit date (TQD) and continued until Day 70. Behavioral group therapy: 10 weekly sessions of manualized group behavioral therapy lasting approximately 50 minutes, conducted by a trained master's or doctoral level clinician Mutual interventions: None	Efficacy: ○ PPA 6 M - exhaled carbon monoxide < 8 ppm Safety: ○ DEATH - inferred 0 ○ SAE ○ CV DEATH - inferred 0 ○ COMPLETED SUICIDE - inferred 0
Gifford 2004-	Study Design:	Overall*	Group 1: 22 mg patches used for 4	Efficacy:

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Reference	Study Details	Patients	Intervention	Outcomes
689	<p>Parallel</p> <p>Nicotine Patch 22mg (N): 43</p> <p>Acceptance and Commitment Therapy (ACT) (N): 33</p> <p>Follow-up lengths: 12 months</p> <p>Sponsor: The National Institutes of Health, National Cancer Institute (CA84813), National Institute on Drug Abuse (DA08634 and DA13106) and by the Department of Veterans Affairs.</p> <p>Protocol availability: NR</p>	<p>Age: 43</p> <p>Female: 59%</p> <p>FTND Score: NR</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 21.4</p> <p>*Data by group allocation is not available.</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>weeks followed by 11 mg patches for 3 weeks. The patients were instructed to wear a new patch each day for the entire 24 hours.</p> <p>Treatment description: describe the administration of the intervention in each group</p> <p>Group 2: seven 50-minute individual sessions and seven 90-minute group sessions. Participants attended one group and one individual session per week for 7 weeks.</p> <p>The protocol focused on helping people notice their internal triggers as they occurred, change what they could and accept what they could not change, make public commitments to behaving in alignment with their values, and practice a variety of constructive actions in response to these triggers.</p>	<p>o PPA 6 M</p> <p>o PPA 12 M</p> <p>- Carbon monoxide (ppm threshold is not reported)</p>
Gilbert 1989-49	<p>Study Design: Parallel</p> <p>Support plus Gum 2mg(N): 112</p> <p>Support alone (N): 111</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: Study funded by the US National Institutes of Health, grant No. RO1CA38334.</p> <p>Protocol availability: NR</p>	<p>Support plus Gum:</p> <p>Age: NR</p> <p>Female: NR</p> <p>FTND Score: NR</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: NR</p> <p>Support alone:</p> <p>Age: NR</p> <p>Female: NR</p> <p>FTND Score: NR</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: NR</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Support plus 2 mg gum</p> <p>Treatment description: The support-plus-gum group received ten quit-tips sheets including two covering the use of gum</p> <p>Group 2: received only the eight sheets that did not pertain to gum use. The prescription was for 2-mg gum and patients were required to pay for it personally.</p> <p>Mutual interventions: Patients in both groups were to receive self-help literature in the form of quit tips at the initial visit.</p>	<p>Efficacy:</p> <p>o CAR 12 M</p> <p>o PPA 12 M</p> <p>o PAR 12 M</p> <p>- cotinine value of < 10ng/mL</p>
Glavas 2003 - 219	<p>Study Design: Parallel</p> <p>Nicotine patch (N): 56</p> <p>Placebo (N): 56</p> <p>Follow-up lengths: 5 years</p> <p>Sponsor: Novartis donated nicotine patches</p> <p>Protocol availability: NR</p>	<p>Nicotine patch:</p> <p>Age: 34.4</p> <p>Female: 66.1</p> <p>FTND Score: NR</p> <p>Years Smoked: 16.4</p> <p>Cigarettes per day: 24.1</p> <p>Placebo:</p> <p>Age: 33.8</p> <p>Female: 66.1</p> <p>FTND Score: NR</p> <p>Years Smoked: 16.5</p> <p>Cigarettes per day: 22.5</p> <p>Are patients willing to quit or have they set a quit date: N</p>	<p>Group 1: 8 transdermal nicotine patches of 3 different sizes (30, 20, and 10 cm²) according to the presumed level of dependence, "heavy" smokers (≥ 20 cigarettes per day) received 30 cm², "medium" smokers (10-19 cigarettes per day) received 20 cm² and the "light" smokers (≤ 10 cigarettes per day) received small 10 cm² patches.</p> <p>The patients were instructed to apply a single patch each morning to non-hairy, clean, and dry skin on the trunk or up per arm; re move it the next morning; and apply a new one. To avoid skin irritation, it was recommended that the same skin site should not be used for at least 7 days.</p> <p>Group 2: 8 matching placebos</p>	<p>Efficacy:</p> <p>o CAR 12 M</p> <p>o CAR > 12 M</p> <p>- quitters <11ppm CO</p>
Glover 2002 - 441	<p>Study Design: Parallel</p>	<p>Sublingual tablet:</p> <p>Age: 43.9</p> <p>Female: 52.5</p>	<p>Group 1: Sublingual nicotine tablet 2 mg</p>	<p>Efficacy:</p> <p>o CAR 6 Months</p> <p>o CAR 12 M</p>

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Reference	Study Details	Patients	Intervention	Outcomes
	<p>Nicotine sublingual tablet 2 mg (N): 120</p> <p>Placebo (N): 121</p> <p>Follow-up lengths: 12 months</p> <p>Sponsor: Funded by Pharmacia and Upjohn</p> <p>Protocol availability: NR</p>	<p>FTND Score: NR</p> <p>Years Smoked: 25.8</p> <p>Cigarettes per day: 28.5</p> <p>Placebo:</p> <p>Age: 41.8</p> <p>Female: 55.4</p> <p>FTND Score: NR</p> <p>Years Smoked: 24.2</p> <p>Cigarettes per day: 29.4</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 2: Placebo</p> <p>All tablets were identical in appearance (round, flat, bevel-edged, 6 mm in diameter). All tablets were packed in press-through packages that contained 15 tablets.</p> <p>Minimal psychological support was provided by research personnel at every follow-up visit after the quit date. This support or behavioral treatment was low intensity (5-10 min for each session) and consisted of handing out the brochure and answering any questions the subject might present. All counseling was conducted on an individual basis.</p>	<p>- CO level < 10ppm</p> <p>Safety:</p> <ul style="list-style-type: none"> o DEATH - <i>inferred 0</i> o SAE o CV DEATH- <i>inferred 0</i> o CV EVENTS
Goldstein 1989-56	<p>Study Design: Parallel</p> <p>Behavioral treatment + fixed nicotine gum (N): 25</p> <p>Behavioral treatment + ad lib nicotine gum (N): 24</p> <p>Education plus fixed schedule (N): 22</p> <p>Education plus ad lib schedule (N): 18</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: Supported by grant IN-45Z from the American Cancer Society and by grant HL-32318 from the National Heart, Lung, and Blood Institute.</p> <p>Protocol availability: NR</p>	<p>Behavioral treatment + fixed nicotine gum:</p> <p>Age: 43</p> <p>Female: 56</p> <p>FTND Score: NR</p> <p>Years Smoked: 24</p> <p>Cigarettes per day:30</p> <p>Behavioral treatment + ad lib nicotine gum:</p> <p>Age: 44</p> <p>Female: 50</p> <p>FTND Score: NR</p> <p>Years Smoked: 25</p> <p>Cigarettes per day:27</p> <p>Education plus fixed schedule:</p> <p>Age: 43</p> <p>Female: 50</p> <p>FTND Score: NR</p> <p>Years Smoked: 25</p> <p>Cigarettes per day:25</p> <p>Education plus ad lib schedule:</p> <p>Age: 39</p> <p>Female: 56</p> <p>FTND Score: NR</p> <p>Years Smoked: 20</p> <p>Cigarettes per day:26</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Behavioral treatment + fixed nicotine gum</p> <p>Group 2: Behavioral treatment + ad lib nicotine gum</p> <p>Mutual interventions: Behavioral treatment</p> <p>Treatment description: The behavioral treatment groups received intensive cognitive and behavioral skills training that included stimulus control, cognitive restructuring, relapse prevention, relaxation training, problem solving, and time management.</p> <p>Group 3: Education plus fixed schedule</p> <p>Group 4: Education plus ad lib schedule</p> <p>Mutual interventions: Education</p> <p>Treatment description: Over an equal amount of contact time the education groups received educational materials about smoking and health, didactic presentations about cognitive and behavioral smoking cessation strategies, and nonspecific group support. The education groups did not receive specific behavioral skills training.</p> <p>Description of Fixed: The subjects in the groups on the fixed nicotine gum schedule were instructed to chew one piece of gum every hour while awake, whether or not they experienced withdrawal symptoms or an urge to smoke. Gum use was gradually tapered by instructing the subjects to increase the interval between doses to 1.5 hours during the second week, 2 hours during weeks 3 and 4, 3 hours</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> o PPA 6 M - CO of less than 8 ppm

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Reference	Study Details	Patients	Intervention	Outcomes
			<p>in weeks 5 and 6, 4 hours in weeks 7 and 8, and 6 hours in weeks 9 and 10. The subjects were told to stop chewing the gum after 10 weeks of use.</p> <p>Description of Ad Lib: The subjects in the groups on the ad lib nicotine gum schedule were told to chew gum whenever they felt an urge to smoke. They were advised to taper their use of gum during the last few weeks of treatment. They were also told to limit their gum intake to a maximum of 30 pieces per day. Gum was not available from the investigators after 10 weeks of use.</p>	
Gonzales 2001 - 438	<p>Study Design: Parallel</p> <p>Bupropion (N): 226</p> <p>Placebo (N): 224</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: Funded by GlaxoWellcome (ZYB40003)</p> <p>Protocol availability: NR</p>	<p>Bupropion:</p> <p>Age: 92</p> <p>Female: 48</p> <p>Fagerstrom score: 7.0</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: NR</p> <p>Placebo:</p> <p>Age: 94</p> <p>Female: 55</p> <p>Fagerstrom score: 7.2</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: NR</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Bupropion SR</p> <p>Treatment description: 150 mg daily on days 1 through 3 and then 150 mg twice daily for the remainder of the 12-week treatment period</p> <p>Group 2: Matching placebo</p> <p>Mutual interventions: Participants at each site received brief individual counseling from trained research counselors based on a standard intervention (ZybanAdvantage Plan) to encourage smoking cessation and to prevent relapse.</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> o CAR 6 Months o PPA 6 M - CO ≤ 10ppm <p>Safety:</p> <ul style="list-style-type: none"> o DEATH - inferred 0 o SAE o CV DEATH- inferred 0 o CV EVENTS
Gonzales 2006 - 47	<p>Study Design: Parallel</p> <p>Varenicline (N): 352</p> <p>Bupropion (N): 329</p> <p>Placebo (N): 344</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: Supported by Pfizer</p> <p>Protocol availability: Y (NCT00141206)</p>	<p>Varenicline:</p> <p>Age: 42.5</p> <p>Female: 50</p> <p>Fagerstrom Score: 5.18</p> <p>Years Smoked: 24.3</p> <p>Cigarettes per day: 21.1</p> <p>Bupropion:</p> <p>Age: 42.0</p> <p>Female: 41.6</p> <p>Fagerstrom Score: 5.19</p> <p>Years Smoked: 24.1</p> <p>Cigarettes per day: 21.0</p> <p>Placebo:</p> <p>Age: 42.6</p> <p>Female: 45.9</p> <p>Fagerstrom Score: 5.38</p> <p>Years Smoked: 24.7</p> <p>Cigarettes per day: 21.5</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Varenicline 0.5-2mg</p> <p>Treatment description: varenicline 0.5 mg/d for days 1 to 3, 0.5 mg twice per day for days 4 to 7, then 1mg twice per day through week 12</p> <p>Group 2: Bupropion 150-30mg</p> <p>Treatment description: bupropion SR 150 mg/d for days 1 to 3, then 150 mg twice per day through week 12.</p> <p>Mutual interventions: All participants were dispensed study drug at the baseline visit (randomization); given Clearing the Air: Quit Smoking Today, a smoking cessation self help booklet as a guide to the quitting process; and instructed to take their first dose the next day. The target quit date was scheduled for day 8 (week 1 visit).</p> <p>A telephone visit was conducted 3 days following the date. During the 12-week drug treatment phase, participants attended weekly clinic visits to assess smoking status, compliance with medications, and</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> o CAR 6 Months o CAR 12 M o PPA 6 M o PPA 12 M - Exhaled CO of less than 10 ppm <p>Safety:</p> <ul style="list-style-type: none"> o DEATH - inferred 0 o SAE o CV DEATH - inferred 0 o CV EVENTS

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Reference	Study Details	Patients	Intervention	Outcomes
			safety. Brief (≤ 10 minute), standardized, individual counseling was provided to assist in problem solving and skills training for relapse prevention following recommendations in the Public Health Service Clinical Practice Guideline	
Gourlay 1995 - 363	<p>Study Design: Parallel</p> <p>Nicotine Patch (N): 315</p> <p>Placebo (N): 314</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: Funding received from Ciba-Geigy</p> <p>Protocol availability: NR</p>	<p>Nicotine patch:</p> <p>Age: 41.1</p> <p>Female: 57.8</p> <p>Fagerstrom Score: 6.4</p> <p>Years Smoked: 23.1</p> <p>Cigarettes per day: 27.7</p> <p>Placebo:</p> <p>Age: 41.7</p> <p>Female: 57.3</p> <p>Fagerstrom Score: 6.4</p> <p>Years Smoked: 24.3</p> <p>Cigarettes per day: 26.7</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Nicotine patch</p> <p>Group 2: Placebo</p> <p>Treatment description: Treatment consisted of four weeks each of a 30 cm² patch (active 21 mg/24 hours or placebo 2-7 mg/24 hours), a 20 cm² patch (active 14 mg/24 hours or placebo 1.8 mg/24 hours), and a 10 cm² patch (active 7 mg/24 hours or placebo 0.9 mg/24 hours). Each patch was to be used for 24 hours but could be removed before bedtime if persistent insomnia occurred.</p> <p>Mutual interventions: The figure shows the design of the study. The behavioural component of the intervention consisted of five to 10 minutes of counselling at each visit⁴ and a booklet containing advice on smoking cessation and instructions for use of the patches.</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ CAR 6 Months ○ PPA 6 M - Exhaled CO of less than 8 ppm <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - inferred 0 ○ SAE- inferred 0 ○ CV DEATH- inferred 0
Grant 2007 - 381	<p>Study Design: Parallel</p> <p>Bupropion SR + NP24 21 mg + Counseling (N): 30</p> <p>Placebo + NP24 21 mg + Counseling (N)*:28</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: National Institute on Alcohol Abuse and Alcoholism</p> <p>Protocol availability: NR</p>	<p>Bup 300 mg + NP24 21 mg + Counseling:</p> <p>Age: 38.5</p> <p>Female: 5</p> <p>FTND Score: 6.1</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 23.2</p> <p>Placebo + NP24 21 mg + Counseling:</p> <p>Age: 40.8</p> <p>Female: 4</p> <p>FTND Score: 6.0</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 27.0</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Bup 300 mg + NP24 21 mg + Counseling</p> <p>Group 2: Placebo + NP24 21 mg + Counseling</p> <p>Bupropion SR or placebo: Participants received 150 mg/day of Bupropion SR for 3 days and then 150 mg bid for 60 days. Placebo followed the same frequency and duration.</p> <p>NP24 21 mg: All participants received a 24 hr nicotine patch at 21 mg/day for 4 weeks, then 14 mg/day for 2 weeks and 7 mg/day for the final 2 weeks.</p> <p>Counseling: All participants attended a 1 hour counseling session on smoking cessation with facilitators and a video.</p> <p>Mutual interventions: None</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ PPA 6 M - biochemically verified: NR <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - inferred 0 ○ SAE - inferred 0 ○ CV DEATH - inferred 0 ○ COMPLETED SUICIDE - inferred 0
Haggstram 2006 -205	<p>Study Design: Parallel</p> <p>Bupropion (N): 53</p> <p>Placebo (N): 51</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: NR</p>	<p>Bupropion:</p> <p>Age: 41.5</p> <p>Female: 58.5</p> <p>Fagerstrom Score: 6.2</p> <p>Pack years: 37.0</p> <p>Cigarettes per day: NR</p> <p>Placebo:</p> <p>Age: 45.5</p> <p>Female: 70.6</p> <p>Fagerstrom Score: 5.9</p>	<p>Group 1: Bupropion</p> <p>Treatment description: In the bupropion group, smokers received an initial dose of 150 mg each morning for 5 days followed by one 150 mg bupropion tablet in the morning and another in the evening on days 6–60.</p> <p>Group 2: Placebo</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ CAR 6 Months - Exhaled CO of less than 10 ppm <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - inferred 0 ○ SAE- inferred 0 ○ CV DEATH- inferred 0

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Reference	Study Details	Patients	Intervention	Outcomes
	Protocol availability: NR	<p>Pack years: 29.1 Cigarettes per day: NR</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Treatment description: In the placebo group, patients received one placebo capsule and one placebo tablet in the morning and evening on days 1–60.</p> <p>Mutual interventions: Follow-up assessments and relapse prevention counseling were conducted during clinic visits at 10, 13 and 26 weeks. In addition, subjects received phone calls during this period in months 4 and 5. All follow-up counseling sessions lasted at least 15-min.</p>	
Hall 2002 -930	<p>Study Design: Parallel</p> <p>Bupropion + Medical Management (N): 36</p> <p>Placebo + Medical Management (N): 37</p> <p>Bupropion + Psychological intervention (N): 37</p> <p>Placebo + Psychological intervention (N): 36</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: National Institute on Drug Abuse (R01 DA02538) and National Cancer Institute (R01 CA71378)</p> <p>Protocol availability: N</p>	<p>Bupropion + Medical Management: Age: 37.1 Female: 41.7 Fagerstrom Scale Score: 4.1 Years Smoked: 19.7 Cigarettes per day: 19.8</p> <p>Placebo + Medical Management: Age: 43 Female: 40.5 Fagerstrom Scale Score: 5.4 Years Smoked: 24.7 Cigarettes per day: 23.0</p> <p>Bupropion + Psychological intervention: Age: 37.9 Female: 46.0 Fagerstrom Scale Score: 5.1 Years Smoked: 21.2 Cigarettes per day: 22.5</p> <p>Placebo + Psychological intervention: Age: 39.3 Female: 47.2 Fagerstrom Scale Score: 4.7 Years Smoked: 21.2 Cigarettes per day: 22.2</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Bupropion + Medical Management</p> <p>Treatment description: Bupropion hydrochloride dosage began at 150 mg/day for the first 3 days. The dosage was increased to 300mg/d where it remained until week 12 when the dose was decreased to 150 mg for 3 days then discontinued. Dose reductions occurred if participant reported unpleasant adverse effects.</p> <p>Group 2: Placebo + Medical Management</p> <p>Mutual interventions: Medical management included advice to stop smoking, antidepressant medication adverse effects monitoring and educational materials. Physicians were 5 licensed psychiatric and internal medicine residents. Participants were provided written information about smoking cessation. (Freedom From Smoking). During week 1, the physician reviewed the treatment rationale and prescription instruction, discussed behavioral factors important to smoking cessation and established a quit date during week 5. This session lasted 10 to 20 minutes. Five-minute visits were scheduled during weeks 2, 6, and 11 during which participants were queried about cessation progress. The physicians responded briefly to questions and provided encouragement. Advice about specific quitting strategies was not offered.</p> <p>Group 3: Bupropion + Psychological Intervention</p> <p>Group 4: Placebo + Psychological Intervention</p> <p>Mutual interventions: All participants participated in the MM sessions previously described. In</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ PPA 6 M ○ PPA 12 M - Carbon monoxide levels of 10 ppm or less and urinary cotinine levels of 60 ng/ml or less <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - <i>inferred 0</i> ○ SAE - <i>inferred 0</i> ○ CV DEATH - <i>inferred 0</i>

Reference	Study Details	Patients	Intervention	Outcomes
			addition they participated in 5 group sessions. Providers were 3 master's-level counselors, the most common smoking treatment provider in the health care organizations were consulted. The intervention provided health-related information for mood management and smoking cessation and discussion of cessation. A core element was the development of a quit-smoking plan and weekly modification of it. Methods used included monitoring of cigarette use and affective states; paper-and-pencil exercises focusing on health-related information, motivation to quit, and decreasing relapse-related thoughts; informational handouts; and brief didactic presentations.	
Hand 2002 - 715	<p>Study Design: Parallel</p> <p>NRT + Advice and Support (N): 136</p> <p>Advice and Support (N): 109</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: NR</p> <p>Protocol availability: N</p>	<p>NRT + Advice and Support:</p> <p>Age≥ 60: 46</p> <p>Female: 79</p> <p>FTND Score: NR</p> <p>Years Smoked: NR</p> <p>Cigarettes per day >25: 47</p> <p>Advice and Support:</p> <p>Age≥ 60: 47</p> <p>Female: 54</p> <p>FTND Score: NR</p> <p>Years Smoked: NR</p> <p>Cigarettes per day >25: 31</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: NRT</p> <p>Treatment description: The dose of the nicotine patch was determined by the number of cigarettes smoked. Those who smoked more than 20 cigarettes per day were given a 30 mg patch for the first week, 20 mg for week 2, and 10 mg for week 3. Those who smoked less than 20 cigarettes per day were given 20 mg patches for the first 2 weeks and a 10 mg patch for week 3. In addition to the patches, all those in the NRT group were given a nicotine inhalator starter pack containing six cartridges and a refill pack containing a further 42 cartridges. The inhalator has a replaceable nicotine cartridge and a mouth piece. Each cartridge provides 10 mg nicotine which the manufacturer advises is appropriate for 20 minutes of heavy use. One cartridge can be used several times. The inhalator therefore provided a total of 480 mg nicotine replacement for each patient for the 3 weeks or a further 20 mg nicotine per day if required.</p> <p>Group 2: Advice and Support</p> <p>Treatment description: The programme started with four weekly sessions during which time the patient was encouraged to set a "quit date" within 7 days of the first visit. The initial session of 45–60 minutes involved a detailed smoking history, as outlined previously, and support literature was given to the patient. This session was followed by three further weekly sessions, each lasting 15–30 minutes.</p> <p>Mutual interventions: Advice and support</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ CAR 6 Months ○ CAR 12 M - Carbon monoxide levels of less than 10 ppm.

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Reference	Study Details	Patients	Intervention	Outcomes
Hanioka 2010 - 66	<p>Study Design: Parallel</p> <p>NP + Counseling (N): 47</p> <p>Non-intervention (N): 44</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: Fukuoka Dental College and Grant-in-Aids for Cancer Research from Japanese Ministry of Health</p> <p>Protocol availability: NR</p>	<p>NP + Counseling: Age: 48.0 Female: 7 FTND Score: NR Years Smoked: 26.7 Cigarettes per day: 24.3</p> <p>Non-intervention: Age: 46.7 Female: 9 FTND Score: NR Years Smoked: 24.1 Cigarettes per day: 20.6</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: NP + Counseling</p> <p>NP: Participants received 6 weeks of nicotine patch therapy but dose and type of patch (16hr or 24 hr) is not reported.</p> <p>Counseling: Participants in this intervention arm received 5 visits starting with baseline then at weeks 2, 4, 8 and 3 months. Visits focused on smoking cessation and behavioral changes with not set duration per visit recorded. (Total Contact Time – 116.2 mins)</p> <p>Group 2: Non-intervention</p> <p>Non-intervention: Participants received initial visit and follow up measurements but were not offered nicotine replacement therapy and has no form of counseling.</p> <p>Mutual interventions: None</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ CAR 6 months ○ CAR 12 M - salivary cotinine level <20 ng/ml <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - inferred ○ SAE - inferred ○ CV DEATH – inferred ○ COMPLETED SUICIDE - inferred
Hanson 2001 – thesis	<p>Study Design: Parallel</p> <p>NP24 14 mg-21 mg + Counseling (N): 50</p> <p>Placebo + Counseling (N): 50</p> <p>Follow-up lengths: 6 months</p> <p>Sponsor: NR</p> <p>Protocol availability: NR</p>	<p>NP24 14 mg-21 mg + Counseling Age: 17 Female: 24 FTND Score: NR Years Smoked: NR Cigarettes per day: 16.6</p> <p>Placebo + Counseling Age: 16.6 Female: 33 FTND Score: NR Years Smoked: NR Cigarettes per day: 16.0</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: NP24 14 mg-21 mg + Counseling</p> <p>NP24 14 mg-21 mg: Participants who smoked ≥ 15 cigarettes/day given nicotine patch for 10 weeks with the first 6 at 21 mg/d, followed by 14 mg/d for 2 weeks and 7 mg/d for 2 weeks. Those who smoked 10-14 cigarettes/day given 14 mg/d for 6 weeks and then 7 mg/day for 4 weeks.</p> <p>Counseling: All participants received 11 sessions meeting once the first week, twice the second week, once a week for the next six weeks and then bi-weekly the final four weeks. The sessions were individualized and lasted 10-15 mins. (Total Contact Time = 110-165 mins).</p> <p>Group 2: Placebo + Counseling</p> <p>Placebo: Placebo patch identical to NP24 21 MG was given with same duration.</p> <p>Mutual interventions: A manual to help quit was given as well as a contingency-management procedure where participants were given points each visit that their CO was ≤8 ppm. At the end, given gift card based on points.</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ NR - BV: NR <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - inferred ○ SAE - inferred ○ CV DEATH - inferred ○ COMPLETED SUICIDE - inferred
Harackiewicz	Study Design:	Overall:	Group 1: NG + intrinsic self-help	Efficacy:

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Reference	Study Details	Patients	Intervention	Outcomes
1987 - 372	<p>Parallel</p> <p>NG + intrinsic self-help manual (N): 45</p> <p>NG + extrinsic self-help manual (N): 45</p> <p>Intrinsic self-help manual (N): 47</p> <p>Extrinsic self-help manual (N): 38</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: Merrell Dow Pharmaceuticals Inc.</p> <p>Protocol availability: NR</p>	<p>Age: 34.5 Female: 107</p> <p>FTND Score: NR</p> <p>Years Smoked: 17.4</p> <p>Cigarettes per day: 26.6</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>manual</p> <p>NG: A supply of nicotine gum was given to participants and they were encouraged to use it as needed but for a recommended duration of 3 months. Dosage and daily use was not reported.</p> <p>Intrinsic self-help manual: Participants received the self-help manual and participated in therapy that focused on using their own methods and ability to quit smoking. (Total Contact Time = NR)</p> <p>Group 2: NG + extrinsic self-help manual</p> <p>Extrinsic self-help manual: Participants received a similar self-help manual to the others but this manual focused on doctor recommended smoking cessation methods and programs. (Total Contact Time = NR)</p> <p>Group 3: Intrinsic self-help manual</p> <p>Group 4: Short self-help manual</p> <p>Short self-help manual: Participants received a short manual similar to the other manual on quitting but with only brief tips and no sessions or NRT was given.</p> <p>Mutual interventions: None</p>	<ul style="list-style-type: none"> ○ CAR 6 months ○ CAR 12 M - expired air carbon monoxide <8 ppm and salivary thiocyanate <10 mg/dl Safety: <ul style="list-style-type: none"> ○ NR
Harackiewicz 1988 - 319	<p>Study Design: Parallel</p> <p>Nicotine gum + Self-help (N): 99</p> <p>Self-help (N): 52</p> <p>Control (booklet) (N): 46</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: Supported by a grant from Merrell Dow Pharmaceuticals</p> <p>Protocol availability: NR</p>	<p>Overall sample</p> <p>Age: 36 Female: 63</p> <p>FTND Score: NR</p> <p>Years Smoked: 17</p> <p>Cigarettes per day: 26.5</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Nicotine gum</p> <p>Treatment description: Gum patients were instructed to chew a piece of gum when they felt an urge to smoke. The guidelines encouraged patients to anticipate smoking situations (e.g., work breaks) and begin chewing before smoking urges developed. Charts were provided for monitoring the conditions under which the gum was chewed. Patients were instructed to gradually eliminate the use of the gum approximately three months after their quit date. While they were tapering off the gum, they were to continue using behavioral and cognitive coping strategies to resist the urge to smoke. These directions were integrated into the self-help program.</p> <p>In the Gum condition, the manual outlined another coping strategy: chewing nicotine gum. After quitting, all patients were to record instances</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ CAR 6 Months ○ CAR 12 M - Biochemical-verified method

Reference	Study Details	Patients	Intervention	Outcomes
			<p>when they conquered an urge to smoke (on charts provided with the manual) in order to learn which coping strategies were most effective for them. A section on “slips” emphasized that if they smoked, they should identify the causes of their relapse, and use the appropriate coping strategies when similar situations arose.</p> <p>Group 2: Self-help The manuals in the Self-Help and Gum conditions were identical except for directions pertaining to nicotine gum.</p> <p>Group 2: Control (booklet) In the control condition, guidelines for quitting were minimal; the booklet contained only general information about smoking and brief tips. Patients first were urged to spend a few days clarifying their smoking patterns and considering their reasons for quitting. To facilitate this process, charts were provided for recording when and why cigarettes were smoked during this preparation period. Patients were then advised to set and prepare for a “quit date”, on which they would stop smoking completely. The manuals outlined various coping strategies for controlling smoking urges (e.g., thinking about the benefits of not smoking, finding substitute activities).</p> <p>Mutual interventions: All booklets outlined a three-month program in which smokers would quit “cold-turkey” after a few days of preparation.</p>	
Hatsukami 2004 - 151	<p>Study Design: Parallel</p> <p>Bupropion (N): 295</p> <p>Placebo (N): 299</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: supported by GlaxoSmithKline</p> <p>Protocol availability: NR</p>	<p>Bupropion: Age: 42.5 Female: 43 FTND Score: 6.4 Years Smoked: NR Cigarettes per day: 29.0</p> <p>Placebo: Age: 42.0 Female: 47 FTND Score: 6.4 Years Smoked: NR Cigarettes per day: 28.5</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Bupropion</p> <p>Treatment description: 26 weeks of sustained-release bupropion (150 mg for days 1 to 3 of therapy, followed by 150 mg twice daily)</p> <p>Group 2: matching placebo</p> <p>Mutual interventions: Written materials suggesting smoking reduction techniques were provided; these materials were discussed with trained or experienced smoking intervention counselors at each monthly visit during brief individual sessions using standardized counseling guidelines.</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ CAR 6 Months - Exhaled carbon monoxide ≤ 10 ppm <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - inferred 0 ○ SAE ○ CV DEATH - inferred 0
Hays 1999-1701	<p>Study Design: Parallel</p> <p>Nicotine patch (N): 321</p>	<p>Nicotine patch: Age: 43.5 Female: 51.4 Fagerstrom Score: 6.1</p>	<p>Group 1: Nicotine 24 hour patch 22mg</p> <p>Group 2: identical Placebo patch</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ PPA 6 M - Expired CO levels of 8ppm or lower were considered

