

## NICE Guidance title: Tobacco: harm-reduction approaches to smoking

### Short title: Tobacco: harm reduction

#### Review 3: The effectiveness of long-term harm reduction approaches without the prior intention of quitting

### APPENDICES

**November 2021:** NICE guidelines PH45 (June 2013) PH48 (November 2013) have been updated and replaced by NG209.

The recommendations labelled [2013] or [2013, amended 2021] in the updated guideline were based on these evidence reviews.

See [www.nice.org.uk/guidance/NG209](http://www.nice.org.uk/guidance/NG209) for all the current recommendations and evidence reviews.

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#### Version

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**APPENDIX A – INCLUDED STUDIES - EVIDENCE TABLES**

<p><b>First author and year:</b> Audrain-McGovern 2011</p> <p><b>Aim of study:</b> To evaluate the efficacy of motivational interviewing (MI) compared with structured brief advice (SBA) for adolescent smoking behaviour change.</p> <p><b>Study Design :</b> Quasi-RCT</p> <p><b>Quality score:</b> +</p> <p><b>External validity score:</b> +</p>	<p><b>Setting:</b> USA. Three adolescent medical sites in and around Pittsburgh.</p> <p><b>Participants:</b> 355 adolescents recruited and self-recruited through flyers and brochures distributed throughout the three sites or referred by their physicians. 54% female, 45% black, 15% other/ mixed race, 40% white, 12% Hispanic. Average CPD 9.80.</p> <p><b>Inclusion:</b> Aged 14-18 years, smoking at least 1 cigarette a month and at least 100 cigarettes in their lifetime, fluency in spoken English, willingness by those aged 14-17 to obtain parental/legal guardian consent.</p> <p><b>Exclusion:</b> Severe mental retardation.</p> <p><b>Motivation of participants:</b> Interest in quitting smoking was not required to participate.</p>	<p><b>Method of allocation:</b> Not stated</p> <p><b>Intervention(s):</b> Three 45-minute office sessions and two 30-minute office or telephone sessions over 12 weeks. Intervention based on motivational enhancement therapy (MET), which adds personalised feedback about assessment results and collaborative development of a formal change plan to standard Motivational Interviewing principles and techniques.</p> <p><b>Control:</b> 5 sessions of structured brief advice (SBA) focusing on “5 A’s” for those interested in quitting and “5 R’s” for those who were not. In each session, 5 A’s/R’s followed by review of self-help materials and a brief check-in to see if help was needed to gain access to services.</p> <p><b>Sample sizes:</b> MI: 177 SBA: 178 (49% female, 50% black) in SBA group.</p> <p><b>Baseline comparisons:</b> Similar except for Hispanic ethnicity.</p> <p><b>Study power:</b> Power calculation not reported.</p>	<p><b>Primary outcomes:</b> Self-reported attempts to reduce and quit smoking Self-reported reduction in CPD. Cotinine-validated 7-day point-prevalence smoking abstinence</p> <p><b>Follow-up periods:</b> End of treatment (week 12) 24-week follow-up</p> <p><b>Method of analysis:</b> Bivariate associations evaluated using <math>\chi^2</math> and <i>t</i>-test analyses. Multivariate analysis using mixed-effects regression models. Variables included as potential predictors in multivariate models for each of four outcomes if the bivariate relationship between predictor and outcome was <math>P \leq .25</math> at either of 2 post-treatment follow-ups. Treatment and effect of time included in each model. Stepwise elimination removed predictor variables from specific regression model if variable had <math>P &lt; .20</math> and retained predictor variable at <math>P &lt; 0.10</math> at re-entry. After main effects model established for a smoking outcome, treatment according to time interaction was tested and retained in the model only if significant.</p>	<p><b>Primary:</b> Treatment group was significantly associated with attempting to cut back (<math>p=0.15</math> at week 24, <math>\chi^2=1.12</math>, <math>p=0.29</math> at week 12). 61% of participants attempted to cut back on smoking at 12 weeks and 64% at 24-week follow-up. White adolescents ~ 80% less likely to attempt to cut back than black adolescents (OR= 0.21, 95% CI 0.08, 0.53). Adolescents in planning stage or higher stage of readiness to cut back at baseline almost 3 times more likely to attempt to cut back their smoking (OR= 2.87, 95% CI 1.26, 6.52). Overall, 66% reported an attempt to quit smoking at 12 weeks and 74% reported an attempt to quit at 24-weeks. White adolescents &gt;80% less likely to attempt to quit compared with black adolescents (OR=0.17 95% CI 0.06, 0.46). Adolescents who received MI ~60% less likely to try to quit than adolescents who received SBA (OR=0 .41, 95% CI 0.17, 0.97). Adolescents in planning or higher stage of readiness to quit smoking at baseline almost 3 times more likely to attempt to quit smoking (OR= 3.13 95% CI: 1.19, 8.26]). 74% of participants had reductions from baseline to the 24- week follow-up and 16% increased. 78% had reductions in smoking from baseline to 12-week follow-up; and 12% increased.</p>	<p><b>Limitations (author):</b> Participants &gt;18 required to have written parental consent to participate which may have affected some characteristics of the sample. Unclear how many adolescents not interested in participating because parents unaware of their smoking. Although the quality of the MI delivered was good, values that were less than ideal on 2 fidelity metrics slightly reduced the confidence in the findings.</p> <p><b>Limitations (review team):</b> No information on allocation method. No power calculation reported.</p> <p><b>Evidence gaps:</b> Which adolescents benefit from which types of intervention?</p> <p><b>Funding sources:</b> Grant from Commonwealth of Pennsylvania Department of Health.</p> <p><b>Applicable to UK?</b> Yes</p>
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		<p><b>Intervention delivery:</b> Both MI and SBA delivered by trained counsellors.</p>		<p>MI adolescents had greater reduction in CPD than those who received SBA (5.3 fewer versus 3.3 fewer). At 24 weeks 12% participants reported 7-day point prevalence abstinence (6% cotinine-verified). At 12 weeks 15% participants reported 7-day point prevalence abstinence (6% cotinine-verified).</p> <p><b>Attrition:</b> 5.1% 163/177 in MI group and 174/178 in SBA group completed 24-week follow-up.</p>	
<p><b>First author and year:</b> Batra 2005 Landfeldt 2003 (poster)</p> <p><b>Aim of study:</b> To investigate the efficacy of 4mg nicotine gum in reducing cigarette consumption among smokers not ready to quit.</p> <p><b>Study Design :</b> Quasi-RCT</p> <p><b>Quality score:</b> +</p> <p><b>External validity score:</b> +</p>	<p><b>Setting:</b> Two medical centres in Germany and Switzerland</p> <p><b>Participants:</b> 364 participants, 40.6% female, mean age 43 years. Mean age of onset of smoking 17.5 years, mean CPD at baseline = 28.</p> <p><b>Inclusion:</b> ≥ 18 years, consuming ≥20 cigarettes a day, smoking regularly for ≥3 years, CO = ≥15 ppm, ≥one failed quit attempt within two years of study but not within previous six months.</p> <p><b>Exclusion:</b> Intent to quit smoking within the next month, current use of nicotine replacement therapy, current involvement in other smoking cessation or smoking reduction programs, having unstable angina pectoris or a myocardial infarction within the preceding three months,</p>	<p><b>Method of allocation:</b> Not stated</p> <p><b>Intervention(s):</b> Intervention participants given 4mg nicotine gum to be used as desired for ≤12 months. Participants instructed to use gum on urge to smoke and to chew 6-24 pieces daily. Told goal was to reduce smoking as much as possible by substituting nicotine in cigarettes with nicotine gum. Participants informed that smoking reduction was the goal but not that 50% reduction was study objective.</p> <p><b>Control:</b> As per intervention group but participants given placebo gum.</p> <p><b>Sample sizes:</b> 953 participants screened; 364 eligible I = 184</p>	<p><b>Primary outcomes:</b> Sustained smoking reduction (decrease ≥50% CPD from baseline) at 6-week, 4-month and 13-month follow-ups. Self-reported reduction CO verified.</p> <p><b>Secondary outcomes:</b> 1- and 7-day point-prevalence abstinence CO verified; intention to quit; cardiovascular risk markers at baseline, 4- and 12-months.</p> <p><b>Follow-up periods:</b> 6 weeks, 4 months and 13 months</p> <p><b>Method of analysis:</b> ITT analysis. Treatment efficacy (proportion of successful reducers) analysed using Fisher exact test, supplemented by point estimates and 95% confidence intervals. Changes from baseline for continuous variables analysed using Wilcoxon signed test. Linear</p>	<p><b>Primary:</b> 13 months sustained smoking reduction (from week 6) excluding quitters (p=0.088): I = 7.1% C = 2.8% 13 month CPD (excluding abstainers): I = 9.14 (+/-6.3) C = 5.25 (+/-5.5)</p> <p><b>Secondary:</b> Seven day point-prevalence abstinence at 13 months (p=0.015): I = 10.9% C = 3.9%</p> <p>One day point-prevalence abstinence at 13 months (p=0.012). I = 12% C = 4.5%</p> <p>At 13 months, 60% agreed that study participation had increased their interest in quitting.</p> <p>At 13 months, sustained reduction in CO levels of ≥20% (p=0.012): I = 13.6% C = 5.6%</p> <p>No statistically significant changes in</p>	<p><b>Limitations (author):</b> Uncertainty whether the reduction rate of 8% is sufficient to establish clinical benefit. High attrition rates.</p> <p><b>Limitations (review team):</b> Desired sample size not reached. No information on allocation method. Three of five authors are Pfizer employees.</p> <p><b>Evidence gaps:</b> Whether the offer of smoking reduction could impede abstinence-motivated smokers. Whether successful reduction can be maintained without nicotine substitution or whether nicotine replacement therapy has to be used permanently to guarantee success.</p>

	<p>receiving psychiatric treatment or medication, and co-occurring alcohol or drug problems.</p> <p><b>Motivations of participants</b> Smokers willing to change their smoking behaviour, but unwilling to quit.</p>	<p>C= 180</p> <p><b>Baseline comparisons:</b> No differences between groups for smoking characteristics or demographics.</p> <p><b>Study power:</b> Power analysis indicated that 197 participants were needed in each group to yield a power of 0.80 at a 2-tailed significance level of .05. This calculation was based on a hypothesis that 20% of the nicotine treatment group and 10% of the placebo group achieve sustained reduction in smoking between the 6-week and 4-month follow-up visits. This sample size was not quite achieved.</p> <p><b>Intervention delivery:</b> Not stated.</p>	<p>models to regress changes in outcome variables on different covariates (eg treatment status, mean cigarette reduction, mean CO reduction, age and sex). Categorical variables investigated using sign test. Comparisons of different sub-groups with respect to score changes made using Kruskal-Wallis test.</p>	<p>mean levels of any cardiovascular risk markers between baseline and month 12 in 20 successful reducers.</p> <p>No serious adverse event related to nicotine treatment, and no discontinuations reportedly resulting from side effects.</p> <p><b>Attrition:</b> 53% of intervention and 38% of control group seen for the 13 month follow-up. 82 additional participants followed by telephone or letter at 13 months (total of 249 participants completed the study).</p> <p><b>Meta-analysis data:</b> 13 months sustained smoking reduction: I = 13/184; C = 5/180 CPD as percentage of baseline: I = 55 (mean 36, SD 33.1); C = 39, (mean 49, SD 33.9) (p&lt;0.0001) 7-day point prevalence abstinence at 13 months: I = 20/184; C = 7/180.</p>	<p><b>Funding sources:</b> The study was supported by Pfizer consumer Healthcare. Batra has received research funding from Pfizer Consumer Healthcare for other research projects. Landfeldt, Westin and Danielsson are Pfizer employees.</p> <p><b>Applicable to UK?</b> Yes, although participants had to make several clinic visits which might be burdensome.</p>
<p><b>First author and year:</b> Beard 2012 in press</p> <p><b>Aim of study:</b> To determine whether providing smokers with a personal monitor for measuring expired-air carbon monoxide (CO) concentrations would be a feasible method of achieving a reduction in smoke intake.</p> <p><b>Study Design :</b> Uncontrolled before and after study</p> <p><b>Quality score:</b></p>	<p><b>Setting:</b> UK – community based</p> <p><b>Participants:</b> 10 smokers recruited from a subset of the Smoking Toolkit Study. M = 6/10; average age 48.6 years (SD 11.56); 14.1 CPD (SD 6.03); 7/10 in full time employment; 2/10 currently using NRT.</p> <p><b>Inclusion:</b> Original subset: smokers who were unwilling or unable to quit.</p> <p><b>Exclusion:</b> None stated</p>	<p><b>Method of allocation:</b> No allocation</p> <p><b>Intervention(s):</b> Participants given a CO monitor and asked to use it regularly throughout the day for 6 weeks with the aim of maintaining a CO reading &lt;10ppm. Advised to use nicotine replacement therapy, but this was not provided.</p> <p>Instructed to record CPD, monitor and NRT usage, CO levels and attempts to keep reading &lt;10ppm</p>	<p><b>Primary outcomes:</b> CPD and abstinence</p> <p><b>Follow-up periods:</b> 6 weeks from baseline</p> <p><b>Method of analysis:</b> T-test analyses to determine any significant difference in CPD from baseline at 2 and 6 weeks. Descriptive statistics for other findings</p>	<p><b>Primary:</b> Average CPD reduced from 14.1 (SD 6.03) at baseline to 9.5 (SD 5.50) at 6-week follow up (p=0.127) 5/10 had made a quit attempt and 1/10 participants abstinent at 6 weeks.</p> <p><b>Attrition:</b> 9/10 participants completed follow-up</p>	<p><b>Limitations (author):</b> None stated</p> <p><b>Limitations (review team):</b> Small uncontrolled pilot study with very limited follow-up</p> <p><b>Evidence gaps:</b> A controlled trial with long-term follow up</p> <p><b>Funding sources:</b> CO monitors provided by Bedfont Scientific. Payments to participants from CRUK research grant. EB received conference funding from Pfizer.</p>

<p>– <b>External validity score:</b> –</p>	<p><b>Motivation of participants:</b> 9/10 wanted to stop smoking and all had made ≥1 quit attempt.</p>	<p><b>Control:</b> No control group <b>Sample sizes:</b> 10 <b>Baseline comparisons:</b> Not applicable – no control group <b>Study power:</b> None provided. <b>Intervention delivery:</b> University researchers</p>			<p>RW research, consultancy and speaker fees from companies that develop and manufacture smoking cessation medications. Also has a share of a patent for a novel nicotine delivery device. <b>Applicable to UK?</b> Yes</p>
<p><b>First author and year:</b> Benowitz 1998 <b>Aim of study:</b> To determine whether transdermal nicotine suppresses nicotine intake from <i>ad libitum</i> cigarette smoking in a dose-dependent manner. <b>Study Design :</b> Controlled study (crossover design) <b>Quality score:</b> – <b>External validity score:</b> –</p>	<p><b>Setting:</b> USA - Clinical Study Centre at San Francisco General Hospital <b>Participants:</b> 11/12 healthy adult males recruited by newspaper adverts. Mean age 41 (SD+/- 6), average 29 CPD (range, 14 +/- 40) <b>Inclusion:</b> Not clearly stated <b>Exclusion:</b> Chronic illness, medication use or drug or alcohol abuse. <b>Motivation of participants:</b> No desire to quit smoking.</p>	<p><b>Method of allocation:</b> Not reported <b>Intervention(s):</b> Crossover design. Four treatment blocks of 5 days each: 0, 1,2 or 3 21mg nicotine patches, representing daily doses of 0, 21, 42 and 63mg nicotine/ day, Higher doses gradually increased over 3 days: 21mg treatment: 21mg patches received for all 5 days; 42mg treatment: 21mg day 1, 42mg days 2-5; 63mg treatment: 21mg day1, 42 mg day 2, 63mg days 3-5. <b>Control:</b> Crossover design with placebo patch. <b>Sample sizes:</b> 11/12 <b>Baseline comparisons:</b> No comparisons provided. <b>Study power:</b> Power calculation not</p>	<p><b>Primary outcomes:</b> Cigarette consumption, plasma nicotine and blood carboxyhaemoglobin. <b>Follow-up periods:</b> 5 day intervention period no further follow-up. <b>Method of analysis:</b> Main hypothesis tested by repeated measures analysis of variance, comparing four patch dose treatment conditions. Presence of a dose response examined by orthogonal contrast test. Individual comparisons by Tukey post test.</p>	<p><b>Outcomes:</b> Subjects smoked average of 15.4 CPD on day 4 across treatment blocks: Placebo (0mg nicotine): 17.2 CPD (SEM +/- 2.4) 63mg patch: 12.7 CPD (SEM +/- 1.3) CPD lowest on 63mg patch vs other treatment conditions, difference not significant. Average nicotine intake per cigarette = 2.5 mg with 0 mg patch and 1.6mg with the 63mg patch. Difference not significant. Suppression of nicotine intake from smoking averaged 3% (95% CI, -37% to 43%), 10% (95% CI, -31% to 50%) and 40% (95% CI, 6% to 74%) in the 21, 42 and 63mg conditions, respectively (p&lt;0.05). <b>Attrition:</b> 11/12 were analysed.</p>	<p><b>Limitations (author):</b> Common cues to cigarette smoking not present on the research ward; potentially explaining why subjects smoked less. <b>Limitations (review team):</b> Lab based study with very small sample. No details of randomisation. Inclusion criteria not provided. Details of eligible population are vague. 5 day intervention period only. No details of wash out. <b>Evidence gaps:</b> Clinical trials of high-dose transdermal nicotine to aid smoking cessation and/or to reduce the harm caused by smoking <b>Funding sources:</b> US Public Health Service, National Institute on Drug Abuse &amp; Division of Research Resources at the NIH</p>

		reported. <b>Intervention delivery:</b> Authors were clinicians and academics.			<b>Applicable to UK?</b> Unclear
<p><b>First author and year:</b> Bolliger BMJ 2000</p> <p>Linked papers: Bolliger 2002 (secondary analysis)</p> <p><b>Aim of study:</b> To determine whether use of an oral nicotine inhaler can result in long term reduction in smoking</p> <p><b>Study Design :</b> RCT</p> <p><b>Quality score:</b> Bolliger 2000 ++ Bolliger 2002 –</p> <p><b>External validity score:</b> +</p>	<p><b>Setting:</b> Switzerland. Two university hospital pulmonary clinics.</p> <p><b>Participants:</b> 400 healthy volunteer smokers recruited via newspaper advertisements. 53% female. Mean age 46.6</p> <p><b>Inclusion:</b> Willing to reduce but unable or unwilling to stop smoking immediately. ≥18 years old; smoking ≥15 CPD; exhaled CO ≥10 ppm; regular smoker for ≥3 years; failed ≥1 serious quit attempt in past 12 months; want to reduce smoking as much as possible with aid of nicotine inhaler; prepared to adhere to protocol.</p> <p><b>Exclusion:</b> Current use of NRT, other behavioural or pharmacological smoking reduction or cessation method, use of other nicotine containing products, any condition which might interfere with the study.</p> <p><b>Motivation of participants</b> Willing to reduce smoking but unable or unwilling to stop smoking immediately.</p>	<p><b>Method of allocation:</b> Computer generated randomisation list</p> <p><b>Intervention(s):</b> 10 mg nicotine/1 mg menthol inhaler used as needed with recommendation to use 6-12 cartridges over 24 hours. Encouraged to decrease use of the inhaler after 4 months but continue treatment for 18 of the 24 months.</p> <p><b>Control:</b> Placebo inhaler.</p> <p>All participants received information on smoking and effect on health.</p> <p><b>Sample sizes:</b> I = 200 C = 200</p> <p><b>Baseline comparisons:</b> More women in active treatment vs placebo groups – 114 vs 96.</p> <p><b>Study power:</b> States that 200 participants per arm was ‘adequate’, but does not provide power calculation.</p> <p><b>Intervention delivery:</b> Treatment dispensed by independent pharmacists.</p> <p>Authors are university researchers and</p>	<p><b>Primary outcomes:</b> Self reported reduction of ≥50% compared to baseline to month four (duration for which the study was powered). CO verified at week 6 and months 3 and 4.</p> <p><b>Secondary outcomes:</b> Smoking cessation (no smoking from week 6) verified by CO ≤10 ppm. Adverse events. Intention to quit.</p> <p><i>Secondary analysis</i> (Bollinger 2002): cardiovascular and quality of life markers.</p> <p><b>Follow-up periods:</b> 1, 2, 3, 6 weeks and 3, 4, 6, 12, 18, 24 months.</p> <p><b>Method of analysis:</b> Logistic regression</p>	<p><b>Primary:</b> Sustained reduction (verified by decreased CO) significantly higher for intervention versus control group at 12 and 24 months. Odds ratios 3.59 (95% CI 1.65, 7.80) p=0.002 and 3.39 (95% CI 1.39, 8.29) p=0.012 respectively.</p> <p>Point prevalent reduction (verified by decreased CO) only significant at 2 months. ORs for 12 and 24 months: 1.53 (95% CI: 0.97, 2.40) p=0.085, 1.27 (95% CI: 0.81, 2.00) p=0.357.</p> <p><b>Secondary:</b> CO verified abstinence: Not significant at 12 or 24 months: 1.36 (95% CI: 0.63, 2.95) p=0.557; 1.26 (95% CI: 0.65, 2.47) p=0.609.</p> <p>Throat irritation (14 vs 4; 95% CI 1.13, 15.6) and coughing (13 vs 4; 95% CI 1.1, 10.6) were significantly more reported in NRT group.</p> <p>No differences between groups for intention to quit.</p> <p>Secondary analysis (Bollinger 2002) found 25 successful reducers at 2 years had significantly greater decrease in plasma cotinine levels than 285 unsuccessful reducers (60% vs 1%, p&lt;0.001), cholesterol/high-density lipoprotein ratios (-2.42 vs -1.67, p=0.025), haemoglobin concentrations (-5.67 vs -1.34 g/l, p=0.023), pulse rate (-3.7 vs +1.0 bpm, p=0.043) and significantly</p>	<p><b>Limitations (author):</b> Differences in % women in each group.</p> <p><b>Limitations (review team):</b> Pharma funded and part authored – although a double blind trial.</p> <p><b>Evidence gaps:</b></p> <p><b>Funding sources:</b> Pharmacia and Upjohn Consumer Healthcare, Sweden.</p> <p><b>Applicable to UK?</b> Yes. Community based study with NRT delivered by independent pharmacists.</p>

		pharmaceutical company (Pharmacia and Upjohn) employees.		<p>improved general health score (9.40 vs 2.34, <math>p=0.049</math>).</p> <p><b>Attrition:</b> 310 (78%) completed to 24 months [83% in the active group; 72% in the placebo group]; ITT analysis used.</p> <p><i>Compliance</i> - Inhaler use decreased over time. Of participants present at 6 weeks (60%) used the inhaler each day; By 18 months the figure was 10%.</p> <p><b>Meta-analysis data:</b> CO verified sustained reduction 24 months: I = 19/200; 6/200, 12 months: I = 26/200; C = 8/200 Proportion of participants with <math>\geq 50\%</math> reduction: 24 months: I = 55/200; C = 46/200. 12 months: I = 59/200; C = 43/200. CPD (percentage of baseline) at 18 months. I: <math>n = 22</math>; mean = 36.2 (29.6). C: <math>n = 8</math>; mean = 67.2 (27.8). CO verified abstinence: 24 months: I=21/200; C=17/200 12 months: I=16/200; C=12/200</p>	
<p><b>First author and year:</b> Borland 1999</p> <p><b>Aim of study:</b> To develop programs to assist smokers in coping with workplace smoking bans and to compare outcomes associated with two types of reduced-smoking intervention to a control condition.</p>	<p><b>Setting:</b> Australia, 41 workplaces from chemical, communications, education, health, and manufacturing industries, including several with predominantly blue-collar workforces.</p> <p><b>Participants:</b> Baseline surveys distributed to 9079 workers, 54% (4903) returned. Sample 49.7% male;</p>	<p><b>Method of allocation:</b> Not stated</p> <p><b>Intervention(s):</b> 1. <u>Group program</u> Self-help manual for weekday smokers who responded to baseline survey. Also offered four session facilitator-led group programme. Manual addressed four sequential stages in learning to control smoking behaviour, with key</p>	<p><b>Primary outcomes:</b> 1. Percentages reporting reduced consumption with evidence of having cut down on workdays; 2. Mean changes in workday cigarette consumption; 3. Changes in frequency of urges to smoke at work; 4. Changes in addiction index.</p> <p><b>Secondary outcomes:</b> Numbers reporting quitting.</p>	<p><b>Primary:</b> No significant difference in any outcome at 6 months.</p> <p><b>Secondary:</b> No significant differences in cessation rates between groups at 6 months. (<math>p=0.69</math>).</p> <p><b>Attrition:</b> Not provided, but reported use of interventions was low. Across two intervention conditions 27% smokers had not received self-</p>	<p><b>Limitations (author):</b> Problems with recruiting worksites into the study. Levels of intervention use low, so the power to detect differences using ITT analyses reduced. Study took place during period of organisational restructuring and in one workplace many staff members made redundant</p>