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Reference	Study Details	Patients	Intervention	Outcomes
	<p>Placebo (N): 322</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: Supported by Elan Pharmaceutical Research Corp</p> <p>Protocol availability: NR</p>	<p>Years Smoked: 25.2 Cigarettes per day > 40: 10.3</p> <p>Placebo: Age: Female: FTND Score: Years Smoked: Cigarettes per day > 40: 9.6</p> <p>Are patients willing to quit or have they set a quit date: NR</p>		<p>to be confirmatory of self-reported abstinence</p> <p>Safety: ○ DEATH ○ CV DEATH ○ CV EVENTS</p>
Hays 2001 - 423	<p>Study Design: Parallel</p> <p>Bupropion SR (N): 214</p> <p>Placebo (N): 215</p> <p>Follow-up lengths: 24 Months</p> <p>Sponsor: Supported by Glaxo Wellcome</p> <p>Protocol availability: NR</p>	<p>Bupropion: Age: 47.0 Female: 54.7 Fagerstrom Tolerance Questionnaire: 7.3 Years Smoked: NR Cigarettes per day: 27.4</p> <p>Placebo: Age: 45.4 Female: 47.9 Fagerstrom Tolerance Questionnaire: 7.1 Years Smoked: NR Cigarettes per day: 26.2</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Drug or behavioral</p> <p>Treatment description: describe the administration of the intervention in each group</p> <p>Group 2: Same as listed under group 1</p> <p>Mutual interventions: The mutual intervention(s) across arms that can be deleted</p> <p><u>If drug list the following:</u> - Mode (gum, patch, tablet, etc.); - dose - duration - frequency - Others?</p> <p><u>If behavioral list the following:</u> - type (self-help, educational, psychological, etc.) - duration - frequency - Others?</p>	<p>Efficacy: ○ PPA 6 M ○ PPA 12 M ○ PPA > 12 M - Biochemically confirmed by an expired CO level of 10 ppm or less</p> <p>Safety: ○ DEATH ○ CV DEATH ○ COMPLETED SUICIDE-inferred 0</p>
Herrera 1995-447	<p>Study Design: Parallel</p> <p>Nicotine gum 2mg (N): 157</p> <p>Nicotine gum 4mg (N): 87</p> <p>Placebo (N): 78</p> <p>Follow-up lengths: 24 Months</p> <p>Sponsor: NR</p> <p>Protocol availability: NR</p>	<p>Nicotine gum 2mg (low/medium): Age: 38.1 Female: NR FTQ Score: 5.3 Years Smoked: NR Cigarettes per day: 15.7</p> <p>Nicotine gum 2mg (high dependence): Age: 38.6 Female: NR FTQ Score: 7.9 Years Smoked: NR Cigarettes per day: 32.5</p> <p>Nicotine gum 4mg: Age: 40.7 Female: NR FTQ Score: 7.9 Years Smoked: NR Cigarettes per day:</p>	<p>Group 1: Nicotine gum 2mg</p> <p>Treatment description: describe the administration of the intervention in each group</p> <p>Group 2: Nicotine gum 4mg</p> <p>Group 3: Placebo</p> <p>Mutual interventions: Behavioral Supportive Treatment: This treatment consisted of 12 group sessions over approximately 6 weeks, two sessions per week, each lasting 60 to 80 min. The group sessions (10 to 15 participants) were divided into four phases. The first phase (2 weeks) included increased awareness of the habit by record keeping of each cigarette smoked to learn about external stimuli connected with smoking. The subjects were further to increase the interval between</p>	<p>Efficacy: ○ CAR 6 Months ○ CAR 12 M ○ CAR > 12 M - Used cotinine and Carbon Monoxide but did not detail the thresholds.</p> <p>Safety: ○ DEATH - inferred 0 ○ SAE- inferred 0 ○ CV DEATH- inferred 0 ○ COMPLETED SUICIDE-inferred 0</p>

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Reference	Study Details	Patients	Intervention	Outcomes
		<p>34.2</p> <p>Placebo:</p> <p>Age: 36.8</p> <p>Female: NR</p> <p>FTQ Score: 5.3</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 15.6</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>cigarettes so as to decrease total intake of nicotine. This was aided by a wrist alarm watch that signaled smoking at longer and longer intervals.</p> <p>Phase 2 (2 to 4 weeks) included continued record keeping and reduction of smoking by the wrist alarm and stimulus control.</p> <p>Familiarization with gum started and reinforced reduced smoking.</p> <p>Relaxation techniques, covert conditioning (associating smoking with negative consequences), and alternative reinforcing behavior to smoking was learned. Thereafter, the quit phase began. During this period (4 to 6 weeks), most of the information and discussions were centered on the nicotine replacement treatment. Use of the behavioral methods was also encouraged and relapse prevention training began with instructions in stress management and cognitive restructuring. A maintenance phase (7 to 12 weeks) offered additional support with one session per week. Eventually individual follow-up sessions at 6, 12, and 24 months were made. In addition to this, participants could come and see the therapist at a set time each week for up to 24 months if they so wished.</p>	
Hertzberg 2001 - 94	<p>Study Design: Parallel</p> <p>Bupropion (N): 10</p> <p>Placebo (N): 5</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: Study was supported in part by Glaxo Wellcome and the National Cancer Institute</p> <p>Protocol availability: NR</p>	<p>Overall:</p> <p>Age: 50</p> <p>Female: NR</p> <p>FTND Score: NR</p> <p>Years Smoked: 57</p> <p>Cigarettes per day: 33</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Bupropion</p> <p>Treatment description: Bupropion SR was begun at 150 mg every morning for 3 or 4 days and then increased to 150 mg twice daily (300 mg/day).</p> <p>Group 2: Placebo</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> o PPA 6 M - Expired Carbon Monoxide measurements with a level of > 10 ppm were considered positive for cigarette smoking <p>Safety:</p> <ul style="list-style-type: none"> o DEATH - inferred 0 o SAE - inferred 0 o CV DEATH - inferred 0 o COMPLETED SUICIDE - inferred 0
Heydari 2012-268	<p>Study Design: Parallel</p> <p>Counseling (N): 91</p> <p>Nicotine patch (N): 92</p> <p>Varenicline (N): 89</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: Funding was provided by the Masih Daneshvari Hospital Research Institute, Tehran.</p> <p>Protocol availability: national study</p>	<p>Counseling:</p> <p>Age: 42.2</p> <p>Female: 42.9</p> <p>Fagerstrom test Score: 5.1</p> <p>Years Smoked: NR</p> <p>Cigarettes per day ≥ 31: 15</p> <p>Nicotine patch:</p> <p>Age: 41.8</p> <p>Female: 47.8</p> <p>Fagerstrom test Score: 5.6</p> <p>Years Smoked: NR</p> <p>Cigarettes per day ≥</p>	<p>Group 1: Counseling</p> <p>Mutual interventions: All three groups received brief (5 minutes) education and counseling on behaviour therapy and cessation in four weekly sessions</p> <p>Group 2: 15 mg/daily nicotine patches for 8 weeks</p> <p>Group 3: varenicline</p> <p>Treatment description: 0.5 mg daily</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> o CAR 6 Months o CAR 12 M - biologically verified by exhaled carbon monoxide measurement <p>Safety:</p> <ul style="list-style-type: none"> o DEATH - inferred 0 o SAE- inferred 0 o CV DEATH- inferred 0 o COMPLETED SUICIDE- inferred 0

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Reference	Study Details	Patients	Intervention	Outcomes
	code IRCT138901111878N2)	<p>31: 11</p> <p>Varenicline: Age: 43.5 Female: 32.6 Fagerstrom test Score: 5.7 Years Smoked: NR Cigarettes per day ≥ 31: 16</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	for the first 3 days, followed by 0.5 mg twice a day for 4 days and subsequently 1 mg twice daily for 8 weeks	
Hilberink 2011 - 120	<p>Study Design: Parallel</p> <p>Usual care (N): 154</p> <p>Counseling + NRT (N): 252</p> <p>Counseling + NRT + Bupropion (N): 291</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: NR</p> <p>Protocol availability: ID NCT00628225.</p>	<p>Usual care: Age: 60.1 Female: 44.6 FTND Score: 4.3 Years Smoked: NR Cigarettes per day:16.8</p> <p>Counseling + NRT: Age: 58.0 Female: 53.5 FTND Score: 4.4 Years Smoked: NR Cigarettes per day:16.9</p> <p>Counseling + NRT + Bupropion: Age: 60.7 Female: 52.2 FTND Score: 4.6 Years Smoked: NR Cigarettes per day:16.9</p> <p>Are patients willing to quit or have they set a quit date: NR</p>	<p>Group 1: Counseling + NRT + Bupropion SR</p> <p>Group 2: Counseling + NRT</p> <p>Mutual interventions: Counseling and NRT</p> <p>Both strategies used the same counseling protocol.</p> <p>Group 3: Usual care</p>	<p>Efficacy: ○ PPA 12 M - Biochemical-verified by cotinine levels</p> <p>Safety: ○ DEATH</p>
Hill 1993 - 321	<p>Study Design: Parallel</p> <p>Behavioral training (N): 22</p> <p>Behavioral training + Nicotine gum (N): 22</p> <p>Behavioral training + Exercise (N): 18</p> <p>Exercise (N): 20</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: Supported by a grant from the Andrus Foundation. Nicotine gum was provided through a grant from Merrell Dow Pharmaceutical</p> <p>Protocol availability: NR</p>	<p>Behavioral training: Age: NR Female: NR FTND Score: NR Years Smoked: NR Cigarettes per day: NR</p> <p>Behavioral training + Nicotine gum: Age: NR Female: NR FTND Score: NR Years Smoked: NR Cigarettes per day: NR</p> <p>Behavioral training + Exercise: Age: NR Female: NR FTND Score: NR Years Smoked: NR Cigarettes per day: NR</p> <p>Exercise:</p>	<p>Group 1: Behavioral training</p> <p>Behavioral training materials were adapted from the smoking cessation program used by the Lung Health Study, Components of behavioral training were as follows: (1) tailored information highlighting the health consequences of smoking in advanced age, (2) specific documentation that older smokers can quit and improve their quality of life, (3) environmental planning that involved removing smoking-related cues (e.g., matches, ashtrays), (4) setting a quit date that involved a contract with fellow group members, (5) relapse prevention training that included identifying high-risk situations, role-playing coping responses to those situations, and problem-solving individual slips between treatment sessions.</p> <p>Participants met for a total of twelve 90-minute sessions across the 3-</p>	<p>Efficacy: ○ PPA 6 M ○ PPA 12 M - verified CO less than 10 ppm indicated not smoking</p>

Reference	Study Details	Patients	Intervention	Outcomes
		<p>Age: NR Female: NR FTND Score: NR Years Smoked: NR Cigarettes per day: NR</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>month treatment program. During the first month participants met eight times (once during week 1, four times during quit week, twice during week 3, and once during week 4). In months 2 and 3 participants met once every two weeks. Between sessions, group leaders contacted individuals by phone to check on their progress and to provide assistance as needed. The total number of group sessions plus phone contacts was equal to the number of formal exercise sessions for the exercise groups. The stated goal of behavioral training was smoking cessation on quit day and maintenance of nonsmoking for the remainder of the treatment program and through each follow-up.</p> <p>Group 2: Behavioral training + Nicotine gum</p> <p>Treatment description: Participants received identical behavioral training to those in group 1. In addition, during the first treatment meeting a project physician evaluated each participant and prescribed nicotine gum. Nicotine gum was provided at no cost to each subject during the 3-month treatment program and was available to participants as needed up to the 4-month follow-up interval. Participants were required to attend group meetings and/or participate in scheduled follow-ups to renew their supply of nicotine gum. Participants were encouraged to use nicotine gum and were given detailed instruction about its use in conjunction with behavioral training as a way to resist the urge to smoke. Although individuals regulated their own gum use (e.g., the number of pieces chewed per day), group leaders encouraged participants to use the gum daily as a way to deal with physical urges to smoke.</p> <p>Mutual interventions: Behavioral training</p> <p>Group 3: Behavioral training + Exercise</p> <p>Treatment description: Participants received behavioral training as described for group 1. The behavioral training schedule was modified to incorporate a regular program of physical exercise. Physical exercise consisted of graduated walking following a standard protocol administered by the exercise leader through the Department of Exercise</p>	

Reference	Study Details	Patients	Intervention	Outcomes
			<p>and Sports Science, College of Health. Specifically, individuals met and walked as a group over a 3-month time period. Both indoor and outdoor walking facilities were available to facilitate regular walking irrespective of weather conditions. The first 60 minutes of each session were devoted to behavioral training, followed by exercise (45 minutes). Because behavioral training required fewer formal group meetings than the exercise program, a percentage of the treatment sessions for group 3 involved only exercise. The exercise component involved three formal group meetings each week during the first month. This was decreased to twice a week during month 2, and once a week during month 3. During months 2 and 3, participants were encouraged to walk at least three times per week. This involved walking with the group at the designated times, as well as walking on their own between group meetings. When a group member failed to attend a formal walking session, a leader contacted that individual by phone to encourage continued walking outside of group meetings and/or to problem-solve group attendance issues when necessary.</p> <p>At each formal group walking session, subjects spent 10 minutes warming up, followed by a period of steady walking which varied from 15 to 35 minutes depending on the individual's baseline level of fitness as determined from an estimated training heart rate from the 1-mile standardized walk at the group orientation meeting. The goal of the walking program was to increase training heart rate to 60-70% of heart-rate reserve and to maintain this target rate for longer periods of time as conditioning improved. Participants were trained to monitor their own heart rate as they walked in order to sustain their target heart rate. At each exercise session, group leaders followed up on the smoking cessation goals that were made during the previous behavioral training session.</p> <p>Group 4: Exercise Group 4 was a placebo control. The exercise protocol was a method of controlling for contact time, given that participants in this condition met as a group with an exercise leader on the same schedule as described for group 3. At the initial session, participants received 1 to 3 minutes of general</p>	

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Reference	Study Details	Patients	Intervention	Outcomes
			<p>encouragement to quit and were given a self-help stop-smoking pamphlet published by the American Cancer Society. The stated purpose of this intervention was to promote smoking cessation through improved fitness. The group leaders were not aware that this was a placebo control condition. At each meeting leaders recorded self-reported smoking status, conducted the prescribed exercise-training protocol, and encouraged group members to quit.</p> <p>Mutual interventions: Exercise</p>	
Hilleman 1994-222	<p>Study Design: Parallel</p> <p>Fixed dose Transdermal Nicotine (N): 69</p> <p>Tapered dose Transdermal Nicotine (N): 71</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: NR</p> <p>Protocol availability: NR</p>	<p>Fixed dose Transdermal Nicotine: Age: 45 Female: 52.2 Fagerstrom Score: 9.8 Years Smoked: 20.3 Cigarettes per day: 27.5</p> <p>Tapered dose Transdermal Nicotine: Age: 47 Female: 57.7 Fagerstrom Score: 9.5 Years Smoked: 19.3 Cigarettes per day: 25.2</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Fixed dose Transdermal Nicotine: Drug or behavioral</p> <p>Treatment description: Fixed-dose transdermal nicotine treatment consisted of the use of transdermal nicotine patch designed to deliver 21 mg or 22 mg per day for 6 weeks with no dosage adjustments.</p> <p>Tapered dose Transdermal Nicotine: Same as listed under group 1</p> <p>Treatment description: Tapered-dose transdermal nicotine treatment consisted of a 21-mg or 22-mg patch daily for 4 weeks, a 14-mg patch for 4 weeks, and a 7-mg patch daily for 4 weeks.</p>	<p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - inferred 0 ○ SAE- inferred 0 ○ CV DEATH- inferred 0 ○ COMPLETED SUICIDE- inferred 0
Hjalmarson 1984 - 2835	<p>Study Design: Parallel</p> <p>Nicotine gum (N): 106</p> <p>Placebo (N): 100</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: NR</p> <p>Protocol availability: NR</p>	<p>Nicotine gum: Age: 42.8 Female: 53.8 FTND Score: NR Years Smoked: NR Cigarettes per day: 23.9</p> <p>Placebo: Age: 41.3 Female: 59 FTND Score: NR Years Smoked: NR Cigarettes per day: 24.2</p> <p>Are patients willing to quit or have they set a quit date: NR</p>	<p>Group 1: Nicotine gum 2mg</p> <p>Group 2: Placebo</p> <p>Mutual interventions: The groups each contained five to ten subjects and met six times in six weeks. Group sessions were led by a psychologist who gave simple advice based on behavior modification principles.</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ CAR 6 Months ○ CAR 12 M - Biochemical-verified method <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH ○ SAE
Hjalmarson 1994 - 2567	<p>Study Design: Parallel</p> <p>Nicotine spray (N): ITT</p> <p>Placebo (N): ITT</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: NR</p>	<p>Nicotine spray: Age: 44.9 Female: 57.6 FTQ Score: 7.2 Years Smoked: 26.9 Cigarettes per day: 21.2</p> <p>Placebo: Age: 44.9 Female: 56.9</p>	<p>Group 1: The nicotine nasal spray delivered 0.5 mg of nicotine per 50-u.L spray. One dose was defined as two sprays, thus delivering 1.0 mg of nicotine.</p> <p>Treatment description: Subjects were encouraged to use the spray frequently, up to a maximum of five doses per hour and 40 doses per day. The recommended duration of spray</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ CAR 6 Months ○ CAR 12 M - CO monoxide < 10 ppm in nonsmokers. <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - inferred 0 ○ SAE- inferred 0 ○ CV DEATH- inferred 0

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Reference	Study Details	Patients	Intervention	Outcomes
	Protocol availability: NR	FTQ Score: 7.3 Years Smoked: 26.6 Cigarettes per day: 21.6 Are patients willing to quit or have they set a quit date: NR	use was 3 months, but spray use could be continued for up to 1 year. describe the administration of the intervention in each group Group 2: Matching placebo	o COMPLETED SUICIDE- inferred 0
Hjalmarson 1997 -1721	Study Design: Parallel Nicotine inhaler (N): 123 Placebo (N): 124 Follow-up lengths: 12 Months Sponsor: This study was supported by a grant from Pharmacia & Upjohn Protocol availability: NR	Nicotine inhaler: Age: 48.0 Female: 61.8 FTQ Score: 7.3 Years Smoked: 30 Cigarettes per day:21.7 Placebo: Age: 47.0 Female: 66.1 FTQ Score: 7.0 Years Smoked: 28.9 Cigarettes per day:21.0 Are patients willing to quit or have they set a quit date: Y	Group 1: Nicotine inhaler Treatment description: The nicotine inhaler consisted of a plastic mouthpiece into which a replaceable cylinder, containing a soft plug impregnated with nicotine and menthol, was inserted. It looked like a cigarette holder. When puffed, the inhaler delivered air saturated with nicotine into the mouth. Each inhaler contained approximately 10 mg of nicotine and 1 mg of menthol. One puff of 50 mL released approximately 13 ng of nicotine at room temperature. To receive 1 mg of nicotine, the participant had to take about 80 puffs. This dosage required them to take 3 to 4 puffs per minute for 20 to 30 minutes. The average smoker receives approximately 1 mg of nicotine from smoking a cigarette, usually after 10 puffs in 10 minutes. Participants were instructed to use the inhaler for 20 to 30 minutes and to puff more frequently than when smoking. An inhaler could be used more than once and participants usually switched to a new inhaler after using the old one 3 to 4 times. The nicotine and the placebo inhaler were identical in appearance, but the placebo inhaler contained only menthol. The inhalers were used on an ad lib basis with a recommended minimum dosage of 4 inhalers per day. Participants who smoked during treatment were encouraged to continue inhaler use and to increase their dosage. After 3 months participants were advised to decrease their inhaler use, but they were allowed to use the inhalers for up to 6 months. Group 2: Placebo Mutual interventions: Participants were assigned to 1 of 24 groups. Each group consisted of 8 to 13 individuals and met 8 times in 6 weeks. Participants were expected to stop smoking by the second group meeting (quit day), and at this session they received the inhalers and were instructed in their use. The inhalers were dispensed by a nurse not	Efficacy: o CAR 6 Months o CAR 12 M - Participants who reported that they were not smoking and who had an exhaled-air carbon monoxide concentration of less than 10 ppm Safety: o DEATH - inferred 0 o SAE- inferred 0 o CV DEATH- inferred 0 o COMPLETED SUICIDE- inferred 0

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Reference	Study Details	Patients	Intervention	Outcomes
			involved in the treatment or assessment procedures. Participants who had received either nicotine or placebo inhalers were included in the same support groups. Two psychologists were involved in the study, each of them treating 12 groups. The group sessions lasted from 45 to 60 minutes, and participants were taught smoking behavior modification skills and how to use the inhalers. At one session a physician talked about the health benefits of smoking cessation. At 3, 6, and 12 months after the quit date, participants were mailed a questionnaire about their smoking behavior and, if not smoking, asked to come to the clinic to have their claim of abstinence verified and for other tests.	
Holt 2005 - 120	<p>Study Design: Parallel</p> <p>Bupropion 300mg/day (N): 88</p> <p>Placebo (N): 46</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: Supported by a research grant from GlaxoSmithKline.</p> <p>Protocol availability: NR</p>	<p>Bupropion:</p> <p>Age: 41.7</p> <p>Female: 69.3</p> <p>FTND Score: 5.8</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: NR</p> <p>Placebo:</p> <p>Age: 38.0</p> <p>Female: 76.1</p> <p>FTND Score: 5.3</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: NR</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Bupropion 300 mg/day</p> <p>Treatment description: bupropion 150 mg once daily for 3 days, then 150 mg twice daily for 7 weeks.</p> <p>Group 2: identical placebo</p> <p>Mutual interventions: Both treatment groups also received smoking cessation counselling.</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ CAR 6 Months ○ CAR 12 Months - Exhaled CO <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - <i>inferred 0</i> ○ SAE - <i>inferred 0</i> ○ CV DEATH - <i>inferred 0</i> ○ COMPLETED SUICIDE - <i>inferred 0</i>
Hughes 1989 - 1300	<p>Study Design: Parallel</p> <p>Nicotine gum (N): 210</p> <p>Placebo (N): 105</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: This study was funded by a grant (DA-04066) and a Research Scientist Development Award (DA-00109) from the National Institute on Drug Abuse, Washington DC. Merrell-Dow Research Institute, Cincinnati, provided all gum</p> <p>Protocol availability: NR</p>	<p>Nicotine gum:</p> <p>Age: 37.4</p> <p>Female: 55</p> <p>FTND Score: 5.7</p> <p>Years Smoked: 19.7</p> <p>Cigarettes per day: 29.8</p> <p>Placebo:</p> <p>Age: 36.6</p> <p>Female: 59</p> <p>FTND Score: 5.8</p> <p>Years Smoked: 18.7</p> <p>Cigarettes per day: 29.2</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Nicotine gum</p> <p>Treatment description: The nicotine gum was the marketed 2-mg dose (Nicorette).</p> <p>Group 2: Placebo</p> <p>Mutual interventions: Nurses gave the subject a booklet of behavioral strategies to combat the habit part of smoking, a booklet on the use of nicotine gum, and a list of public and private smoking cessation clinics, including those at the health maintenance organization. The nurse was trained in smoking cessation counseling and also gave ten to 12 minutes of individual advice. Subjects then received six to ten minutes of physician advice</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ CAR 12 M ○ PPA 12 M - Biochemical-verified method cotinine level <15 ng/ml <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - <i>inferred 0</i> ○ SAE - <i>inferred 0</i> ○ CV DEATH - <i>inferred 0</i> ○ COMPLETED SUICIDE - <i>inferred 0</i>
Hughes 1990- 1175	<p>Study Design: Parallel</p>	<p>Nicotine gum 4 mg:</p> <p>Age: 40.2</p>	<p>Group 1: Nicotine gum 4mg</p>	<p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - <i>inferred 0</i>

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
	<p>Nicotine gum 4 mg (N): 19</p> <p>Nicotine gum 2 mg (N): 20</p> <p>Placebo (N): 19</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: This work was supported by Grants DA-03728 and DA-04066 and Research Scientist Development Award DA-00109 (to J.R.H.) from the National Institute on Drug Abuse.</p> <p>Protocol availability: NR</p>	<p>Female: 74</p> <p>FTND Score: 6.2</p> <p>Years Smoked: 22.4</p> <p>Cigarettes per day: 31.9</p> <p>Nicotine gum 2 mg:</p> <p>Age: 43.9</p> <p>Female: 50</p> <p>FTND Score: 5.8</p> <p>Years Smoked: 25.8</p> <p>Cigarettes per day: 27.4</p> <p>Placebo:</p> <p>Age: 34.1</p> <p>Female: 47</p> <p>FTND Score: 6.6</p> <p>Years Smoked: 16.8</p> <p>Cigarettes per day: 30.2</p> <p>Are patients willing to quit or have they set a quit date: NR</p>	<p>Group 2: Nicotine gum 2 mg</p> <p>Group 3: Placebo</p> <p>Placebo gum contained no nicotine but did contain flavoring agents to imitate the taste of active gum.</p>	<p>○ SAE - inferred 0</p> <p>○ CV DEATH - inferred 0</p> <p>○ COMPLETED SUICIDE - inferred 0</p>
Hughes 2003 - 946	<p>Study Design: Parallel</p> <p>Nicotine patch (N): 61</p> <p>Placebo (N): 54</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor:</p> <p>Protocol availability: Y/N</p>	<p>Nicotine patch:</p> <p>Age: 43</p> <p>Female: 28</p> <p>FTQ Score: 7.9</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 30</p> <p>Placebo:</p> <p>Age: 43</p> <p>Female: 37</p> <p>FTQ Score: 7.6</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 29</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Nicotine patch 21 mg worn over 24 hours</p> <p>Treatment description: Subjects in the NP group began the 21-mg dose on their quit date and used it for the next 6 weeks. Then they received 14 mg/day for 2 weeks, 7 mg for 2 weeks, and placebo for 2 weeks</p> <p>Group 2: Placebo (0 mg)</p> <p>Those in the placebo group received matching placebo patches for the entire 12 weeks.</p> <p>Mutual interventions: At the precessation visit, subjects received a stopsmoking booklet. At this visit and the first six post-quit date visits, subjects attended a 1-hr behavioral therapy group session. Groups were led by graduate students in psychology or trained tobacco cessation counselors and usually consisted of four to eight subjects. Topics included resisting urges, coping with withdrawal symptoms, handling being around other smokers, and so on. Alcohol use or alcohol cravings were not discussed as specific topics; on the few occasions that these concerns arose, prior successful strategies for handling alcohol cravings were reviewed. During the second 6 weeks, subjects were seen every 2 weeks for brief (15 min) individual behaviorally based counseling.</p>	<p>Efficacy:</p> <p>○ CAR 6 Months - Biochemical-verified method CO levels less than 10 ppm</p> <p>Safety:</p> <p>○ DEATH - inferred 0</p> <p>○ SAE - inferred 0</p> <p>○ CV DEATH - inferred 0</p> <p>○ COMPLETED SUICIDE - inferred 0</p>

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
Hughes 2011-955	<p>Study Design: Parallel</p> <p>Varenicline (N): 107</p> <p>Placebo (N): 111</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: Pfizer Inc. via an unrestricted grant plus provided medication and placebo; Senior Scientist Award DA-000490 to J.R.H. and grant DA011557 to J.R.H.; and the Larson Endowment at the University of Nebraska Medical Center to S.I.R.</p> <p>Protocol availability: NR</p>	<p>Varenicline:</p> <p>Age: 45</p> <p>Female: 39</p> <p>FTND Score: 4.9</p> <p>Years Smoked: NR</p> <p>Cigarettes per day:19</p> <p>Placebo:</p> <p>Age: 45</p> <p>Female: 39</p> <p>FTND Score: 4.3</p> <p>Years Smoked: NR</p> <p>Cigarettes per day:17</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Varenicline</p> <p>Placebo</p> <p>Treatment description: Participants took one pill/day (0.5 mg/day or placebo) for the first 3 days, then two pills/day (0.5 mg each or placebo) for 4 days, and then two pills/day (1.0 mg each or placebo) for the remainder of treatment.</p> <p>Mutual interventions: Brief counseling about reduction occurred at baseline, 2, 4, and 8 weeks later.</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ PPA 6 M - Biochemical-verified method <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - inferred 0 ○ SAE ○ CV DEATH - inferred 0 ○ COMPLETED SUICIDE - inferred 0
Hurt 1990 -1529	<p>Study Design: Parallel</p> <p>NP24 30 mg (N): 31</p> <p>Placebo (N): 31</p> <p>Follow-up lengths: 56 weeks</p> <p>Sponsor: Elan Pharmaceutical Research Corporation</p> <p>Protocol availability: NR</p>	<p>NP24 30 mg</p> <p>Age: NR</p> <p>Female: 16</p> <p>FTND Score: 6.7</p> <p>Years Smoked: 20 (median)</p> <p>Cigarettes per day: 30 (median)</p> <p>Placebo</p> <p>Age: NR</p> <p>Female: 17</p> <p>FTND Score: 5.9</p> <p>Years Smoked: 19 (median)</p> <p>Cigarettes per day: 25 (median)</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: NP24 30 mg</p> <p>NP24 30 mg: Phase 1: The 24hr nicotine patch was given for 6 weeks at 30mg/d for those smoking >20 cigarettes/d. Phase 2: Participants who were still smoking were offered either 15 mg/d or 30 mg/d dosage for weeks 6-18.</p> <p>Group 2: Placebo</p> <p>Placebo: The placebo patch was given at for the same duration as those in the NP24 30 mg/d group for the first 6 weeks. For those still smoking after 6 weeks, they continued on the placebo until week 12. At week 12, if they were still smoking they were offered either 30 mg/d or 15 mg/d active nicotine patch until week 18.</p> <p>Mutual interventions: None</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ PPA 6 months ○ PPA 12 M ○ PAR 40 wks - exhaled air carbon monoxide ≤ 10 ppm <p>Safety:</p> <ul style="list-style-type: none"> ○ NR
Hurt 1994-595	<p>Study Design: Parallel</p> <p>Nicotine patch (N): 120</p> <p>Placebo patch (N): 120</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: This study was supported by a grant from Lederle Laboratories, Pearl River, NY.</p> <p>Protocol availability: NR</p>	<p>Nicotine patch:</p> <p>Age:42.8</p> <p>Female: 51.7</p> <p>FTND Score: 6.3</p> <p>Years Smoked: 23.7</p> <p>Cigarettes per day: 28.8</p> <p>Placebo:</p> <p>Age: 43.6</p> <p>Female: 55.8</p> <p>FTND Score: 6.8</p> <p>Years Smoked: 25.8</p> <p>Cigarettes per day:30.6</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: 8 weeks of 22mg nicotine patch</p> <p>Group 2: placebo patch</p> <p>Mutual interventions: Based on the National Cancer Institute program, subjects received smoking cessation advice from a physician. Follow-up and relapse prevention were provided by a study nurse during individual counseling sessions. Brief individualized counseling using the booklet, "Clearing the Air," was provided by the nurse.</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ PPA 6 M ○ PPA 12 M - Biochemical-verified method by CO of 8ppm or less <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - inferred 0 ○ SAE - inferred 0 ○ CV DEATH - inferred 0 ○ COMPLETED SUICIDE - inferred 0