<p><b>Study Design :</b> Cluster quasi-RCT</p> <p><b>Quality score:</b> +</p> <p><b>External validity score:</b> +</p>	<p>mean age 37.2 years.18.6% smokers with analyses on 736 smokers who reported that they smoked on workdays.</p> <p><b>Inclusion:</b> To participate in the study a company had to agree to accept the intervention condition to which it was randomly allocated.</p> <p><b>Exclusion:</b> None stated.</p> <p><b>Motivation of participants:</b> Not stated/no motivational requirement as whole worksites were recruited.</p>	<p>ideas, tips and suggestions, plus protocol exercises for before, during and after work. Group leaders followed written protocol linked to self-help manual, and participants used manual as necessary. Smokers told about program when surveyed and sent invitation with information on taking part. Programs also advertised via notice boards, staff newsletters and other media (time frame unclear).</p> <p>2. <u>Self-help</u> : manual only.</p> <p>For group and self-help interventions manuals made available from workplace occupational health and safety departments.</p> <p><b>Control:</b> Measurement only.</p> <p><b>Sample sizes:</b> 736 of 9079 workers surveyed reported smoking on workdays. Comprised: 16.1% Group program 17.9% Self-help program, 19.1% Control.</p> <p><b>Baseline comparisons:</b> None reported</p> <p><b>Study power:</b> No power calculation reported</p> <p><b>Intervention delivery:</b> Authors university researchers. No information given on group facilitators.</p>	<p><b>Follow-up periods:</b> 2 and 6 months</p> <p><b>Method of analysis:</b> Analyses included cross-tabulation and <math>\chi^2</math> tests for categorical variables and analysis of variance for continuous variables. Maentel-Haentzel <math>\chi^2</math> tests used for trends across categories. Main analyses were by intention to treat.</p>	<p>help booklet, 43% of those who had received it had not used it, and only 30% reported use of at least some of it. Only 43% of group intervention remembered an offer to attend sessions and only 10% attended.</p>	<p>between baseline and follow-up surveys; exacerbating already high drop-out rates.</p> <p>Lack of interest in the program. Authors felt they did not do enough to promote the reduction strategy as a genuine alternative.</p> <p><b>Limitations (review team):</b> Self-report of smoking status only.</p> <p><b>Evidence gaps:</b> None stated.</p> <p><b>Funding sources:</b> National Health and Medical Research Council Public Health Research and Development Committee Australia project grant.</p> <p><b>Applicable to UK?</b> Yes</p>
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<p><b>First author and year:</b> Carpenter 2004</p> <p><i>Linked paper:</i> Carpenter 2003 (pilot study so only 2004 results from reported)</p> <p><b>Aim of study:</b> To study the effect of a smoking reduction intervention on the incidence of subsequent quit attempts and point prevalence abstinence.</p> <p><b>Study Design :</b> Quasi-RCT</p> <p><b>Quality score:</b> +</p> <p><b>External validity score:</b> +</p>	<p><b>Setting:</b> USA, community based (study conducted entirely via telephone and postal mailings)</p> <p><b>Participants:</b> 616 smokers via proactive telephone calls made by national marketing company using database ‘enriched’ with known smokers. Gender: 68% female (R-NRT), 74% (MT), 68% (NT); Age: 38 (R-NRT), 39 (MT), 41 (NT); Ethnicity: 89% Caucasian (R-NRT), 89% (MT), 88% (NT); Education: 87% high school graduate (R-NRT), 83% (MT), 86% (NT); FTND score: 5.6 (R-NRT), 5.5 (MT), 5.4 (NT)</p> <p><b>Inclusion:</b> Not currently interested in quitting; smoking <math>\geq 10</math> CPD; age <math>\geq 18</math> years.</p> <p><b>Exclusion:</b> Nursing, pregnant or planning to be pregnant in next 9 months. Cardiovascular disease or hypertension not controlled with medication. Taking prescription medication for depression or asthma. Not accessible by telephone.</p> <p><b>Motivation of participants</b> All participants were not interested in quitting; the recruitment process offered a choice of cessation and non cessation studies.</p>	<p><b>Method of allocation:</b> Not stated</p> <p><b>Intervention(s):</b> Reduction aided by NRT (R-NRT): Three telephone calls at weeks 0, 3 and 6, focusing on behavioural reduction strategies, use of NRT, and problem solving where necessary. Participants could choose to receive NRT gum (4mg) or patch (7, 14 or 21 mg) for six weeks. At week 6 brief advice given to quit. Those who committed to quit given additional NRT. Motivational treatment (MT): Telephone calls at weeks 0, 3 and 6 with discussions focusing on 5Rs, At week 6 brief advice given to quit. Those who committed to quit given NRT.</p> <p><b>Control:</b> No treatment (NT).</p> <p><b>Sample sizes:</b> R-NRT = 212 MT = 197 NT = 207</p> <p><b>Baseline comparisons:</b> NT group less concerned about health risks than MT group (<math>p &lt; 0.01</math>), and more sceptical about reduction than NRT and MT groups (<math>p &lt; 0.05</math>). MT group slightly fewer CPD than those in NRT group</p>	<p><b>Primary outcomes:</b> CPD for last 7 days (self-reported) Intentions to quit in the next 1 and 6 months 7-day point-prevalence abstinence Stage of change Self-efficacy Quit attempts Side effects associated with concomitant use of NRT and cigarettes.</p> <p><b>Follow-up periods:</b> Six and 24 weeks post baseline.</p> <p><b>Method of analysis:</b> Logistic regression analyses with post hoc pairwise comparisons to test effect of interventions on quit attempts and point-prevalence abstinence. Post hoc comparisons corrected for multiple testing using Tukey’s test. Repeated measures analyses of covariance with baseline values as covariates to examine smoking reduction, readiness to quit, and self-efficacy. <math>\chi^2</math> test to determine if rate of serious adverse events <math>&gt; 5\%</math>.</p>	<p><b>Primary:</b> Cigarette reduction: At week 24 all groups reduced mean CPD, but reductions significantly greater (<math>p &lt; 0.05</math>) in R-NRT and MT groups than in NT group. No difference between R-NRT and MT participants.  Among continuing smokers, 21% R-NRT, 20% MT and 11% NT had reduced smoking by <math>\geq 50\%</math>. Percentage reduction between weeks 0 and 6 significantly predicted abstinence at week 24: OR 1.03 (95% CI: 1.02, 1.05).  Quit attempts: Over 24 weeks, both R-NRT and MT groups were more likely than NT group to make 24 hour quit attempt. R-NRT: OR 4.2 (95% CI=2.6, 6.7), MT: OR 5.6 (95% CI: 3.5, 9.1). R-NRT group less likely than MT group to make a 24 hour quit attempt (ns): OR 0.7 (95% CI: 0.5; 1.1).  Readiness to quit: Increased across all groups. By week 24, R-NRT and MT participants had similar intentions to quit. Intention to quit in R-NRT and MT groups significantly greater than NT participants (<math>p &lt; 0.05</math>; data in graph form only).  Abstinence: At week 24 18% R-NRT and 23% MT participants reported 7-day point-prevalence abstinence compared with 4% NT participants (<math>p &lt; 0.01</math> for both comparisons).  Self efficacy: At week 24 R-NRT and MT</p>	<p><b>Limitations (author):</b> Reduction intervention consists of two interventions (reduction counselling and NRT). Provision of free NRT may have encouraged more quit attempts and possibly false reports of abstinence to receive more NRT. No biochemical verification of quit attempts or abstinence. Sample predominantly female and Caucasian.</p> <p><b>Limitations (review team):</b> Outcome assessment not blinded.</p> <p><b>Evidence gaps:</b> None stated</p> <p><b>Funding sources:</b> Study supported by National Institute on Drug Abuse (NIDA) grant, NIDA training grant and NIDA Senior Scientist Award. GlaxoSmithKline Consumer Healthcare supplied NRT.</p> <p><b>Applicable to UK?</b> Yes</p>
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		<p>(p&lt;0.05). Baseline differences entered as covariates in subsequent data analyses</p> <p><b>Study power:</b> Power calculation not reported.</p> <p><b>Intervention delivery:</b> University researchers</p>		<p>participants did not significantly differ, but both had significantly greater self-efficacy scores than NT participants (p&lt;0.01).</p> <p>Adverse events: 21% of participants who used NRT for reduction reported an adverse event compared to 9% of those who used NRT only for a quit attempt (week 6-24) (p&lt;0.01).</p> <p><b>Attrition:</b> 197/3080 (6%) of scheduled interviews were missed.</p>	
<p><b>First author and year:</b> Carpenter 2007</p> <p><b>Aim of study:</b> To examine the impact of genetic testing for alpha-1-antitrypsin (AAT) deficiency, a condition that usually results in emphysema in individuals exposed to cigarette smoke.</p> <p><b>Study Design :</b> Secondary analysis of an uncontrolled before and after study</p> <p><b>Quality score:</b> -</p> <p><b>External validity score:</b> -</p>	<p><b>Setting:</b> USA. AAT genetic testing centre at the Medical University of South Carolina</p> <p><b>Participants:</b> 729 cigarette smokers from 4,344 who completed a test kit. <i>'Primarily middle aged white women who reported smoking approximately one pack per day'</i> N=729: 55% non deficient, 38% carrier, 7% severely AAT deficient. N=205 (completers): 58% non deficient, 33% carrier, 9% severely AAT deficient.</p> <p><b>Inclusion:</b> Aged 18+ and smoker at time of testing.</p> <p><b>Exclusion:</b> None stated.</p> <p><b>Motivation of participants:</b> Actively sought AAT testing. Motivations regarding smoking unknown.</p>	<p><b>Method of allocation:</b> Not applicable</p> <p><b>Intervention(s):</b> AAT testing. Results sent with a brochure advising smoking cessation. AAT deficient and carriers offered genetic counselling session.</p> <p><b>Control:</b> Uncontrolled</p> <p><b>Sample sizes:</b> 729</p> <p><b>Baseline comparisons:</b> Uncontrolled</p> <p><b>Study power:</b> Power calculation not reported.</p> <p><b>Intervention delivery:</b> Mailed questionnaire with research staff calling non-responders. Authors are university researchers.</p>	<p><b>Primary outcomes:</b> CPD, ≥50% reduction in CPD, quit attempts, and possible steps towards quitting</p> <p><b>Follow-up periods:</b> 3 months after receipt of AAT status.</p> <p><b>Method of analysis:</b> X<sup>2</sup> and Kruskal-Wallis analysis of variance. Logistic regression for odds of quit attempts/cessation for carriers and those with severe AAT, controlled for sex, age, education and baseline nicotine dependence.</p>	<p><b>Primary:</b> After controlling for baseline differences odds of quit attempt were 3.3 x higher (95% CI 1.1, 10.0) among AAT deficient versus non deficient individuals. There were no group differences in abstinence at 3 months. 59% of severely AAT deficient smokers reduced their CPD by ≥50% compared with less than 20% in carriers and normals.</p> <p><b>Attrition:</b> 205/729 questionnaires returned (28%) but 5 light smokers (&lt;5 CPD) removed. Thus follow up = 27.4% [200/729]</p>	<p><b>Limitations (author):</b> No control group, low response rate, self report, not generalisable since so few with AAT deficiency.</p> <p><b>Limitations (review team):</b> <i>Extremely</i> weak study design. Secondary analysis of a before and after study with high attrition and self reported outcomes. Tangential relevance to review only since motivations of participants uncertain. Could be relevant to review 4?</p> <p><b>Evidence gaps:</b> None stated.</p> <p><b>Funding sources:</b> Alpha-1 Foundation, a non profit organisation for AAT detection research.</p> <p><b>Applicable to UK?</b> Impossible to tell. Very poor study.</p>

<p><b>First author and year:</b> Chan 2011</p> <p><b>Aim of study:</b> To examine the effectiveness of smoking reduction counselling plus free nicotine replacement therapy (NRT) for smokers not willing to quit.</p> <p><b>Study Design :</b> RCT</p> <p><b>Quality score:</b> ++</p> <p><b>External validity score:</b> +</p>	<p><b>Setting:</b> Hong Kong, China; community-based.</p> <p><b>Participants:</b> 1154 Chinese smokers recruited via the local media and contacting cohorts of smokers who had received previous cessation counselling but failed to quit.</p> <p><b>Inclusion:</b> Chinese, aged ≥18 years, smoked ≥2 CPD; no intention to quit in the near future but were interested in reducing smoking; no contraindication to NRT; were not following other forms of smoking cessation or reduction interventions.</p> <p><b>Exclusion:</b> Pregnant or intending to become pregnant within the next 6 months; psychologically or physically unable to communicate; on regular psychotropic medications or any serious health problems that made NRT use unsuitable, such as recent stroke, palpitation or other life-threatening conditions.</p>	<p><b>Method of allocation:</b> Serially labelled, opaque and sealed envelope. Computerised random numbers generated by the research assistant before subject recruitment.</p> <p><b>Intervention(s):</b> A1: 15 mins face-to-face counselling on smoking reduction based on MI techniques and 3 mins adherence to NRT information at baseline, 1 week and 4 weeks with 4 weeks of free NRT (choice of patch or gum – no dosage information). A2: as above without adherence intervention.</p> <p><b>Control:</b> Simple cessation advice at baseline.</p> <p>At baseline, all subjects received a self-help quitting pamphlet, 'Tips for Quit Smoking', produced by Hong Kong Council on Smoking and Health.</p> <p><b>Sample sizes:</b> Eligible: 6385 (5231 refused to participate) A1 = 479 A2 = 449 C = 226</p> <p><b>Baseline comparisons:</b> Demographic variables, smoking profiles, history of quitting and self-efficacy to</p>	<p><b>Primary outcomes:</b> Self-reported 7-day point prevalence tobacco abstinence at 6 months; self reported reduction of ≥50% in cigarette consumption at 6 months; and 4-week NRT adherence rate at 3 months</p> <p><b>Secondary outcomes:</b> Biochemically validated reduction (&gt;1ppm exhaled CO reduction) and 7-day point prevalence abstinence at 6 months; adherence rate to NRT over the previous 8 weeks at 3 months</p> <p><b>Follow-up periods:</b> 6 months</p> <p><b>Method of analysis:</b> Rates of tobacco abstinence, reduction and adherence between groups compared using Pearson's c2, together with odds ratios and absolute risk differences with 95% confidence intervals. Rates of reduction in CO level by ≥50% and mean change in CO levels from baseline to 6 months compared among validated reducers between groups.</p>	<p><b>Note: Results for intervention groups A1 and A2 are not reported separately.</b></p> <p><b>Primary:</b> At 6 months: Self reported ≥50% reduction: I=472/928, C=58/226, OR=3.0 (95% CI=2.2, 4.2, p&lt;0.001). Self reported cessation: I=158/928, C=23/226, OR=1.8 (95% CI=1.1, 2.9, p=0.011).</p> <p><b>Secondary:</b> At 6 months: Validated ≥50% reduction: I=178/928, C=22/226, OR=2.2 (95% CI=1.4, 3.5, p=0.001). CO-validated cessation: I=74/928, C=10/226, OR=1.9 (95% CI=1.0, 3.7, p=0.066). No significant difference in 3 month adherence rates over the previous four or eight weeks.</p> <p><b>Attrition:</b> Completed questionnaire A1 = 427/479 A2 = 405/449 C = 216/226 Refused biochemical validation tests: A1 = 121/479 (25%) A2 = 112/449 (25%) C = 25/226 (11%)</p>	<p><b>Limitations (author):</b> Large difference identified between the self reported results and those confirmed</p> <p><b>Limitations (review team):</b> Despite groups A1 and A2 receiving slightly different interventions, the results are reported together. Significantly higher proportion of males. Large number of participants refused to undertake biochemical confirmation tests despite offer of HK\$100 (later HK\$200) travel allowance.</p> <p><b>Evidence gaps:</b></p> <p><b>Funding sources:</b> Health and Health Services Research Fund, Hong Kong SAR (Project No 01030611). Nicotine gum/patches provided free by McNeil AB (Helsingborg, Sweden)</p> <p><b>Applicable to UK?</b> Significant cultural differences, but a community setting.</p>
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		<p>resist smoking similar in all three groups at baseline, except more male subjects in control group and higher CO level in group A2.</p> <p>Low numbers of females in all groups vs percentage of women smokers in Chinese population (42.6% - WHO)</p> <p><b>Study power:</b> Required sample size calculated based on three primary outcome measures to provide ≥90% power with a 5% significance level using 2:1 ratio.</p> <p><b>Intervention delivery:</b> Trained smoking cessation counsellors. Authors were university researchers.</p> <p><b>Motivation of participants</b> No intention to quit in the near future, but interested in reducing smoking.</p>			
<p><b>First author and year:</b> Cunningham 2006</p> <p><b>Aim of study:</b> Whether framing health information as safer smoking tips might motivate change in cigarette smokers.</p> <p><b>Study Design :</b> Non-RCT</p> <p><b>Quality score:</b> +</p> <p><b>External validity score:</b></p>	<p><b>Setting:</b> Canada; community;</p> <p><b>Participants:</b> At baseline 54 respondents; mean age 46.3 (SD 11.5); 58% male; 44% married; 28% had some post-secondary education; 50% currently employed</p> <p><b>Inclusion:</b> Daily smokers, 18 years or older</p> <p><b>Exclusion:</b></p>	<p><b>Method of allocation:</b> Not provided</p> <p><b>Intervention(s):</b> Participants asked if they knew about a range of safer smoking tips</p> <p><b>Control:</b> Respondents asked to share their current harm reduction activities.</p> <p><b>Sample sizes:</b> I = 27 C = 27</p>	<p><b>Outcomes:</b> CPD, type of cigarette and any quit attempts.</p> <p><b>Follow-up periods:</b> 3 months</p> <p><b>Method of analysis:</b> repeated measures analysis of variance</p>	<p><b>Results:</b> No main effect of time (p&gt;0.05) Mean CPD at three month follow-up I = 20.1 (S.D&gt; 8.4) vs baseline 23.2 (S.D. 8.1); C = 23.1 (S.D. 14.1) vs baseline C=21.2 (S.D. 12.2). No significant difference for quit attempts (analysis not reported). No respondents quit smoking.</p> <p><b>Attrition:</b> 20%. At 3 month follow-up I = 20/27 C=23/27</p>	<p><b>Limitations (author):</b> No biochemical verification for CPD or compensation in smoking behaviour may have had impact</p> <p><b>Limitations (review team):</b> Small sample size, no randomisation</p> <p><b>Evidence gaps:</b> Further research to assess if health information framed as safer smoking tips might motivate reductions in cigarette smoking</p>

<p>+</p>	<p>Not provided</p> <p><b>Motivation of participants:</b> 81% of respondents reported at least one serious quit attempt.</p>	<p><b>Baseline comparisons:</b> No significant differences</p> <p><b>Study power:</b> Power calculation not reported.</p> <p><b>Intervention delivery:</b> Not reported.</p>			<p><b>Funding sources:</b> Ontario Tobacco Research Unit</p> <p><b>Applicable to UK?</b> Yes</p>
<p><b>First author and year:</b> Davis 2011</p> <p><b>Aim of study:</b> To compare the effectiveness of brief motivational interviewing versus prescriptive counselling among smokers who are not ready to quit.</p> <p><b>Study Design :</b> Quasi-RCT</p> <p><b>Quality score:</b> +</p> <p><b>External validity score:</b> -</p>	<p><b>Setting:</b> USA. Lab-based study designed to simulate outpatient visits to GPs.</p> <p><b>Participants:</b> 218 pre-contemplative and contemplative smokers recruited directly and through advertisement. 55% male; 76% Caucasian; mean age 37.6; mean years smoked 21.1; mean CPD 25.4.</p> <p><b>Inclusion:</b> Smokers not ready to quit, pre-contemplators or contemplators</p> <p><b>Exclusion:</b> None stated</p> <p><b>Motivation of participants:</b> Smokers not ready to quit.</p>	<p><b>Method of allocation:</b> Not stated</p> <p><b>Intervention(s):</b> A 15 minute MI session delivered in a lab setting but designed to match the time available in the average health professional-patient interaction.</p> <p><b>Control:</b> A 15 minute prescriptive interview delivered in a lab-setting as above</p> <p>In both conditions smokers who made a plan to quit or reduce were phoned the day prior to their quit/reduction day. All interventions were videotaped and coded for intentions to reduce or quit</p> <p><b>Sample sizes:</b> 116 recruited into MI group (109 included in final analysis). 114 recruited into prescriptive group (109 included in final analysis).</p> <p><b>Baseline comparisons:</b> Two groups comparable at baseline on age, gender, total years smoked, age at first</p>	<p><b>Primary outcomes:</b> 13 outcomes comprising: Intentions to quit or reduce within 6 months, 1 month or 1 week. Verbal report of 24 hour and 72 hour 50% reduction or quit at 1- or 6-months. Urinary cotinine-verified 50% reduction or quit at 1- or 6-months</p> <p><b>Follow-up periods:</b> 1 and 6 months</p> <p><b>Method of analysis:</b> Demographic characteristics and outcomes examined using t-tests and <math>\chi^2</math> statistics. Generalized linear model used to analyse primary outcome. Dependent variable was composite outcome measure for smoking reduction. Independent variables and their order of entry were gender, age, ethnicity, CPD (to assure the groups were similar at baseline), treatment assignment (to evaluate the differential treatment effect), and interaction terms (to examine subgroup differences).</p>	<p><b>Primary:</b> Two MI and 5 prescriptive participants had verified reduction of <math>\geq 50\%</math>. One MI participant was verified abstinent at 1- and 6-month follow-up. There were no differences by treatment group assignment on any outcome measure.</p> <p><b>Attrition:</b> Of the 218 smokers, 71% were available at 1 month and 56% at 6 months.</p>	<p><b>Limitations (author):</b> None stated.</p> <p><b>Limitations (review team):</b> High attrition rate.</p> <p><b>Evidence gaps:</b> None stated</p> <p><b>Funding sources:</b> Grant from Arizona Disease Control Research Commission.</p> <p><b>Applicable to UK?</b> Yes, albeit most health professional-patient interactions in the UK do not last as long as 15 minutes.</p>

		<p>cigarette, lifetime packs and spirometry. Caucasians overrepresented in MI group. Smokers in prescriptive group had higher Fagerstrom scores.</p> <p><b>Study power:</b> Powered to detect a 15% difference in proportions in self-reported quit rates; but level of power is not stated and no power calculation for reduction was performed.</p> <p><b>Intervention delivery:</b> Authors are university researchers and two provided training on the interventions. Unclear who delivered them in practice.</p>			
<p><b>First author and year:</b> Etter 2007 <i>Linked papers:</i> Etter 2002 Etter 2004 Dar 2005</p> <p><b>Aim of study:</b> Whether a reduction of cigarette consumption obtained after 6 months of NRT was maintained 5 years after the end of treatment.</p> <p><b>Study Design :</b> RCT</p> <p><b>Quality score:</b> +</p> <p><b>External validity score:</b> ++</p>	<p><b>Setting:</b> Switzerland (Geneva, Vaud, Valais)</p> <p><b>Participants:</b> 923 members of the general adult population (aged 18-60) answering call to participate (via physicians, newspaper adverts, random emails)</p> <p><b>Inclusion:</b> Smoking <math>\geq</math> 20 CPD, smoked for <math>\geq</math> 3 yrs, no intention to quit in next 6 months, in good health.</p> <p><b>Exclusion:</b> List of medical indications (Etter 2002): Pregnant, breastfeeding, treatment for psychiatric disorder, DSM diagnosis and several major health conditions.</p>	<p><b>Method of allocation:</b> Computer generated list of random numbers (Etter 2002).</p> <p><b>Intervention(s):</b> NRT - choice of 15 mg patch, 4 mg gum, 10 mg inhaler or combination. After testing, participants ordered the amount and type of product they needed and received products by mail every other week for 6 months.</p> <p><b>Control:</b> 1. Matching placebo 2. No intervention control</p> <p>All participants received an educational booklet. Everything sent by post.</p> <p><b>Sample sizes:</b></p>	<p><b>Primary outcomes:</b> Self-report CPD at all follow up; smoking intensity (0-100 scale); depth of smoking (0-10 scale) by self report (6 months only)</p> <p><b>Secondary outcomes:</b> Pleasure of smoking, enjoyment of taste, ability to refrain. One month- and one week-abstinence. All by self report at 6 months only.</p> <p><b>Follow-up periods:</b> 6 months 2 years (26 months) 5 years (66 months)</p> <p><b>Method of analysis:</b> Independent t-tests for means, U-tests for medians, <math>\chi^2</math> for proportions. Logistic regression models for association between</p>	<p><b>Primary:</b> At 5 years (66 months; Etter 2007), outcomes for all groups were similar compared to baseline. Decreases in CPD for NRT, placebo and control were 7.9, -6.6 and -6.3 respectively excluding quitters (<math>p \geq .43</math>).</p> <p>20.9% in NRT group vs. 21.4% in placebo and 18.3% in control groups (<math>p \geq .48</math>) decreased CPD by <math>\geq 50\%</math> compared with baseline (excludes quitters). Smoking cessation rates similar across groups; continuous abstinence: 7.2%, 6.3% and 4.6% (<math>p &gt; .16</math>).</p> <p>Respective figures for 2 years (26 months; Etter 2004): decreases of 9.8, 7.7 and 7.7 CPD (all <math>p \leq .02</math>). 31.3% in NRT group vs. 21.9% in placebo (<math>p=0.014</math>) and 24.4% in</p>	<p><b>Limitations (author):</b> No biochemical assessment but valid reasons provided (to limit attrition).</p> <p><b>Limitations (review team):</b> None</p> <p><b>Evidence gaps:</b> None</p> <p><b>Funding sources:</b> Swiss National Science and the Swiss Federal Office of Public Health. Products supplied by Pharmacia. Etter and Zellwegger received reimbursement from Pharmacia for attending international conferences. Etter paid by Novartis for lectures. Institute of Social &amp;</p>

	<p><b>Motivations of participants:</b> No intention to quit smoking in the next six months (pre-contemplation stage of change)</p>	<p>NRT – 265 Placebo – 269 No intervention – 389</p> <p><b>Baseline comparisons:</b> Fewer women in nicotine group; otherwise similar.</p> <p><b>Study power:</b> No power calculation reported.</p> <p><b>Intervention delivery:</b> Authors are university researchers.</p>	<p>reduction in CPD at baseline and subsequent cessation. Study drop-outs were treated as smokers.</p>	<p>control (p=0.052) decreased CPD by ≥50% compared with baseline.</p> <p>Cigarette consumption in NRT group at 6 months (Etter 2002) decreased by mean of 10.9 CPD, compared to 8.7 in placebo and 4.9 in no-treatment control group compared to baseline (p ≤.02).</p> <p>At 6 months (Etter 2002) greater reductions in smoking intensity and quantity of smoke inhaled in NRT vs placebo and placebo vs control groups (p &lt; .001)</p> <p><b>Secondary:</b> At 6 months (Etter 2002) some statistically significant differences in psychological characteristics between NRT and control groups but none between NRT and placebo groups.</p> <p>----- NRT usage at 5 years (Etter 2007): fewer participants using NRT than at 2 years. Same proportion of participants in all groups (daily + occasional use NRT: Nicotine, 12%; placebo, 9%; no treatment, 11%; p=0.48). NRT users more likely to be current smokers (82%). During previous 30 days, former smokers used NRT for longer (median=30 days) than current smokers (median, 10 days; p=0.003). Abstinence in former smokers: 11 using NRT daily, median=123 days ; 109 not using NRT, median=826 days (p=0.003)</p> <p><b>Attrition:</b> 879 (95%) were followed to 6 months (Etter 2002), 846 (92%) followed to 26 months (Etter 2004) and 671</p>	<p>Preventive Medicine received financial support from Novartis to develop an educational programme for Nicotinell users. Zelgweger received research funding from Pharmacia.</p> <p><b>Applicable to UK?</b> Yes</p>
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				(73%) followed to 66 months. <b>Meta-analysis data</b> (Etter 2004). Smoking cessation at 26 months: I = 32/265; C=29/269. Proportion of participants with at least a 50% reduction in the CPD: I= 83/265; C= 59/269.	
<p><b>First author and year:</b> Fagerström 1997</p> <p><b>Aim of study:</b> To examine whether stable smoking reduction over 5 weeks is possible if nicotine intake is supplemented from NRT; whether a personal choice of medication is important for achieving a better effect; and whether motivation is influenced by the opportunity to reduce smoking</p> <p><b>Study Design :</b> Partial RCT (cross-over study without placebo control group)</p> <p><b>Quality score:</b> -</p> <p><b>External validity score:</b> +</p>	<p><b>Setting:</b> Sweden. Community-based.</p> <p><b>Participants:</b> 170 participants identified through newspaper advertisements. [Data reported for 143 participants who provided complete info.] In groups 1 and 2 respectively: mean age 44.7 and 46.7; female: 60% and 65%. Mean CPD 22.6 (SD 7.0) and mean FTQ 7.0 (SD 1.9).</p> <p><b>Inclusion:</b> ≥15 CPD; ≥ 20 years; healthy.</p> <p><b>Exclusion</b> Pipe and cigar smokers, smokeless tobacco users or people on any medication or NRT.</p> <p><b>Motivation of participants:</b> Smokers that did not want to or could not give up smoking.</p>	<p><b>Method of allocation:</b> Not stated</p> <p><b>Intervention(s):</b> One-week familiarisation period with different NRT medications (2mg gum, 2mg tablet, patch, vaporiser or nasal spray – no dosage information), then randomised into two intervention groups and two phases: Phase 1 (2 weeks duration): Group 1 Further randomised to specific nicotine replacement (gum, patch, nasal spray, vaporiser or tablet). Group 2) Free choice of preferred NR medication. Phase 2 (2 weeks duration): participants crossed over to receive the alternative condition. Both groups encouraged to smoke less, but sufficient to feel comfortable throughout study period.</p> <p><b>Control:</b> No placebo or usual care control group</p> <p><b>Sample sizes:</b></p>	<p><b>Primary outcomes:</b> Self-reported cigarette consumption and exhaled CO, mean cotinine (ng/ml), total withdrawal score, preference for free-choice condition, rating of medications (in staying off cigarettes, reducing craving, smoking cessation, similarity to cigarettes), motivation to quit, amount of medication used, adverse effects.</p> <p><b>Follow-up periods:</b> Weekly during 5 week study period. No post study follow-up.</p> <p><b>Method of analysis:</b> Means and standard deviations. Linear regression to assess change in total withdrawal score.</p>	<p><b>Primary:</b> Five weeks from baseline: for full study population self-reported CPD declined from 22.6 (SD 7.0) to 10.4 (SD 1.0) (p&lt;0.001); 54% decrease, with biggest drop (37%) during week 1. CO readings decreased from 22.7 (SD 8.5) to 14.8 (SD 8.4) ppm (p&lt;0.001), confirming 35% decrease in smoking. Authors reported (though little data in paper) overall effect of free choice on self-reported CPD reduction was 3.1 vs 1.1 (p&lt;0.001). Overall effect of choice on CO reduction (combining both phases): 2.7 vs 0.9 ppm (p&lt;0.05). No significant effect between conditions on medication use. No clear medication preference emerged, though patch and vaporiser seemed not as good in reducing craving as gum and spray, and spray was rated most similar to cigarettes. Cotinine levels remained steady, suggesting subjects were titrating nicotine to their original levels.</p> <p><b>Attrition:</b> Results presented on 143/170 volunteers providing complete information (84%).</p>	<p><b>Limitations (author):</b> No placebo control. Large reduction seen during the run-in week could have occurred because it would be easier to reduce from the highest number of cigarettes smoked than later, after some reduction had already taken place.</p> <p><b>Limitations (review team):</b> Results from study groups merged without explanation, so effectiveness of different phases and treatments cannot be ascertained. No raw data for two groups. High potential for contamination – no wash-out period between run-in or two following intervention phases. No post-intervention follow-up. No power calculation. Unclear how many participants received each formulation during Phases 1 and 2.</p> <p><b>Evidence gaps:</b> None reported</p>

		<p>Group 1 69 Group 2 74</p> <p><b>Baseline comparisons:</b> No significant differences</p> <p><b>Study power:</b> Power calculation not reported.</p> <p><b>Intervention delivery:</b> Authors were all pharmaceutical company employees at time of study.</p>			<p><b>Funding sources:</b> All authors were employees of Pharmacia &amp; Upjohn, which manufactures nicotine replacement products. No other funding information was available.</p> <p><b>Applicable to UK?</b> Yes.</p>
<p><b>First author and year:</b> Fossum 2004</p> <p>Background info from Aborrelius 2001</p> <p><b>Aim of study:</b> To evaluate the effects of the counselling method “Smoke-free children”, which focuses on protecting the infant from environment tobacco.</p> <p><b>Study Design :</b> Controlled before and after study</p> <p><b>Quality score:</b> -</p> <p><b>External validity score:</b> +</p>	<p><b>Setting:</b> Sweden. Child health centres</p> <p><b>Participants:</b> 37 child health nurses (CHNs)</p> <p><b>Inclusion:</b> CHNs from 5/24 counties with the highest prevalence of maternal smoking in 1997.</p> <p><b>Exclusion:</b> None stated</p> <p><b>Motivation of participants:</b> None stated.</p>	<p><b>Method of allocation:</b> Not stated</p> <p><b>Intervention(s):</b> 2-day initial training and a follow-up session in “Smoke-free children” by a previously trained leader according to a standardized program which included video-recorded role playing and ensuing feedback from the leader</p> <p><b>Control:</b> No training</p> <p><b>Sample sizes:</b> I = 17 CHNs (26 mothers) C1 = 16 CHNs (11 mothers) C2 = 4 CHNs (4 mothers)</p> <p><b>Baseline comparisons:</b> Intervention and Control 1 group communities matched for size, birth rate, SES and prevalence of smoking during pregnancy. Additional Control group 2 CHNs were recruited from one of the five counties. Mothers recruited by control group CHNs had slightly less schooling and more female</p>	<p><b>Primary outcomes:</b> Maternal self-reported CPD verified by saliva cotinine at 1 month pre-birth (baseline) and 3 months post-birth.</p> <p>Child’s exposure to ETs by recall 3 months post-birth*</p> <p>Assessment of intervention CHN’s counselling methods by questionnaire. [Change was not assessed]</p> <p><b>Follow-up periods:</b> Relates to period after training not post-delivery of counselling to mothers.</p> <p><b>Method of analysis:</b> ANCOVA and non-parametric tests; Mann–Whitney, Chi-squared, Fisher’s exact test, and Spearman rank correlation were used. Statistical significance at <math>p &lt; 0.05</math> with <math>p &lt; 0.1</math> interpreted as a tendency.</p>	<p><b>Primary:</b> Cotinine-verified CPD results at 3 months post-birth: <u>Intervention</u> (22/26 mothers) Baseline: mean (SD) : 12.7 (6.6); Three months: mean (SD) 12.9 (6.2) <u>Control</u> (8/15 mothers) Baseline: mean (SD) : 8.4 (3.9); Three months: mean (SD) 7.1 (2.8) * Results not reported – not relevant to this review.</p> <p><b>Attrition:</b> 22 of 26 mothers in intervention and 8/14 mothers in control provided saliva cotinine samples.</p>	<p><b>Limitations (author):</b> Small sample; potential selection bias</p> <p><b>Limitations (review team):</b> Not clear that additional control group of nurses were matched with the intervention group. No information on content/duration of counselling provided to mothers. Intervention only delivered to 23/26 mothers. No ITT analysis Discrepancy between control numbers reported in table and text.</p> <p><b>Evidence gaps:</b> None stated.</p> <p><b>Funding sources:</b> Swedish National Institute of Public Health, Swedish Cancer Society, Swedish Heart and Lung Foundation, Swedish Asthma and Allergy Association, Stockholm County Asthma and Allergy Foundation,</p>