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
Hurt 1997 - 1195	<p>Study Design: Parallel</p> <p>Placebo (N): 153</p> <p>Bupropion 100 mg(N): 153 Bupropion 150 mg(N): 153 Bupropion 300 mg(N): 156</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: Supported by a grant from Glaxo Wellcome.</p> <p>Protocol availability: NR</p>	<p>Placebo: Age: 43 Female: 59.5 Fagerstrom Score: 7.3 Years Smoked: NR Cigarettes per day: 26.5</p> <p>Bupropion 100 mg: Age: 44.1 Female: 58.2 Fagerstrom Score: 7.3 Years Smoked: NR Cigarettes per day: 26.2</p> <p>Bupropion 150 mg: Age: 42.3 Female: 50.3 Fagerstrom Score: 7.3 Years Smoked: NR Cigarettes per day: 27.5</p> <p>Bupropion 300 mg: Age: 45 Female: 50.6 Fagerstrom Score: 7.3 Years Smoked: NR Cigarettes per day: 27.2</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Placebo: taken twice a day</p> <p>Sustained release Bupropion 100 mg: 50 mg twice a day</p> <p>Sustained release Bupropion 150 mg: 150 mg each morning and placebo each evening</p> <p>Sustained release Bupropion 300 mg: 150 mg per day for three days, followed by 150 mg twice a day</p> <p>Treatment description: all tablets were identical in appearance.</p> <p>Mutual interventions: Each subject received a brief, personalized message to stop smoking from the physician and self-help material based on the National Cancer Institute program. In this program, which has been validated as an effective intervention for smoking cessation, the physician asks each patient whether he or she smokes, advises all smokers to stop smoking, helps the patient set a quitting date, and arranges a follow-up visit.</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ PPA 6 M ○ PPA 12 M - Biochemical-verified method <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH ○ SAE ○ CV DEATH ○ CV EVENTS ○ COMPLETED SUICIDE – inferred 0
Jamrozik 1984 - 794	<p>Study Design: Parallel</p> <p>NG 2mg (N): 101</p> <p>Placebo (N): 99</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: Oxford District Research Committee and the Nuffield Dominions Trust</p> <p>Protocol availability: NR</p>	<p>NG 2mg Age: NR Female: NR FTND Score: NR Years Smoked: NR Cigarettes per day: NR</p> <p>Placebo Age: NR Female: NR FTND Score: NR Years Smoked: NR Cigarettes per day: NR</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: NG 2mg</p> <p>NG 2 mg: Nicotine gum was given for a minimum of 3 months at 2 mg dose.</p> <p>Group 2: Placebo</p> <p>Placebo: Identical to NG 2 mg in appearance and packaging, given for the same duration.</p> <p>Mutual interventions: None</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ CAR 6 months - exhaled air carbon monoxide ≤ 10 ppm <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - inferred ○ SAE - inferred ○ CV DEATH - inferred
Jarvik 1984 - 790	<p>Study Design: Parallel</p> <p>NG 2 mg + Counseling (N): 25</p> <p>Placebo + Counseling (N): 23</p>	<p>NG 2 mg + Counseling: Age: NR Female: NR FTND Score: NR Years Smoked: NR Cigarettes per day: NR</p>	<p>Group 1: NG 2 mg + Counseling</p> <p>NG 2 mg: Participants given 2 mg dose of nicotine gum to use as needed and duration not reported.</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ CAR 6 Months ○ CAR 12 M - expired air carbon monoxide

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
	<p>Follow-up lengths: 12 Months</p> <p>Sponsor: National Institute on Drug Abuse and VA Medical Research Service</p> <p>Protocol availability: NR</p>	<p>Placebo + Counseling: Age: NR Female: NR FTND Score: NR Years Smoked: NR Cigarettes per day: NR</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Counseling: Participants visits daily for the first week, then weekly for 4 weeks and at 3, 6 and 1 year times for 30 mins counseling sessions. (Total Contact Time = ~360 mins)</p> <p>Group 2: Placebo + Counseling</p> <p>Placebo: Placebo gum given to participants to use as needed.</p> <p>Mutual interventions: None</p>	<p>Safety: o NR</p>
Jarvis 1982 - 537	<p>Study Design: Parallel</p> <p>NG 2 mg + Counseling (N): 58</p> <p>Placebo + Counseling (N): 58</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: Medical Research Council and Department of Health and Social Security</p> <p>Protocol availability: NR</p>	<p>NG 2 mg + Counseling: Age: 41.0 Female: 29 FTND Score: NR Years Smoked: NR Cigarettes per day: 30.9</p> <p>Placebo + Counseling: Age: 38.4 Female: 35 FTND Score: NR Years Smoked: NR Cigarettes per day: 26.5</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: NG 2 mg + Counseling</p> <p>NG 2 mg: Participants were given 2 mg nicotine gum to take as needed daily and for a minimum of 3 months.</p> <p>Counseling: Group meetings held weekly for six weeks for one hour each. (Total Contact Time = 360)</p> <p>Group 2: Placebo + Counseling</p> <p>Placebo: Placebo contained 1 mg of nicotine with no buffer to decrease absorption but mimic taste of NG 2 mg. Duration was recommended as minimum 3 months.</p> <p>Mutual interventions: None</p>	<p>Efficacy: o CAR 12 M o PPA 12 M o PAR 12 M - expired air carbon monoxide</p> <p>Safety: o DEATH - inferred o SAE o CV DEATH- inferred</p>
Jensen 1990 - 831	<p>Study Design: Parallel</p> <p>Silver acetate + Counseling (N): 203</p> <p>NG 2 mg + Counseling (N): 211</p> <p>Placebo + Counseling (N): 82</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: NR</p> <p>Protocol availability: NR</p>	<p>Silver acetate + Counseling: Age: 41.8 Female: 117 FTND Score: 6.3 Years Smoked: 22.8 Cigarettes per day: 21.7</p> <p>NG 2 mg + Counseling: Age: 42.7 Female: 116 FTND Score: 6.3 Years Smoked: 23.1 Cigarettes per day: 21.8</p> <p>Placebo + Counseling: Age: 41.4 Female: 41 FTND Score: 6.2 Years Smoked: 21.6 Cigarettes per day: 21.0</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Silver acetate + Counseling</p> <p>Silver acetate: Participants were given gum containing 6 mg of silver acetate and restricted to six pieces/day for 6 weeks. Then, advised to taper use over next six weeks.</p> <p>Counseling: Participants met at the initial meeting and then at weeks 1, 2, 3, 4, 6, 12, 26, and 52 for group support. Lectures, materials and booklets were reviewed to help quit. (Total Contact Time = NR)</p> <p>Group 2: NG 2 mg + Counseling</p> <p>NG 2 mg: Participants were given gum containing 2 mg of nicotine and could be taken as needed for six weeks. Then, advised to taper use over next six weeks.</p> <p>Group 3: Placebo + Counseling</p> <p>Placebo: Ordinary, unflavored, sugar free gum given as placebo and could be taken as needed first six weeks. After, advised to reduce use for final six weeks.</p>	<p>Efficacy: o CAR 6 months o CAR 12 M - expired air carbon monoxide</p> <p>Safety: o NR</p>

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Reference	Study Details	Patients	Intervention	Outcomes
Mutual interventions: None				
Jorenby 1999 - 685	<p>Study Design: Parallel</p> <p>Bup 300 mg + NP24 21 mg (N): 245</p> <p>Bup 300 mg (N): 244</p> <p>NP 24 21 mg (N): 244</p> <p>Placebo (N): 160</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: Glaxo Wellcome</p> <p>Protocol availability: NR</p>	<p>Bup 300 mg + NP24 21 mg:</p> <p>Age: 43.9</p> <p>Female: 121</p> <p>FTND Score: 7.3</p> <p>Years Smoked: 26.7</p> <p>Cigarettes per day: 26.8</p> <p>Bup 300 mg:</p> <p>Age: 42.3</p> <p>Female: 126</p> <p>FTND Score: 7.4</p> <p>Years Smoked: 24.6</p> <p>Cigarettes per day: 25.5</p> <p>NP 24 21 mg:</p> <p>Age: 44.0</p> <p>Female: 126</p> <p>FTND Score: 7.4</p> <p>Years Smoked: 26.8</p> <p>Cigarettes per day: 26.5</p> <p>Placebo:</p> <p>Age: 42.7</p> <p>Female: 94</p> <p>FTND Score: 7.5</p> <p>Years Smoked: 25.6</p> <p>Cigarettes per day: 28.1</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Bup 300 mg + NP24 21 mg</p> <p>Bup 300 mg: 150 mg of Bupropion in the morning and placebo in the evening for the first 3 days and then 150 mg Bup bid for the rest of the 63 days.</p> <p>NP24 21 mg: Daily 24 hr patch starting on quit day (day 8) for eight weeks. Weeks 2-7 were 21 mg/d, week 8 was 14 mg/d and week 9 was 7 mg/d.</p> <p>Group 2: Bup 300 mg</p> <p>Group 3: NP 24 21 mg</p> <p>Group 4: Placebo</p> <p>Placebo: All participants in this group took placebo of Bup bid for the 63 days and a placebo patch for the weight week treatment period.</p> <p>Mutual interventions: None</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ CAR 6 Months ○ CAR 12 M ○ PPA 6 M ○ PPA 12 M - expired air carbon monoxide ≤ 10 ppm <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - inferred ○ SAE ○ CV DEATH- inferred
Jorenby 2006 - 56	<p>Study Design: Parallel</p> <p>Var 2 mg + Counseling (N): 344</p> <p>Bup 300 mg + Counseling (N): 342</p> <p>Placebo + Counseling (N): 341</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: Pfizer inc.</p> <p>Protocol availability: Y, NCT00143364</p>	<p>Var 2 mg + Counseling:</p> <p>Age: 44.6</p> <p>Female: 154</p> <p>FTND Score: 5.39</p> <p>Years Smoked: 27.1</p> <p>Cigarettes per day: 22.5</p> <p>Bup 300 mg + Counseling:</p> <p>Age: 42.9</p> <p>Female: 136</p> <p>FTND Score: 5.39</p> <p>Years Smoked: 25.4</p> <p>Cigarettes per day: 21.8</p> <p>Placebo + Counseling:</p> <p>Age: 42.3</p> <p>Female: 143</p> <p>FTND Score: 5.16</p> <p>Years Smoked: 24.4</p> <p>Cigarettes per day: 21.5</p>	<p>Group 1: Var 2 mg + Counseling</p> <p>Var 2 mg: Given 1 mg of varenicline bid for twelve weeks with initial dose to full strength for first week. Also received bid dose of placebo bupropion for twelve weeks.</p> <p>Counseling: All participants received ≤ 10 mins of counseling at baseline visit and 11 weekly follow up visits. Also received 5 mins phone call 3 days after quit date (8 days after baseline visit). (Total Contact Time = ≤125 mins)</p> <p>Group 2: Bup 300 mg + Counseling</p> <p>Bup 300 mg: Given 150 mg of bupropion bid for twelve weeks with initial dose to full strength for first week. Also received bid dose of placebo varenicline for twelve weeks.</p> <p>Group 3: Placebo + Counseling</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ PPA 6 months ○ PPA 12 M ○ CAR 6 months ○ CAR 12 M - expired air carbon monoxide ≤ 10 ppm <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH ○ SAE ○ CV DEATH

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Reference	Study Details	Patients	Intervention	Outcomes
		Are patients willing to quit or have they set a quit date: NR	Placebo: Received bid doses of placebo varenicline and bupropion for twelve weeks of treatment. Mutual interventions: None	
Joseph 1996 - 1792	<p>Study Design: Parallel</p> <p>NP24 21 mg (N): 294</p> <p>Placebo (N): 290</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: Hoechst Marion Roussel</p> <p>Protocol availability: NR</p>	<p>NP24 21 mg: Age: 61 Female: NR FTND Score: 6.4 Years Smoked: 44 Cigarettes per day: 28</p> <p>Placebo: Age: 60 Female: NR FTND Score: 6.4 Years Smoked: 44 Cigarettes per day: 28</p> <p>Are patients willing to quit or have they set a quit date: NR</p>	<p>Group 1: NP24 21 mg</p> <p>NP24 21 mg: Participants were given a 21 mg nicotine patch for 6 weeks, then 14 mg for 2 weeks and 7 mg for final two weeks for a total treatment period of 10 weeks.</p> <p>Group 2: Placebo</p> <p>Placebo: Participants received daily placebo patches of the same size, appearance and odor of the active patch for a treatment period of 10 weeks.</p> <p>Mutual interventions: Participants received a NCI pamphlet on quitting as well as an initial 15 mins counseling and 2 10 mins counseling at weeks 1 and 6. (Total Contact Time = 35 mins)</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ PPA 6 months - expired air carbon monoxide ≤ 10 ppm <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH ○ SAE
Kalman 2011 - 111	<p>Study Design: Parallel</p> <p>Bup 300 mg + NP24 21 mg + Counseling (N): 73</p> <p>Placebo + NP24 21 mg + Counseling (N): 70</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: NR</p> <p>Protocol availability: ?, NCT00304707</p>	<p>Bup 300 mg + NP24 21 mg + Counseling: Age: 47.8 Female: NR FTND Score: 5.8 Years Smoked: NR Cigarettes per day: 19.7</p> <p>Placebo + NP24 21 mg + Counseling: Age: 49.2 Female: NR FTND Score: 5.9 Years Smoked: NR Cigarettes per day: 19.2</p> <p>Are patients willing to quit or have they set a quit date: NR</p>	<p>Group 1: Bup 300 mg + NP24 21 mg + Counseling</p> <p>Bup 300 mg: Participants were given 150 mg of bupropion once daily for the first 3 days and then 150 mg bid for the remainder of the 8 week Tx.</p> <p>NP24 21 mg: All participants received an active nicotine patch for 7 weeks starting on quit day. Dosage was 21 mg for 4 weeks, then 14 mg for 2 weeks and 7 mg for final week.</p> <p>Counseling: Participants received 8 weekly counseling sessions beginning 1 week prior to quit day. Also received a manual on quitting for the sessions. (Total Contact Time = NR)</p> <p>Group 2: Placebo + NP24 21 mg + Counseling</p> <p>Placebo: Participants received a placebo identical to Bup 300 mg with the same frequency and duration of Tx.</p> <p>Mutual interventions: None</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ PPA 6 months ○ PAR 6 months - salivary cotinine levels ≤15 ng.ml <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - inferred ○ SAE - inferred ○ CV DEATH - inferred

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
Killen 1997 - 663	<p>Study Design: Parallel</p> <p>NP24 21 mg + Video (N): 109</p> <p>NP24 21 mg (N): 103</p> <p>Placebo + Video (N): 108</p> <p>Placebo (N): 104</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: Public Health Service and National Heart, Lung and Blood Institute</p> <p>Protocol availability: NR</p>	<p>NP24 21 mg + Video: Age: 47.47 Female: 52 FTND Score: 16.7 (modified) Years Smoked: NR Cigarettes per day: 24.84</p> <p>NP24 21 mg: Age: 44.84 Female: 52 FTND Score: 16.63 (modified) Years Smoked: NR Cigarettes per day: 23.05</p> <p>Placebo + Video: Age: 46.89 Female: 53 FTND Score: 16.68 (modified) Years Smoked: NR Cigarettes per day: 23.69</p> <p>Placebo: Age: 42.21 Female: 54 FTND Score: 17.14 (modified) Years Smoked: NR Cigarettes per day: 22.52</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: NP24 21 mg + Video</p> <p>NP24 21 mg: Participants were given 21 mg nicotine patches for 8 weeks and then 14 mg weeks 9-12 and 7 mg weeks 13-16.</p> <p>Video: Participants watched a 20 mins video on smoking cessation during their first session and were given a copy of the video to watch as needed. (Total Contact Time = ~ 20 mins)</p> <p>Group 2: NP24 21 mg</p> <p>Group 3: Placebo + Video</p> <p>Placebo: Participants were given placebo patches identical to the active patch for the entire 16 week Tx.</p> <p>Group 4: Placebo</p> <p>Mutual interventions: All participants received a self-help treatment manual to aid in quitting.</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ PPA 6 months ○ PPA 12 M ○ PAR 6 months - saliva cotinine <20 ng/ml or expired air carbon monoxide <9 ppm <p>Safety:</p> <ul style="list-style-type: none"> ○ NR
Killen 1999 - 226	<p>Study Design: Parallel</p> <p>NP16 15 mg (N): 202</p> <p>NP16 25 mg (N): 206</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: US Public Health Service Grant from National Cancer Institute</p> <p>Protocol availability: NR</p>	<p>NP16 15 mg: Age: 46.55 Female: 85 FTND Score: 18.9 (modified) Years Smoked: NR Cigarettes per day: 36.64</p> <p>NP16 25 mg: Age: 47.86 Female: 85 FTND Score: 18.42 (modified) Years Smoked: NR Cigarettes per day: 35.17</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: NP16 15 mg</p> <p>NP16 15 mg: Participants were given 2 patches daily to use over 16 hours. One patch delivered 15 mg of nicotine and the second was a placebo. Treatment was over 6 weeks with no tapering.</p> <p>Group 2: NP16 25 mg</p> <p>NP16 25 mg: Participants were given 2 patches daily to use over a 16 hour period. One patch delivered 15 mg and the other 10 mg of nicotine. Treatment was over 6 weeks with no tapering.</p> <p>Mutual interventions: Participants received a self-help treatment booklet to help manage cravings. (Total Contact Time = NR)</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ PPA 6 months ○ PPA 12 M - expired air carbon monoxide <9 ppm <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - inferred ○ SAE ○ CV DEATH - inferred
Killen 2004 - 729	<p>Study Design: Parallel</p>	<p>NP24 21 mg-14 mg + Placebo + Skills:</p>	<p>Group 1: NP24 21 mg-14 mg + Placebo + Skills</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ PPA 6 months

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Reference	Study Details	Patients	Intervention	Outcomes
	<p>NP24 21 mg-14 mg + Placebo + Skills (N): 108</p> <p>NP24 21 mg-14 mg + Bup 150 mg + Skills (N): 103</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: National Cancer Institute</p> <p>Protocol availability: NR</p>	<p>Age: 17.32 Female: 34 FTND Score: 16.63 (modified) Years Smoked: NR Cigarettes per day: 15.65</p> <p>NP24 21 mg-14 mg + Bup 150 mg + Skills: Age: 17.32 Female: 32 FTND Score: 16.80 (modified) Years Smoked: NR Cigarettes per day: 15.12</p> <p>Are patients willing to quit or have they set a quit date: NR</p>	<p>NP24 21 mg-14 mg: All participants received a nicotine patch for 8 weeks. If they smoked >15 cigarettes/day they received 21 mg weeks 1-4, 14 mg weeks 5-6, and 7 mg weeks 7-8. If they smoked 10-15 cigarettes/day they received 14 mg weeks 1-6 and 7 mg weeks 7-8.</p> <p>Skills: All participants met weekly during the 8 week Tx in groups for 45 mins each session. These sessions helped all participants change behaviors to aid in quitting. (Total Contact Time = 360 mins)</p> <p>Placebo: Participants were given a placebo identical to Bup 150 mg that they took once daily for 9 weeks.</p> <p>Group 2: NP24 21 mg-14 mg + Bup 150 mg + Skills</p> <p>Bup 150 mg: Participants were given 150 mg of bupropion SR to be taken once daily for 9 weeks. It was taken after the initial skills training and 1 week prior to quite date.</p> <p>Mutual interventions: None</p>	<p>- expired air carbon monoxide <9 ppm</p> <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - inferred ○ SAE - inferred ○ CV DEATH - inferred
Kornitzer 1995 - 41	<p>Study Design: Parallel</p> <p>NP16 15 mg + NG 2 mg (N): 149</p> <p>NP16 15 mg + Placebo gum (N): 150</p> <p>Placebo patch + Placebo gum (N): 75</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: Pharmacia Consumer Pharma</p> <p>Protocol availability: NR</p>	<p>NP16 15 mg + NG 2 mg: Age: 38 Female: 61 FTND Score: 5.9 Years Smoked: 21.6 Cigarettes per day: 23.9</p> <p>NP16 15 mg + Placebo gum: Age: 38.8 Female: 57 FTND Score: 6.0 Years Smoked: 22.1 Cigarettes per day: 26.3</p> <p>Placebo patch + Placebo gum: Age: 41.1 Female: 28 FTND Score: 6.3 Years Smoked: 23.5 Cigarettes per day: 25.4</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: NP16 15 mg + NG 2 mg</p> <p>NP16 15 mg: Participants received 15 mg nicotine patches daily for 12 weeks (16 hr use,day), followed by 6 weeks of 10 mg and 6 weeks of 5 mg patches/day.</p> <p>NG 2 mg: Nicotine gum containing 2 mg per piece to be used as needed for 6 months with a minimum daily recommended intake of 4 pieces/day.</p> <p>Group 2: NP16 15 mg + Placebo gum</p> <p>Placebo gum: Contained capsaicin to simulate the taste of nicotine and was recommended to be taken as needed for 6 months, minimum of 4/day.</p> <p>Group 3: Placebo patch + Placebo gum</p> <p>Placebo patch: Participants were given daily use patch that was identical in appearance and packaging as active patch. Taken for 24 week Tx period.</p> <p>Mutual interventions: None</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ CAR 6 months ○ CAR 12 M - expired air carbon monoxide ≤ 10 ppm <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - inferred ○ SAE - inferred ○ CV DEATH - inferred
Kralikova 2009 - 433	<p>Study Design: Parallel</p>	<p>Nlnh 10 mg or NG 4 mg: Age: 46.1</p>	<p>Group 1: Nlnh 10 mg or NG 4 mg</p> <p>Nlnh 10 mg or NG 4 mg: Participants</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ CAR 12 M ○ PPA 12 M

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Reference	Study Details	Patients	Intervention	Outcomes
	<p>Ninh 10 mg or NG 4 mg (N): 209</p> <p>Placebo (N): 105</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: McNeil AB, Helsingborg, Sweden</p> <p>Protocol availability: NR</p>	<p>Female: 120 FTND Score: 5.8 Years Smoked: NR Cigarettes per day: 25.7</p> <p>Placebo: Age: 46.6 Female: 63 FTND Score: 6.2 Years Smoked: NR Cigarettes per day: 25.2</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>were offered their choice of nicotine inhalers (10 mg) or nicotine gum (4 mg) for a treatment schedule of 6 months, followed by 3 months of voluntary tapering. Recommended dosage was 6-12 inhaler cartridges/day but maximum 12/day and as needed for gum with a maximum of 24 pieces/day.</p> <p>Group 2: Placebo</p> <p>Placebo: Participants were given the choice of inhaler or gum but were given a placebo version that matched the active nicotine versions. They followed the same Tx and dosage as the active group.</p> <p>Mutual interventions: None</p>	<p>- expired air carbon monoxide <10 ppm</p> <p>Safety: ○ DEATH - inferred ○ SAE - inferred</p>
Lacasse 2008 - 1215	<p>Study Design: Parallel</p> <p>NP24 + Counseling (N): 99</p> <p>Usual care (N): 97</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: NR</p> <p>Protocol availability: NR</p>	<p>NP24 + Counseling: Age: 52 Female: 36 FTND Score: 5.1 Years Smoked: NR Cigarettes per day: 20.4</p> <p>Usual care: Age: 52 Female: 31 FTND Score: 5.5 Years Smoked: NR Cigarettes per day: 22.8</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: NP24 + Counseling</p> <p>NP24 + Counseling: Participants were given a supply of nicotine patches based on their dependence (21 mg, 14 mg or 7 mg). The duration was during their hospital stay and then 8 weeks after discharge. Participants also received minimum of 1 initial session and 1 counseling session lasting 15 mins. (Total Contact Time = NR)</p> <p>Group 2: Usual care</p> <p>Usual care: Participants were not given any smoking cessation aids or any instruction on how to quit smoking. They received standard care and were discharged with follow up.</p> <p>Mutual interventions: None</p>	<p>Efficacy: ○ PPA 12 M - urinary continine assay</p> <p>Safety: ○ DEATH ○ CV DEATH</p>
Leischow 1996 - 364	<p>Study Design: Parallel</p> <p>Ninh 10 mg (N): 111</p> <p>Placebo Inh (N): 111</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: Pharmacia Upjohn, Helsingborg, Sweden</p> <p>Protocol availability: NR</p>	<p>Ninh 10 mg: Age: 43.8 Female: 60 FTND Score: 6.0 Years Smoked: 25.8 Cigarettes per day: 26.3</p> <p>Placebo Inh: Age: 44.4 Female: 64 FTND Score: 6.9 Years Smoked: 26.0 Cigarettes per day: 25.8</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Ninh 10 mg</p> <p>Ninh 10 mg: Participants were given a supply of 10 mg nicotine inhalers to use as needed for the first 3 months staying within a range of 4-20 per day (minimum 6/day encouraged). After, their use was calculated and tapered by 75% use in month 4, 50% in month 5, 25% in month 6 and cessation after 6 months.</p> <p>Group 2: Placebo Inh</p> <p>Placebo Inh: Participants were given placebo inhalers to use as needed within the range of 4-20/day for the first 3 months and then tapered by % usage for the next 3 months.</p>	<p>Efficacy: ○ CAR 6 months ○ CAR 12 M - expired air carbon monoxide <10 ppm</p> <p>Safety: ○ DEATH - inferred ○ SAE - inferred ○ CV DEATH - inferred</p>

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Reference	Study Details	Patients	Intervention	Outcomes
			Mutual interventions: Participants received brief advise on smoking cessation and watched a short 10 mins video.(Total Contact Time = NR)	
Lerman 2004 - 426	<p>Study Design: Parallel</p> <p>NP24 21 mg + Counseling (N): 175</p> <p>Ninh 1 mg + Counseling (N): 175</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: National Cancer Institute and National Institute on Drug Abuse and Public Health Services</p> <p>Protocol availability: NR</p>	<p>NP24 21 mg + Counseling:</p> <p>Age: NR</p> <p>Female: 51</p> <p>FTND Score: NR</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: NR</p> <p>Ninh 1 mg + Counseling:</p> <p>Age: NR</p> <p>Female: 41</p> <p>FTND Score: NR</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: NR</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: NP24 21 mg + Counseling</p> <p>NP24 21 mg: Participants were given 24 hr nicotine patches at 21 mg for 4 weeks, then 14 mg for 2 weeks, and 7 mg for the final two weeks. Total Tx period was 8 weeks, starting on quit day.</p> <p>Counseling: All participants received 7 sessions of behavioral counseling to aid in smoking cessation. Each session lasted roughly 1.5 hours and included 10-14 members. (Total Contact Time = 630 mins)</p> <p>Group 2: Ninh 1 mg + Counseling</p> <p>Ninh 1 mg: Participants were given nicotine inhalers for an 8 week Tx period, beginning on quit day. The inhalers were 1 mg dose (0.5 mg per nostril) and it was recommended to use 8-40 times/day with a maximum of 5 doses/hr. After the first 4 weeks, participants were told to taper by one third for the next two weeks and then another third the final two weeks.</p> <p>Mutual interventions: None</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ PPA 6 months ○ CAR 6 months - expired air carbon monoxide <10 ppm <p>Safety:</p> <ul style="list-style-type: none"> ○ NR
Levine 2010 - 543	<p>Study Design: Parallel</p> <p>Bup 300 mg + Counseling (N): 195</p> <p>Placebo + Counseling (N): 154</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: National Institute on Drug Abuse</p> <p>Protocol availability: Y, NCT00006170</p>	<p>Bup 300 mg + Counseling:</p> <p>Age: 41.6</p> <p>Female: NR</p> <p>FTND Score: 5.1</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 20.5</p> <p>Placebo + Counseling:</p> <p>Age: 42.5</p> <p>Female: NR</p> <p>FTND Score: 5.3</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 20.9</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Bup 300 mg + Counseling</p> <p>Bup 300 mg: Participants were given 150 mg of bupropion sustained release once/day for the first 2 days and then bid for the rest of the 26 week Tx.</p> <p>Counseling: All participants received 12, 90 minute group sessions over 3 months by clinicians. (Total Contact Time = 1080 mins)</p> <p>Group 2: Placebo + Counseling</p> <p>Placebo: Participants were given a placebo identical to the Bup 300 mg once daily for the first two days and then bid for the rest of the 26 week Tx..</p> <p>Mutual interventions: None</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ PPA 6 months ○ PPA 12 M ○ PAR 6 months ○ PAR 12 M - expired air carbon monoxide <8 ppm and salivary cotinine levels <15µg/L <p>Safety:</p> <ul style="list-style-type: none"> ○ NR

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Reference	Study Details	Patients	Intervention	Outcomes
Lewis 1998 - 296	<p>Study Design: Parallel</p> <p>MC (N): 61</p> <p>CAP (N): 62</p> <p>CPP (N): 62</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: Elan Pharmaceutical Research Corporation</p> <p>Protocol availability: NR</p>	<p>MC: Age: 43.0 Female: 26 FTND Score: 6.6 Years Smoked: 25.4 Cigarettes per day: 22.5</p> <p>CAP: Age: 43.4 Female: 27 FTND Score: 6.6 Years Smoked: 26.3 Cigarettes per day: 24.0</p> <p>CPP: Age: 44.7 Female: 32 FTND Score: 6.9 Years Smoked: 27.5 Cigarettes per day: 24.9</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Minimal Care (MC)</p> <p>MC: Participants received a brief 2-3 mins motivational message and a copy of the National Cancer Institute self-help smoking cessation pamphlet.</p> <p>Group 2: Counseling + Active Nicotine Patch (CAP)</p> <p>CAP: Participants received initial counseling of the 2-3 mins message and a Q and A with the physician, followed by 4 follow up phone calls lasting 10-15 mins at weeks 1, 3, 6, and 24. This group also received the active nicotine patch with a dosage of 22 mg for the first 3 weeks and 11 mg for the last 3 weeks. (Total Contact Time = 45-65 mins)</p> <p>Group 3: Counseling + Placebo Patch (CPP)</p> <p>CPP: Participants received initial counseling of the 2-3 mins message and a Q and A with the physician, followed by 4 follow up phone calls lasting 10-15 mins at weeks 1, 3, 6, and 24. This group also received the placebo patch that was identical to the active patch for 6 weeks. (Total Contact Time = 45-65 mins)</p> <p>Mutual interventions: None</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ PPA 6 months - expired air carbon monoxide <10 ppm <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - inferred ○ SAE - inferred ○ CV DEATH - inferred
Malcolm 1980 - 295	<p>Study Design: Parallel</p> <p>NG 2 mg + Counseling (N): 73</p> <p>Placebo + Counseling (N): 63</p> <p>Control + Counseling (N): 58</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: McNeil AB, Helsingborg, Sweden</p> <p>Protocol availability: NR</p>	<p>NG 2 mg + Counseling: Age: 44 Female: NR FTND Score: NR Years Smoked: NR Cigarettes per day: 25.6</p> <p>Placebo + Counseling: Age: 45 Female: NR FTND Score: NR Years Smoked: NR Cigarettes per day: 26.3</p> <p>Control + Counseling: Age: 44 Female: NR FTND Score: NR Years Smoked: NR Cigarettes per day: 25.4</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: NG 2 mg + Counseling</p> <p>NG 2 mg: Participants were given 2 mg nicotine gum and advised to chew at least 10 pieces/day for 30 mins. Tx duration was encouraged for at least the first 3 months.</p> <p>Counseling: Each participant participated in an initial visit and then 4 more visits throughout the first month. Each visit provided 20 mins of encouragement and counseling on smoking cessation. (Total Contact Time = 80 mins)</p> <p>Group 2: Placebo + Counseling</p> <p>Placebo: Participants were given a placebo gum that contained capsicum to mimic the active gum. They were encourage to take a minimum of 10 pieces/day for at least 3 months.</p> <p>Group 3: Control + Counseling</p> <p>Control: The control group didn't receive an intervention but</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ CAR 6 months - carboxyhaemoglobin estimation in venous blood <1.6% <p>Safety:</p> <ul style="list-style-type: none"> ○ NR