		<p>babies.</p> <p><b>Study power:</b> Power calculation not reported.</p> <p><b>Intervention delivery:</b> Authors academic researchers at the Karolinska Institute</p>			<p>Solstickan Foundation</p> <p><b>Applicable to UK?</b> Yes</p>
<p><b>First author and year:</b> Foulds 1992</p> <p><b>Aim of study:</b> Effect of transdermal nicotine patches on ad libitum cigarette smoking</p> <p><b>Study Design :</b> Quasi-RCT (crossover )</p> <p><b>Quality score:</b> +</p> <p><b>External validity score:</b> -</p>	<p><b>Setting:</b> UK Research Centre</p> <p><b>Participants:</b> 34 adult volunteers; 27 female; mean age 39 (range 19-60); mean CPD 20 (range 10-40); mean years of smoking 22.2 (range 2-43)</p> <p><b>Inclusion:</b> ≥10 CPD; smoked regularly for ≥2 years</p> <p><b>Exclusion:</b> Not provided</p> <p><b>Motivation of participants:</b> Not provided</p>	<p><b>Method of allocation:</b> Not stated.</p> <p><b>Intervention(s):</b> After 1 week baseline subjects received either 1 week nicotine patches (releasing 15±3.5 mg over a 16 h period), followed by 1 week placebo patches or vice versa. No wash out period. Patches provided in a way that implied they were randomly mixed. Subjects were told to smoke as usual and record consumption for the 3 weeks.</p> <p><b>Control:</b> Crossover in which both groups received active and placebo patches.</p> <p><b>Sample sizes:</b> 30</p> <p><b>Baseline comparisons:</b> Not provided</p> <p><b>Study power:</b> 0.80 power with α=0.05 to detect a nicotine placebo difference in CO.</p> <p><b>Intervention delivery:</b> Researchers in research</p>	<p><b>Primary outcomes:</b> Nicotine placebo (N-P) difference in CO, CPD recorded via diary; plasma nicotine, cotinine and thiocyanate taken at weekly lab visit; subjective ratings of smoking and side effects.</p> <p><b>Follow-up periods:</b> No follow-up – data at end of 14 day intervention period</p> <p><b>Method of analysis:</b> All measures first analysed for order effects, power of this analysis generally weak but was improved by inclusion of baseline (no patch) measure as a covariate and alpha set at .10. For two measures in which an order effect was present analysis proceeded with first period observation only in between-subject analysis with baseline measure as covariate using F-tests from a regression analysis. Where no order effects found, one sided t-tests carried out based on within-subject variation. Probability value of &lt;.05 considered significant.</p>	<p><b>Primary:</b> N-P difference : pre-cig CO: -3.5 (95% CI: -5.7, -1.3) p&lt;0.05; post-cig CO: -4.1 (95% CI: -6.4, -1.7) p&lt;0.001. Pre- and post-cig plasma nicotine respectively: 9.2 (95% CI: 4.5, 13.9)p&lt;0.001 7.9 (95% CI: -3.3, 12.5)p&lt;0.05 N-P difference for CPD for first 6 days not significant -0.8 (-1.7, 0.1). N-P difference for CPD lab visit day -1.3 (-2.3, -0.3), p&lt;0.05. N-P difference of frequency of urges to smoke -10 (-16, -4), p&lt;0.05 N-P difference for strength of urges to smoke -8 (-13, -2), p&lt;0.01</p> <p><b>Attrition:</b> 4 females dropped out in week 1. Data complete for all participants who received treatment.</p>	<p><b>Limitations (author):</b> Other cues not replicated with the lab are likely to impact on cigarette consumption</p> <p><b>Limitations (review team):</b> No information on recruitment of participants or their motivations. Allocation method not provided. Small clinical trial within research centre.</p> <p><b>Evidence gaps:</b> None stated</p> <p><b>Funding sources:</b> MRC and ICRF</p> <p><b>Applicable to UK?</b> UK study but lab setting.</p>

<p><b>First author and year:</b> Glasgow 2009 <i>Linked papers:</i> Glasgow 2008 Levinson 2008 <b>Aim of study:</b> Effectiveness over 3 and 12 months of a smoking reduction program relative to an enhanced usual care in patients identified in health care setting <b>Study Design :</b> RCT <b>Quality score:</b> ++ <b>External validity score:</b> ++</p>	<p><b>Setting:</b> USA. Kaiser Permanente Colorado - HMO. <b>Participants:</b> 320 adult smokers. Identified via HMO's electronic database of medical records. Female: I = 73.2%, C = 71.8%; Mean age: I = 54.8, C = 56.0. Latino: I = 3.7%, C = 6.5%. <b>Inclusion:</b> Current smokers, ≥18 yrs; scheduled for outpatient surgery or diagnostic procedure <b>Exclusion:</b> Smoked &lt; 10 cigarettes, could not read or understand English; cancelled/ postponed medical procedure; unavailable for study duration. <b>Motivation of participants:</b> Not interested in quitting.</p>	<p>centre. <b>Method of allocation:</b> computer algorithm <b>Intervention(s):</b> Combination of telephone counselling and tailored newsletters over 6 months. <b>Control:</b> Enhanced usual care. <b>Sample sizes:</b> Eligible: 1064 Intervention: 164 Control=156 <b>Baseline comparisons:</b> No significant differences. <b>Study power:</b> Power calculation not reported. <b>Intervention delivery:</b> Trained phone callers</p>	<p><b>Primary outcomes:</b> Self report ≥50% reduction in CPD; CPD; ≥50% reduction in biochemical CO and CO levels at baseline, 3 and 12 months; abstinence. <b>Follow-up periods:</b> 3 and 12 months <b>Method of analysis:</b> Repeated measures analyses. Multiple regression to identify moderator variables.</p>	<p><b>Primary:</b> At 12 month ≥50% reduction in CPD (I=25% &amp; C=18.6%) and 50% reduction in CO (I=14% &amp; C=18.6%) non-significant. Mean (SD) CPD: I=15.8 (10.3); C=15.3 (9.2). Mean (SD) CO levels (SD) of I= 24.9 (14.0) &amp; C=24.3 (13.8). Abstinent: I=11 &amp; C=7. At 3 month ≥50% reduction in CPD (I=15.9% &amp; C=7.7%) p&lt;0.05, RR=2.06 and ≥50% reduction in CO (I=11% &amp; C=5.8%) non-significant, RR=1.9. No. of CPD mean (SD) of I=17.2 (9.6) &amp; C=17.3 (8.7). CO levels mean (SD) of I= 25.5 (13.5) &amp; C=26.3 (13.2). No. that quit I=1 &amp; C=2. <b>Attrition:</b> At 12 months I=37% &amp; C=18%</p>	<p><b>Limitations (author):</b> Exclusion of Spanish-speaking smokers; high attrition rate; conducted in one health care setting <b>Limitations (review team):</b> None <b>Evidence gaps:</b> Does adding components such as NRT or “teachable moment” to an upcoming medical procedure actually enhances effects or if broader, less expensive smoking reduction option might work as well. Procedures to enhance retention <b>Funding sources:</b> National Cancer Institute <b>Applicable to UK?</b> Yes</p>
<p><b>First author and year:</b> Gray 2005 <b>Aim of study:</b> To test whether a single session of motivational interviewing (MI) focussing on drinking alcohol, and cigarette and cannabis smoking, would successfully lead to reductions in use or problems. <b>Study Design :</b> Controlled before and</p>	<p><b>Setting:</b> UK based (appears to be largely in London) <b>Participants:</b> 162 young people mean age 17 years; 53% female; 29% had been in trouble with the police; 48% white in MI group, 21% white in control group; 52% with part time job in MI group, 34% in control group. <b>Inclusion:</b> Daily cigarette smokers, weekly drinkers or weekly cannabis smokers.</p>	<p><b>Method of allocation:</b> UK FE colleges (urban and rural). Separate (London) colleges for recruitment of control group. <b>Intervention(s):</b> Single MI session. <b>Control:</b> No intervention. Subjects paid £5 for completing 3 month questionnaire. <b>Sample sizes:</b> Total: 162 MI: 59</p>	<p><b>Primary outcomes:</b> <i>Smoking</i> - Prevalence, cigarettes smoked per week, cut down/quit attempts. All self report by questionnaire with some telephone completion with non-responders. Alcohol and cannabis consumption. <b>Follow-up periods:</b> 3 months post MI session. <b>Method of analysis:</b> T-tests for independent and <math>\chi^2</math> or Fishers Exact Test for categorical</p>	<p><b>Primary:</b> <i>Smoking</i> - Cigarettes smoked in previous week by MI group changed from 34.7 to 33.0 compared with 34.6 to 27.3 for the control group (not significant). 73% of the MI group reported trying to quit or cut down one or more times over the study period compared to 45% of the control group. <b>Attrition:</b> 87% (141/162) were followed up.</p>	<p><b>Limitations (author):</b> Self reported data. Non equivalent groups. Potential variation in MI delivery. <b>Limitations (review team):</b> Very little information given on the content of the MI session. Motivations of participants (and youth workers) unknown. <b>Evidence gaps:</b> Need for larger individual studies with statistical</p>

<p>after (CBA)</p> <p><b>Quality score:</b> –</p> <p><b>External validity score:</b> +</p>	<p><b>Exclusion:</b></p> <p><b>Motivation of participants:</b> Unknown.</p>	<p>Control: 103</p> <p><b>Baseline comparisons:</b> Major differences though regression analyses used.</p> <p><b>Study power:</b> Power calculation not reported.</p> <p><b>Intervention delivery:</b> MI-trained youth workers. Authors university researchers.</p>	<p>variables. Regression to control for baseline variations.</p>		<p>power.</p> <p><b>Funding sources:</b> No dedicated funding.</p> <p><b>Applicable to UK?</b> Yes – UK based.</p>
<p><b>First author and year:</b> Griffiths 2010</p> <p><b>Aim of study:</b> To examine the impact of a brief group intervention developed for individuals with severe mental illness (SMI) that integrates evidence-based and recovery-oriented strategies to address tobacco addiction.</p> <p><b>Study Design :</b> Uncontrolled before and after</p> <p><b>Quality score:</b> –</p> <p><b>External validity score:</b> –</p>	<p><b>Setting:</b> Developed. Ontario, Canada.</p> <p><b>Participants:</b> 56 subjects with severe and persistent mental illness. 76% female, average age 49 (SD 9.24), average years education 12.3 (SD 2.94), 38% with major depressive disorder, 38% bipolar affective disorder, 12% schizophrenia, 9% schizoaffective disorder.</p> <p><b>Inclusion:</b> Current diagnosis of a major mental illness, history of extensive in/out patient treatment, significant disability in one or more major life domains (eg vocational and social).</p> <p><b>Exclusion:</b> None stated.</p> <p><b>Motivation of participants:</b> No information provided</p>	<p><b>Method of allocation:</b> Convenience sample referred from Tobacco Addiction Recovery Program (TARP).</p> <p><b>Intervention(s):</b> 12 weekly 2-hour group counselling sessions held in public-hospital affiliated outpatient settings - TARP program (well described) with free NRT; participants develop a quit/reduce smoking action plan.</p> <p><b>Control:</b> No control group</p> <p><b>Sample sizes:</b> 56</p> <p><b>Baseline comparisons:</b> N/A no control group</p> <p><b>Study power:</b> Power calculation not reported.</p> <p><b>Intervention delivery:</b> Two facilitators from range of disciplines (eg nurse, occupational therapist, recreational therapist) led</p>	<p><b>Primary outcomes:</b> Self reported CPD, tobacco dependence, use of NRT.</p> <p><b>Follow-up periods:</b> None. Data immediately post 12-week intervention.</p> <p><b>Method of analysis:</b> Paired-samples t tests for the 34 completers only. Standard deviations.</p>	<p><b>Primary:</b> From 34 completers: 13 (44%) reported quitting smoking, of 20 reducers, 78% reduced the amount smoked by <math>\geq 50\%</math>. Across full group, average CPD reduced from 27.97 (SD 16.23) to 4.38 (5.55).</p> <p>Self efficacy in terms of ability to resist tobacco increased significantly (<math>p &lt; 0.001</math>).</p> <p>Samples sizes too small to explore effect of NRT use.</p> <p><b>Attrition:</b> 34/56 (61%) completed the program. 52% of those who discontinued had schizophrenia, were more likely to be younger and male (both <math>p &lt; 0.05</math>).</p>	<p><b>Limitations (author):</b> Self reported outcomes only. No control group. Small sample size</p> <p><b>Limitations (review team):</b> No follow up period. No ITT analysis. (Convenience) sample too small to generalise.</p> <p><b>Evidence gaps:</b></p> <p><b>Funding sources:</b> No information provided</p> <p><b>Applicable to UK?</b> TARP does not appear to be offered within the UK.</p>