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Reference	Study Details	Patients	Intervention	Outcomes
			<p>participated in measurements and meetings throughout the study.</p> <p>Mutual interventions: None</p>	
Marshall 1985 - 1397	<p>Study Design: Parallel</p> <p>Low Contact NG (N): 100</p> <p>High Contact NG (N): 100</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: NR</p> <p>Protocol availability: NR</p>	<p>Overall: Age: 41</p> <p>Female: 132</p> <p>FTND Score: NR</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 22.1</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Low Contact NG</p> <p>Low Contact NG: Participants received a pamphlet and a supply of nicotine gum but were not counseled beyond that. Duration and dosage not reported.</p> <p>Group 2: High Contact NG</p> <p>High Contact NG: Participants received a supply of nicotine gum and a pamphlet but dosage and duration was not reported. Some counseling at initial visit as well as 1, 2, 4, and 12 weeks later. (Total Contact Time = NR)</p> <p>Mutual interventions: None</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ CAR 12 M - expired air carbon monoxide <10 ppm <p>Safety:</p> <ul style="list-style-type: none"> ○ NR
McCarthy 2008 - 717	<p>Study Design: Parallel</p> <p>Bup 300 mg + Counseling (N): 113</p> <p>Bup 300 mg (N): 116</p> <p>Placebo + Counseling (N): 121</p> <p>Placebo (N): 113</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: National Cancer Institute and National Institute on Drug Abuse</p> <p>Protocol availability: NR</p>	<p>Bup 300 mg + Counseling: Age: 36.76</p> <p>Female: 52</p> <p>FTND Score: 5.10</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 21.87</p> <p>Bup 300 mg: Age: 41.03</p> <p>Female: 57</p> <p>FTND Score: 5.12</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 22.47</p> <p>Placebo + Counseling: Age: 37.82</p> <p>Female: 63</p> <p>FTND Score: 4.95</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 21.98</p> <p>Placebo: Age: 39.42</p> <p>Female: 61</p> <p>FTND Score: 5.27</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 21.37</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Bup 300 mg + Counseling</p> <p>Bup 300 mg: Participants began taking Bupropion 150 mg SR once a day a week prior to quit date and then after 4 days increased to 150 mg bid for the rest of the 9 week Tx.</p> <p>Counseling: Participants received two initial visits (one on quite day) and five follow up sessions over the first 4 weeks of Tx. Each of these sessions focused on smoking cessation and lasted 10 mins each. (Total Contact Time = 60 mins)</p> <p>Group 2: Bup 300 mg</p> <p>Group 3: Placebo + Counseling</p> <p>Placebo: Participants received a Bup 150 mg placebo that was identical in pill and packaging to the active pill. They took the pill once a day for the first 4 days of the week before quite day and then increased to bid for the rest of the 9 week Tx.</p> <p>Group 4: Placebo</p> <p>Mutual interventions: None</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ PPA 6 months ○ PPA 12 M ○ PAR 12 M - expired air carbon monoxide <10 ppm <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - inferred ○ CV DEATH - inferred
Molyneux	Study Design:	Usual Care:	Group 1: Usual Care	Efficacy:

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Reference	Study Details	Patients	Intervention	Outcomes
2003 - 484	<p>Parallel</p> <p>Usual Care (N): 92</p> <p>Counseling (N): 91</p> <p>NRT + Counseling (N): 91</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: Pharmacia Consumer Healthcare</p> <p>Protocol availability: NR</p>	<p>Age: 51.0</p> <p>Female: 54</p> <p>FTND Score: 5</p> <p>Years Smoked: 35.4</p> <p>Cigarettes per day: 15</p> <p>Counseling:</p> <p>Age: 47.8</p> <p>Female: 51</p> <p>FTND Score: 4</p> <p>Years Smoked: 32.1</p> <p>Cigarettes per day: 20</p> <p>NRT + Counseling:</p> <p>Age: 49.3</p> <p>Female: 58</p> <p>FTND Score: 5</p> <p>Years Smoked: 33.1</p> <p>Cigarettes per day: 20</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Usual Care: Patients who had their smoking status reported but did not participate in an additional formal interventions.</p> <p>Group 2: Counseling</p> <p>Counseling: Participants received a 20 mins counseling session on smoking cessation as well as an advice leaflet and were made aware of the availability of NRT. (Total Contact Time = 20 mins)</p> <p>Group 3: NRT + Counseling</p> <p>NRT + Counseling: Participants received the 20 mins counseling session and all 5 types of nicotine replacement therapy was made available as follows: NP (15 mg, 16 hr), NG (2 or 4 mg), Nlnh (10 mg), nicotine sublingual (2 mg) of NS (0.5 mg/spray). Tx was offered for a period of 6 weeks. (Total Contact Time = 20 mins)</p> <p>Mutual interventions: None</p>	<p>○ PPA 12 M</p> <p>○ CAR 12 M</p> <p>- expired air carbon monoxide</p> <p>Safety:</p> <p>○ NR</p>
Moolchan 2005 – e407	<p>Study Design:</p> <p>Parallel</p> <p>NP24 21 mg + Counseling (N): 34</p> <p>NG 2 mg-4 mg + Counseling (N): 46</p> <p>Placebo + Counseling (N): 40</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: National Institute on Drug Abuse, Intramural Research Program</p> <p>Protocol availability: NR</p>	<p>NP24 21 mg + Counseling:</p> <p>Age: 15.4</p> <p>Female: 21</p> <p>FTND Score: 7.0</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 17.7</p> <p>NG 2 mg-4 mg + Counseling:</p> <p>Age: 15.0</p> <p>Female: 32</p> <p>FTND Score: 7.09</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 18.9</p> <p>Placebo:</p> <p>Age: 15.2</p> <p>Female: 31</p> <p>FTND Score: 7.0</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 19.6</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: NP24 21 mg + Counseling</p> <p>NP24 21 mg: Participants were given 24hr nicotine patches for 12 weeks at 21 mg/d unless they were <100 lbs and smoked <20 cigarettes/d (in that case, they were given 14 mg/d). Participants were also given placebo gum to use as needed.</p> <p>Counseling: Every participant also attended a weekly counseling session for 11 weeks, each session lasting 45 mins. (Total Contact Time = 495 mins)</p> <p>Group 2: NG 2 mg-4 mg + Counseling</p> <p>NG 2 mg-4 mg: Participants were given nicotine gum with a dosage of 2 mg if smoked <24 cigarettes/day and 4 mg if >24 cigarettes/day. They were told to use the gum as needed with a goal of daily use half of what they smoked in cigarettes/day (ex. 10 pieces = 1 pack). Participants were also given daily 24 use placebo patches for the 12 week Tx.</p> <p>Group 3: Placebo + Counseling</p> <p>Placebo: Participants were given both a daily use placebo patch as well as placebo gum that they were to take as needed. Placebo was identical to</p>	<p>Efficacy:</p> <p>○ PPA 6 months</p> <p>- expired air carbon monoxide</p> <p>Safety:</p> <p>○ DEATH - inferred</p> <p>○ SAE - inferred</p> <p>○ CV DEATH - inferred</p>

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
			active Tx. Mutual interventions: None	
Muramoto 2007-1068	<p>Study Design: Parallel</p> <p>Bupropion SR 150 mg/d (N): 105</p> <p>Bupropion SR 300 mg/d (N): 104</p> <p>Placebo (N): 103</p> <p>Follow-up lengths: 6 Months (26 wks)</p> <p>Sponsor: The National Cancer Institute (grant R01 CA77081)</p> <p>Protocol availability: Y (NCT00344695)</p>	<p>Bupropion SR 150 mg/d: Age: 16 (median) Female: 53.3% FTND Score: NR Years Smoked: 4.0 (median) Cigarettes per day: 10 (median, IQR 8)</p> <p>Bupropion SR 300 mg/d: Age: 16 (median) Female: 42.3% FTND Score: NR Years Smoked: 4.0 (median) Cigarettes per day: 12 (median, IQR 9)</p> <p>Placebo: Age: 16 (median) Female: 41.7% FTND Score: NR Years Smoked: 4.0 (median) Cigarettes per day: 11 (median, IQR 11)</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Sustained release bupropion tablet once a day for the first 3 days, then 1 study medication tablet taken twice daily (morning and evening) for 6 weeks</p> <p>Group 2: Sustained release bupropion tablet once a day for the first 3 days, then 1 study medication tablet taken twice daily (morning and evening) for 6 weeks</p> <p>Group 3: Placebo, with same regimen as Group 1 and 2 drugs.</p> <p>Mutual interventions: - During treatment period – brief individual cessation counseling (10-20mins) standardized to address a series of topics addressing teaching skills related to changing smoking behaviors eg. Identifying social support, identifying motivations and barriers to quitting, recognition of triggers for smoking, management of nicotine craving and withdrawal symptoms, and stress management. Patients were also given the state quit line telephone number.</p>	<p>Efficacy: o PPA 6 M (26wk) - expired carbon monoxide ≤ 10 ppm</p> <p>Safety: o DEATH - inferred 0 o SAE o CV DEATH- inferred 0 o SUICIDAL IDEATION o COMPLETED SUICIDE- inferred 0</p>
Myung 2007-1065	<p>Study Design: Parallel</p> <p>Nicotine patch + Behaviour counseling (N): 59</p> <p>Placebo patch + Behaviour counseling (N): 59</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: This study was supported in part by patches from an anonymous pharmaceutical company.</p> <p>Protocol availability: NR</p>	<p>Nicotine patch + Behaviour counseling: Age: 36.6 Female: 0% FTND Score: 2.8 Years Smoked: 17.1 Cigarettes per day: 15.0</p> <p>Placebo patch + Behaviour counseling: Age: 36.7 Female: 0% FTND Score: 3.0 Years Smoked: 16.5 Cigarettes per day: 15.3</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Nicotine patch + Behaviour counseling</p> <p>Group 2: Placebo patch + Behaviour counseling</p> <p>Nicotine or placebo patch: Participants were recommended to apply 30 cm² transdermal nicotine patches (with 57 mg of nicotine in each patch, delivering 21 mg/day) or placebo for 14 days; then 20 cm² transdermal nicotine patches (with 38 mg of nicotine in each patch, delivering 14 mg/day) or placebo from 15 to 28 days; and 10 cm² transdermal nicotine patches with 19 mg of nicotine in each patch, delivering 7 mg/day) or placebo from 29 to 42 days.</p> <p>Behaviour counseling: The subjects were given seven one-on-one behavioral counseling by three doctors trained in smoking cessation therapy at visits scheduled at 1, 2, 4, and 7 weeks and 3, 6 and 12 months. Each session lasted for about 10</p>	<p>Efficacy: o NR</p> <p>Safety: o DEATH - inferred 0 o SAE o CV DEATH- inferred 0 o COMPLETED SUICIDE- inferred 0</p>

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
			minutes, making the total counseling time for about 70 minutes. Mutual interventions: None	
Nakamura 2007-1040	<p>Study Design: Parallel</p> <p>Varenicline 0.25 mg BID (N): 153</p> <p>Varenicline 0.5 mg BID (N): 156</p> <p>Varenicline 1 mg BID (N): 156</p> <p>Placebo (N): 154</p> <p>Follow-up lengths: 12 months (52 weeks)</p> <p>Sponsor: Pfizer Inc.</p> <p>Protocol availability: Y, NCT00139750</p>	<p>Varenicline 0.25 mg BID: Age: 40.2 Female: 27.3% FTND Score: 5.6 Years Smoked: 20.9 Cigarettes per day: 24.9</p> <p>Varenicline 0.5 mg BID: Age: 39.0 Female: 28.9% FTND Score: 5.5 Years Smoked: 20.1 Cigarettes per day: 23.8</p> <p>Varenicline 1 mg BID: Age: 40.1 Female: 20.8% FTND Score: 5.4 Years Smoked: 21.5 Cigarettes per day: 24.0</p> <p>Placebo: Age: 39.9 Female: 24.0% FTND Score: 5.7 Years Smoked: 20.9 Cigarettes per day: 23.1</p> <p>(* Baseline characteristics and smoking status only for nicotine-dependent participants)</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Varenicline 0.25 mg BID + Brief smoking-cessation counseling</p> <p>Group 2: Varenicline 0.5 mg BID + Brief smoking-cessation counseling</p> <p>Group 3: Varenicline 1 mg BID + Brief smoking-cessation counseling</p> <p>Group 4: Matching placebo + Brief smoking-cessation counseling</p> <p>Varenicline or placebo group: Participants were instructed to implement dose titration to full dose during week 1 of treatment: 0.25 mg QD for 7 days in the 0.25 mg BID group, 0.5 mg QD for 7 days in the 0.5 mg BID group, and 0.5 mg QD for 3 days followed by 0.5 mg BID for 4 days in the 1 mg BID group.</p> <p>Brief smoking-cessation counseling: Based on US Agency for Health Care Policy and Research guidelines, each counseling session lasted up to 10 minutes at each clinic visit, beginning at baseline and continuing weekly during the 12-week treatment and at 13, 16, 24, 36, 44 and 52 weeks. The 13 counseling session lasted no more than 130 minutes.</p> <p>Mutual interventions: - An educational booklet on smoking cessation - Six smoking cessation counseling by telephone contact at TQD (target quit date) + 3 days, and weeks 20, 28, 32, 40, and 48. Each telephone contact lasted up to 5 minutes. Total contact time was no more than 30 minutes.</p>	<p>Efficacy*: o CAR 6 M o CAR 12 M o PPA 6 M o PPA 12 M - expired carbon monoxide ≤10 ppm (* Efficacy outcomes were only reported for nicotine-dependent participants)</p> <p>Safety: o DEATH o SAE o CV DEATH o COMPLETED SUICIDE</p>
Niaura 1994-70	<p>Study Design: Parallel</p> <p>Nicotine gum (N): 84</p> <p>No treatment (N): 89</p> <p>Follow-up lengths: 12 months (52 weeks)</p> <p>Sponsor: The National Cancer Institute (grant CA50087 & CA44022) & the National Heart, Lung and Blood Institute (grant HL32318)</p> <p>Protocol availability: NR</p>	<p>Nicotine gum: Age: 41.2 Female: 47.8% FTQ Score: 6.6 Years Smoked: 22.4 Cigarettes per day: 30.4</p> <p>No treatment: Age: 43.4 Female: 52.7% FTQ Score: 6.5 Years Smoked: 24.9 Cigarettes per day: 29.1</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Nicotine gum Participants were instructed to chew nicotine gum (2 mg) <i>ad libitum</i>.</p> <p>Group 2: No treatment</p> <p>Mutual interventions: - 5-week treatment program (brief counseling + self help materials): During treatment phase, all participants were given four 15-min individual sessions with a psychiatrist (MGG) or licensed clinical psychologist (RN). Initial session reviewed subjects' smoking history, introduced them to self-help materials, oriented them to the protocol and set a quit date. Subsequent sessions</p>	<p>Efficacy: o CAR 6 M o CAR 12 M o PPA 6 M o PPA 12 M - expired carbon monoxide ≤8 ppm (if using gum) -saliva cotinine <20ng/ml (7d measure)</p> <p>Safety: o NR</p>

Reference	Study Details	Patients	Intervention	Outcomes
Niaura 1999-685	<p>Study Design: Parallel</p> <p>Brief CBT: 32</p> <p>Intensive CBT + Nicotine gum (N): 35</p> <p>Intensive CBT + Cue exposure (N): 31</p> <p>Intensive CBT + Cue exposure + Nicotine gum (N): 31</p> <p>Follow-up lengths: 12 months</p> <p>Sponsor: In part by HL32318 and by a Merit Review Grant from the Medical Research Service of the Department of Veterans Affairs</p> <p>Protocol availability: NR</p>	<p>Overall:</p> <p>Age: 43.5</p> <p>Female: 50%</p> <p>Fagerstrom Tolerance Score: 6.4</p> <p>Years Smoked: 26.9</p> <p>Cigarettes per day: 27.8</p> <p>Data by groups is not available.</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>reviewed self-help materials, reviewed progress toward preparing for smoking cessation and helped solve any problems</p> <p>Group 1: Brief cognitive-behavioral treatment (CBT)</p> <p>Group 2: : Intensive CBT + Nicotine gum</p> <p>Group 3: Intensive CBT + Cue exposure</p> <p>Group 4: Intensive CBT + Cue exposure + Nicotine gum</p> <p>The above two CBT contained 5 sessions during weeks 1 to 4, and were conducted b PhD-level therapists:</p> <p>Brief CBT lasted 15 minutes per session, in which therapists mainly reviewed subjects’ progress and reinforced their use of the ALA manual.</p> <p>Intensive CBT lasted 60 minutes per session and were structured around the information and exercise presented in the ALA manual. Treatment components included: self-monitoring to identify and manage smoking triggers via smoking diary; management of nicotine withdrawal symptoms through pharmacological (nicotine gum) and non-pharmacological means; reviewing reasons for quitting smoking; developing behavioral and coping strategies to deal with high-risk situations; relapse prevention training with a focus on managing the abstinence violation effect; time and stress management; increasing social support for not smoking; and controlling weight gain.</p> <p>Nicotine gum (2 mg) <i>ad libitum</i>.</p> <p>Cue exposure: In 5 sessions (1.25 hour/session), subjects were instructed to imagine themselves in the highest-risk situations, and to describe and monitor their urge to smoke. Their spontaneously occurring coping strategies were also reinforced.</p> <p>Mutual interventions:</p> <ul style="list-style-type: none"> - A brief cessation treatment session, to complete a baseline assessment battery, including a Smoking Triggers Interview (STI) which personalized hierarchy of high-risk-for-relapse for 	<p>Efficacy:</p> <ul style="list-style-type: none"> o PPA 6 M o PPA 12 M <p>- expired carbon monoxide < 8 ppm</p> <p>Safety:</p> <ul style="list-style-type: none"> o NR

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
			participants - American Lung Association (ALA) self-help manual, <i>Freedom from Smoking for You and Your Family</i> . - Signed a quit smoking contract	
Niaura 2008-1931	Study Design: Parallel Varenicline 0.5-2mg/d (N): 160 Placebo (N): 160 Follow-up lengths: 12 months (52 weeks) Sponsor: Pfizer Inc. Protocol availability: Y (NCT00150228)	Varenicline : Age: 41.5 Female: 49.7% FTND Score: 5.40 Years Smoked: 24.9 Cigarettes per day: 22.2 Placebo: Age: 42.1 Female: 46.5% FTND Score: 5.35 Years Smoked: 25.7 Cigarettes per day: 22.3 Are patients willing to quit or have they set a quit date: Y	Group 1: Varenicline + Brief smoking-cessation counseling Group 2: Placebo + Brief smoking-cessation counseling Varenicline or Placebo: Participants were instructed to take 0.5mg tablets with 240mL water according to the following dosing regimen - one tablet once daily (i.e., 0.5 mg/day) for 3 days, followed by one tablet twice daily (i.e., 1.0 mg/day) for 4 days. After the seventh day, participants began a flexible dosing schedule, wherein they were allowed to modify their own dosage as often as they wished; however, they were instructed to take at least one tablet daily but not to exceed two tablets twice daily (i.e., 0.5–2.0 mg/day). Brief smoking-cessation counseling: During 12-week treatment phase, participants attended weekly clinic visits to receive brief (up to 10 min) counseling in accordance with the US Public Health Service guideline. The total counseling time was no more than 120 minutes. Mutual interventions: - Participants were given an educational booklet, <i>Clearing the Air: How to Quit Smoking . . . and Quit for Keeps</i> at the baseline visit	Efficacy: o CAR 6 M o CAR 12 M o PPA 6 M o PPA 12 M - expired carbon monoxide ≤ 10 ppm Safety: o DEATH - inferred 0 o SAE o CV DEATH- inferred 0 o CV EVENTS o COMPLETED SUICIDE- inferred 0
Nides 2006-1561	Study Design: Parallel Varenicline 0.3 mg/d + SC counseling (N): 128 Varenicline 1.0 mg/d + SC counseling (N): 128 Varenicline 2.0 mg/d + SC counseling (N): 127 Bupropion SR 300 mg/d + SC counseling (N): 128 Placebo + SC counseling (N): 127 Follow-up lengths: 12 months (52 weeks) Sponsor: Pfizer Inc. Protocol availability: NR	Varenicline 0.3 mg/d + SC counseling: Age: 41.9 Female: 50% FTND Score: 5.7 Years Smoked: 24.6 Cigarettes per day: 20.3 Varenicline 1.0 mg/d + SC counseling: Age: 42.9 Female: 56.3% FTND Score: 5.5 Years Smoked: 25.4 Cigarettes per day: 20.1 Varenicline 2.0 mg/d + SC counseling: Age: 41.9 Female: 49.6% FTND Score: 5.6 Years Smoked: 23.4 Cigarettes per day:	Group 1: 0.3mg varenicline QD + SC counseling Group 2: 1.0mg varenicline QD + SC counseling Group 3: 1.0mg varenicline BID + SC counseling The above groups were dosed for 6 weeks, and then received 1-week blinded placebo to preserve treatment blinding. Group 4: Bupropion 300 mg/d + SC counseling Sustained-release oral bupropion dosed for 7 weeks, with titration from 150 mg once daily (days 1-3) to 150 mg twice daily through week 7 Group 5: Matching oral placebo + SC counseling Standardized, individual smoking	Efficacy: o CAR 6 M o CAR 12 M - expired carbon monoxide ≤ 10 ppm Safety: o DEATH o SAE o CV DEATH o CV EVENTS o COMPLETED SUICIDE - observed from randomization to 30 days after the last dose of study medication (7-week treatment)

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
		18.9 Bupropion SR 300 mg/d + SC counseling: Age: 40.5 Female: 54.8% FTND Score: 5.2 Years Smoked: 23.4 Cigarettes per day: 19.5 Placebo + SC counseling: Age: 41.6 Female: 48% FTND Score: 5.5 Years Smoked: 23.9 Cigarettes per day: 21.5 Are patients willing to quit or have they set a quit date: Y	cessation counseling (SC counseling): During the 7-week treatment phase, subjects were given weekly standardized, individual smoking cessation counseling (up to 10 minutes) from trained staff. Mutual interventions: - A smoking cessation booklet, <i>Clearing the Air: How to Quit Smoking . . . and Quit for Keeps</i> at the baseline visit - Post-treatment- subjects could choose to participate in this phase where they received additional brief smoking cessation and relapse prevention counseling at subsequent clinic visits at weeks 12, 24 and 52.	
Nollen 2007 - 911	Study Design: Parallel Nicotine patch + Culturally-targeted materials (N): 250 Nicotine patch + Standard care materials (N): 250 Follow-up lengths: 6 months Sponsor: Cancer Research Foundation of America and a Robert Wood Johnson Foundation Generalist Faculty Award Protocol availability: NR	Nicotine patch + Culturally-targeted materials: Age: 42.8 Female: 55.2% FTND Score: NR Years Smoked: NR Cigarettes per day: 17.9 Nicotine patch + Standard care materials: Age: 43.1 Female: 65.2% FTND Score: NR Years Smoked: NR Cigarettes per day: 18.0 Are patients willing to quit or have they set a quit date: Y	Group 1: Nicotine patch + Culturally-targeted materials Group 2: Nicotine patch + Standard care materials Transdermal nicotine patch: participants were instructed to apply 21 mg patch for Weeks 1 to 4, 14 mg patch for Weeks 5 to 6, and 7 mg patch for Weeks 7 to 8. Culturally-targeted materials: <i>The Harlem Health Connection's Kick-It Video</i> (40 minutes) and <i>Pathways to Freedom: Winning the Fight Against Tobacco</i> guide were developed with input from African Americans. Both are targeted to African Americans in that they conform to visible ethnic/ cultural characteristics as well as norms, values, beliefs, and historical, environmental, and social forces relevant to African Americans. Standard care materials: The materials were designed for a general audience, which included the American Medical Association's video <i>How to Quit</i> (48 minutes) and the American Lung Association's widely used <i>Freedom From Smoking</i> guide. Mutual interventions: - \$5 for transportation costs at the 4-week and 6-month follow-up visits, and \$250 lottery entry for those returning at Week 4 and Month 6	Efficacy: o PPA 6 M - expired carbon monoxide < 10 ppm Safety: o DEATH - inferred 0 o SAE - inferred 0 o CV DEATH - inferred 0 o COMPLETED SUICIDE - inferred 0
Okuyemi 2007 - 43	Study Design: Parallel	Nicotine gum + SC MI and education materials:	Group 1: Nicotine gum + Motivation counseling and education materials on smoking session (SC MI)	Efficacy: o PPA 6 M - expired carbon monoxide

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
	<p>Nicotine gum + SC MI and education materials (N): 66</p> <p>FV MI and education materials (N): 107</p> <p>Follow-up lengths: 6 months</p> <p>Sponsor: NR</p> <p>Protocol availability: NR</p>	<p>Age: 43 Female: 53% FTND Score: NR</p> <p>Years Smoked: NR Cigarettes per day: 19</p> <p>FV MI and education materials: Age: 48 Female: 68 FTND Score: NR Years Smoked: NR Cigarettes per day: 16</p> <p>Are patients willing to quit or have they set a quit date: N</p>	<p>Nicotine gum 4 mg was supplied for 8 weeks.</p> <p>Group 2: FV MI and education materials</p> <p>FV MI and education materials: Participants received a package that included a bag of fresh fruits and vegetables, a cookbook, dietary education materials, and two videos on fruits and vegetables (FV).</p> <p>Both SC and FV MI counseling sessions were conducted in-person at each household at Weeks 0 and 3, and via telephone at Day 10 and Weeks 5 and 20. The five counseling sessions applied directive, egalitarian, and empathic and uses a client-centered set of techniques and strategies including reflective listening and agenda setting designed to help clients work through their ambivalence about behavior change, resolve their own barriers, and explore potential untapped sources of motivation, and conducted by a trained master's-level counselors who followed semi-structured counseling scripts. In general, participants received counseling from the same person for all five sessions.</p> <p>Mutual interventions: - Gifts as incentives at each visit and \$120</p>	<p>≤ 10 ppm</p> <p>Safety: o NR</p>
Oncken 2006-1571	<p>Study Design: Parallel</p> <p>Varenicline 0.5mg BID titrated (N): 130</p> <p>Varenicline 0.5mg BID non-titrated (N): 129</p> <p>Varenicline 1.0 mg BID titrated (N): 130</p> <p>Varenicline 1.0 mg BID non-titrated (N): 129</p> <p>Placebo (N): 129</p> <p>Follow-up lengths: 12 months (52 weeks)</p> <p>Sponsor: Pfizer Inc.</p> <p>Protocol availability: NR</p>	<p>Varenicline 0.5 mg BID titrated + Brief SC counseling: Age: 43.5 Female: 46.9% FTND Score: 5.4 Years Smoked: 25.0 Cigarettes per day: 21.3</p> <p>Varenicline 0.5mg BID non-titrated + Brief SC counseling: Age: 42.9 Female: 55.0% FTND Score: 5.5 Years Smoked: 26.0 Cigarettes per day: 20.9</p> <p>Varenicline 1.0 mg BID titrated + Brief SC counseling: Age: 42.2 Female: 51.5% FTND Score: 5.3 Years Smoked: 24.0 Cigarettes per day: 20.9</p>	<p>Group 1: Varenicline 0.5 mg BID titrated + Brief SC counseling Varenicline 0.5mg once daily for 7 days, then 0.5mg twice daily for 11 weeks (oral tablets)</p> <p>Group 2: Varenicline 0.5 mg twice daily for 12 weeks + Brief SC counseling</p> <p>Group 3: Varenicline 1.0 mg BID titrated + Brief SC counseling Varenicline 1.0 mg once daily for 3 days, then 0.5mg twice daily for 4 days, then 1.0mg twice daily for 11 weeks</p> <p>Group 4: 1.0mg twice daily for 12 weeks + Brief SC counseling</p> <p>Group 5: 2 placebo tablets twice daily for 12 weeks + Brief SC counseling</p> <p>Brief smoking cessation (SC) counseling: Participants were given up to 10 minutes counseling on smoking cessation at their weekly visit during the 12-week treatment. The total counseling time was up to 130 minutes.</p>	<p>Efficacy: o CAR 12 Months o PPA 6 M o PPA 12 M - expired carbon monoxide ≤10ppm</p> <p>Safety: o DEATH o SAE o CV DEATH o CV EVENTS o SUICIDAL IDEATION o COMPLETED SUICIDE</p>

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
		<p>Varenicline 1.0 mg BID non-titrated + Brief SC counseling: Age: 43.7 Female: 51.2% FTND Score: 5.5 Years Smoked: 25.7 Cigarettes per day: 20.8</p> <p>Placebo + Brief SC counseling: Age: 43.0 Female: 48.1% FTND Score: 5.8 Years Smoked: 25.3 Cigarettes per day: 20.4</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Mutual interventions: - Subjects received a smoking cessation booklet at the baseline visit - A brief telephone counseling (up to 5mins) 3 days after the target quit date.</p>	
Oncken 2007-296 + Oncken 2006- 1141	<p>Study Design: Parallel</p> <p>Nicotine patch + Intensive group counseling (N): 57</p> <p>Placebo patch + Intensive group counseling (N): 95</p> <p>Follow-up lengths: 16 Months</p> <p>Sponsor: Jointly by The Patrick and Catherine Weldon Donaghue Foundation, The University of Connecticut Center on Aging, and NIH grants R01 DA13334, and M01 RR06192 (University of Connecticut General Clinical Research Center) and P50AA15632.</p> <p>Protocol availability: NR</p>	<p>Nicotine patch + Intensive group counseling: Age: 54.0 Female: 100% FTND Score: NR Years Smoked: 33.4 Cigarettes per day: 21.6</p> <p>Placebo patch + Intensive group counseling: Age: 56.6 Female: 100% FTND Score: NR Years Smoked: 35.1 Cigarettes per day: 21.4</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Nicotine patch + Intensive group counseling</p> <p>Group 2: Placebo patch + Intensive group counseling</p> <p>Nicotine or placebo patch: Participants were instructed to use 21-mg nicotine transdermal system or placebo patch for 12 weeks, then titrate down the nicotine or placebo patch with the following schedule: 14-mg patch daily for 2 weeks, and a 7-mg patch daily for the next 2 weeks.</p> <p>Intensive group counseling: During the 12-week treatment phase, participants were required to attend 4 sessions of group counseling at each of visits 2 to 5. Each session lasted approximately 2.0 hours and included a range of motivational and cognitive behavioral techniques, information on tobacco effects and expected outcomes of quitting; skills training to elicit extra-treatment support for quitting; contingency contracting; relaxation training; monitoring of smoking urges and antecedents to smoking behavior; development, rehearsal and implementation of specific cognitive and behavioral problem solving plans to cope with acute nicotine withdrawal, smoking urges, and relapse risks; and supportive group discussions.</p> <p>Mutual interventions: None</p>	<p>Efficacy: o PPA 16 Months o PAR 16 M (M 4-16) - exhaled carbon monoxide ≤ 8 ppm</p> <p>Safety: o DEATH - inferred 0 o SAE o CV EVENT o CV DEATH - inferred 0 o COMPLETED SUICIDE - inferred 0</p>
Ortega 2011-3	<p>Study Design: Parallel</p> <p>NRT + Intensive CBT (N): 924</p>	<p>NRT + Intensive CBT: Age: 61.1 Female: 12% FTQ Score: 6 Years Smoked: NR</p>	<p>Group 1: NRT + Intensive CBT Nicotine replacement therapy (NRT): Nicotine patches or chewing gum would be dosed to the degree of physical dependence of the smoker by</p>	<p>Efficacy: o CAR 12 Months - expired carbon monoxide < 7 ppm</p>

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
	<p>Intensive CBT (N): 919</p> <p>Follow-up lengths: 12 months</p> <p>Sponsor: NR</p> <p>Protocol availability: NR</p>	<p>Cigarettes per day: NR</p> <p>Intensive CBT:</p> <p>Age: 63.7</p> <p>Female: 13%</p> <p>FTQ Score: 6</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: NR</p> <p>Are patients willing to quit or have they set a quit date: N</p>	<p>following the SEPAR recommendations for the pharmacological treatment of smoking up to a maximum of 12 weeks. During the hospital stay, NRT was provided free of charge, whereas after release the patients incurred this fee.</p> <p>Group 2: Intensive CBT</p> <p>Intensive cognitive-behavioral treatment (CBT): The cognitive intervention was performed by a specially-trained nurse in 30-45 min sessions every 3 days until the patients' release. During the sessions, the patients received advice to quit smoking and the potential risks of tobacco use were commented, as were as the benefits of cessation. Knowledge, beliefs and potential barriers for smoking cessation were evaluated, and arguments were given to try to overcome these. Factors related to the ongoing tobacco habit were discussed, and strategies were provided for behavior modification. Risk factors for relapse were identified, and self-management methods and relaxation techniques to control them were discussed. After the hospital stay, the patient had two options of receiving follow-up consultation- outpatient visits or telephone contacts. Both options would have same frequency and be at one week, 15 days, one month and then at 2, 3, 6, and 12 months.</p> <p>Mutual interventions: None</p>	<p>Safety:</p> <ul style="list-style-type: none"> o NR
Pack 2008-237	<p>Study Design: Parallel</p> <p>Nicotine Lozenge (N): 205</p> <p>Nicotine Gum (N): 203</p> <p>Follow-up lengths: 12 months</p> <p>Sponsor: The National Cancer Institute Grant (P50CA084724) & the National Institute on Drug Abuse Grant (P50DA019706)</p> <p>Protocol availability: NR</p>	<p>Nicotine Lozenge:</p> <p>Age: 43.3</p> <p>Female: 43.9%</p> <p>FTND Score: 6.0</p> <p>Years Smoked: 26.3</p> <p>Cigarettes per day: 23.6</p> <p>Nicotine Gum:</p> <p>Age: 41.8</p> <p>Female: 43.8%</p> <p>FTND Score: 5.9</p> <p>Years Smoked: 25.3</p> <p>Cigarettes per day: 22.6</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Nicotine lozenge</p> <p>Group 2: Nicotine gum</p> <p>Mutual interventions:</p> <ul style="list-style-type: none"> - In addition to being randomized to the 2 drug treatment groups, patients were randomized to the Wisconsin Tobacco Quit Line group (including a baseline call to the Quit Line in which smoking cessation counseling was provided in addition to 3 follow-up calls during treatment) OR the self-help brochure group. 	<p>Efficacy:</p> <ul style="list-style-type: none"> o PPA 6 M o PPA 12 M - expired carbon monoxide $\leq 10\text{ppm}$ <p>Safety:</p> <ul style="list-style-type: none"> NR
Paoletti 1996-643	<p>Study Design: Parallel</p> <p>Nicotine Patch 15mg (N): 150</p> <p>Nicotine Patch 25mg (N): 87</p>	<p>Nicotine Patch 15mg:</p> <p>Age: 41.6</p> <p>Female: 64.6%</p> <p>FTQ Score: 6.3</p> <p>Years Smoked: 18.7</p> <p>Cigarettes per day:</p>	<p>Group 1: 1 active 15mg patch (30cm²) + 1 placebo patch (20cm²) worn for 16h (both applied in the morning and removed at bedtime)</p> <p>Group 2: 1 active 15mg patch (30cm²)</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> o CAR 6 M o CAR 12 M - expired carbon monoxide $\leq 10\text{ppm}$ - blood serum sample

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
	<p>Placebo Patch (N): 60</p> <p>Follow-up lengths: 12 months</p> <p>Sponsor: Pharmacia grant</p> <p>Protocol availability: NR</p>	<p>27.6</p> <p>Nicotine Patch 25mg: Age: 42 Female: 38% FTQ Score: 7.0 Years Smoked: 18.7 Cigarettes per day: 30</p> <p>Placebo Patch: Age: 44 Female: 53% FTQ Score: 5.4 Years Smoked: 20.9 Cigarettes per day: 23</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>+ 1 active 10mg patch (20cm²) worn for 16h (both applied in the morning and removed at bedtime)</p> <p>Group 3: 2 placebo patches (30cm² and 20cm²) worn for 16h (both applied in the morning and removed at bedtime)</p> <p>Mutual interventions: NR</p>	<p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH- inferred 0 ○ SAE- inferred 0 ○ CV DEATH- inferred 0 ○ COMPLETED SUICIDE- inferred 0
Piper 2007-947	<p>Study Design: Parallel</p> <p>Bupropion SR + Nicotine gum (N): 228</p> <p>Bupropion SR + Placebo gum (N): 224</p> <p>Placebo Bupropion SR + Placebo gum (N): 156</p> <p>Follow-up lengths: 12 months</p> <p>Sponsor: National Institutes of Health grants CA84724-05 and DA0197-06</p> <p>Protocol availability: NR</p>	<p>Bupropion SR + Nicotine gum: Age: 41.14 Female: 55.7% FTND Score: 5.69 Years Smoked: NR Cigarettes per day: 22.09</p> <p>Bupropion SR + Placebo gum: Age: 42.26 Female: 60.3% FTND Score: 5.70 Years Smoked: NR Cigarettes per day: 23.39</p> <p>Placebo Bupropion SR + Placebo gum: Age: 42.03 Female: 57.7% FTND Score: 5.48 Years Smoked: NR Cigarettes per day: 21.57</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Active bupropion SR (150mg pills, twice daily) plus active 4mg nicotine gum</p> <p>Group 2: Active bupropion SR (150mg pills, twice daily) plus placebo nicotine gum</p> <p>Group 3: Placebo bupropion SR pills plus placebo nicotine gum</p> <p>Participants were instructed to begin taking their study pills a week before their target quit date and continue taking the pills for 9 weeks (8 weeks postquit) and to begin chewing their study gum on their quit date and continue using the gum for 8 weeks. Staff encouraged participants to chew as many as to 12 pieces of gum per day to cope with withdrawal symptoms and aid their quit attempt.</p> <p>Mutual interventions: - All patients received brief (10min) smoking cessation counseling at the baseline session, the quit date session and the first postquit session (3x10 min sessions over 3 weeks). The counseling, provided by bachelor-degree-level staff, was designed to provide the most effective elements recommended by the Public Health Service guideline: intra-treatment social support, information and problem solving, and aid in seeking extra-treatment social support.</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ PPA 6 M ○ PPA 12 M - expired carbon monoxide ≤10ppm (6 & 12M) OR blood sample (12M) <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH- inferred 0 ○ SAE- inferred 0 ○ CV DEATH- inferred 0 ○ COMPLETED SUICIDE- inferred 0
Piper 2009-1253	<p>Study Design: Parallel</p> <p>Bupropion SR (N): 264</p> <p>Nicotine lozenge (N): 260</p> <p>Nicotine patch (N): 262</p> <p>Bupropion SR + Nicotine lozenge</p>	<p>Bupropion SR: Age: 43.9 Female: 58.3% FTND Score: 5.4 Years Smoked: NR Cigarettes per day: 21.4</p> <p>Nicotine lozenge: Age: 45.3</p>	<p>Group 1: 150 mg, bid for 9 weeks total- 1week pre-quit and 8 weeks post-quit</p> <p>Group 2: 2 or 4 mg, based on appropriate dose for dependence level per package instructions, for 12 weeks post-quit</p> <p>Group 3: 24-hour patch- 21, 14, and</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ PPA 6 M - expired carbon monoxide ≤10ppm <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH ○ SAE ○ CV DEATH ○ CV EVENTS

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
	(N): 262 Nicotine patch + Nicotine lozenge (N): 267 Placebo (N): 189 Follow-up lengths: 6 months Sponsor: NIH/NIDA (grant #P50 DA019706) and the General Clinical Research Centers Program of the National Center for Research Resources (grant #M01 RR03186) Protocol availability: NR	Female: 58.1% FTND Score: 5.2 Years Smoked: NR Cigarettes per day: 21.6 Nicotine patch: Age: 44.9 Female: 58.4% FTND Score: 5.4 Years Smoked: NR Cigarettes per day: 21.4 Bupropion SR + Nicotine lozenge: Age: 45.3 Female: 58.8% FTND Score: 5.3 Years Smoked: NR Cigarettes per day: 21.0 Nicotine patch + Nicotine lozenge: Age: 44.2 Female: 57.3% FTND Score: 5.5 Years Smoked: NR Cigarettes per day: 21.93 Placebo: Age: 43.1 Female: 58.7% FTND Score: 5.5 Years Smoked: NR Cigarettes per day: 21.0 Are patients willing to quit or have they set a quit date: Y	7mg titrated down over 8 weeks post-quit Group 4: combination therapy following the same regimen as group 1 and group 2 Group 5: combination therapy following the same regimen as group 2 and group 3 Group 6: There were five distinct placebo conditions, matched to each of the active treatment conditions (i.e., placebo bupropion, placebo lozenge, placebo patch, placebo patch + lozenge and placebo bupropion + lozenge); however, since there were no statistically significant differences amongst the placebo conditions in 7-day point-prevalence outcomes at 6-months post-quit, the placebo conditions were combined into a unified placebo condition. Participants were instructed to start medications on the designated quit date, except for bupropion SR, which they were instructed to initiate 1 week prior to the quit date as per the package insert instructions. Mutual interventions: - All participants received six one-on-one counseling sessions based upon the PHS Guideline. Study staff who provided counseling and conducted study sessions were bachelor-level trained case managers, supervised by a licensed clinical psychologist. Sessions lasted 10–20 minutes and occurred over 7 weeks with the first two counseling sessions occurring prior to quitting and the subsequent five occurring on the quit date or thereafter.	○ COMPLETED SUICIDE-inferred 0
Pirie 1992-1238	Study Design: Parallel FSS (N): 103 FSS and Nicotine (N): 108 FSS and Behavior (N): 108 FSS, Nicotine and Behavior (N): 98 Follow-up lengths: 12 Months Sponsor: National Cancer Institute Protocol availability: NR	FSS: Age: 42.3 Female: NR FTND Score: NR Years Smoked: NR Cigarettes per day: 25.6 FSS and NG: Age: 42.9 Female: NR FTND Score: NR Years Smoked: NR Cigarettes per day: 27.1 FSS and Behavior: Age: 44 Female: NR FTND Score: NR	Group 1: Freedom from smoking (FSS) FSS: 8 week program with an orientation plus 7 treatment sessions (Total contact time = 480 mins). Group 2: FSS and Nicotine gum (NG) NG: 2 mg Nicotine during Tx and for 3 months after. Group 3: FSS and Behavior Behavior: weight control program at each of 8 sessions focusing on exercise and decreased caloric intake (Total contact time = NR). Group 4: FSS, NG and Behavior	Efficacy: ○ CAR 6 Months ○ CAR 12 M ○ PPA 6 M ○ PPA 12 M - expired air carbon monoxide ≤ 10 ppm Safety: ○ NR

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
		<p>Years Smoked: NR Cigarettes per day: 26.9</p> <p>FSS, NG and Behavior: Age: 43.4 Female: NR FTND Score: NR Years Smoked: NR Cigarettes per day: 25.1</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Mutual interventions: None</p>	
Planer 2011-1055	<p>Study Design: Parallel</p> <p>Bupropion SR (N): 75</p> <p>Placebo (N): 76</p> <p>Follow-up lengths: 12 months</p> <p>Sponsor: GlaxoSmithKline (non-restricted educational grant)</p> <p>Protocol availability: NR</p>	<p>Bupropion SR: Age: 52.4 Female: 23.0% FTND Score: 7.3 Years Smoked: NR Cigarettes per day: 32.3</p> <p>Placebo: Age: 51.5 Female: 17.3% FTND Score: 7.3 Years Smoked: NR Cigarettes per day: 30.1</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: 150 mg pill once a day for 3 days, and then twice a day for 2 months</p> <p>Group 2: Placebo pill following the same regimen as group 1</p> <p>Mutual interventions: - Counseling consisting of at least 15 minutes of motivational support was given to all participants during hospitalization and continued after discharge. - Post treatment- At least 2 planned face-to-face encounters with a study physician and a research nurse were performed after hospital discharge (at 1 and 2 months) and by telephone-based follow-up thereafter. - Telephone calls included motivational support. Any patient who returned to smoking was given at least 10 minutes of motivational support to attempt quitting again; the drug regimen was not changed. The total planned time of face-to-face and telephone call interviews was at least 100 minutes during the first 2 months, and at least 100 minutes during the following 10 months.</p>	<p>Efficacy: NR (not biochemically verified)</p> <p>Safety: o DEATH o SAE- inferred 0 o CV DEATH- inferred 0 o CV EVENTS o SUICIDAL IDEATION o COMPLETED SUICIDE- inferred 0</p>
Prapavessis 2007-1416	<p>Study Design: Parallel</p> <p>CBT (N): 66</p> <p>Ex (N): 76</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: National Heart Foundation of New Zealand</p> <p>Protocol availability: NR</p>	<p>OverallL Age: 38.1 Female: 142 FTND Score: NR Years Smoked: 20.3 Cigarettes per day: NR</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Cognitive Behavior Therapy (Pre CBT) + no nicotine patch</p> <p>CBT: three 45 min supervised group education sessions for 12 weeks</p> <p>Group 2: Pre CBT + Nicotine patch (NP24 21 MG)</p> <p>NP24 21 mg – three steps over 10 weeks: 1 – 21 mg once daily for 6 weeks; 2 – 14 mg once daily for 2 weeks; 3 – 7 mg once daily for 2 weeks</p> <p>Group 3: Exercise program (Ex) + no nicotine patch</p> <p>Ex - three 45 min supervised exercise sessions for 12 weeks.</p>	<p>Efficacy: o CAR 12 M o PPA 12 M - expired air carbon monoxide < 10 ppm and nicotine < 10 ng/mL</p> <p>Safety: o NR</p>

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
			Group 4: Ex + NP24 21 MG Mutual interventions: None	
Puska 1979-141	Study Design: Parallel Nicotine Gum (N): 116 Placebo (N): 113 Follow-up lengths: 6 Months Sponsor: NR Protocol availability: NR	Nicotine Gum: Age: NR Female: NR FTND Score: NR Years Smoked: NR Cigarettes per day: NR Placebo: Age: NR Female: NR FTND Score: NR Years Smoked: NR Cigarettes per day: NR Are patients willing to quit or have they set a quit date: Y	Group 1: Nicotine Gum – 4 mg nicotine gum taken as needed during Tx and after as long as necessary. Group 2: Placebo – chewing gum made to resemble nicotine gum in taste given during Tx and after as long as necessary Mutual interventions: None	Efficacy: ○ NR - Biochemical-verified: NR Safety: ○ DEATH - inferred 0 ○ SAE - inferred ○ CV DEATH - inferred ○ COMPLETED SUICIDE - inferred
Puska 1995-231	Study Design: Parallel Nicotine patch + Nicotine gum (N): 150 Placebo patch + Nicotine gum (N): 150 Follow-up lengths: 12 months (52 weeks) Sponsor: NR Protocol availability: NR	Nicotine patch + Nicotine gum: Age: 40.1 Female: 48% FTQ Score: 5.7 Years Smoked: 21.7 Cigarettes per day: 20.6 Placebo patch + Nicotine gum: Age: 39.3 Female: 43% FTQ Score: 5.6 Years Smoked: 20.8 Cigarettes per day: 21.9 Are patients willing to quit or have they set a quit date: Y	Group 1: One 15mg nicotine patch of 16hr administration (used daily for 12 weeks followed by one 10mg patch daily for three weeks then one 5mg patch for the final three weeks) plus 2mg nicotine gum used ad libitum. Subjects were encouraged to use at least four pieces a day and gum was allowed for the 12 month study period; however, withdrawal was encouraged after 6 months. Group 2: Placebo patches plus 2mg nicotine gum following the same regimens as group 1 Mutual interventions: - General smoking cessation advice delivered by public health nurses involving conventional instructions on study medication use and behavioural aspects of smoking cessation within the short time periods	Efficacy: ○ CAR 6 M (26 wks) ○ CAR 12 M - expired carbon monoxide ≤10ppm Safety: ○ DEATH- inferred 0 ○ SAE- inferred 0 ○ CV DEATH- inferred 0 ○ COMPLETED SUICIDE- inferred 0
Ray 2007-1237	Study Design: Parallel Transdermal nicotine (N): 182 Nicotine nasal spray (N): 192 Follow-up lengths: 6 months Sponsor: National Cancer Institute and National Institute on Drug Abuse (grant # P50CA/DA84718) Protocol availability: NR	All patients: Age: 46.8 Female: 47% FTND Score: 5.54 Years Smoked: NR Cigarettes per day: 24 Data by groups is not available. Are patients willing to quit or have they set a quit date: Y	Group 1: Nicoderm CQ transdermal nicotine (dosage not given) initiated on the morning of the target quite date after 2 weeks of counseling Group 2: Nicotrol nicotine spray (dosage not given) initiated on the morning of the target quite date after 2 weeks of counseling Mutual interventions: - Participants received seven sessions of standardized behavioral counseling during treatment in addition to the 2 weeks of counseling prior to treatment.	Efficacy: ○ PPA 6 M - expired carbon monoxide ≤10ppm Safety: NR
Registered	Study Design:	BUP 300 mg	Group 1: BUP 300 mg	Efficacy:

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Reference	Study Details	Patients	Intervention	Outcomes
(GSK) 2001	<p>Parallel</p> <p>BUP 300 mg (N): 143</p> <p>Placebo (N): 143</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: Glaxo Smith Kline</p> <p>Protocol availability: NR</p>	<p>Age: 42.9</p> <p>Female: 68</p> <p>FTND Score: NR</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: NR</p> <p>Placebo</p> <p>Age: 42.1</p> <p>Female: 70</p> <p>FTND Score: NR</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: NR</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>BUP HD: bid equally divided doses of bupropion hydrochloride for seven weeks.</p> <p>Group 2: Placebo</p> <p>Placebo: bid doses of placebo for seven weeks.</p> <p>Mutual interventions: None</p>	<p>○ CAR 6 months</p> <p>○ CAR 12 M</p> <p>○ PPA 6 months</p> <p>○ PPA 12 M</p> <p>- exhaled air carbon monoxide ≤ 10 ppm</p> <p>Safety:</p> <p>○ DEATH - inferred 0</p> <p>○ SAE</p> <p>○ CV DEATH</p> <p>○ SUICIDAL IDEATION</p> <p>○ COMPLETED SUICIDE</p>
Reid 2008 - 68	<p>Study Design: Parallel</p> <p>NP24 21 mg + SC (N): 153</p> <p>No Tx (N): 72</p> <p>Follow-up lengths: 24 weeks</p> <p>Sponsor: NR</p> <p>Protocol availability: NR</p>	<p>NP24 21 mg + SC</p> <p>Age: 41.6</p> <p>Female: 75 (49%)</p> <p>FTND Score: NR</p> <p>Years Smoked: 25.2</p> <p>Cigarettes per day: 22.3</p> <p>No Tx</p> <p>Age: 42.1</p> <p>Female: 70</p> <p>FTND Score: NR</p> <p>Years Smoked: 24.3</p> <p>Cigarettes per day: 21.6</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: NP24 21 mg + SC counseling</p> <p>NP24 21 mg + SC: Nicotine patch started on quit date and given at 21 mg/day weeks 1-6 and 14 mg/day weeks 7 and 8. Counseling for 9 sessions over 6 week period, two a week for weeks 1-2 and one a week for weeks 3-6 (Total Contact Time = NR).</p> <p>Group 2: No Tx</p> <p>No Tx: Substance abuse, treatment as usual (TAU).</p> <p>Mutual interventions: None</p>	<p>Efficacy:</p> <p>○ PPA 6 months</p> <p>- exhaled air carbon monoxide ≤ 10 ppm</p> <p>Safety:</p> <p>○ NR</p>
Rennard 2006-555	<p>Study Design: Parallel</p> <p>Nicotine inhaler (N): 215</p> <p>Placebo inhaler (N): 214</p> <p>Follow-up lengths: 15 months</p> <p>Sponsor: NR</p> <p>Protocol availability: NR</p>	<p>Nicotine inhaler:</p> <p>Age: 45.9</p> <p>Female: 59.1%</p> <p>FTND Score: 6.5</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 29.3</p> <p>Placebo inhaler:</p> <p>Age: 44.8</p> <p>Female: 51.4%</p> <p>FTND Score: 6.6</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 30.4</p> <p>Are patients willing to quit or have they set a quit date: No</p>	<p>Group 1: 10-mg nicotine inhaler (Nicotrol/Nicorette, Pfizer Consumer Healthcare) to be used ad libitum with a recommended dose of 6–12 cartridges per day, for up to 12 months. Inhaler included 1mg of menthol</p> <p>Group 2: Matched placebo inhaler identical to the active treatment with the nicotine excluded to be used ad libitum with a recommended dose of 6–12 cartridges per day, for up to 12 months. Inhaler included 1mg of menthol.</p> <p>Mutual interventions: NR</p>	<p>Efficacy:</p> <p>○ PPA 12 M</p> <p>○ PPA > 12 M (15mths)</p> <p>- expired carbon monoxide ≤10ppm and blood samples (12 & 15M)</p> <p>Safety:</p> <p>○ DEATH - inferred 0</p> <p>○ SAE</p> <p>○ CV DEATH - inferred 0</p> <p>○ COMPLETED SUICIDE - inferred 0</p>
Rennard 2012-343	<p>Study Design: Parallel</p> <p>Varenicline 1mg BID (N): 493</p> <p>Placebo (N): 166</p> <p>Follow-up lengths: 6 months (24</p>	<p>Varenicline 1mg BID:</p> <p>Age: 43.9</p> <p>Female: 40.0%</p> <p>FTND Score: 5.6</p> <p>Years Smoked: 26.0</p> <p>Cigarettes per day: 21.3</p>	<p>Group 1: Varenicline 1 mg twice daily (b.i.d.) titrated to the full dose during the first week (0.5 mg once daily for 3 days then 0.5 mg b.i.d. for 4 days) and taken for 12 weeks.</p> <p>Group 2: Matched placebo dosing with identical appearance to</p>	<p>Efficacy:</p> <p>○ CAR 6 M</p> <p>○ PPA 6 M</p> <p>- expired carbon monoxide ≤10ppm</p> <p>Safety:</p> <p>○ DEATH</p>

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Reference	Study Details	Patients	Intervention	Outcomes
	<p>weeks)</p> <p>Sponsor: Pfizer Inc.</p> <p>Protocol availability: Y (NCT00691483)</p>	<p>Placebo:</p> <p>Age: 43.2</p> <p>Female: 40.4%</p> <p>FTND Score: 5.4</p> <p>Years Smoked: 24.6</p> <p>Cigarettes per day: 21.5</p> <p>Are patients willing to quit or have they set a quit date: Y (self-selected quit date between Days 8 and 35)</p>	<p>varenicline</p> <p>Mutual interventions:</p> <p>- Participants received brief (up to 10min) smoking cessation counseling consistent with Agency for Healthcare Research and Quality guidelines at each clinic visit (during treatment period and follow-up) or telephone contact (post treatment)</p> <p>- At baseline subjects received the <i>Clearing the Air: Quit Smoking Today</i> self-help book</p>	<ul style="list-style-type: none"> ○ SAE ○ CV DEATH ○ CV EVENTS ○ SUICIDAL IDEATION ○ COMPLETED SUICIDE
Richmond 1993 - 187	<p>Study Design: Parallel</p> <p>SBC (N): 150</p> <p>SBCN (N): 200</p> <p>AN (N): 100</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: Department of Health, Housing and Community Services, Community Health Anti-TB assoc., Glaxo Australia, and the Drug and Alcohol Directorate, NSW Department of Health.</p> <p>Protocol availability: NR</p>	<p>Overall</p> <p>Age: 35</p> <p>Female: 270</p> <p>FTND Score: NR</p> <p>Years Smoked: 17</p> <p>Cigarettes per day: 22</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Structured Behavioral Change Therapy (SBC)</p> <p>SBC: consisted of 6 visits with two in the first two weeks, and then four at 1 wk, 3 wks, 3 months and 6 months later. Each visit roughly 25 mins long. (Total Contact Time = 150 mins)</p> <p>Group 2: Structured Behavioral Change + Nicotine Gum (SBCN)</p> <p>Nicotine Gum: Dosage not reported but daily nicotine gum patch given to patients from first week until 3 month follow up.</p> <p>Group 3: GP advice + Nicotine Gum (AN)</p> <p>AN: Consisted of an initial visit and two follow up visits at 3 and 6 months. Each visit roughly 8 mins (Total Contact Time = 24 mins)</p> <p>Mutual interventions: None</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ CAR 6 months ○ CAR 12 M ○ PPA 6 months ○ PPA 12 M - exhaled air carbon monoxide ≤ 10 ppm <p>Safety:</p> <ul style="list-style-type: none"> ○ NR
Richmond 1994-130,1997-27,617,2007-282	<p>Study Design: Parallel</p> <p>NP 21 mg* 10 wks + CBT (N): 158</p> <p>Placebo + CBT (N): 157</p> <p>Follow-up lengths: 10 yrs</p> <p>Sponsor: Marion Merrelt Dow</p> <p>Protocol availability: NR</p>	<p>NP 21 mg*10 wks + CBT</p> <p>Age: 42</p> <p>Female: 81</p> <p>FTND Score: NR</p> <p>Years Smoked: 24.3</p> <p>Cigarettes per day: 28.5</p> <p>Placebo + CBT</p> <p>Age: 41</p> <p>Female: 82</p> <p>FTND Score: NR</p> <p>Years Smoked: 23.6</p> <p>Cigarettes per day: 30.3</p> <p>Are patients willing to quit or have they set a quit date: NR</p>	<p>Group 1: NP 21 mg*10 wks + CBT</p> <p>NP 21 mg*10 wks : Nicotine patch worn for 24hrs giving 21 mg first 6 wks, 14 mg next two wks, and 7 mg the final two wks</p> <p>CBT: A cognitive behavioral therapy given to all participants for five consecutive weeks with 2 hours each week (Total contact time = 600 mins)</p> <p>Group 2: Placebo + CBT</p> <p>Placebo: Nicotine patch of 1 mg per day given for the ten wks as a placebo to mimic the patch.</p> <p>Mutual interventions: None</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ CAR 6 Months ○ CAR 12 M ○ CAR > 12 M (2,3 yrs) ○ PPA 6 months ○ PPA 12 M ○ PAR 12 M - exhaled air carbon monoxide ≤ 10 ppm <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - inferred ○ SAE - inferred ○ CV DEATH - inferred ○ COMPLETED SUICIDE - inferred
Rigotti 2006 - 1080	<p>Study Design: Parallel</p>	<p>BUP 300 mg + CB C</p> <p>Age: 56.7</p> <p>Female: 38</p>	<p>Group 1: BUP 300 mg + CB C</p> <p>BUP 300 mg : bid 150 mg dosage of</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ CAR 12 M ○ PPA 12 M

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
	<p>BUP 300 mg (N): 127</p> <p>Placebo (N): 127</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: NHLBI, the NIH General clinical research centers program, and Glaxo Smith Kline</p> <p>Protocol availability: Y, NCT00181818</p>	<p>FTND Score: 5.3</p> <p>Years Smoked: 38.8</p> <p>Cigarettes per day: 23.1</p> <p>Placebo + CB C</p> <p>Age: 54.9</p> <p>Female: 38</p> <p>FTND Score: 5.0</p> <p>Years Smoked: 36.5</p> <p>Cigarettes per day: 20.5</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>bupropion hydrochloride for 300 mg daily for 12 wks.</p> <p>CB C: Cognitive behavioral counseling given during hospitalization and by telephone at 2 days, 1, 3, 8 and 12 weeks. (Total Contact Time = 80-95 mins)</p> <p>Group 2: Placebo + CB C</p> <p>Placebo: bid doses of placebo for twelve weeks.</p> <p>Mutual interventions: None</p>	<p>- Saliva cotinine</p> <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH ○ SAE ○ CV DEATH ○ CV EVENTS ○ COMPLETE SUICIDE
Rigotti 2009 266	<p>Study Design: Parallel</p> <p>NP24 21 mg + Rimonabant (N): 369</p> <p>Placebo + Rimonabant (N): 366</p> <p>Follow-up lengths: 24 weeks</p> <p>Sponsor: Sanofi-Aventis</p> <p>Protocol availability: Y, NCT00458718</p>	<p>NP24 21 mg + Rimonabant</p> <p>Age: 43.4</p> <p>Female: 215</p> <p>FTND Score: 5.8</p> <p>Years Smoked: 25.7</p> <p>Cigarettes per day: 23.3</p> <p>Placebo + Rimonabant</p> <p>Age: 43.2</p> <p>Female: 214</p> <p>FTND Score: 5.8</p> <p>Years Smoked: 25.2</p> <p>Cigarettes per day: 23.4</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: NP24 21 mg + Rimonabant</p> <p>NP 24: Nicotine patch for 10 weeks given at 21 mg for 8 wks, 14 mg for 1 wk and 7 mg for 1 wk the week after baseline visit. Cognitive behavioral therapy at the 4 visits for ≤10 mins each (Total Contact Time ≤ 40 mins)</p> <p>Rimonabant: Given at 20 mg daily for 9 wks the day after baseline visit.</p> <p>Group 2: Placebo + Rimonabant</p> <p>Placebo: Placebo patch given for 10 wks started 1 wk after baseline visit. Cognitive behavioral therapy at the 4 visits for ≤10 mins each (Total Contact Time ≤ 40 mins)</p> <p>Mutual interventions: None</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ NR - Biochemical-verified: NR <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - inferred 0 ○ SAE ○ CV DEATH ○ SUICIDAL IDEATION ○ COMPLETED SUICIDE
Rigotti 2010-221	<p>Study Design: Parallel</p> <p>Varenicline 1mg BID (N): 355</p> <p>Placebo (N): 359</p> <p>Follow-up lengths: 12 months (52 weeks)</p> <p>Sponsor: Pfizer Inc.</p> <p>Protocol availability: Y (NCT00282984)</p>	<p>Varenicline 1mg BID:</p> <p>Age: 57</p> <p>Female: 24.8%</p> <p>FTND Score: 5.6</p> <p>Years Smoked: 40</p> <p>Cigarettes per day: 22.1</p> <p>Placebo:</p> <p>Age: 55.9</p> <p>Female: 17.8%</p> <p>FTND Score: 5.7</p> <p>Years Smoked: 39</p> <p>Cigarettes per day: 22.9</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Varenicline 0.5 mg once daily for 3 days, 0.5 mg b.i.d. for 4 days and then 1.0 mg twice daily for a total of 12 weeks. Participants started the drug the day after randomization.</p> <p>Group 2: Identical placebo regimen to group 1.</p> <p>Mutual interventions:</p> <ul style="list-style-type: none"> - During treatment- participants had weekly clinic visits that included 10 minutes of smoking counseling following clinical practice guidelines and 1 telephone call made 3 days after the quit date. - Post treatment- participants made 7 clinic visits (weeks 13, 16, 24, 32, 40, 48, and 52) and received 5 telephone calls (weeks 14, 20, 28, 36, and 44) that provided additional brief smoking counseling. 	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ CAR 6 M ○ CAR 12 M ○ PPA 6 M ○ PPA 12 M - expired carbon monoxide ≤10ppm <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH ○ SAE ○ CV DEATH ○ CV EVENTS ○ SUICIDAL IDEATION ○ COMPLETED SUICIDE ○ AGGRESSION
Rovina 2009-279	<p>Study Design: Parallel</p> <p>Bupropion SR + brief counseling (N):</p>	<p>Bupropion SR + brief counseling:</p> <p>Age: 44.65</p> <p>Female: 30.5%</p>	<p>Group 1: Bupropion SR given at a dose of 150mg per day for the first 6 days, 150mg b.d. for 7 weeks and 150mg once a day for the rest of the</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ CAR 6 M ○ CAR 12 M - expired carbon monoxide