		each group. Authors university researchers.			
<p><b>First author and year:</b> Gulliver 2008</p> <p><b>Aim of study:</b> To investigate the differential efficacy of three brief motivational interviewing interventions to yield changes in smoking behaviour among psychiatrically complex military veterans</p> <p><b>Study Design :</b> Quasi-RCT</p> <p><b>Quality score:</b> +</p> <p><b>External validity score:</b> +</p>	<p><b>Setting:</b> Boston, USA, community based</p> <p><b>Participants:</b> 208 military veterans recruited by flyers circulated through Boston VA healthcare system. 97% male; mean age 49; 67.3% Caucasian, average level of education 12.7 years; 75.2% unemployed and/or disabled; modal annual income &lt;\$10,000; 86.5% never married, separated or divorced. Sample complicated by substance use and psychiatric comorbidity [96% history of mental health care; 66% diagnosis of substance use disorder; 62% ≥1 non-substance use Axis I psychiatric diagnosis]. 39.5% also presented with lung-related disease in previous three months.</p> <p><b>Inclusion:</b> Aged ≥18 years; daily smokers; planning to remain in Boston area for ≥6 months.</p> <p><b>Exclusion:</b> There were no criteria related to psychiatric conditions, substance abuse history, or physical conditions.</p> <p><b>Motivation of participants:</b> Patients had not presented for smoking cessation or expressed any motivation to quit.</p>	<p><b>Method of allocation:</b> Not stated</p> <p><b>Intervention(s):</b> 1) MI plus instruction in deep breathing (MI/BI): as well as the MI session participants were instructed to breathe deeply and slowly for five minutes, with diaphragmatic deep breathing technique demonstrated to them and to practice three times daily. 2) MI plus instruction in use of incentive spirometer for practice in breathing/diaphragmatic control (MI/IS): following MI session participants shown how to use spirometer and instructed to practice three times daily.</p> <p><b>Control:</b> MI only (MI): a single session of MI lasting 40 to 50 minutes.</p> <p><b>Sample sizes:</b> MI/BI = 74 MI/IS = 67 MI = 67</p> <p><b>Baseline comparisons:</b> No significant differences between groups on any baseline demographic or smoking-related variable, or in psychiatric comorbidity. [Note: not all variables available for all participants-</p>	<p><b>Primary outcomes:</b> Point prevalence abstinence, defined as zero CPD, reported on the day of assessment. Self-reported abstinence verified by CO &lt;10ppm. CO also measured to assess changes across time points. Self-reported CPD.</p> <p><b>Follow-up periods:</b> Monthly for 6 months.</p> <p><b>Method of analysis:</b> To test treatment effects on point prevalence abstinence, CPD, and CO levels, generalised estimating equations with compound symmetric covariance matrix specified. All analyses included linear effect of time and controlled for baseline levels of nicotine dependence and perceived importance of quitting smoking. Analyses of CPD and CO levels also included respective variable at baseline as covariate. The treatment condition dummy-coded with MI/BI as reference group, allowing authors to test differences between MI/IS and MI/BI and between MI/IS and MI alone. Worst-case analyses conducted - assumed missing equalled smoking for point prevalence abstinence and substituted baseline levels of CPD and CO for missing data.</p>	<p><b>Primary:</b> At six months: Point prevalence abstinence 6.8% in MI/BI group, 4.5% in MI/IS group and 6.0% in MI group. CPD decreased from &gt;20 at baseline to the mid to low teens at follow-up (data presented in graph only). Lowest in the MI/BI group, followed by the MI/IS group.</p> <p>Treatment conditions did not differ significantly on point prevalence abstinence (<math>p&gt;0.30</math>) or CPD (<math>p&gt;0.65</math>). CO levels (also presented graphically) shown to have fallen from baseline to 6-month follow-up in MI/BI and MI/IS groups but increased in the MI group. MI/BI group had significantly lower CO levels during follow-ups than those receiving MI/IS (<math>B=-.57</math>, <math>SE=.19</math>, <math>p=0.003</math>). Differences between MI/IS and MI were non-significant (<math>B=-.29</math>, <math>SE=.19</math>, <math>p=0.12</math>).</p> <p><b>Attrition:</b> All participants completed assigned intervention. Monthly follow-up data obtained on at least one occasion for 71.6% of the participants. However, missing data were common, with only 39.9% providing data for all six monthly follow-ups.</p>	<p><b>Limitations (author):</b> No non-MI control group. Therapist adherence to MI procedures not systematically evaluated. Relatively short follow-up period (6 months) and data only looked at point prevalence abstinence rather than sustained abstinence. Extent to which participants practiced intervention techniques (BI or IS) outside the intervention itself and 9 participants in MI only condition reported using these techniques. Participants had contact with research staff who administered smoking assessment at each time point, which may have influenced their motivation to quit smoking and thus contributed to the outcome. Population was almost entirely (97%) male.</p> <p><b>Limitations (review team):</b> Significant attrition. No information on allocation methods.</p> <p><b>Evidence gaps:</b> Not reported</p> <p><b>Funding sources:</b> VA Research Enhancement Award Program grant, NIDA</p>

		<p>varied from n= ≥190.]</p> <p><b>Study power:</b> Power approx .80, depending on the degree of correlation between time points for a given outcome, for detecting differences between conditions of medium size (d=.50) using generalised estimating equations for the primary analyses. Effects as small as d=.40 could be detected with power of .80 in analyses with no missing data.</p> <p><b>Intervention delivery:</b> Study therapists all doctoral level psychologists with a minimum of three years' experience treating addictions and were trained using Motivational Interviewing Professional Training Series.</p>			<p>grants, and funding from the Department of Veterans Affairs.</p> <p><b>Applicable to UK?</b> Yes</p>
<p><b>First author and year:</b> Hanson 2008</p> <p><b>Aim of study:</b> To determine if adolescents not interested in quitting smoking can reduce cigarette consumption, and if cigarette reduction leads to a corresponding and significant reduction in biomarkers of exposure</p> <p><b>Study Design :</b> Quasi-RCT</p>	<p><b>Setting:</b> USA, high schools in the suburbs of Minneapolis-St Paul.</p> <p><b>Participants:</b> 103 participants aged 13-19; mean age 16.6 years, 57.8% female, 86.3% Caucasian, mean CPD 11.8; 61.4% had received psychiatric treatment; 41.7% used psychiatric medication.</p> <p><b>Inclusion:</b> Smoking ≥5 CPD for ≥six months; not using any other tobacco products more than once per week; wanting to</p>	<p><b>Method of allocation:</b> Not stated</p> <p><b>Intervention(s):</b> Two intervention groups: NRT patch and NRT gum. Patch usage: ≥15 CPD: 14mg patch during Week 1, increased to 21mg during last three weeks, those smoking 10-14 CPD started with 7mg, increased to 14 mg, 5-9 CPD 7mg patch for all four weeks. Gum: recommended usage</p>	<p><b>Primary outcomes:</b> CPD, expired CO levels, urinary cotinine levels.</p> <p><b>Secondary outcomes:</b> Abstinence</p> <p><b>Follow-up periods:</b> 3 and 6 months.</p> <p><b>Method of analysis:</b> Analysis of Variance applied to test overall equality of means of continuous variables among treatment groups, <math>\chi^2</math> tests to test difference of distributions of categorical variables. For repeated measurement</p>	<p><b>Primary:</b> No differences across treatment groups at either follow-up time points for any smoking related variables (all p&gt;0.05). Across all treatment groups participants reduced mean CPD significantly at end-of-treatment and follow-up visits compared to baseline (all adjusted p values &lt;.0001). At end of treatment 49.4% participants reduced smoking by ≥50%. CO levels decreased significantly at end of treatment but increased at follow-up visits. Levels significantly</p>	<p><b>Limitations (author):</b> No placebo patch or gum. The study was not blinded. Limited power to detect inter-group differences. Feasibility of replicating the study in the community may be limited in terms of the cost of providing medication, CBT, and participants' compensation. Sample may be unrepresentative of adolescent smokers - very high level of co-morbidity among participants.</p>

<p><b>Quality score:</b> +</p> <p><b>External validity score:</b> ++</p>	<p>reduce smoking but not having set a quit date within the next two months; not using NRT or bupropion; not taking medication contra-indicated for use with study medications; not abusing alcohol or drugs; not experiencing severe emotional problems within the past year; not taking psychoactive medications that were not stabilised or were likely to change during the course of the study.</p> <p><b>Exclusion:</b> None stated.</p> <p><b>Motivation of participants:</b> Participants not interested in quitting.</p>	<p>based on participants' baseline level of smoking: one piece of 2mg gum substituted for one cigarette.</p> <p><b>Control:</b> 400mg folic acid daily.</p> <p>Participants across all three groups met weekly for six weeks.</p> <p>Baseline = visits 1 and 2. During next four weeks participants began using study medications and reduced smoking. Participants told to reduce smoking by 25% during Week3 and by 50% during Weeks 4-6.</p> <p>Participants also received CBT at each visit designed to help reduce smoking. At end of week 6, participants asked if they wanted to set a quit date within one week. Those who chose to do received four additional weeks of their choice of medication and CBT sessions designed to help them quit.</p> <p><b>Sample sizes:</b> Patch = 34 Gum = 33 Control = 36</p> <p><b>Baseline comparisons:</b> No significant differences between groups in demographic variables, although patch group showed some substantial non-significant, differences in</p>	<p>outcomes, linear mixed model with random subject effect used to evaluate treatment group and time effects (means reported are least square means). Interaction term introduced in initial model and removed if it was insignificant. Time (visit) was treated as a discrete variable. Akaike Information Criterion applied in model selection. Adjustment of p-values for multiple comparisons performed by Bonferroni method. Significance level set at 5%.</p>	<p>higher in gum group than in patch group at third visit (p=0.05). Cotinine levels did not decrease significantly at end of treatment or at follow-up visits. Mean cotinine levels decreased at three-month follow up visit but increased significantly at six month follow-up visit (p=0.04).</p> <p><b>Secondary:</b> 53/103 participants entered smoking cessation treatment. Patch = 21; gum = 13; control = 19). 30-day abstinence 4.9% at six months 6.8% at three months 0% at end of treatment. 7-day point prevalence abstinence: 6.8% at six month follow-up; 12.6% at three month follow-up; 1.9% at the end of treatment; No significant difference for 7 or 30 day abstinence rates (all adjusted values p &gt;.05).</p> <p><b>Attrition:</b> 91.3% of participants completed the study (Week 6). 85.1% completed the three month follow-up visit and 71.3% completed the six month follow-up.</p>	<p>Advertising a smoking reduction programme in schools could influence adolescents to think smoking at a reduced level poses no health issues or quitting isn't necessary.</p> <p><b>Limitations (review team):</b> As above.</p> <p><b>Evidence gaps:</b> None stated</p> <p><b>Funding sources:</b> None stated</p> <p><b>Applicable to UK?</b> Three of 14 schools in the study for students who had recently completed drug or alcohol treatment - not representative of UK. No reason why intervention couldn't be delivered to adolescent smokers in a general school setting.</p>
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		<p>certain baseline variables - lower number of females and higher duration of prior abstinence.</p> <p><b>Study power:</b> No power calculation provided.</p> <p><b>Intervention delivery:</b> Authors are university researchers. No information on who delivered CBT component.</p>			
<p><b>First author and year:</b> Hatsukami 2005 <i>Linked paper:</i> Hecht 2004</p> <p><b>Aim of study:</b> To study the consistency of risk measures for cardiovascular disease and to examine the dose response relationship as the number of cigarettes is reduced.</p> <p><b>Study Design :</b> Quasi RCT (but results presented as per uncontrolled before and after study)</p> <p><b>Quality score:</b> -</p> <p><b>External validity score:</b> +</p>	<p><b>Setting:</b> USA - Minnesota</p> <p><b>Participants:</b> 151 adult cigarette smokers recruited via advertisements on radio or in metropolitan and campus newspapers. Age 44.73 years; gender: 45.7% male; FTND: 6.07</p> <p><b>Inclusion:</b> 15 – 45 CPD for past year; age 18 to 70; interested in significantly reducing cigarette use, but no plans to quit in next 30 days.</p> <p><b>Exclusion:</b> Psychiatric diagnoses; using other tobacco or nicotine products; pregnancy; unstable medical condition; contraindications for NRT use.</p> <p><b>Motivation of participants:</b> Participants were interested in reducing cigarette use but not quitting.</p>	<p><b>Method of allocation:</b> Not stated</p> <p><b>Intervention(s):</b> After baseline, planned reduction from baseline levels to: 75% in first 2 weeks, 50% in weeks 3-4 25% in weeks 5-6.</p> <p>Participants given 4 mg gum and instructions on how to achieve reduction (substitution, timed interval use and situational use). Recommendations for gum usage based on CPD. Those who found it difficult to achieve 50% or 75% goals offered 14mg nicotine patch to be used with gum.</p> <p><b>Control:</b> Wait list - after baseline (2 weeks), participants maintained and monitored smoking for a further 6 weeks. Followed by reduction as per</p>	<p><b>Primary outcomes:</b> Measurement of complete blood count, lipoprotein profile (serum), urinary anatabine and cotinine at baseline, weeks 4, 6 and 12 (to determine consistency of cardiovascular biomarkers during <i>ad libitum</i> smoking and dose-response when CPD reduced). Smoking reduction and abstinence: self reported CPD. Respiratory symptoms,</p> <p><b>Follow-up periods:</b> 26 weeks from baseline.</p> <p><b>Method of analysis:</b> Pearson correlation coefficients were calculated between every pair of the baseline data for each variable (wait list control data) Paired t tests were used to investigate the effects of reduction on mean biomarker values.</p>	<p><b>Primary:</b> <i>Note: no separate data for intervention and control (wait list) groups.</i> At 26 weeks: 41/151 (27%) achieved <math>\geq 40\%</math> reduction in CPD; 11/151 participants (7%) achieved biochemically verified 30 day abstinence. At 12 weeks: Among non-abstinent <math>\geq 40\%</math> reducers (64/151), significant improvements found in many biomarkers vs mean baseline values (hemoglobin, hematocrit, RBC and WBC counts, lipids, BP, heart rate, respiratory symptoms, all <math>p &lt; 0.0167</math>).</p> <p><b>Attrition:</b> 98/151 participants completed treatment to Week 12: I = 37; C = 16 (3 during wait phase)</p>	<p><b>Limitations (author):</b> Short time scale for measurement of biomarkers (they may adjust slowly to reduced smoking)</p> <p><b>Limitations (review team):</b> Authors do not present results separately for intervention and control (wait list) groups. Significant attrition (&lt;35%) over 12 weeks.</p> <p><b>Evidence gaps:</b> Authors report that, although smoking reduction improves biomarker measurements, it is unclear whether these changes translate into significant health improvements.</p> <p><b>Funding sources:</b> The study was supported by a National Institutes of Health grant.</p> <p><b>Applicable to UK?</b></p>