Reference	Study Details	Patients	Intervention	Outcomes
94	<p>Bupropion SR + NSGT (N): 35</p> <p>Bupropion SR + CBGT (N): 40</p> <p>CBGT (N): 36</p> <p>Follow-up lengths: 12 months</p> <p>Sponsor: NR</p> <p>Protocol availability: NR</p>	<p>FTND Score: 7.2</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 37.8</p> <p>Bupropion SR + NSGT:</p> <p>Age: 45.3</p> <p>Female: 34.3%</p> <p>FTND Score: 8</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 38.1</p> <p>Bupropion SR + CBGT:</p> <p>Age: 44.7</p> <p>Female: 50%</p> <p>FTND Score: 7.4</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 34.7</p> <p>CBGT:</p> <p>Age: 44.5</p> <p>Female: 52.8%</p> <p>FTND Score: 7</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 34.2</p> <p>Are patients willing to quit or have they set a quit date: Y (set for 2nd week of treatment; between day 10-15)</p>	<p>treatment period (19 weeks total). Brief counsel by the chest physician (15 minutes-1hr) included information about the effects of smoking on health, information about nicotine dependence and tobacco withdrawal symptoms, strategies for quitting (e.g. making a quitting plan, managing stress and weight gain) and avoiding relapse. Information was given about the correct use of medication and the expectations of its contribution in the smoking cessation effort.</p> <p>Group 2: Bupropion SR in combination with a nonspecific supportive and motivational group therapy (NSGT) conducted by a specialized psychologist. Bupropion SR given as same regimen in Group 1. Frequency of therapy was once a week for the first month and every 3 weeks thereafter for the 19-week period, and was supported by specialized psychologists. Every group consisted of at the most of 10 participants and the duration of the session was set as an hour. Therapy allowed for training of behavioral skills (based on learning theory), including learning and rehearsing new behaviors (e.g. refusing cigarettes), use response substitution, and monitoring and planning for 'high risk' situations.</p> <p>Group 3: Bupropion SR in combination with a specific cognitive behavioral group therapy (CBGT) conducted by a specialized psychologist. Bupropion SR given as same regimen in Group 1. Frequency of therapy was the same regimen as group 2 and sessions focused on the effort to change thoughts, beliefs and attitudes to quitting and to alter negative mood in the formal way.</p> <p>Group 4: Cognitive behavioral group therapy (CBGT) conducted by a specialized psychologist delivered with the same regimen as group 3.</p> <p>Mutual interventions: - Individual counseling (approximately 10-30 minutes) provided by the same physician at each visit in all groups.</p>	<p>≤10ppm</p> <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH- inferred 0 ○ SAE- inferred 0 ○ CV DEATH- inferred 0 ○ CV EVENTS-?? ○ COMPLETED SUICIDE- inferred 0
Russell 1993-1308 & Stapleton 1995-31	<p>Study Design: Parallel</p> <p>Nicotine patch (N): 800</p> <p>Placebo patch (N): 400</p> <p>Follow-up lengths: 12 months (52 weeks)</p>	<p>Nicotine patch:</p> <p>Age: 40.3</p> <p>Female: 58.1%</p> <p>FTND Score: NR</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 23.6</p> <p>Placebo patch:</p>	<p>Group 1: 30 cm² patch containing 0.83 mg nicotine/cm² incorporated into the adhesive layer to deliver an average of 15 mg nicotine into the bloodstream over 16 hours. A new patch was applied each day and removed before bed.</p> <p>Group 2: Placebo patches were</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ CAR 6 M ○ CAR 12 M - expired carbon monoxide ≤10ppm and saliva cotinine <20ng/ml <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH- inferred 0

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
	<p>Sponsor: Pharmacia AB</p> <p>Protocol availability: NR</p>	<p>Age: 41.5</p> <p>Female: 55.2%</p> <p>FTND Score: NR</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 24.2</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>identical in size and appearance but contained no nicotine. Same regimen used as group 1.</p> <p>Half of those in the active patch group were randomized at entry to receive a dose increase at week 1 if necessary, while the other half remained on standard dosage. Thus all subjects who had not stopped smoking completely after 1 week of treatment or were in great difficulty were offered an extra 10 mg patch, which was a placebo in all but the dose increase group.</p> <p>Mutual interventions: - A six page printed booklet was given to each subject at baseline to inform of essential information about the patch and how to give up smoking.</p>	<p>○ SAE- inferred 0</p> <p>○ CV DEATH- inferred 0</p> <p>○ COMPLETED SUICIDE- inferred 0</p>
Sachs 1993-1881	<p>Study Design: Parallel</p> <p>Nicotine patch (N): 113</p> <p>Placebo patch (N): 107</p> <p>Follow-up lengths: 12 months</p> <p>Sponsor: US Public Health Service grant (DA-04986) from the National Institute on Drug Abuse and grants from Kabi Pharmacia AB and Parke-Davis</p> <p>Protocol availability: NR</p>	<p>Nicotine patch:</p> <p>Age: 47.5</p> <p>Female: 59%</p> <p>FTQ Score: 6.7</p> <p>Years Smoked: 28.7</p> <p>Cigarettes per day: 27.3</p> <p>Placebo patch:</p> <p>Age: 47.8</p> <p>Female: 59%</p> <p>FTQ Score: 6.6</p> <p>Years Smoked: 28.5</p> <p>Cigarettes per day: 28.9</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Active transdermal nicotine patch delivering 15mg of nicotine per day, worn from early morning to evening; replaced daily. The initial size dispensed to all subjects was 30-cm², the active patch releasing 15±3.5 mg of nicotine per 16 hours. After 12 full weeks of treatment, subjects began 6 weeks of tapering with 3-week use of 20-cm² patches and then 3-week use of 10-cm² patches.</p> <p>Group 2: Placebo patch identical in appearance to active patches used with same regimen as group 1.</p> <p>Mutual interventions: -During each visit, subjects received brief, commonsense smoking cessation advice, from a medical perspective, from one of the project nurses, on an as-needed basis.</p>	<p>Efficacy:</p> <p>○ CAR 6 M</p> <p>○ CAR 12 M</p> <p>- expired carbon monoxide ≤9ppm</p> <p>Safety:</p> <p>○ DEATH- inferred 0</p> <p>○ SAE</p> <p>○ CV DEATH- inferred 0</p> <p>○ CV EVENTS</p> <p>○ COMPLETED SUICIDE - inferred 0</p>
Schmitz 2007-699	<p>Study Design: Parallel</p> <p>Bupropion + CBT (N): 41</p> <p>Bupropion + ST (N): 37</p> <p>Placebo + CBT (N): 39</p> <p>Placebo + ST (N): 37</p> <p>Follow-up lengths: 12 months</p> <p>Sponsor: National Institute on Drug Abuse (grant DA08888)</p> <p>Protocol availability: NR</p>	<p>Bupropion + CBT:</p> <p>Age: 46.5</p> <p>Female: 100%</p> <p>FTND Score: 6.2</p> <p>Years Smoked: 27.9</p> <p>Cigarettes per day: 24.6</p> <p>Bupropion + ST:</p> <p>Age: 47</p> <p>Female: 100%</p> <p>FTND Score: 6.1</p> <p>Years Smoked: 27.4</p> <p>Cigarettes per day: 21.1</p> <p>Placebo + CBT:</p> <p>Age: 50</p> <p>Female: 100%</p> <p>FTND Score: 5.1</p> <p>Years Smoked: 31</p> <p>Cigarettes per day: 20</p>	<p>Group 1: Sustained-release bupropion tablets (300 mg/day; 150 mg/day for 3 days, followed by 150 mg twice daily) taking one tablet (150 mg) in the morning and one tablet (150 mg) in the evening with at least 8 hours, but not more than 12 hours, between doses. Cognitive Behaviour Therapy (CBT) was delivered weekly by a therapist and cotherapist pair for 60-min group sessions over 7 weeks. CBT was based on the relapse prevention model and adapted for use with cigarette smokers. Key topics included identification of smoking triggers, functional analysis, handling of lapses, lifestyle balancing, and problem solving. The therapy style was active and directive, with role playing used regularly as a training technique. Between-session practice assignments were reviewed at the subsequent session.</p>	<p>Efficacy:</p> <p>○ PPA 6 M</p> <p>○ PPA 12 M</p> <p>- expired carbon monoxide ≤10ppm and salivary cotinine <15ng/ml</p> <p>Safety:</p> <p>NR</p>

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
		<p>Placebo + ST: Age: 47.7 Female: 100% FTND Score: 5.5 Years Smoked: 27.7 Cigarettes per day: 20.2</p> <p>Are patients willing to quit or have they set a quit date: Y (on day 10)</p>	<p>Group 2: Sustained-release bupropion tablets following the same regimen as group 1. Supportive therapy (ST) was delivered weekly by a therapist and cotherapist pair for 60-min group sessions over 7 weeks. Therapists facilitated group discussion around topics related to quitting in general. Participants were encouraged to share and discuss aspects of their smoking cessation experiences and give feedback to other group members. Therapists refrained from using skills-training techniques or giving direct advice. Home practice assignments and self-monitoring were not allowed. The therapist manual was an adaptation of a health belief intervention.</p> <p>Group 3: Matching unmarked placebo tablets plus cognitive behavior therapy following the same regimen as group 1.</p> <p>Group 4: Matching unmarked placebo tablets plus supportive therapy following the same regimen as group 2.</p> <p>Mutual interventions: NR</p>	
Schneider 1983 - 253	<p>Study Design: Parallel</p> <p>NG (N): 43</p> <p>Placebo (N): 53</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: National Institute on Drug Abuse</p> <p>Protocol availability: NR</p>	<p>NG Age: 40 Female: 30 FTND Score: NR Years Smoked: 23 Cigarettes per day: 35</p> <p>Placebo Age: 37 Female: 30 FTND Score: NR Years Smoked: 20 Cigarettes per day: 31</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: NG + CS</p> <p>NG: Nicotine gum given as frequently as required daily for as long as desired by patient.</p> <p>CS: Clinic support only to main clinic patients where patients met with a counselor for 45 mins each session for 9 sessions (1/day 1st wk and weekly for 4 more wks) (Total Contact Time = 405 mins)</p> <p>Group 2: Placebo + CS</p> <p>Placebo: Placebo gum given as frequently as needed for as long as patient desires.</p> <p>Group 3: NG</p> <p>Group 4: Placebo</p> <p>Mutual interventions: None</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ PPA 6 months ○ PPA 12 M - exhaled air carbon monoxide <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - inferred 0 ○ SAE - inf ○ CV DEATH – inf ○ COMPLETED SUICIDE - inferred 0
Schneider 1995 - 1671	<p>Study Design: Parallel</p> <p>NNS (N): 128</p> <p>Placebo (N): 127</p> <p>Follow-up lengths: 12 Months</p>	<p>NNS Age: 39.9 Female: 61 FTND Score: 7.3 Years Smoked: 22.8 Cigarettes per day: 28.8</p>	<p>Group 1: NNS</p> <p>NNS: Nicotine nasal spray at 0.5 mg/spray administered 8-32 doses/day for 1st 6 wks and then ≤ 32 doses/day for maximum 6 months.</p> <p>Group 2: Placebo</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ CAR 6 months ○ CAR 12 M ○ PPA 6 months ○ PPA 12 M - exhaled air carbon monoxide and saliva cotinine

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
	<p>Sponsor: First author's VA Merit Review and Pharmacia (Sweden)</p> <p>Protocol availability: NR</p>	<p>Placebo</p> <p>Age: 39.7</p> <p>Female: 53</p> <p>FTND Score: 7.2</p> <p>Years Smoked: 28.6</p> <p>Cigarettes per day: 28.6</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Placebo: Placebo nasal spray containing oleo resin piperine (mimic side effects) for maximum 32 doses over 6 month period.</p> <p>Mutual interventions: Written instruction on how to use the nasal spray and a book on how to use nicotine gum. (Total Contact Time = ???)</p>	<p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - inferred 0 ○ SAE - inferred ○ CV DEATH – inferred ○ COMPLETED SUICIDE - inferred 0
Schneider 1996 - 1293	<p>Study Design: Parallel</p> <p>Inhaler (N): 112</p> <p>Placebo (N): 111</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: First author's VA Merit Review and by Pharmacia & Upjohn (Sweden)</p> <p>Protocol availability: NR</p>	<p>Inhaler</p> <p>Age: 43.7</p> <p>Female: 40</p> <p>FTND Score: 7.5</p> <p>Years Smoked: 25.3</p> <p>Cigarettes per day: 29.2</p> <p>Placebo</p> <p>Age: 44.4</p> <p>Female: 42</p> <p>FTND Score: 7.2</p> <p>Years Smoked: 26.1</p> <p>Cigarettes per day: 26.2</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Inhaler</p> <p>Inhaler: Active nicotine inhaler administered at minimum 4/day and maximum 20/day for up to 6 months. Dosage per inhaler is ~5 mg of nicotine and menthol to decrease irritancy.</p> <p>Group 2: Placebo</p> <p>Placebo: Placebo inhalers contained only menthol to mimic active inhaler and were administered minimum 4 and maximum 20/day for up to 6 months.</p> <p>Mutual interventions: None</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ CAR 6 months ○ CAR 12 M - exhaled air carbon monoxide and saliva cotinine <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - inferred 0 ○ SAE – inferred 0 ○ CV DEATH – inferred 0 ○ COMPLETED SUICIDE - inferred 0
Schnoll 2010 - 144	<p>Study Design: Parallel</p> <p>NP 21 mg*8 wks (N): 287</p> <p>NP 21 mg*24 wks (N): 288</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: National Cancer Institute and National Institute on Drug Abuse</p> <p>Protocol availability: Y, NCT00364156</p>	<p>NP 21 mg*8 wks</p> <p>Age: 44.9</p> <p>Female: 129</p> <p>FTND Score: 5.3</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 21.3</p> <p>NP 21 mg*24 wks</p> <p>Age: 44.8</p> <p>Female: 125</p> <p>FTND Score: 5.2</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 21.1</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: NP 21 mg * 8 wks</p> <p>NP 21 mg*8 wks: given standard Tx of 21 mg Nicotine patch for 8 wks and then placebo patch for the other 16 weeks.</p> <p>Group 2: NP 21 mg * 24 wks</p> <p>NP 21 mg*24 wks: given 21 mg nicotine patch for 24 wks.</p> <p>Mutual interventions: None</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ CAR 6 months ○ CAR 12 M ○ PPA 6 months ○ PPA 12 M ○ PAR 12 M - exhaled air carbon monoxide <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - inferred 0 ○ SAE ○ CV DEATH ○ CV EVENTS
Schnoll 2010 - 237	<p>Study Design: Parallel</p> <p>NP24 21 mg + SC Counseling (N): 321</p> <p>NL 2-4 + SC Counseling (N): 321</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: NR</p>	<p>NP24 21 mg + SC Counseling</p> <p>Age: 44.7</p> <p>Female: 195</p> <p>FTND Score: NR</p> <p>Years Smoked: 26.7</p> <p>Cigarettes per day: 20.6</p> <p>NL 2-4 + SC Counseling</p> <p>Age: 44.8</p>	<p>Group 1: NP24 21 mg + SC Counseling</p> <p>NP24 21 mg: Nicotine patch was given for 12 weeks with the first 6 at 21 mg/d, followed by 14 mg/d for 2 weeks and 7 mg/d for 4 weeks.</p> <p>Sc Counseling: All participants received 5 sessions, with initial session >60 mins, the second on quit date over the phone and the following</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ PPA 6 months - exhaled air carbon monoxide ≤ 10 ppm <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH ○ SAE ○ CV DEATH ○ CV EVENTS

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
	Protocol availability: NR	Female: 170 FTND Score: NR Years Smoked: 26.8 Cigarettes per day: 20.1 Are patients willing to quit or have they set a quit date: Y	three as follow up over the phone. (Total Contact Time = > 60 mins). Group 2: NL 2-4 + SC Counseling NL 2-4: Nicotine lozenge was given for 12 weeks at 2 mg/d to those who don't smoke in first 30 mins of day and 4 mg/d to those who do smoke within 30 mins. Dosage was about 9 lozenges/day for 6 weeks, about 5 lozenges/day for 3 weeks and then about 3 lozenges/day for final 3 weeks. Mutual interventions: None	o COMPLETED SUICIDE
Schnoll 2010 - 811	Study Design: Parallel Bup 300 mg + NP24 14 mg-21 mg + Counseling (N): 132 Placebo + NP 24 14 mg-21 mg + Counseling (N): 114 Follow-up lengths: 27 Weeks Sponsor: National Cancer Institute Protocol availability: NR	Bup 300 mg + NP24 14 mg-21 mg + Counseling Age: 53.4 Female: 69 FTND Score: 3.2 Years Smoked: NR Cigarettes per day: 17.4 Placebo + NP 24 14 mg-21 mg + Counseling Age: 53.7 Female: 49 FTND Score: 3.2 Years Smoked: NR Cigarettes per day: 17.2 Are patients willing to quit or have they set a quit date: NR	Group 1: Bup 300 mg + NP24 14 mg-21 mg + Counseling Bup 300 mg: given sustained release bupropion for 9 weeks beginning two weeks before quit date (on 3rd week of trial). Dosage was 150 mg (1 pill) daily for the first week and then 300 mg (bid) for the next 8 weeks. NP 24 14 mg-21 mg: All patients received transdermal nicotine patch. Patients smoking ≤10 cigarettes/day started 14mg/day for 4 wks followed by 7mg/day for 4 wks. Patients smoking ≥10 cigarettes/days started 21mg/day for 2 wks then 2 wks of 14mg/day and 4 wks of 7mg/day Counseling: 5 cessation sessions (3 in person, 2 phone) starting at wk 1. Group 2: Placebo + NP 24 14 mg-21 mg + Counseling Placebo: Placebo given 2 weeks before quit date after week 1 of trial for 9 weeks. Mutual interventions: None	Efficacy: o PPA 6 months - exhaled air carbon monoxide ≤10 ppm Safety: o DEATH - inferred 0 o SAE - inferred o CV DEATH - inferred o COMPLETED SUICIDE - inferred
Schuermans 2004 - 634	Study Design: Parallel Pre NP16 15 mg + Counseling + NP16 15 mg (N): 100 Pre Placebo + Counseling + NP16 15 mg (N): 100 Follow-up lengths: 6 Months Sponsor: Swiss Science Foundation and Pfizer Protocol availability: NR	Pre NP16 15 mg + Counseling + NP16 15 mg Age: 43.2 Female: 43 FTND Score: 5.8 Years Smoked: 21.7 Cigarettes per day: 23.1 Pre Placebo + Counseling + NP16 15 mg Age: 43.7 Female: 45 FTND Score: 6.3 Years Smoked: 25.4 Cigarettes per day:	Group 1: Pre NP16 15 mg + Counseling + NP16 15 mg Pre NP16 HD: Active nicotine patches 15mg/16hr for 2 weeks pre-treatment. Counseling: Counseling provided at each visit for 20 mins each visit with an extra 10-15 mins at initial visit. Total of six visits for counseling. (Total Contact Time = 135 mins) NP16 15 mg: From quite date all patients received active NP 15mg/16hr for 8 weeks followed by 10mg/16hr for 2 weeks and 5mg/16hr for 2 weeks.	Efficacy: o CAR 6 months - exhaled air carbon monoxide ≤ 10 ppm Safety: o DEATH o SAE - inferred

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
		26.4 Are patients willing to quit or have they set a quit date: Y	Group 2: Pre Placebo + Counseling + NP16 15 mg Pre Placebo: Placebo patches given for 2 weeks pre-treatment. Mutual interventions: None	
Segnan 1991 239	Study Design: Parallel Minimal Counseling (N): 62 Repeated Counseling (N): 275 Repeated Counseling + NG (N): 294 Repeated Counseling + Spirometry (N): 292 Follow-up lengths: 12 Months Sponsor: Health education grant from Piedmont Health Authority Protocol availability: NR	Minimal Counseling Age: NR Female: 20 FTND Score: NR Years Smoked: NR Cigarettes per day: NR Repeated Counseling Age: NR Female: 109 FTND Score: NR Years Smoked: NR Cigarettes per day: NR Repeated Counseling + NG Age: NR Female: 108 FTND Score: NR Years Smoked: NR Cigarettes per day: NR Repeated Counseling + Spirometry Age: NR Female: 117 FTND Score: NR Years Smoked: NR Cigarettes per day: NR Are patients willing to quit or have they set a quit date: Y	Group 1: Minimal Counseling Minimal counseling: one counseling session and brochure on cessation. Group 2: Repeated Counseling Repeated Counseling: had initial counseling session but also returned for sessions at 1, 3, 6 and 9 month intervals. (Total Contact Time = NR) Group 3: Repeated Counseling + NG NG: Patients given nicotine gum for 3 months and advised on dosage (NR). Group 4: Repeated Counseling + Spirometry Spirometry: Patients brought in for spirometry lung test and advised of condition of lungs on next visit. Mutual interventions: None	Efficacy: ○ PPA 6 months ○ PPA 12 M - exhaled air carbon monoxide ≤ 10 ppm Safety: ○ NR
Shiffman 2002 - 1267	Study Design: Parallel NL 2 mg (N): 459 Placebo (N): 909 NL 4 mg (N): 450 Follow-up lengths: 12 Months Sponsor: Glaxo Smith Kline Protocol availability: NR	NL 2 mg Age: 41.1 Female: 262 FTND Score: 2.6 Years Smoked: NR Cigarettes per day: 17.7 Placebo Age: 42.3 Female: 513 FTND Score: 4.4 Years Smoked: NR Cigarettes per day: 22 NL 4 mg Age: 44.3 Female: 255 FTND Score: 6.1 Years Smoked: NR Cigarettes per day: 26.3	Group 1: NL 2 mg NL 2 mg: Selected here if they didn't smoke within 30 mins of waking. Take 2mg lozenge every 1-2 hrs first 6 weeks for minimum of 9 per day. Weeks 7-9 reduce dosage to every 2-4 hrs and weeks 10-12 reduce to every 4-8 hrs. Final 12-24 weeks use occasionally as needed for dosage. Group 2: Placebo Placebo: After first week, were randomized from both arms to receive placebo lozenges following the dosages mentioned in the treatment arms. Group 1: NL 4 mg NL 4 mg: Selected here if they smoked	Efficacy: ○ CAR 6 months ○ CAR 12 M - exhaled air carbon monoxide ≤ 10 ppm Safety: ○ DEATH ○ SAE

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
		Are patients willing to quit or have they set a quit date: Y	<p>within 30 mins of waking. Take 4mg lozenge every 1-2 hrs first 6 weeks for minimum of 9 per day. Weeks 7-9 reduce dosage to every 2-4 hrs and weeks 10-12 reduce to every 4-8 hrs. Final 12-24 weeks use occasionally as needed for dosage.</p> <p>Mutual interventions: Patients were provided with written user's guide and behavioral guidance at first 4 visits for 5-10 mins. (Total Contact Time = 20-40 mins)</p>	
Shiffman 2009 - 96	<p>Study Design: Parallel</p> <p>NG 2 mg (N): 819</p> <p>Placebo (N): 1648</p> <p>NG 4 mg (N): 830</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: Glaxo Smith Kline</p> <p>Protocol availability: NR</p>	<p>NG 2 mg</p> <p>Age: 42.1</p> <p>Female: 514</p> <p>FTND Score: 4.4</p> <p>Years Smoked: 24.1</p> <p>Cigarettes per day: 17.7</p> <p>Placebo</p> <p>Age: 44.3</p> <p>Female: 969</p> <p>FTND Score: 5.7</p> <p>Years Smoked: 26.9</p> <p>Cigarettes per day: 25.1</p> <p>NG 4 mg</p> <p>Age: 46.1</p> <p>Female: 395</p> <p>FTND Score: 6.9</p> <p>Years Smoked: 29.2</p> <p>Cigarettes per day: 32</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: NG 2 mg</p> <p>NG 2 MG: Quitting was over a period where they reduced cigarettes/day by 1 hr each day until they quit (substituting gum every hour). Patients took 2mg gum every 1-2 hrs first 6 weeks. Next 3 weeks reduce dosage to every 2-4 hrs and last 3 weeks reduce to every 4-8 hrs. Final 12-24 weeks use occasionally as needed for dosage.</p> <p>Group 2: Placebo</p> <p>Placebo: After quitting, were randomized from both arms to receive placebo gum following the dosages mentioned in the treatment arms.</p> <p>Group 1: NG 4 mg</p> <p>NG 4 mg: Quitting was over a period where they reduced cigarettes/day by 1 hr each day until they quit (substituting gum every hour). Patients took 4mg gum every 1-2 hrs first 6 weeks. Next 3 weeks reduce dosage to every 2-4 hrs and last 3 weeks reduce to every 4-8 hrs. Final 12-24 weeks use occasionally as needed for dosage.</p> <p>Mutual interventions: None</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ CAR 6 months - exhaled air carbon monoxide ≤ 10 ppm <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - inferred 0 ○ SAE - inferred ○ CV DEATH - inferred ○ COMPLETED SUICIDE - inferred
Simon 2004 - 1797	<p>Study Design: Parallel</p> <p>BUP 300 mg + NP24 21 mg + Counseling (N): 123</p> <p>Placebo + NP24 21 mg + Counseling (N): 126</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: Grant from California Tobacco-Related Disease Research Program</p> <p>Protocol availability: NR</p>	<p>BUP 300 mg + NP24 21 mg + Counseling</p> <p>Age: 50</p> <p>Female: 15</p> <p>FTND Score: 3.8</p> <p>Years Smoked: 39</p> <p>Cigarettes per day: 22</p> <p>Placebo + NP24 21 mg + Counseling</p> <p>Age: 49</p> <p>Female: 20</p> <p>FTND Score: 4.0</p> <p>Years Smoked: 39</p> <p>Cigarettes per day: 23</p>	<p>Group 1: BUP 300 mg + NP24 21 mg + Counseling</p> <p>BUP 300 mg: 7 weeks of sustained release bupropion hydrochloride at 150 mg/day for 3 days and then 150 mg bid.</p> <p>NP24 21 mg: Dosage specific to individual. Average dosage of nicotine patch was 4 weeks 21 mg/day, 2 weeks 14 mg/day, and then 2 weeks 7 mg/day</p> <p>Counseling: Each participant received one initial in person session and then</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ CAR 12 M - saliva cotinine ≥ 15 ng/ml <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH ○ SAE - inferred

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
		Are patients willing to quit or have they set a quit date: Y	5 telephone sessions at week 1, 3 and then monthly for the first 3 months. Each session was ≤ 30 mins. (Total Contact Time = ≤ 180 mins) Group 2: Placebo + NP24 21 mg + Counseling Placebo: 7 week placebo treatment at 1 dose/daily for 3 days and then bid dosage. Mutual interventions: Self-help literature given out on the initial visit.	
Simon 2009 - 663	Study Design: Parallel BUP 300 mg + Counseling (N): 42 Placebo + Counseling (N): 43 Follow-up lengths: 6 Months Sponsor: California Tobacco-Related Disease Research Program Protocol availability: NR	BUP 300 mg + Counseling Age: 55 Female: 3 FTND Score: 4.4 Years Smoked: 43 Cigarettes per day: 16 Placebo + Counseling Age: 57 Female: 0 FTND Score: 4.4 Years Smoked: 44 Cigarettes per day: 16 Are patients willing to quit or have they set a quit date: Y	Group 1: BUP 300 mg + Counseling BUP 300 mg: 7 weeks of sustained release bupropion hydrochloride at 150 mg/day for 3 days and then 150 mg bid. Counseling: Each participant received one initial in person session and then 5 telephone sessions at week 1, 3 and then monthly for the first 3 months. Each session was ≤ 30 mins. (Total Contact Time = ≤ 180 mins) Group 2: Placebo + Counseling Placebo: 7 week placebo treatment at 1 dose/daily for 3 days and then bid dosage. Mutual interventions: None	Efficacy: ○ CAR 6 M - saliva cotinine ≥ 15 ng/ml Safety: ○ DEATH ○ SAE
Sonderskov 1997 - 309	Study Design: Parallel NP24 14 mg (N): 119 Placebo (N): 267 NP24 21 mg (N): 136 Follow-up lengths: 26 weeks Sponsor: Ciba-Geigy Protocol availability: NR	NP24 14 mg Age: 38.2 Female: 89 FTND Score: 6.1 Years Smoked: 20.2 Cigarettes per day: NR Placebo Age: 39.4 Female: 166 FTND Score: 7.2 Years Smoked: 21.2 Cigarettes per day: NR NP24 21 mg Age: 39.1 Female: 75 FTND Score: 7.0 Years Smoked: 22.2 Cigarettes per day: NR Are patients willing to quit or have they set a quit date: Y	Group 1: NP24 14 mg NP24 14 mg: Patients that smoke < 20 cigarettes/day given 14 mg/d nicotine patch for 8 weeks, then 7 mg/d for 4 weeks. Group 2: Placebo Placebo: Placebo with identical dosage and duration to NP24 14 MG and HD. Group 3: NP24 21 mg NP24 21 mg: Patients that smoke >20 cigarettes/day given 21 mg/d nicotine patch for 4 weeks, then 14 mg/d for 4 weeks, and then 7 mg/d for final 4 weeks. Mutual interventions: None	Efficacy: ○ NR - BV: NR Safety: ○ DEATH - inferred ○ SAE ○ CV DEATH - inferred ○ COMPLETED SUICIDE - inferred
Stein 2006 - 599	Study Design: Parallel	NP24 14 mg- 21 mg + Maximal Tx Age: 39.9	Group 1: NP24 14 mg- 21 mg + Maximal Tx	Efficacy: ○ PPA 6 months - exhaled air carbon

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
	<p>NP24 14 mg- 21 mg + Maximal Tx (N): 191</p> <p>NP24 14 mg- 21 mg + Minimal Tx (N): 192</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: National Cancer Institute</p> <p>Protocol availability: NR</p>	<p>Female: 92</p> <p>FTND Score: NR</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 26.3</p> <p>NP24 14 mg- 21 mg + Minimal Tx</p> <p>Age: 40.3</p> <p>Female: 88</p> <p>FTND Score: NR</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 27.2</p> <p>Are patients willing to quit or have they set a quit date: NR</p>	<p>NP24 14 mg- 21 mg: For those smoking <2 packs/d, 8 wk nicotine patch treatment with 21mg/d first 4 wks, 14 mg/d 2 wks and 7 mg/d final 2 wks. For those smoking >2 packs/d, 12 wk nicotine patch with 42 mg/d first 4 wks, 35 mg/d next 2 wks, 28 mg/d two wks, 21 mg/d two wks, 14 mg/d for 1 wk and 7 mg/d final wk.</p> <p>Maximal Tx: Attended three motivational sessions. First was assessment for 30 mins, second was around quit date/follow up for 15-30 mins and final was follow up for 15 mins. (Total Contact Time = 60-75 mins)</p> <p>Group 2: NP24 14 mg- 21 mg + Minimal Tx</p> <p>Minimal Tx: Received only 2 visits, first only ≤3 mins and the second a short follow up. This method followed the National Cancer Institute's 4 As model.</p> <p>Mutual interventions: None</p>	<p>monoxide</p> <p>Safety:</p> <ul style="list-style-type: none"> ○ NR
Steinberg 2009 - 447	<p>Study Design: Parallel</p> <p>NP24 21 mg (N): 64</p> <p>NP24 21 mg + Ninh + Bup 150 mg (N): 63</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: Cancer Institute of New Jersey and Robert Wood Johnson Foundation</p> <p>Protocol availability: NR</p>	<p>NP24 21 mg</p> <p>Age: NR</p> <p>Female: 42</p> <p>FTND Score: 5.23</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: NR</p> <p>NP24 21 mg + Ninh + Bup 150 mg</p> <p>Age: NR</p> <p>Female: 40</p> <p>FTND Score: 5.16</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: NR</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: NP24 21 mg</p> <p>NP24 21 mg: 10 week treatment of 21 mg/d for 6 wks, then 14 mg/d for 2 wks, then 7 mg/d for the final 2 wks.</p> <p>Group 2: NP24 21 mg + Ninh + Bup 150 mg</p> <p>NP24 21 mg + Ninh + Bup 150 mg: Began with 21 mg/d NP, a nicotine inhaler as needed, and bupropion, 150 mg/d. Duration of treatment followed symptoms, after 14 consecutive symptom free days, reduced dosage to 14 mg/d NP for 2 weeks and then 7 mg/d for two more weeks. Two weeks after discontinuing the patch, bupropion was stopped and inhaler used as needed.</p> <p>Mutual interventions: None</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ PPA 6 months - exhaled air carbon monoxide <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH ○ SAE ○ CV DEATH ○ CV EVENTS ○ COMPLETED SUICIDE
Steinberg 2011 - 1127	<p>Study Design: Parallel</p> <p>Var 2 mg (N): 40</p> <p>Placebo (N): 39</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: Robert Wood Johnson Foundation</p> <p>Protocol availability: NR</p>	<p>Var 2 mg</p> <p>Age: NR</p> <p>Female: 16</p> <p>FTND Score: NR</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: NR</p> <p>Placebo</p> <p>Age: NR</p> <p>Female: 16</p> <p>FTND Score: NR</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: NR</p>	<p>Group 1: Var 2 mg + Hospital based behavioral Tx</p> <p>Var 2 mg: 12 wk treatment of varenicline at dosage of 0.5 mg/d for 3 days, then 0.5 mg/d for 4 days, then 1 mg bid till the end of 12 wks.</p> <p>Hospital based behavioral Tx: Series of sessions in the hospital provided by coordinator, first last 10-15 mins. (Total Contact Time = NR)</p> <p>Group 2: Placebo + Hospital based</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ NR <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH ○ SAE ○ CV DEATH ○ CV EVENTS ○ COMPLETED SUICIDE

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
		Are patients willing to quit or have they set a quit date: NR	behavioral Tx Placebo: Placebo treatment given daily over the 12 week treatment period. Mutual interventions: None	
Sutherland 1992 - 324	Study Design: Parallel NS 0.5 mg + Group Tx (N): 116 Placebo + Group Tx (N): 111 Follow-up lengths: 12 Months Sponsor: Medical Research Council and the Imperial Cancer Research fund Protocol availability: NR	NS 0.5 mg + Group Tx Age: 38.9 Female: 73 FTND Score: NR Years Smoked: 21.6 Cigarettes per day: 24.9 Placebo + Group Tx Age: 40.4 Female: 73 FTND Score: NR Years Smoked: 23.5 Cigarettes per day: 26.9 Are patients willing to quit or have they set a quit date: Y	Group 1: NS 0.5 mg + Group Tx NS 0.5 mg: Nasal spray gave 0.5 mg per spray and a dose was considered 1 mg. Patients advised to use as needed but to not exceed 5 mg/h and 40 mg/d. Recommended duration of use was for 3 months. Group Tx: Group therapy of 6 sessions over a month, each lasting 60-75 mins (Total Contact Time = 360-450 mins) Group 2: Placebo + Group Tx Placebo: Dosage for the placebo was the same as the NS LD group and the placebo spray contained piperine to mimic the nasal spray. Mutual interventions: None	Efficacy: ○ CAR 6 months ○ CAR 12 M ○ PAR 12 M - exhaled air carbon monoxide ≤ 10 ppm Safety: ○ DEATH – inferred ○ SAE - inferred ○ CV DEATH - inferred ○ CV EVENTS ○ COMPLETED SUICIDE - inferred
Sutherland 1994 - 195	Study Design: Parallel NS 1 mg + Counseling (N): 116 Placebo + Counseling (N): 111 Follow-up lengths: 12 Months Sponsor: NR Protocol availability: NR	NS 1 mg + Counseling Age: NR Female: NR FTND Score: NR Years Smoked: NR Cigarettes per day: NR Placebo + Counseling Age: NR Female: NR FTND Score: NR Years Smoked: NR Cigarettes per day: NR Are patients willing to quit or have they set a quit date: Y	Group 1: NS 1 mg + Counseling NS HD: Nicotine spray given at 1 mg/dose (two squirts of 0.5 mg/dose) and instructed to use as needed but only for 3 months and to not exceed 5 doses/hr and 40 doses/day. Counseling: All participants received 6 sessions of supportive therapy over a one month period. (Total Contact Time = ???). Group 2: Placebo + Counseling Placebo: A placebo spray with 2 squirts/dose and used as needed over a 3 month period. Mutual interventions: None	Efficacy: ○ PAR 6 months ○ PAR 12 M - exhaled air carbon monoxide ≤ 10 ppm Safety: ○ DEATH - inferred ○ SAE ○ CV DEATH - inferred ○ COMPLETED SUICIDE - inferred
Sutton 1987 - 1210	Study Design: Parallel NG 2 mg + Consultations (N): 270 No Tx (N): 64 Follow-up lengths: 12 Months Sponsor: Medical Research Council Protocol availability: NR	Overall Age: 34.3 Female: 234 FTND Score: NR Years Smoked: NR Cigarettes per day: 15.5 Are patients willing to quit or have they set a quit date: Y	Group 1: NG 2 mg + Consultations NG 2 mg: Participants were given 2 mg nicotine gum packages and advised on use. No dose and duration is listed. Consultations: Consultations were held twice with participants, the first assessment being ≤ 30 mins and the second being ≤ 15 mins. (Total Contact Time = ≤45 mins) Group 2: No Tx	Efficacy: ○ CAR 12 M ○ PAR 12 M - exhaled air carbon monoxide ≤ 10 ppm Safety: ○ NR

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
			No Tx: Participants that did not participate in the trial and were the no-intervention control group. Mutual interventions: None	
Swan 2003 - 2337	<p>Study Design: Parallel</p> <p>Bup 150 mg + FC (N): 382</p> <p>Bup 150 mg + ZAP (N): 381</p> <p>Bup 300 mg + FC (N): 383</p> <p>Bup 300 mg + ZAP (N): 378</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: National Cancer Institute</p> <p>Protocol availability: NR</p>	<p>Bup 150 mg + FC</p> <p>Age: 46.1</p> <p>Female: 228</p> <p>FTND Score: 5.8</p> <p>Years Smoked: 27.7</p> <p>Cigarettes per day: 23.8</p> <p>Bup 150 mg + ZAP</p> <p>Age: 45</p> <p>Female: 230</p> <p>FTND Score: 5.7</p> <p>Years Smoked: 26.3</p> <p>Cigarettes per day: 22.7</p> <p>Bup 300 mg + FC</p> <p>Age: 44.6</p> <p>Female: 216</p> <p>FTND Score: 5.8</p> <p>Years Smoked: 25.9</p> <p>Cigarettes per day: 23.1</p> <p>Bup 300 mg + ZAP</p> <p>Age: 44.5</p> <p>Female: 201</p> <p>FTND Score: 5.8</p> <p>Years Smoked: 26.3</p> <p>Cigarettes per day: 23.2</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Bup 150 mg + FC</p> <p>Bup 150 mg: one 150 mg dose daily, 1 week before quit date until 7 weeks after quit date.</p> <p>FC: Mailing of self-help materials, an initial in-depth telephone counseling and 4 follow up calls. Also had access to a toll-free quite-line for a year.</p> <p>Group 2: Bup 150 mg + ZAP</p> <p>ZAP: Less intensive behavioral program called zyban advantage plan. Data from 5 pre-assessment surveys tailored material to the individual. Included a 5-10 mins call from the coordinator and access to 24 hr support line.</p> <p>Group 3: Bup 300 mg + FC</p> <p>Bup 300 mg: two 150 mg doses daily, 1 week before quit date until 7 weeks after quit date.</p> <p>Group 4: Bup 300 mg + ZAP</p> <p>Mutual interventions: None</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ NR <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH ○ SAE - inferred ○ CV DEATH ○ COMPLETED SUICIDE
Tashkin 2001 - 1571	<p>Study Design: Parallel</p> <p>Bup 300 mg + Counseling (N): 204</p> <p>Placebo + Counseling (N): 200</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: Glaxo Wellcome Inc.</p> <p>Protocol availability: NR</p>	<p>Bup 300 mg + Counseling</p> <p>Age: 53.2</p> <p>Female: 93</p> <p>FTND Score: 7.1</p> <p>Years Smoked: 52.6</p> <p>Cigarettes per day: 28.7</p> <p>Placebo + Counseling</p> <p>Age: 54.5</p> <p>Female: 92</p> <p>FTND Score: 7.0</p> <p>Years Smoked: 51.4</p> <p>Cigarettes per day: 27.6</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Bup 300 mg + Counseling</p> <p>Bup 300 mg: Given bupropion SR 150 mg/d for 3 days and then 150 mg bid for the rest of the 12 week treatment.</p> <p>Counseling: 10 personalized counseling sessions beginning with initial call and then during 9 visits at weeks 1-7, 10 and 12. Duration of these visits was not reported. (Total Contact Time = NR)</p> <p>Group 2: Placebo + Counseling</p> <p>Placebo: Placebo with identical dosage and duration to Bup HD.</p> <p>Mutual interventions: None</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ CAR 6 months ○ PPA 6 months - exhaled air carbon monoxide ≤ 10 ppm <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - inferred ○ SAE ○ CV DEATH - inferred ○ CV EVENTS ○ COMPLETED SUICIDE - inferred
Tashkin 2011 -	Study Design:	Var 2 mg + Counseling	Group 1: Var 2 mg + Counseling	Efficacy:

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Reference	Study Details	Patients	Intervention	Outcomes
591	<p>Parallel</p> <p>Var 2 mg + Counseling (N): 250</p> <p>Placebo + Counseling (N): 250</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: Pfizer Inc.</p> <p>Protocol availability: Y, NCT00285012</p>	<p>Age: 57.2</p> <p>Female: 93</p> <p>FTND Score: 6.2</p> <p>Years Smoked: 40.4</p> <p>Cigarettes per day: 25.3</p> <p>Placebo + Counseling</p> <p>Age: 57.1</p> <p>Female: 95</p> <p>FTND Score: 5.9</p> <p>Years Smoked: 40.6</p> <p>Cigarettes per day: 23.6</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Var 2 mg: Given varenicline 0.5 mg/d for 3 days, then 0.5 mg bid, then 1.0 mg bid for the rest of a total of 12 weeks.</p> <p>Counseling: Twelve sessions and a phone call during Tx each ≤ 10 mins. In 40 week follow up, seven visits and five phone calls each ≤ 10 mins. (Total Contact Time = ≤ 250 mins)</p> <p>Group 2: Placebo + Counseling</p> <p>Placebo: Placebo with identical dosage and duration to Var HD.</p> <p>Mutual interventions: Educational booklet on smoking cessation</p>	<p>○ CAR 6 months</p> <p>○ CAR 12 M</p> <p>○ PPA 6 months</p> <p>○ PPA 12 M</p> <p>- exhaled air carbon monoxide ≤ 10 ppm</p> <p>Safety:</p> <p>○ DEATH</p> <p>○ SAE</p> <p>○ CV DEATH</p> <p>○ SUICIDAL IDEATION</p> <p>○ COMPLETED SUICIDE</p> <p>○ AGGRESSION</p>
Tonnesen 1988 - 15	<p>Study Design: Parallel</p> <p>Nicotine gum 4 mg + GC: 27</p> <p>Nicotine gum 2 mg + GC: 93</p> <p>Placebo gum + GC (N): 53</p> <p>Follow-up lengths: 2 Years</p> <p>Sponsor: In part by Danish National Tuberculosis Foundation.</p> <p>Protocol availability: NR</p>	<p>Nicotine gum 4 mg + GC:</p> <p>Age: 46.6</p> <p>Female: 56%</p> <p>FTND Score: NR</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 25.8</p> <p>Nicotine gum 2 mg + GC:</p> <p>Age: 44.8</p> <p>Female: 56%</p> <p>FTND Score: NR</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 23.1</p> <p>Placebo gum + GC:</p> <p>Age: 44.9</p> <p>Female: 53%</p> <p>FTND Score: NR</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 20.3</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Nicotine gum 4 mg + Group Counseling (GC)</p> <p>Group 2: Nicotine gum 2 mg + GC</p> <p>Group 3: Placebo gum + GC</p> <p>Nicotine or placebo gum: For highly dependent smokers, gum containing 4 mg of nicotine were given at first six weeks and followed by gum containing 2 mg, or gum containing 2 mg of nicotine for the entire test period. For medium or low dependent smokers, gum containing 2 mg of nicotine or placebo was given. The participants were instructed to start using at least six pieces of gum for two to six weeks. The recommended dose was 4 to 14 pieces per day for the first two months, with a gradual reduction over the following weeks (gum was available for two years). Each subject adjusted his or her daily intake of gum depending on the symptoms produced by abstinence.</p> <p>Group Counseling: It included 12 to 15 members in each of 13 counseling groups, which led by a physician. There were 6 afternoon sessions (one and a half hours per session at 0, 1, 2, 6, 12 and 16 weeks) for every participant, and one additional session (at 20 weeks) for those still using the gum at week 16.</p> <p>Mutual interventions:</p> <ul style="list-style-type: none"> - Group discussion - Instructional video tapes 	<p>Efficacy:</p> <p>○ CAR 6 Months</p> <p>○ CAR 12 M</p> <p>○ CAR 2 Years</p> <p>- exhaled carbon monoxide < 8 ppm</p> <p>Safety:</p> <p>○ DEATH - inferred 0</p> <p>○ SAE</p> <p>○ CV DEATH - inferred 0</p> <p>○ COMPLETED SUICIDE - inferred 0</p>
Tonnesen 1988 - 17	<p>Study Design: Parallel</p> <p>Nicotine gum 4 mg + GC: 54</p> <p>Nicotine gum 2 mg + GC: 62</p>	<p>Overall:</p> <p>Age: 44.8</p> <p>Female: 55%</p> <p>FTND Score: NR</p> <p>Years Smoked: NR</p> <p>Cigarettes per day:</p>	<p>Group 1: Nicotine gum 4 mg + GC</p> <p>Group 2: Nicotine gum 2 mg + GC</p> <p>Nicotine or placebo gum: The subjects were instructed to stop smoking</p>	<p>Efficacy:</p> <p>○ PPA 6 M</p> <p>○ PPA 12 M</p> <p>○ PPA 22 M</p> <p>- confirmed by expired air carbon monoxide analysis,</p>

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Reference	Study Details	Patients	Intervention	Outcomes
	<p>Advice (N): 56</p> <p>Follow-up lengths: 22 Months</p> <p>Sponsor: H. Lundbeck A/S, Denmark and Danish National Tuberculosis Society.</p> <p>Protocol availability: NR</p>	<p>21.6</p> <p>Data by groups is not available.</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>completely at the first meeting and use at least six pieces of Nicorette (2 or 4 mg nico-gum) daily for at least six weeks. No upper limit was given, but the subjects were informed that the usual number of pieces of gum was 6-20 pieces daily, depending on the experienced abstinence symptoms, so-called self titration of nicotine.</p> <p>Group Counseling: The group meetings included 10 to 12 members and were led by a physician. There were 6 afternoon meetings of 1.5-2.5 hours duration in a four month period (week 0-1-2-6-12-16).</p> <p>Group 2: Advice, written information on how to stop smoking on their own.</p> <p>Mutual interventions:</p> <ul style="list-style-type: none"> - Two different slide tape programs (25 minutes playing time each) were each shown twice, at the start and after one week and after 1.5 and 3 months. 	<p>with cut-off point not being specified</p> <p>Safety:</p> <ul style="list-style-type: none"> o DEATH - inferred 0 o SAE - inferred 0 o CV DEATH - inferred 0 o COMPLETED SUICIDE - inferred 0
<p>Tonnesen 1991-311 + Tonnesen 1992-241 + Mikkelsen 1994-95</p>	<p>Study Design: Parallel</p> <p>Nicotine patch (N): 145</p> <p>Placebo patch (N): 144</p> <p>Follow-up lengths: 3 Years</p> <p>Sponsor: Kabi Pharmacia Therapeutics</p> <p>Protocol availability: NR</p>	<p>Nicotine patch:</p> <p>Age: 45.3</p> <p>Female: 69%</p> <p>Fagerstrom Score: 7.1</p> <p>Years Smoked: 25.9</p> <p>Cigarettes per day: 21</p> <p>Placebo patch:</p> <p>Age: 45.1</p> <p>Female: 71%</p> <p>Fagerstrom Score: 7.4</p> <p>Years Smoked: 26.7</p> <p>Cigarettes per day: 22</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Nicotine patch</p> <p>Group 2: Placebo patch</p> <p>Nicotine or placebo patch: Participants were instructed to daily use nicotine or placebo patch in the morning to the medial region of the arm or the upper gluteal region and remove the patch at bedtime. To reduce local skin irritation, the patch was recommended to be placed on the contralateral site the next day. The nicotine patch was 30 cm² in size, releasing 15 ±3.5 mg of nicotine over a period of 16 hours. The subjects were told to use the patches for 12 weeks, and they were then offered 20 patches of 20 cm² and 20 patches of 10 cm² to reduce the dosage over a 4-week period, if they wished.</p> <p>Mutual interventions:</p> <ul style="list-style-type: none"> - Introductory presentation on smoking cessation - Brief advice at each visit, by physician 	<p>Efficacy:</p> <ul style="list-style-type: none"> o CAR 12 M o PAR 6 W-12 M o PAR 1Y-2Y o PAR 1Y-3Y - exhaled carbon monoxide ≤ 10 ppm <p>Safety:</p> <ul style="list-style-type: none"> o DEATH o SAE
<p>Tonnesen 1993-1268</p>	<p>Study Design: Parallel</p> <p>Nicotine inhaler (N): 145</p> <p>Placebo inhaler (N): 141</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: Kabi Pharmacia Therapeutics, Helsingborg, Sweden.</p> <p>Protocol availability: NR</p>	<p>Nicotine inhaler:</p> <p>Age: 39</p> <p>Female: 58%</p> <p>FTQ Score: 7.4</p> <p>Years Smoked: 21</p> <p>Cigarettes per day: 20</p> <p>Group 2:</p> <p>Age: 39</p> <p>Female: 63%</p> <p>FTQ Score: 7.3</p> <p>Years Smoked: 20</p> <p>Cigarettes per day: 20</p>	<p>Group 1: Nicotine inhaler</p> <p>Group 2: Placebo inhaler</p> <p>Nicotine or Placebo inhaler: The subjects were advised to use 2-10 nicotine inhalers per day ad libitum. One puff of 50 mL releases about 0.1 µmol of nicotine at room temperature. They were instructed to inhale deeply and to puff about 10 times more often compared with smoking a cigarette. One inhaler</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> o CAR 6 Months o CAR 12 M - exhaled carbon monoxide < 10 ppm <p>Safety:</p> <ul style="list-style-type: none"> o DEATH - inferred 0 o SAE o CV DEATH - inferred 0 o COMPLETED SUICIDE - inferred 0

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Reference	Study Details	Patients	Intervention	Outcomes
		Are patients willing to quit or have they set a quit date: Y	would be good for 300 puffs, and subjects were told to replace it with a new one when they felt the nicotine inhaler had no more effect. After 3 months, they were offered a tapering period during the next 3 months with a monthly reduction of 25% of the number of inhalers per day used in the third month. After the 6-month visit no more inhalers were available. Mutual interventions: - Introductory presentation on smoking cessation - Brief advice at each visit, by physician	
Tonnesen 1996 - 1619	Study Design: Parallel Fixed dose NS 1 mg/h + Counseling (N): 44 Ad Libitum NS 0.5 mg/spray + Counseling (N): 45 Follow-up lengths: 12 Months Sponsor: NR Protocol availability: NR	Fixed dose NS 1 mg/h + Counseling: Age: 52 Female: 31 FTND Score: 6.0 Years Smoked: NR Cigarettes per day: 22 Fixed dose NS 1 mg/h + Counseling: Age: 47 Female: 31 FTND Score: 6.2 Years Smoked: NR Cigarettes per day: 22 Are patients willing to quit or have they set a quit date: Y	Group 1: Fixed dose NS 1 mg/h + Counseling Fixed dose NS 1 mg/h: Participants received 10 ml nicotine nasal sprays and told to administer fixed dosing of 1 mg/h for 6 months, with recommended tapering after month 3 (maximum of 12 month Tx). Counseling: All participants attended visits at week 0, 1, 2, 3, 6 and month 3, 6, 9, and 12. Each visit ended with a group counseling session of 20-40 mins. (Total Contact Time = 180-360 mins) Group 2: Ad Libitum NS 0.5 mg/spray + Counseling Ad Libitum NS 0.5 mg/spray: Participants received 10 ml nicotine nasal sprays and told to administer Ad libitum dosing of up to 5 mg/h and 40 mg/day for 6 months, with recommended tapering after month 3 (maximum of 12 month Tx). Mutual interventions: None	Efficacy: o CAR 6 months o CAR 12 M - expired air carbon monoxide Safety: o DEATH - inferred o SAE - inferred o CV DEATH - inferred o COMPLETED SUICIDE - inferred
Tonnesen 1999-238	Study Design: Parallel 25 mg Nicotine patch for 22 weeks (N): 715 25 mg Nicotine patch for 8 weeks (N): 715 15 mg Nicotine patch for 22 weeks (N): 715 15 mg Nicotine patch for 8 weeks (N): 716 Placebo (N): 714	25 mg Nicotine patch for 22 weeks: Age: 40 Female: 48% FTQ Score: 5.6 Years Smoked: NR Cigarettes per day: 28 25 mg Nicotine patch for 8 weeks: Age: 41 Female: 47% FTQ Score: 5.6 Years Smoked: NR Cigarettes per day: 26 15 mg Nicotine patch	Group 1: 25 mg Nicotine patch for 22 weeks 15 mg patch plus 10mg patch for 22 weeks, followed by 15 mg patch for 2 weeks and 10 mg patch for 2 weeks Group 2: 25 mg Nicotine patch for 8 weeks 15 mg patch plus 10 mg patch for 8 weeks, followed by 15 mg patch for 2 weeks and 10 mg patch for 2 weeks Group 3: 15 mg Nicotine patch for 22 weeks 15 mg nicotine patch plus placebo patch for 22 weeks, followed by 10 mg patch for 4 weeks	Efficacy: o CAR 6 Months o CAR 12 M - exhaled carbon monoxide < 10 ppm Safety: o DEATH - inferred 0 o CV DEATH - inferred 0 o COMPLETED SUICIDE - inferred 0

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Reference	Study Details	Patients	Intervention	Outcomes
	<p>Follow-up lengths: 12 Months</p> <p>Sponsor: Pharmacia & Upjohn, Helsingborg, Sweden.</p> <p>Protocol availability: NR</p>	<p>for 22 weeks:</p> <p>Age: 40 Female: 48% FTQ Score: 5.6 Years Smoked: NR Cigarettes per day: 26</p> <p>15 mg Nicotine patch for 8 weeks: Age: 41 Female: 49% FTQ Score: 5.4 Years Smoked: NR Cigarettes per day: 27</p> <p>Placebo: Age: 41 Female: 48% FTQ Score: 5.6 Years Smoked: NR Cigarettes per day: 27</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 4: 15 mg Nicotine patch for 8 weeks 15 mg nicotine patch plus placebo patch for 8 weeks, followed by 10 mg patch for 4 weeks</p> <p>Group 5: Placebo Two placebo patches for a total of 26 weeks.</p> <p>Participants were instructed to wear the patches which contained 0.83 mg.cm⁻² nicotine and delivered 15 mg (30 cm²) and 10 mg (20 cm²) of nicotine during 16 h, respectively. The patches were applied in the morning on the arm or in the hip region and removed at bedtime.</p> <p>Mutual interventions: - Brochure containing advice on smoking cessation and nicotine patch therapy</p>	
Tonnesen 2000-717	<p>Study Design: Parallel</p> <p>Nicotine patch 5 mg (N): 109</p> <p>Nicotine patch 15 mg (N): 104</p> <p>Nicotine inhaler (N): 118</p> <p>Nicotine patch 15 mg + Nicotine inhaler (N): 115</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: Pharmacia & Upjohn, Helsingborg, Sweden and Danish Lung Foundation.</p> <p>Protocol availability: NR</p>	<p>Nicotine patch 5 mg: Age: 49 Female: 50% FTND-A Score: 1.6 Years Smoked: NR Cigarettes per day: 18.8</p> <p>Nicotine patch 15 mg: Age: 50 Female: 54% FTND-A Score: 1.6 Years Smoked: NR Cigarettes per day: 18.1</p> <p>Nicotine inhaler: Age: 48 Female: 54% FTND-A Score: 1.5 Years Smoked: NR Cigarettes per day: 18.1</p> <p>Nicotine patch 15 mg + Nicotine inhaler: Age: 50 Female: 57% FTND-A Score: 1.7 Years Smoked: NR Cigarettes per day: 19.3</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Nicotine patch 5 mg</p> <p>Group 2: Nicotine patch 15 mg</p> <p>Group 3: Nicotine inhaler</p> <p>Group 4: Nicotine patch 15 mg + Nicotine inhaler</p> <p>Nicotine patches 5 or 15 mg: The participants were instructed to apply one patch in the morning on the arm or in the hip region and removed at bedtime. The maximal plasma nicotine concentration of 13 ng.mL⁻¹ is attained after 8 h with the 15-mg nicotine patch.</p> <p>Nicotine inhaler: It consisted of a mouthpiece and a plastic nicotine container with, 10 mg of nicotine and the possibility of releasing up to 5 mg of nicotine when used. A plasma concentration of 10±20 ng.mL⁻¹ is attained in clinical use. The subjects were advised to use between 4 and 12 nicotine containers per day ad libitum. They were instructed to inhale deeply and to puff about 10 times more often when compared to smoking a cigarette. They were told to use the inhaler at least every hour except during sleep.</p> <p>The above NRT products were recommended to be used for up to 3 months with the possibility of continuing treatment for up to 9 months on an individual basis.</p> <p>Mutual interventions:</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> o CAR 6 Months o CAR 12 M o PPA 12 M - exhaled carbon monoxide < 10 ppm <p>Safety:</p> <ul style="list-style-type: none"> o NR

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Reference	Study Details	Patients	Intervention	Outcomes
<p>Tonnesen 2003-184</p>	<p>Study Design: Parallel</p> <p>Bupropion SR (N): 530</p> <p>Placebo 2 (N): 180</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: GlaxoSmithKline</p> <p>Protocol availability: NR</p>	<p>Bupropion SR: Age: 42.4 Female: 52% FTND Score: 5.5 Years Smoked: NR Cigarettes per day: 22.4</p> <p>Placebo: Age: 41.9 Female: 50% FTND Score: 5.4 Years Smoked: NR Cigarettes per day: 23.5</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>- < 15-minute counseling by nurse - Booklet</p> <p>Group 1: Bupropion SR</p> <p>Group 2: Placebo</p> <p>Bupropion SR or placebo: Participants were instructed to take Bupropion SR 150 mg or placebo once daily during days 1–3 of the 7-week treatment phase and then twice daily for the remainder of the treatment phase.</p> <p>Mutual interventions: - Short individual counseling at each visit (10-15 minutes) and telephone contact (5-10 minutes) - Motivational support - Take-home written material with advice</p>	<p>Efficacy: o CAR 6 Months o CAR 12 M o PPA 6 M o PPA 12 M - exhaled carbon monoxide < 10 ppm</p> <p>Safety: o DEATH o SAE</p>
<p>Tonnesen 2006 - 334</p>	<p>Study Design: Parallel</p> <p>Placebo + LBS (N): 88</p> <p>Placebo + HBS (N): 97</p> <p>Nicotine sublingual tablet + LBS (N): 95</p> <p>Nicotine sublingual tablet + HBS (N): 90</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: Mainly by Danish Medical Research Council, and partly by Pfizer Consumer Healthcare (grant support \$25,000)</p> <p>Protocol availability: NR</p>	<p>Placebo + LBS: Age: 62.5 Female: 55% FTND Score: 6.4 Years Smoked: NR Cigarettes per day: 20.2</p> <p>Placebo + HBS: Age: 61.2 Female: 53% FTND Score: 6.4 Years Smoked: NR Cigarettes per day: 19.9</p> <p>Nicotine sublingual tablet + LBS: Age: 59.2 Female: 53% FTND Score: 6.0 Years Smoked: NR Cigarettes per day: 20.1</p> <p>Nicotine sublingual tablet + HBS: Age: 61.3 Female: 49% FTND Score: 5.9 Years Smoked: NR Cigarettes per day: 18.3</p> <p>Are patients willing to quit or have they set a quit date: N</p>	<p>Group 1: Placebo + Low behavioral support (LBS)</p> <p>Group 2: Placebo + High behavioral support (HBS)</p> <p>Group 3: Nicotine sublingual tablet + LBS</p> <p>Group 4: Nicotine sublingual tablet + HBS</p> <p>Nicotine sublingual tablet or Placebo: Subjects were recommended to use nicotine sublingual tablet or placebo for 12 weeks. The recommended dose of study medication for subjects was dependent on their baseline cigarette consumption: - for those smoking ≥ 16 cigarettes per day, use 1 to 2 tablets per hour (minimum of 10 tablets and maximum of 40 tablets per day); - for those smoking 10-15 cigarettes per day, use 1 tablet per hour (6 to 30 tablets per day); - for those smoking 6 to 9 cigarettes per day were instructed to use 1 tablet per hour (3 to 10 tablets per day)and</p> <p>Low behavioral support (LBS): Four visits scheduled at study entry , after 2 weeks, and after 6 and 12 months; and six telephone calls after 1, 4, 6, 9, and 12 weeks and 9 months.</p> <p>High behavioral support (HBS): Seven visits scheduled at study entry , after 2, 4, 8, and 12 weeks, and after 6 and 12 months; and five telephone calls after 1, 6, 10, and 4.5 and 9 months.</p> <p>The above visits were on an individual basis and were conducted by trained</p>	<p>Efficacy: o CAR 12 M o PPA 6 M o PPA 12 M - exhaled carbon monoxide < 10 ppm</p> <p>Safety: o DEATH o SAE - inferred 0</p> <p>Safety data was not extractable for four groups, but available by medication groups.</p>