		<p>intervention group -----.</p> <p>All participants monitored their cigarette consumption for 2 weeks (baseline)</p> <p><b>Sample sizes:</b> I = 102 C = 49</p> <p><b>Baseline comparisons:</b> Not reported</p> <p><b>Study power:</b> No power calculation presented, but authors report a sample size of 64 non-abstinent participants achieving a 40% reduction and describe it as sufficient.</p> <p><b>Intervention delivery:</b> Authors are university researchers.</p>			Yes
<p><b>First author and year:</b> Hatsukami 2007</p> <p><b>Aim of study:</b> To determine if higher NRT doses in conjunction with smoking are safe and may promote significant reductions in cigarette smoking and biomarkers of exposure</p> <p><b>Study Design :</b> Uncontrolled before and after</p> <p><b>Quality score:</b></p>	<p><b>Setting:</b> Developed. Minnesota community</p> <p><b>Participants:</b> Volunteers from multi-media advertising</p> <p><b>Inclusion:</b> Aged 18-70, smoked 20-25 CPD over past year, interested in reducing but no plans to set quit date in next 2 months, good or stable physical health with no cardiovascular disease history, good or stable mental health</p> <p><b>Exclusion:</b></p>	<p><b>Method of allocation:</b> Community recruitment via radio, television, flyers and newspaper advertisements</p> <p><b>Intervention(s):</b> Two weekly baseline visits followed by 5 weeks escalation of NRT patch – week 3 15 mg, week 4 30 mg, week 5 45mg. Then two weeks de-escalation (week 6 30 mg, week 7 15 mg). Instruction to smoke as much as needed. \$10 paid for each visit during treatment and \$25 for follow up visit</p>	<p><b>Primary outcomes:</b> Self reported CPD (diary cards), CO, urinary cotinine (NB – NRT use), nicotine withdrawal, physiological measures.</p> <p><b>Secondary outcomes:</b> Relationship of NRT dose to smoking reduction and toxicant exposure</p> <p><b>Follow-up periods:</b> End of 5 week treatment period. 5 weeks post treatment (for health status only).</p> <p><b>Method of analysis:</b> ANOVA models to link outcomes to baseline levels. Restricted</p>	<p><b>Primary:</b> Reductions in CPD week by week were significant to week 5 but not from weeks 5 to 7. CPD from week 3 to 4 (15 to 30 mg NRT) reduced by 5.81 (p&lt;0.0001). For CO, significant reductions were noted from weeks 3 to 4 (15mg to 30 mg patch) (-3.36, p=0.0004) and weeks 4 to 5 (30 mg to 45 mg) (-3.25, p=0.0016). No differences were found for weeks 5 to 7.</p> <p>There was some evidence of greater inhalation per cigarette as CPD reduced.</p> <p><b>Secondary:</b></p>	<p><b>Limitations (author):</b> Self reported CPD, lack of placebo control, some variations in the way patches were applied (eg 45 mg patch at noon rather than in the morning).</p> <p><b>Limitations (review team):</b> Analysis for still-smoking completers only. No post-treatment follow up.</p> <p><b>Evidence gaps:</b></p> <p><b>Funding sources:</b> National Institute on Drug</p>

<p>– <b>External validity score:</b> –</p>	<p>Specific medical conditions (eg cardiovascular), medication use that might affect or be affected by tobacco use, pregnant or nursing <b>Motivation of participants:</b> Not immediately interested in quitting</p>	<p><b>Control:</b> No control <b>Sample sizes:</b> 64 initially, 25 remained in study. Analysis on 20 still smoking completers. <b>Baseline comparisons:</b> No control <b>Study power:</b> Not provided <b>Intervention delivery:</b> Authors are university researchers</p>	<p>only to those who had not quit smoking and received full treatment course</p>	<p>2/25 subjects could not tolerate the 45 mg patch. <b>Attrition:</b> Adherence to NRT use measured and 87.1-91.4% over the seven weeks. Only 25 in study from 64 expressing interest – 20 still smoking completers (31%).</p>	<p>Abuse. GlaxoSmithKline provided the patches. <b>Applicable to UK?</b> Yes, feasible.</p>
<p><b>First author and year:</b> Horn 2007 <b>Aim of study:</b> To examine the efficacy of an emergency department based motivational teenage smoking intervention. <b>Study Design :</b> RCT <b>Quality score:</b> + <b>External validity score:</b> ++</p>	<p><b>Setting:</b> USA. Emergency Department in suburban, university affiliated hospital in Morgantown, West Virginia. <b>Participants:</b> 75 adolescent smokers attending an emergency department initially enrolled. One participant was discharged before finishing the assessment. This left a baseline sample 75 smokers aged 14-19 years. 57.3% were female and 96.0% were white, the mean age was 17.8 years. One participant withdrew following the MTI assessment, bringing the final sample to 74. <b>Inclusion:</b> Participants were eligible if they 1) reported smoking on 1 or more days in the past 30 days, 2) provided written assent and consent (a parent or guardian had to be present).</p>	<p><b>Method of allocation:</b> Sequentially numbered folders containing intervention or control forms in single pile sorted by SAS random number function. Providers blinded during initial screening and did not know patient's group assignment until folder was opened after screening. <b>Intervention(s):</b> The motivational tobacco intervention was delivered in the emergency department and consisted of 1) screening; 2) a 15 to 30 minute patient-tailored face-to-face motivational interview including a readiness assessment, a reflection on smoking behaviours, and a health inventory; 3) a stage matched self-help, take home workbook with audio; 4) one handwritten personal postcard within 3 days of the</p>	<p><b>Primary outcomes:</b> Self-reported quitting and days of continuous abstinence Self-reported reduction in CPD <b>Follow-up periods:</b> 6 months <b>Method of analysis:</b> Baseline differences examined using multiple <math>\chi^2</math> and t-test analyses, with level of significance (.05) divided by 10 (.005) to correct for controlling heightened error. <math>\chi^2</math> analyses to calculate both intent-to-treat and compliant sample quit rates (compliant sample analysis to assess relative efficacy of I vs C and intent-to-treat to assess intervention efficacy independently). Reduction rates from baseline calculated and mean percentage rates among teenagers reducing for baseline. Attrition analysis conducted to identify baseline differences</p>	<p><b>Primary:</b> Intervention patients showed greater initial reduction than control but 6-month post-baseline values were not significant (20.5% versus 6.1% reduced CPD compared to baseline; <math>p=0.15</math>). Differences in quit rates at 6 months post baseline were not statistically significant (2.5% versus 2.9%, <math>p=0.55</math>) <b>Attrition:</b> 28 participants (37%) provided information on quitting at the six month follow-up; 26 (35%) provided information on reduction.</p>	<p><b>Limitations (author):</b> Recruitment problematic; many participants in too much pain or emotional distress, or having psychiatric problems and therefore not approached. Obtaining consent and assent for younger teenagers challenging and older participants over-represented. The majority of study participants were white. Low retention rates. <b>Limitations (review team):</b> As above <b>Evidence gaps:</b> None stated <b>Funding sources:</b> United States Department of Health and Human Services, Agency for Healthcare Research and Quality. <b>Applicable to UK?</b></p>

	<p><b>Exclusion:</b> Participants were ineligible if they 1) arrived in police custody, 2) had communication deficits, such as an inability to speak English, or were severely hearing-, vision-, or speech-impaired, 3) were deemed mentally incompetent, 4) had life or limb threatening conditions, or 5) were verbally or physically combative.</p> <p><b>Motivation of participants:</b> Not stated</p>	<p>ED visit; and 5) three follow-up “booster” phone calls at 1, 3, and 6 months post ED visit.</p> <p><b>Control:</b> Representing standard care: 1) screening; 2) ≤2 minutes generic advice to quit smoking; 3) referral to Health Line - state 1-800 telephone help information line; 4) one follow-up call 6-months post ED visit.</p> <p>-----</p> <p>Providers approached patients for both conditions in ED waiting area following check-in</p> <p><b>Sample sizes:</b> Eligible = 128 Baseline = 75 I = 41 C = 34</p> <p><b>Baseline comparisons:</b> Participants equivalent for most baseline variables. Only significant difference CPD at weekends (I &gt; C; p=0.03).</p> <p><b>Study power:</b> No power calculation reported</p> <p><b>Intervention delivery:</b> Intervention providers had relevant backgrounds in social work, psychology, and public health education. They received ~75 hours of training on MI strategies, study protocol and study forms. Training conducted by the researchers.</p>	<p>between those providing 6-month data and those who did not. 2 x 2 (present/absent x I/C) MANOVA performed on factors of weekday, weekend CPD, nicotine dependence, age, and previous quit attempts.</p>		<p>Yes, although feasibility of delivering interventions in accident and emergency departments seems limited to me.</p>
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<p><b>First author and year:</b> Hovell 2000</p> <p><b>Aim of study:</b> To test the efficacy of behavioural counselling for smoking mothers in reducing young children's exposure to environmental tobacco smoke.</p> <p><b>Study Design :</b> RCT</p> <p><b>Quality score:</b> ++</p> <p><b>External validity score:</b> ++</p>	<p><b>Setting:</b> USA – San Diego, California</p> <p><b>Participants:</b> 108 low income mothers who were using a supplemental nutrition programme. 21% black; 28% Hispanic. 47% white. 4% other 46%: single mothers 12% employed Education: 39%: &lt; high school diploma; 29%: some college (3% graduates) Mean age (SD): I = 28.5(6.6); C: 29 (6.9)</p> <p><b>Inclusion:</b> English and Spanish speaking mothers with child(ren) &lt;4 years who smoked ≥2 CPD and exposed their child(ren) to the smoke from ≥1 CPD.</p> <p><b>Exclusion:</b> Breast feeding, no telephone.</p> <p><b>Motivation of participants.</b> Not defined.</p>	<p><b>Method of allocation:</b> Random numbers were used to stratify assignment by three ethnic groups.</p> <p><b>Intervention(s):</b> Seven individualised counselling sessions over three months (3 in person, 4 by phone). Mothers set long term goals at first session, signed contracts and were given 'No Smoking' signs and stickers; at subsequent sessions new objectives were set and positive feedback given where appropriate.</p> <p><b>Control:</b> Usual nutritional counselling and brief advice about smoking and child ETS exposure.</p> <p><b>Sample sizes:</b> Eligible: 162 Intervention: 53 Control: 55</p> <p><b>Baseline comparisons:</b> Well matched</p> <p><b>Study power:</b> Exceeded 0.80 for all dependent variables.</p> <p><b>Intervention delivery:</b> Graduate students with 20 hours of training and weekly supervision by case review.</p>	<p><b>Primary outcomes:</b> Mother's reported smoking, with saliva cotinine verification at 9 months. Cessation at 9 months Nicotine monitoring and child urinary cotinine concentrations were also measured.</p> <p><b>Follow-up periods:</b> 12 months from baseline (9 months follow-up.)</p> <p><b>Method of analysis:</b> Dependent variables were adjusted by logarithmic or square root transformation. Differential rate of change in reported exposure and cotinine estimates of exposure relied on analyses of repeated measures over time. The effects of counselling were analysed using GEE, with linear components of time as "within subjects" factors and the interaction as a "between subjects" factor. Calculated differential change from baseline to end of follow up and then repeated this for baseline to three months (counselling effect) and from three months to end of follow up (maintenance effect).</p>	<p><b>Primary:</b> During follow up, counselled mothers' cotinine concentrations decreased to 80.6 ng/ml at 12 months from baseline, while those of the controls increased to 112.9 ng/ml. Non-significant difference between groups by time (P = 0.06), suggesting a possible decrease in the relative level of smoking for counselled mothers compared with controls. There were no significant differences in the numbers of mothers who stopped smoking (I = six; C = 4).</p> <p><b>Attrition:</b> Loss to follow-up: I = 9/53 and C = 3/55.</p>	<p><b>Limitations (author):</b> None reported.</p> <p><b>Limitations (review team):</b> None</p> <p><b>Evidence gaps:</b> Interventions that combine formal counselling for quitting smoking with counselling for reducing children's exposure to environmental tobacco smoke. Should also extend follow up to assess how long the effects of counselling are maintained and the developmental trends in exposure to environmental tobacco smoke.</p> <p><b>Funding sources:</b> Grant No 027946 SFP awarded to MFH from the Robert Wood Johnson Foundation Smoke-Free Families Program, and by discretionary funds from the Center for Behavioral Epidemiology and Community Health. No competing interests.</p> <p><b>Applicable to UK?</b> Yes, potentially.</p>
<p><b>First author and year:</b> Hurt 2000</p> <p><b>Aim of study:</b> To determine if</p>	<p><b>Setting:</b> Developed. USA. Rochester, Minnesota (presumably but not stated).</p>	<p><b>Method of allocation:</b> Volunteers in response to press releases and media adverts.</p>	<p><b>Primary outcomes:</b> CPD (self report by diaries), CO, cotinine (NB nicotine used), withdrawal symptoms, use of</p>	<p><b>Primary:</b> Subjects reported reductions in CPD. Baseline: 41.9 ± 3.2, 12 weeks: 18.2 ± 8.2, 24 weeks: 26.7 ± 10.8</p>	<p><b>Limitations (author):</b> None stated</p> <p><b>Limitations (review team):</b> Very small sample size. No</p>