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Reference	Study Details	Patients	Intervention	Outcomes
			nurses. Each visit lasted 20 to 30 min, and each telephone call was 10 min. The total contact time was 2.5 and 4.5 hours for the low-support and high-support groups, respectively. Mutual interventions: - Take-home material with tips on smoking cessation.	
Tonnesen 2012 - 548	Study Design: Parallel Nicotine mouth spray (N): 318 Placebo mouth spray (N): 161 Follow-up lengths: Months Sponsor: NR Protocol availability: Y, NCT00882375	Nicotine mouth spray: Age: 47.0 Female: 43.1% FTND Score: 5.3 Years Smoked: NR Cigarettes per day: 22.7 Placebo mouth spray: Age: 46.2 Female: 45.3% FTND Score: 5.4 Years Smoked: NR Cigarettes per day: 22.7 Are patients willing to quit or have they set a quit date: Y	Group 1: Nicotine mouth spray Group 2: Placebo mouth spray Nicotine mouth spray or placebo mouth spray: During weeks 1–6, subjects were instructed to use 1-2 sprays when they normally would have smoked a cigarette or when they experienced an urge to smoke; the second spray could be used if cravings were not reduced within a few minutes of the first spray. The recommended maximum dose was four sprays per hour, and 64 sprays per day. After the 6-week full dose period, subjects were instructed to reduce spray use so that by the end of week 9 they were using half of the average number of sprays used per day during weeks 1–6, then to continue to reduce to not more than four sprays per day by week 12. Occasional use (not more than four sprays per day) was permitted during weeks 13–24. Mutual interventions: - Low-intensity counseling (< 10 minutes) at baseline visit - Brief advice (< 3 minutes) at 1, 2, 4, 6, 8, 12, 16, 20 and 24 week's visits.	Efficacy: ○ CAR 6 Months ○ CAR 12 M ○ PPA 12 M - exhaled carbon monoxide < 10 ppm Safety: ○ DEATH ○ SAE ○ CV EVENTS
Tonstad 2003 - 946	Study Design: Parallel Bupropion SR (N): 315 Placebo (N): 314 Follow-up lengths: 12 Months Sponsor: GlaxoSmithKline Protocol availability: NR	Bupropion SR: Age: 55.6 Female: 26% FTQ Score: 6.5 Years Smoked: NR Cigarettes per day: 25.2 Placebo: Age: 55.1 Female: 21% FTQ Score: 6.6 Years Smoked: NR Cigarettes per day: 25.6 Are patients willing to quit or have they set a quit date: Y	Group 1: Bupropion SR Group 2: Placebo Bupropion SR or placebo: Participants were instructed to take either bupropion SR (150 mg/day on days 1–3; 150 mg twice daily on days 4–49) or placebo during the 7-week treatment phase. Mutual interventions: - Brief motivational support (10-15 min) *11 sessions. Including the baseline visit, participants received the support at weekly visit during the 7-week treatment. During the follow-up, they received the support at 12, 26 and 52 weeks.	Efficacy: ○ CAR 6 Months ○ CAR 12 M ○ PPA 6 M ○ PPA 12 M - exhaled carbon monoxide < 10 ppm Safety: ○ DEATH ○ SAE ○ CV EVENTS
Transdermal Nicotine Study Group 1991 - 3133	Study Design: Parallel Nicotine patch 21 mg + BGSP (N): 262	Nicotine patch 21 mg + BGSP: Age: 43.1 Female: 60% Fagerstrom Score: 7.2	Group 1: Nicotine patch 21 mg + Behavioral Group Support Program (BGSP) Group 2: Nicotine patch 14 mg + BGSP	Efficacy: ○ CAR 6 Months - exhaled carbon monoxide ≤ 8 ppm

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
	<p>Nicotine patch 14 mg + BGSP (N): 275</p> <p>Placebo patch + BGSP (N): 271</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: Alza Corp.</p> <p>Protocol availability: NR</p>	<p>Years Smoked: 24.9</p> <p>Cigarettes per day: 31.1</p> <p>Nicotine patch 14 mg + BGSP:</p> <p>Age: 42.5</p> <p>Female: 59%</p> <p>Fagerstrom Score: 7.0</p> <p>Years Smoked: 24.0</p> <p>Cigarettes per day: 31.0</p> <p>Placebo patch 14 mg + BGSP:</p> <p>Age: 43.2</p> <p>Female: 63%</p> <p>Fagerstrom Score: 7.1</p> <p>Years Smoked: 24.2</p> <p>Cigarettes per day: 30.5</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 3: Placebo patch + BGSP</p> <p>Nicotine or placebo patch: The transdermal nicotine system uses rate-control membrane technology to deliver 21 or 14 mg of nicotine for 24 hours. Placebo systems contained nicotine in the drug reservoir to mimic the odor of active systems but delivered less than 1 mg of nicotine in 24 hours. Participants were instructed to apply the patch daily to a clean, dry skin site on the upper torso or to the upper, outer arm on a 7-day cycle.</p> <p>Behavioral Group Support Program: The semi-standardized group support sessions were conducted weekly during the first six weeks, then biweekly from 7 to 12 weeks. Each group could contain a maximum of 25 patients, but most had five to 15 patients. The group sessions lasted from 45 to 60 minutes and included 1 to 2 minutes per patient for review of individual progress, followed by a discussion of applicable behavior modification techniques.</p> <p>Mutual interventions: None</p>	<p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - inferred 0 ○ SAE - inferred 0 ○ CV DEATH - inferred 0 ○ COMPLETED SUICIDE - inferred 0
Tsai 2007 - 1027	<p>Study Design: Parallel</p> <p>Varenicline (N): 125</p> <p>Placebo (N): 124</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: Pfizer Inc.</p> <p>Protocol availability: Y, NCT00141167</p>	<p>Varenicline:</p> <p>Age: 39.7</p> <p>Female: 15.1%</p> <p>FTND Score: 5.2</p> <p>Years Smoked: 20.2</p> <p>Cigarettes per day: 23.4</p> <p>Placebo:</p> <p>Age: 40.9</p> <p>Female: 7.3%</p> <p>FTND Score: 5.0</p> <p>Years Smoked: 22.1</p> <p>Cigarettes per day: 22.7</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Varenicline</p> <p>Group 2: Placebo</p> <p>Varenicline or placebo: Participants were instructed to use a titration scheme over the course of 1 week, starting 0.5 mg QD for 3 days followed by 0.5 mg BID for 4 days, then with full dosage starting at the end of the first week of dosing.</p> <p>Mutual interventions:</p> <ul style="list-style-type: none"> - Educational booklet on smoking cessation - 10-minute counseling at baseline and 1, 2, 3, 4, 6, 8, 10, and 12 weeks - ≤ 5-minute brief telephone counseling at 3 days after quit date and 5, 7, 9, and 11 weeks 	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ CAR 6 Months ○ PPA 6 M - exhaled carbon monoxide ≤ 10 ppm <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - inferred 0 ○ SAE ○ CV DEATH - inferred 0 ○ COMPLETED SUICIDE - inferred 0
Tsukahara 2010 - 771	<p>Study Design: Parallel</p> <p>Varenicline (N): 16</p> <p>Nicotine patch (N): 16</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: Ministry of Education, Science and Culture of Japan (grants-in-aid No. 21590960), Central Research Institute of Fukuoka University (research grant</p>	<p>Varenicline:</p> <p>Age: 45.4</p> <p>Female: 14.3%</p> <p>FTND Score: NR</p> <p>Years Smoked: 25.4</p> <p>Cigarettes per day: 27.9</p> <p>Nicotine patch:</p> <p>Age: 46.8</p> <p>Female: 21.4%</p> <p>FTND Score: NR</p> <p>Years Smoked: 27.1</p> <p>Cigarettes per</p>	<p>Group 1: Varenicline</p> <p>0.5-2 mg daily: 0.5 mg after meals for 3 days, 0.5 mg BID for days 4-7, 1 mg BID for days 8-84</p> <p>Group 2: Nicotine patch</p> <p>52.5-17.5 mg nicotine daily: 52.5 mg for 4 weeks, 35 mg for 2 weeks, and 17.5 mg for 2 weeks</p> <p>Mutual interventions: None</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ NR <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - inferred 0 ○ SAE - inferred 0 ○ CV DEATH - inferred 0 ○ COMPLETED SUICIDE - inferred 0

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
	2005–2009) and FU-Global program (research grant 2008–2009). Protocol availability: NR	day:25.4 Are patients willing to quit or have they set a quit date: Y		
Uyar 2007 - 922	Study Design: Parallel Nicotine patch (N): 50 Bupropion SR (N): 50 Control (N): 31 Follow-up lengths: 6 Months Sponsor: NR Protocol availability: NR	Nicotine patch: Age: 36.3 Female: 20% FTND Score: 4.5 Years Smoked: NR Cigarettes per day: NR Bupropion SR: Age: 36.0 Female: 12% FTND Score: 4.8 Years Smoked: NR Cigarettes per day: NR Control: Age: 36.0 Female: 30% FTND Score: 3.9 Years Smoked: NR Cigarettes per day: NR Are patients willing to quit or have they set a quit date: Y	Group 1: Nicotine patch Nicotine transdermal patches were applied daily 21 mg for the first 2 weeks, followed by 14 mg daily for 2 weeks, and finally 7 mg daily for the next 2 weeks. Patients were advised to apply patches to the upper portion of the body, preferably on their shoulder or arms, switching after 24 hours and not to apply on the same site. Group 2: Bupropion SR Bupropion sustained release tablets were prescribed a 150 mg for the first 3 days followed by 150 mg bid for 6 weeks. Group 3: Control Mutual interventions: - Information booklet	Efficacy: ○ PPA 6 M - exhaled carbon monoxide < 10 ppm Safety: ○ DEATH - inferred 0 ○ SAE - inferred 0 ○ CV EVENTS ○ CV DEATH - inferred 0 ○ COMPLETED SUICIDE - inferred 0
Wagena 2005-2286	Study Design: Parallel Bupropion SR (N): 86 Placebo (N): 89 (* Data of Nortiptyline arm is not extracted.) Follow-up lengths: 6 Months Sponsor: Netherlands Asthma Foundation, Leusden (grant 3.2.00.21), and Netherlands Organization for Health Research and Development (grant 2200.0111) Protocol availability: NR	Bupropion SR: Age: 51.1 Female: 60.5% FTND Score: 6.2 Years Smoked: NR Cigarettes per day: 24.2 Placebo: Age: 51.3 Female: 48.3% FTND Score: 5.9 Years Smoked: NR Cigarettes per day: 23.6 Are patients willing to quit or have they set a quit date: Y	Group 1: Bupropion SR Group 2: Placebo Bupropion SR or placebo: Participants were instructed to take Bupropion SR or placebo 150 mg once daily, for days 1 through 6, followed by 150 mg twice daily for days 7 through 84. Mutual interventions: - Individual face-to face counseling (10-20 minutes) * 3 sessions from 1 of 3 master's level counselors trained in counseling smokers who want to quit, at baseline and 1 and 3 weeks after quit date - Supportive telephone call * 6 from a counselor on the quit date and 2, 4, 6, 8, and 11 weeks after quit date	Efficacy: ○ CAR 6 Months ○ PPA 6 M - Urinary cotinine ≤ 60 ng/mL Safety: ○ DEATH ○ SAE ○ CV DEATH ○ COMPLETED SUICIDE
Wallstrom 2000 - 1161	Study Design: Parallel Nicotine sublingual tablet (N): 123 Placebo (N): 124 Follow-up lengths: 12 Months Sponsor: NR Protocol availability: NR	Nicotine sublingual tablet: Age: 44.5 Female: 63% FTQ Score: 6.3 Years Smoked: 26.1 Cigarettes per day: 18.2 Placebo: Age: 44.7 Female: 3.6% FTND Score: 7.1 Years Smoked: 26.9 Cigarettes per day: 20.6	Group 1: Nicotine sublingual tablet Group 2: Placebo Nicotine sublingual tablet or placebo: Participants were instructed to use the medication based on their baseline nicotine dependence. Highly dependent smokers who scored ≥ 7 on the Fagerström Tolerance Questionnaire (FTQ) were recommended to use two tablets (4 mg of nicotine) per hour, up to a maximum of 40 tablets per day, whereas low dependent smokers with an FTQ score < 7 were	Efficacy: ○ CAR 6 Months ○ CAR 12 M - exhaled carbon monoxide < 10 ppm Safety: ○ DEATH - inferred 0 ○ SAE ○ CV DEATH - inferred 0 ○ CV EVENTS ○ COMPLETED SUICIDE - inferred 0

Reference	Study Details	Patients	Intervention	Outcomes
		Are patients willing to quit or have they set a quit date: Y	<p>recommended to use one tablet per hour, up to a maximum of 20 tablets/day. Subjects were advised to use the full treatment dose for 3 months. After this time-point, treatment could be tapered off up to the 6-month visit if necessary; at the 3-month visit subjects were instructed to reduce the dose by 25% during each of the following months (i.e. months 3–4, 4–5 and 5–6). No further medication was dispensed after the 6-month visit.</p> <p>Mutual interventions:</p> <ul style="list-style-type: none"> - A guide to smoking cessation - 5-minute counseling * 8 sessions (at baseline, and visits after 1, 2, 3, and 6 weeks, and after 3 and 6, and 12 months). 	
Wang 2009 - 384	<p>Study Design: Parallel</p> <p>Varenicline (N): 165</p> <p>Placebo (N): 168</p> <p>Follow-up lengths: 24 Months</p> <p>Sponsor: Pfizer Inc.</p> <p>Protocol availability: Y, NCT00371813</p>	<p>Varenicline:</p> <p>Age: 39.0</p> <p>Female: 3.0%</p> <p>FTND Score: 5.27</p> <p>Years Smoked: 20.3</p> <p>Cigarettes per day: 23.4</p> <p>Placebo:</p> <p>Age: 38.5</p> <p>Female: 7.3%</p> <p>FTND Score: 5.51</p> <p>Years Smoked: 19.6</p> <p>Cigarettes per day: 21.3</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Varenicline</p> <p>Group 2: Placebo</p> <p>Varenicline or placebo: Participants were instructed to use a titration scheme over the course of 1 week, starting one 0.5 mg tablet for the first 3 days, followed by two 0.5 mg tablets for 4 days, then with two 1 mg tablets from 8 to 84 days.</p> <p>Mutual interventions:</p> <ul style="list-style-type: none"> - Educational booklet on smoking cessation - ≤ 10-minute counseling* 20 sessions <ul style="list-style-type: none"> a. During the 12-week treatment: clinical visits at baseline, and 1, 2, 3, 4, 6, 8, 9, 10, 11, and 12 weeks, and telephone contacts at 5 and 7 weeks b. During the 12-week follow-up: clinical visits at 13, 16, 20 and 24 weeks, and telephone contacts at 14, 18 and 22 weeks 	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ CAR 6 Months - exhaled carbon monoxide ≤ 10 ppm <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH ○ SAE ○ CV DEATH ○ COMPLETED SUICIDE
Ward 2012 - 394	<p>Study Design: Parallel</p> <p>Nicotine patch + Behavioral cessation counseling (N): 134</p> <p>Placebo + Behavioral cessation counseling (N): 135</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: PHS grant 1R01DA024876</p> <p>Protocol availability: Y, NCT01085032</p>	<p>Nicotine patch + Behavioral cessation counseling:</p> <p>Age: 39.9</p> <p>Female: 24.6%</p> <p>FTND Score: 5.9</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 28.1</p> <p>Placebo + Behavioral cessation counseling:</p> <p>Age: 40.0</p> <p>Female: 18.5%</p> <p>FTND Score: 5.6</p> <p>Years Smoked: NR</p> <p>Cigarettes per day: 27.4</p>	<p>Group 1: Nicotine patch + Behavioral cessation counseling</p> <p>Group 2: Placebo + Behavioral cessation counseling</p> <p>Nicotine or placebo patch: Participants were instructed to use a 24-hour dosing and step-down algorithm. Patients who smoked ≥10 cigarettes/day received a 2-week supply of 21-mg patches, then a 2-week supply of 14-mg patches, then a 2-week supply of 7-mg patches. Patients who smoked 5–9 cigarettes per day received a 4-week supply of 14-mg patches, then a 2-week supply of 7-mg patches.</p>	<p>Efficacy:</p> <ul style="list-style-type: none"> ○ CAR 6 Months ○ CAR 12 M ○ PAR 6 M ○ PAR 12 M - exhaled carbon monoxide <10 ppm <p>Safety:</p> <ul style="list-style-type: none"> ○ DEATH - inferred 0 ○ SAE ○ CV DEATH - inferred 0 ○ COMPLETED SUICIDE - inferred 0

Reference	Study Details	Patients	Intervention	Outcomes
		Are patients willing to quit or have they set a quit date: Y	Mutual interventions: - Behavioral cessation counseling: A brief '5A'-based intervention (ask, advise, assess, assist arrange) for all smokers at each visit, including 3 individual, in-person sessions (approximately 30 minutes each) and 5 brief (approximately 10-minute) phone calls, which were delivered by the cessation coordinator. Intervention contacts began 4 days prior to, and ended 45 days after, quit day. - treatment manual, as online supporting information	
Warner 2005-1138	Study Design: Parallel Nicotine patch (N): 59 Placebo (N): 62 Follow-up lengths: 6 Months Sponsor: Minnesota Partnership for Action Against Tobacco, Minneapolis, Minnesota (grant No. RC 2002-0020), and Mayo Foundation, Rochester, Minnesota. Protocol availability: NR	Nicotine patch: Age: 52.2 Female: 50% FTND Score: NR Years Smoked: NR Cigarettes per day: 22.8 Placebo: Age: 47.1 Female: 48% FTND Score: NR Years Smoked: NR Cigarettes per day: 23.5 Are patients willing to quit or have they set a quit date: N	Group 1: Nicotine patch Group 2: Placebo Nicotine or placebo patch: Participants smoking 10–20 cigarettes/day received a patch dose of 21 mg/day, those smoking 21–40 cigarettes/day received a dose of 35 mg/day (requiring two patches), and those smoking more than 40 cigarettes/day received a dose of 42 mg/day. Participants started the patch on the morning of surgery, and continued to 30 days after discharge. Mutual interventions: None	Efficacy: ○ NR Safety: ○ DEATH - inferred 0 ○ SAE ○ CV DEATH - inferred 0 ○ COMPLETED SUICIDE - inferred 0
Wennike 2003-1395	Study Design: Parallel Nicotine gum (N): 205 Placebo (N): 206 Follow-up lengths: 2 Years Sponsor: Pharmacia AB, Sweden Protocol availability: NR	Nicotine gum: Age: 45 Female: 65% FTND Score: 6.4 Years Smoked: 28.0 Cigarettes per day: 24 Placebo: Age: 44 Female: 59% FTND Score: 6.4 Years Smoked: 27.9 Cigarettes per day: 24 Are patients willing to quit or have they set a quit date: N	Group 1: Nicotine gum Group 2: Placebo Nicotine or placebo gum: Subjects who scored 5 or less in the Fagerström Test for Nicotine Dependence (FTND) were instructed to use either nicotine 2 mg gum or placebo, whereas those who scored 6–10 used nicotine 4 mg gum or placebo. Treatment was free of charge and provided for <i>ad libitum</i> use for up to 12 months. Mutual interventions: - Moderate behavioural smoking reduction information - Discussion on general implications of smoking	Efficacy: ○ PPA 12 M ○ PPA 24 M - exhaled carbon monoxide < 10 ppm Safety: ○ DEATH - inferred 0 ○ CV DEATH - inferred 0 ○ COMPLETED SUICIDE - inferred 0
Westman 1993 - 1917	Study Design: Parallel Nicotine patch (N): 79 Placebo (N): 80 Follow-up lengths: 6 Months Sponsor: TBS Laboratories, Piscataway, NJ.	Nicotine patch: Age: 41.9 Female: 57.0% FTQ Score: 6.6 Years Smoked: 22.5 Cigarettes per day: 28.9 Placebo: Age: 41.7 Female: 56.2%	Group 1: Nicotine patch Group 2: Placebo Nicotine or placebo patch: Participants were instructed to wear two patches during the first 4 weeks, which delivered approximately 25 mg of nicotine per day. For the next 2 weeks, they would wear one patch daily, which delivered 12.5 mg of	Efficacy: ○ CAR 6 Months - exhaled carbon monoxide < 8 ppm Safety: ○ DEATH - inferred 0 ○ SAE - inferred 0 ○ CV DEATH - inferred 0 ○ COMPLETED SUICIDE -

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
	Protocol availability: NR	FTQ Score: 6.6 Years Smoked: 23.1 Cigarettes per day:30.8 Are patients willing to quit or have they set a quit date: Y	nicotine per day. Patches were to be worn on the hairless area of the chest and sides of the body. Mutual interventions: Self-help material concerning the benefits of smoking cessation, nicotine withdrawal symptoms, strategies for coping, and relapse prevention. Supportive telephone counseling *4 sessions, at 1, 2, 3, and 5 weeks. Each session contained supportive advice individualized to the subject's needs. Two brief (< 5 minutes) encouragement or suggestions provided by the counselors.	inferred 0
Williams 2007-793	Study Design: Parallel Varenicline (N): 251 Placebo (N): 126 Follow-up lengths: 53 Weeks Sponsor: Pfizer Inc. Protocol availability: Y, NCT00143299	Varenicline: Age: 48.2 Female: 49.4% FTND Score: 5.50 Years Smoked: 30.7 Cigarettes per day: 23.2 Placebo: Age: 46.6 Female: 51.6% FTND Score: 6.05 Years Smoked: 29.9 Cigarettes per day:23.4 Are patients willing to quit or have they set a quit date: Y	Group 1: Varenicline Group 2: Placebo Varenicline or placebo: Participants were instructed to use a titration scheme over the course of 1 week, starting 0.5 mg QD in the evening for 3 days followed by 0.5 mg BID for 4 days. From day 8, participants received 1 mg BID until the end of 52 weeks. Mutual interventions: - Educational booklet on smoking cessation - ≤ 10-minute counseling at baseline, weekly visits from 1 to 8 weeks, every 4-week visits from 12 to 52 weeks, and 53 weeks	Efficacy: ○ PPA 24 M ○ PPA 52 M ○ PPA 53 M - exhaled carbon monoxide ≤ 10 ppm Safety: ○ DEATH ○ SAE ○ CV DEATH ○ CV EVENTS ○ COMPLETED SUICIDE
Williams 2011-654 + Pfizer 2011	Study Design: Parallel Varenicline (N): 85 Placebo (N): 43 Follow-up lengths: 6 Months Sponsor: Pfizer Inc. Protocol availability: Y, NCT00644969	Varenicline: Age: 40.2 Female: 22.6% FTND Score: 6.6 Years Smoked: 23.7 Cigarettes per day: 23.5 Placebo: Age: 43.0 Female: 23.3% FTND Score: 6.3 Years Smoked: 24.9 Cigarettes per day:22.3 Are patients willing to quit or have they set a quit date: Y	Group 1: Varenicline Group 2: Placebo Varenicline or placebo: Participants were instructed to use a titration scheme over the course of 1 week, starting 0.5 mg QD in the evening for 3 days and followed by 0.5 mg BID (1 morning, 1 evening) for 4 days. From the week 2 to the week 12 visit, patients took two 1-mg tablets BID (1 morning, 1 evening) daily. Mutual interventions: - Smoking cessation counseling a. During 12-week treatment period: ≤ 30 minutes, at weekly clinical visits b. During 12-week no treatment, follow-up period: Four brief counseling at clinic visits at 13, 16, 20 and 24 weeks, supplemented with brief telephone contacts at 14, 18, and 22 weeks. Each session lasted less than 10 minutes, was one-to-one and tailored to individual needs,	Efficacy: ○ PPA 6 M - exhaled carbon monoxide ≤ 10 ppm Safety: ○ DEATH ○ SAE ○ CV DEATH ○ CV EVENTS ○ SUICIDAL IDEATION ○ COMPLETED SUICIDE

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention and was conducted by the same counselors.	Outcomes
Wittchen 2011-28	<p>Study Design: Parallel</p> <p>Minimal intervention (N): 81</p> <p>Cognitive-behavioral therapy (N): 175</p> <p>NRT + CBT (N): 105</p> <p>Bupropion + CBT (N): 108</p> <p>Follow-up lengths: 6 Months</p> <p>Sponsor: Federal Ministry of Education and Research (Grant: 01EB 0440 - 0441, 01EB 0142)</p> <p>Protocol availability: Y, NCT00141167</p>	<p>Minimal intervention: Age: 41.5 Female: 46.2% FTND Score: 3.2 Years Smoked: NR Cigarettes per day: 18.1</p> <p>Cognitive-behavioral therapy Age: 42.4 Female: 50.9% FTND Score: 4.0 Years Smoked: NR Cigarettes per day: 18.7</p> <p>NRT + CBT Age: 41.9 Female: 57.8% FTND Score: 3.2 Years Smoked: NR Cigarettes per day: 20.1</p> <p>Bupropion + CBT Age: 45.0 Female: 50.9% FTND Score: 3.7 Years Smoked: NR Cigarettes per day: 21.8</p> <p>Placebo: Age: 40.9 Female: 7.3% FTND Score: 5.0 Years Smoked: 22.1 Cigarettes per day: 22.7</p> <p>Are patients willing to quit or have they set a quit date: Y</p>	<p>Group 1: Minimal intervention (MI)</p> <p>Group 2: Cognitive-behavioral therapy, CBT</p> <p>Group 3: NRT + CBT</p> <p>Group 4: Bupropion + CBT</p> <p>Minimal intervention: Two brief (5–10 minutes) feedback sessions (at 2 and 12 weeks), in which the non-smoking diary for the last weeks was reviewed, along with a repeat of the motivational intervention and the motivational sheet information. Subjects who had stopped were reinforced; those who had not yet stopped smoking were encouraged to do so.</p> <p>Cognitive-behavioral therapy: In addition to MI elements, participants also received 4-5 counseling sessions (20-30 minutes per session, at baseline, 2, 4, 6 (optional) and 12 weeks), cognitive-behavioral self-help manual and homework exercises. The counseling sessions were conducted by physicians.</p> <p>NRT: Physicians were allowed to prescribe a nicotine-replacement product in accordance with the subject's choice (patches: NiQuitin 21-mg, 14-mg, 7-mg; Nicotinell 52.5-mg, 35-mg, 17.5-mg; Nicorette 24.9-mg, 16.6-mg, 8.3-mg; gum: Nicotinell 2-mg, 4-mg; Nicorette: 2-mg, 4-mg; nasal spray 10-mg/10 ml). The intervention period was 9 to 12 weeks.</p> <p>Bupropion: The dose schedule for bupropion sustained-release was one 150 mg per day for the first six days, and two 150 mg per day thereafter, until 9 to 12 weeks.</p> <p>Mutual interventions: - standardized face-to-face oral brief motivational intervention to quit smoking (<3 minutes) - Motivational information sheet</p>	<p>Efficacy: o NR</p> <p>Safety: o DEATH - inferred 0 o SAE o CV DEATH - inferred 0 o COMPLETED SUICIDE - inferred 0</p>
Wong 2012-755	<p>Study Design: Parallel</p> <p>Varenicline (N): 151</p> <p>Placebo (N): 135</p> <p>Follow-up lengths: 12 Months</p> <p>Sponsor: Department of Anesthesia,</p>	<p>Varenicline: Age: 51.9 Female: 45.0% FTND Score: 4.8 Years Smoked: NR Cigarettes per day: 17.8</p> <p>Placebo: Age: 53.3</p>	<p>Group 1: Varenicline</p> <p>Group 2: Placebo</p> <p>Varenicline or placebo: The patients were instructed to initiate the study medication (or placebo) exactly 1 week before the target quit date, 24 hours before surgery. They received the study medication or placebo for a total of 12 weeks, including a 1-week</p>	<p>Efficacy: o PPA 6 M o PPA 12 M - Biochemically confirmed self-report of no smoking or use of any nicotine containing products, but the approach and cut-off point were not provided</p>

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
	Toronto Western Hospital, University Health Network, University of Toronto; University Health Network Foundation, Toronto, Ontario, Canada; and Pfizer Canada Incorporated, Kirkland, Quebec, Canada Protocol availability: Y, NCT01320462	Female: 49.6% FTND Score: 4.9 Years Smoked: NR Cigarettes per day: 17.0 Are patients willing to quit or have they set a quit date: Y	titration as follows: days 1–3: 0.5 mg once daily; days 4–7: 0.5 mg twice daily; and days 8–12 weeks: 1 mg twice daily. Mutual interventions: - 15-minute standardized counseling *2 sessions, one occurred before the operation and another one 24 hours after surgery. The counseling sessions were conducted by trained and certified research coordinators. - Follow-up telephone brief counseling (< 5 minutes)*15: weekly call for the first 4 weeks, at the end of 8 weeks, then every 4 weeks from 3 to 12 months.	Safety: o DEATH o SAE o CV EVENTS
Zellweger 2005 - 240	Study Design: Parallel Bupropion SR (N): 518 Placebo (N): 172 Follow-up lengths: 12 Months Sponsor: NR Protocol availability: NR	Bupropion SR: Age: 40.3 Female: 64% FTQ Score: 6.1 Years Smoked: NR Cigarettes per day: 22.3 Placebo: Age: 40.3 Female: 64% FTQ Score: 6.2 Years Smoked: NR Cigarettes per day: 23.8 Are patients willing to quit or have they set a quit date: Y	Group 1: Bupropion SR Group 2: Placebo Bupropion SR or placebo: Participants were instructed to take bupropion SR or placebo (days 1-3, 150 mg/day; days 4-49, 150 mg twice daily) or placebo (twice daily) throughout the 7-week treatment phase. Participants began taking their study medication the day following the baseline visit. Mutual interventions: - Weekly brief individualized motivational support (10-15 minutes) in 7-week treatment period	Efficacy: o CAR 12 Months o PPA 6 M o PPA 12 M - exhaled carbon monoxide < 10 ppm Safety: o DEATH - inferred 0 o SAE o CV EVENTS o CV DEATH - inferred 0 o COMPLETED SUICIDE - inferred 0
Zernig 2008-2024	Study Design: Parallel Bupropion SR (N): 413 Psychotherapy (N): 366 Follow-up lengths: 12 Months Sponsor: Governmental Styrian Regional Health Care System (Steiermaerkische Gebietskrankenkasse, STGKK), and partly supported by Austrian Science Fund Protocol availability: Y, EudraCT-Nr. 2005-006189-32 (European Medicines Agency)	Bupropion SR: Age: 43.6 Female: 58.1% FTQ Score: 5.5 Years Smoked: 26.1 Cigarettes per day: NR Psychotherapy: Age: 43.3 Female: 56.6% FTQ Score: 5.3 Years Smoked: 26.3 Cigarettes per day: NR Are patients willing to quit or have they set a quit date: Y	Group 1: Bupropion SR Participants were instructed to start a dose run-up period of 1 week to a final 150 mg bupropion SR twice daily on day 7, and had the treatment for 9 weeks. Group 2: Psychotherapy PDM® is a manual-based short psychotherapeutic intervention that was developed according to psychodynamic theory but is administered and monitored in a cognitive behavioural setting. It consists of very brief psychoeducation and supervised training in autosuggestion techniques (guided imageries) that are administered during a single 1.5-day programme (day 1, 0900–2000 hours; day 2, 0900–1300 hours). Groups of approximately 30 participants were introduced to five guided imagery scenarios aimed at strengthening the following psychotherapeutically defined aspects of functioning: (i) king/queen: to enhance self-management, decidedness, assertiveness, self-	Efficacy: o CAR 6 Months o CAR 12 M o PPA 6 M o PPA 6 M - exhaled carbon monoxide ≤ 9 ppm Safety: o DEATH - inferred 0 o SAE - inferred 0 o CV DEATH - inferred 0 o COMPLETED SUICIDE - inferred 0

[A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF PHARMACOLOGIC INTERVENTIONS FOR SMOKING CESSATION]

Reference	Study Details	Patients	Intervention	Outcomes
			<p>determination, self-assurance; (ii) the inner child: to enhance feelings of security and competence in relationships and team competence; (iii) organs: to stimulate natural functions of organs and the awareness of bodily functions; (iv) gold: to enhance self-worth and trust in one's abilities; and (v) freedom: to enhance autonomy. Guided imagery and psychoeducation were accompanied by exposure to an orange-lemon-cinnamon scent (delivered by oil burners) as a reminder cue to facilitate retrieval of the contents of the training programme and the associated bodily reactions, emotions and cognitions.</p> <p>Mutual interventions: None</p>	