<p>smoking reduction using a nicotine inhaler in heavy cigarette smokers who wanted to reduce but not stop smoking results in decreased levels of known biomarkers of harm.</p> <p><b>Study Design :</b> Uncontrolled before and after</p> <p><b>Quality score:</b> –</p> <p><b>External validity score:</b> –</p>	<p><b>Participants:</b> 23 heavy cigarette smokers. Mean age 49.1 ±11.9 years, 57% female, 41.9 ± 3.2 CPD at baseline.</p> <p><b>Inclusion:</b> ≥18 years, interested in reducing but not stopping smoking, ≥40 CPD over past 12 months, regular smoker for ≥10 years, no risk of pregnancy during study.</p> <p><b>Exclusion:</b> Pregnancy, use of nicotine or tobacco products other than cigarettes during past 30 days, current use of any behavioural or pharmacological smoking cessation programme, unstable angina or myocardial infarction during past 3 months, non-nicotine dependence, excessive exposure to fumes, non-tobacco smoke or environmental tobacco smoke, use of antiepileptic medications.</p> <p><b>Motivation of participants:</b> Want to reduce but not stop smoking</p>	<p><b>Intervention(s):</b> Weekly (10-15 minute) behavioural counselling sessions and NRT provision for 12 weeks. Participants instructed to reduce CPD from 40 to 10 using a schedule: week 1-4 to 30 CPD weeks 5- 8 to 20 CPD weeks 9-24 to 10 CPD. Use of inhaler supplying up to 5 mg nicotine per cartridge. Subjects asked to use ≥6 but no more than 16 nicotine inhaler cartridges per day. Follow up phone calls at 16 weeks and final assessment at 24 weeks.</p> <p><b>Control:</b> No control</p> <p><b>Sample sizes:</b> 23</p> <p><b>Baseline comparisons:</b> No control</p> <p><b>Study power:</b> Not provided</p> <p><b>Intervention delivery:</b> Counselling by an experienced research assistant. Authors are university researchers.</p>	<p>inhaler.</p> <p>Also blood thiocyanate, 4-aminobiphenyl haemoglobin adducts, urine NNAL and NNAL-glucuronide (nitrosamines)</p> <p><b>Follow-up periods:</b> 24 weeks from baseline (12 weeks post intervention) CO measured each week in weeks 0-12, cotinine at 0, 4, 8 and 12 weeks.</p> <p><b>Method of analysis:</b> One sample signed rank test for cotinine and CO. Means ± standard deviations. Linear regression to test associations.</p>	<p>CO levels (ppm) were not significantly reduced from baseline at any measured time point. Baseline: 30.4 ± 9.0, 12 weeks: 24.1 ± 8.3, 24 weeks: 26.0 ± 8.0</p> <p>Inhaler cartridge use was 2.5 ± 2.9 in week 1, 2.4 ± 2.8 in week 4, 1.1 ± 1.8 by week 12. Inhaler use was inversely associated with smoking rate.</p> <p>Follow-up data is for 16 completers</p> <p><b>Attrition:</b> 16/23 subjects (70%) completed 12-week intervention and follow-up.</p>	<p>control group. Significant attrition during intervention period. No ITT analysis</p> <p><b>Evidence gaps:</b> None stated</p> <p><b>Funding sources:</b> Part funding from McNeil Consumer Products</p> <p><b>Applicable to UK?</b> Probably not. Expert Advisory Group advice that intensive counselling is unlikely to be feasible in a UK setting.</p>
<p><b>First author and year:</b> Irvine 1999</p> <p><b>Aim of study:</b> To investigate whether parents of asthmatic children would stop</p>	<p><b>Setting:</b> UK. Tayside and Fife, Scotland</p> <p><b>Participants:</b> 501 families with an asthmatic child living with a parent who smoked.</p>	<p><b>Method of allocation:</b> Not stated.</p> <p><b>Intervention(s):</b> Baseline visit: parents given information on passive smoking, followed by a</p>	<p><b>Primary outcomes:</b> Child cotinine concentrations*</p> <p><b>Secondary outcomes:</b> Self-report changes in smoking: CPD Same room as child*</p>	<p><b>Primary:</b> * Results not reported – not relevant to this review.</p> <p><b>Secondary outcomes:</b> Self-report CPD (p=0.65) Smoked less (<i>including 12 parents</i>)</p>	<p><b>Limitations (author):</b> None stated.</p> <p><b>Limitations (review team):</b> Unclear whether study is adequately powered (underpowered for primary</p>

<p>smoking or alter their smoking habits to protect their children from environmental tobacco smoke.</p> <p><b>Study Design :</b> Quasi-RCT</p> <p><b>Quality score:</b> +</p> <p><b>External validity score:</b> ++</p>	<p><b>Index parent (main carer):</b> 21% male; 16% completed higher education; 21% in non-manual employment; 39% owner-occupiers; 76% living with partners.</p> <p><b>Inclusion:</b> Children aged 2-12. If both parents smoked, main carer was identified as 'index parent'.</p> <p><b>Exclusion:</b> Children not taking asthma medications or not diagnosed with asthma. Smoking parent seldom at home, children unable to provide saliva samples.</p> <p><b>Motivation of participants:</b> Not stated.</p>	<p>discussion on asthma, passive smoking, effects of ETS, and potential benefits to the child of avoiding it. Financial and health benefits discussed. Parents given information on how to seek help to stop smoking, advised if they couldn't stop smoking that smoking in a different room or outside the home could help to protect their child, and advised child's exposure to tobacco smoke could be reduced further by discouraging visitors from smoking. Given leaflet designed to reinforce and with info on seeking help to stop smoking. Also commercially available leaflet by Advisory Council on Drug and Alcohol Education). At 4 and 8 months after baseline visit, parents sent further leaflet with letter encouraging cessation.</p> <p><b>Control:</b> Commercial leaflet on smoking but no additional info on passive smoking and asthma. Not advised to stop smoking to protect child.</p> <p><b>Sample sizes:</b> Eligible families: 803 Baseline: 501 Follow-up data for 435 families: I= 213; C= 222</p> <p><b>Baseline comparisons:</b> No significant differences reported.</p>	<p>In the home*</p> <p><b>Follow-up periods:</b> One year after initial visit</p> <p><b>Method of analysis:</b> <math>\chi^2</math> and t-tests for baseline and follow-up comparisons. Data analysed for completers only</p>	<p><i>I=7; C=5 who had stopped smoking):</i> I=59 (28%); C=55 (25%) Smoked same amount: I= 59 (28%); C=55 (25%) Smoked more: I=58 (27%); C=47 (21%)</p> <p><b>Attrition:</b> Follow-up data for 435 families (86.8%)</p>	<p>outcome which is not included). Results for completers only. No ITT analysis.</p> <p><b>Evidence gaps:</b> None stated.</p> <p><b>Funding sources:</b> Wellcome Trust (grant number 039282/Z/93/Z). No competing interests declared.</p> <p><b>Applicable to UK?</b> Yes – a UK study</p>
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		<p><b>Study power:</b> Calculated for primary outcome - not relevant to this review. 248 children in each group to detect decrease in cotinine concentrations from 86% to 74% in children with concentrations &gt;0.6 ng/ml with a power of 90%.</p> <p><b>Intervention delivery:</b> Research nurses.</p>			
<p><b>First author and year:</b> Jiménez-Ruiz 2002</p> <p><b>Aim of study:</b> To study the efficacy of nicotine gum in helping hard core smokers with severe chronic obstructive pulmonary disease (COPD) to quit.</p> <p><b>Study Design :</b> Uncontrolled before and after</p> <p><b>Quality score:</b> -</p> <p><b>External validity score:</b> -</p>	<p><b>Setting:</b> Developed. Smoker’s clinic, Madrid, Spain.</p> <p><b>Participants:</b> 17 smokers with severe COPD (FEV<sub>1</sub> 38-47% of predicted normal). 88% male. Mean age 55±15 years, mean 42±9 CPD.</p> <p><b>Inclusion:</b> Severe COPD (&lt;50% predicted normal), smoking &gt;30 CPD,</p> <p><b>Exclusion:</b></p> <p><b>Motivation of participants:</b> Unable to quit</p>	<p><b>Method of allocation:</b> Consecutive patients at clinic (unclear whether COPD or smoker’s clinic).</p> <p><b>Intervention(s):</b> Provision of 4-mg nicotine gum with instructions on use for 18 months. Advised to use as much as they wanted to reduce CPD as much as possible.</p> <p><b>Control:</b> No control group</p> <p><b>Sample sizes:</b> 17</p> <p><b>Baseline comparisons:</b> No control group</p> <p><b>Study power:</b> Not reported</p> <p><b>Intervention delivery:</b> Authors were clinical researchers (University hospital)</p>	<p><b>Primary outcomes:</b> CPD, nicotine use, spirometric tests at 12 and 18 months. Expired CO, adverse events at each visit.</p> <p><b>Follow-up periods:</b> 18 months. Weekly clinic visits to 6 weeks, then monthly.</p> <p><b>Method of analysis:</b> Values (CPD, ppm CO) plus standard deviations.</p>	<p><b>Primary:</b> A 12 and 18 months 5 patients (29%) continued to use nicotine gum (10-12 pieces per day) and had substantially reduced their CPD compared to baseline 6 ± 7 CPD at 18 months compared to 39 ± 11 at baseline (expired CO 12 ± 3 vs 31 ± 6). 12 patients had stopped using NRT within the 12 months and relapsed to baseline CPD levels.</p> <p><b>Attrition:</b> None</p>	<p><b>Limitations (author):</b></p> <p><b>Limitations (review team):</b> Very small uncontrolled study.</p> <p><b>Evidence gaps:</b> None stated</p> <p><b>Funding sources:</b> No information provided</p> <p><b>Applicable to UK?</b> No - too small to generalise.</p>
<p><b>First author and year:</b> Joseph 2008</p> <p><b>Aim of study:</b></p>	<p><b>Setting:</b> USA, Minnesota and Minneapolis.</p>	<p><b>Method of allocation:</b> Computer generated random assignment.</p>	<p><b>Primary outcomes:</b> All assessed at follow up visits at 1, 3, 6, 12 and 18 months:</p>	<p><b>Primary:</b> Smoking reduction: At 18 months: SR smokers reduced from 27.7 CPD (baseline) to 17.9 CPD.</p>	<p><b>Limitations (author):</b> Suboptimal power to exclude some important differences in clinical</p>



<p>To determine the effect of a smoking reduction intervention on smoking behaviour, symptoms of heart disease and biomarkers of tobacco exposure.</p> <p><b>Study Design :</b> RCT</p> <p><b>Quality score:</b> +</p> <p><b>External validity score:</b> ++</p>	<p><b>Participants:</b> 152 smokers (≥15 cigs/day) aged 18 – 80. Age: 57.49 (I), 58.39 (C) Gender: 89.74% male (I), 87.84% (C) Ethnicity: 96.05% white (I), 87.32% (C) Education: 71.43% high school graduate (I), 72.22% (C); 16.88% college graduate (I), 16.67% (C) Income: &lt;\$30k/year: 65.67% (I), 70.31% (C) FTND score: 6.03 (I), 5.95 (C)</p> <p><b>Inclusion:</b> Cardiovascular disorder (confirmed by medical records).</p> <p><b>Exclusion:</b> Unstable angina within the past 2 weeks. Unstable psychiatric or substance abuse disorders. Any contraindication to NRT (including pregnancy or intention to become pregnant).</p> <p><b>Motivation of participants</b> Unwilling and uninterested in setting a quit date in the next 30 days.</p>	<p><b>Intervention(s):</b> Smoking Reduction (SR): Counselling and adjunctive NRT therapy. Behavioural strategies: different strategies were described and participants choose most appealing option NRT: substitute 4 mg gum for each cigarette, switching to patch if using &gt; 6 pieces per day or if not reducing with gum alone.</p> <p><b>Control:</b> Usual care (UC): Initial counsellor visit to encourage participant to seek cessation assistance. No other counselling or pharmacotherapy.</p> <p><b>Sample sizes:</b> SR: n= 78 UC: n=74</p> <p><b>Baseline comparisons:</b> No significant differences between groups.</p> <p><b>Study power:</b> Given sample sizes, authors state the study had 80% power to detect an absolute increase in cigarette reduction of 20% at 6 months and 70% at 12 and 18 months.</p> <p><b>Intervention delivery:</b> University researchers</p>	<p>Smoking behaviours Symptoms/severity of heart disease Quality of Life Adverse events 6 minute walk test Biomarkers: CO (expired air), total cotinine (urine), total nicotine (urine), white blood cell count, fibrinogen (blood), NNAL, total NNAL, 1-HOP (urine). C-reactive protein (blood)</p> <p><b>Follow-up periods:</b> Study period was 18 months but support for reduction was given to SR participants throughout this time. Effectively no post-intervention period therefore.</p> <p><b>Method of analysis:</b> Smoking reduction: Student’s t-test conducted on differences to compare treatments. Clinical outcomes: t-tests or chi-squared tests. Biomarkers: t-tests on rates of changes per month from baseline to the last follow up date. Proportions of subjects experiencing severe adverse event or cardiac event: Fisher’s exact test.</p>	<p>UC subjects reduced from 27.0 CPD (baseline) to 18.2 CPD (p=0.694). At 12 months: SR smokers reduced to 17.6 CPD. UC subjects reduced to 20.5 CPD (p=0.088). At 6 months: SR smokers reduced to 16.8 CPD. UC subjects reduced to 19.6 CPD (p=0.202).</p> <p>Smoking abstinence: At 18 months:9/78 (SR) vs 9/74 (UC) At 12 months: 6/78 (SR) vs 4/74 (UC) At 6 months: 7/78 (SR) vs 5/74 (UC) All non significant..</p> <p>Clinical Outcomes: 6 minute walk (18 months): decline in distance walked from baseline was greater in UC subjects (535 feet vs 224 feet in SR, p=0.01) but proportion of participants completing the walk was greater for UC subjects (52% UC vs 30% SR, p=0.039)</p> <p>Otherwise no significant differences. Adverse events: Serious events were approximately equally distributed other than need for urgent cardiac care at 6 months (n=0 SR vs n=5 UC, p=0.02)</p> <p>Biomarkers: Nicotine and cotinine: No significant differences at any time point between treatment groups. Expired CO: decrease in both groups to a similar extent (SR baseline 24 ppm, 18 months 16 ppm, gradient -0.21; UC baseline 25 ppm, 18 months 18 ppm,gradient -0.47)</p> <p>Secondary analyses: <b>Attrition:</b> Follow up response rate:</p>	<p>outcomes. Limited generalisability (study population are mainly male, heavily dependent smokers with a high prevalence of co-morbid mental health disorders)</p> <p><b>Limitations (review team):</b> Reducers not verified by CO reduction. Assessors unblinded.</p> <p><b>Evidence gaps:</b></p> <p><b>Funding sources:</b> National Cancer Institute and National Institute Drug Abuse Grant. Authors state that they do not have any conflicts of interest.</p> <p><b>Applicable to UK?</b> Yes</p>
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				<p>18 months: 64.1%-68.5%</p> <p>12 months: 69.2%-70.3%</p> <p>6 months: 75.7%-82.1%</p> <p>3 months: 79.7%-82.1%</p> <p>1 month: 82.4%-88.5%</p>	
<p><b>First author and year:</b> Kelly 2006</p> <p><b>Aim of study:</b> To evaluate the effectiveness of an individually delivered brief MI intervention for middle high school students caught smoking in the school context.</p> <p><b>Study Design :</b> Quasi-RCT.</p> <p><b>Quality score:</b> +</p> <p><b>External validity score:</b> ++</p>	<p><b>Setting:</b> Australia. Three state high schools in Brisbane.</p> <p><b>Participants:</b> 56 students referred by school administrators for violating school tobacco (34% female) aged 14-16 years; average scholastic grade “sound achievement”; from lower SES families. Average 51 CPW and smoked ~ 6 days per week. Nicotine dependence levels generally low.</p> <p><b>Inclusion:</b> 1) The drug of concern was tobacco; 2) parent/guardian active/informed consent was obtained.</p> <p><b>Exclusion:</b> None stated</p> <p><b>Motivation of participants:</b> Not stated</p>	<p><b>Method of allocation:</b> Not stated</p> <p><b>Intervention(s):</b> One hour motivational interviewing session, following principles of MI. Therapy manual used to define content and process of intervention.</p> <p><b>Control:</b> Standard care: advice and education delivered in one hour session guided by therapy manual.</p> <p>-----</p> <p>Reading materials provided to both groups, but only reviewed during control session.</p> <p><b>Sample sizes:</b> I = 30 C = 26</p> <p><b>Baseline comparisons:</b> No statistically significant differences except average achievement (higher in C) and smoking days per week (lower in C).</p> <p><b>Study power:</b> No power calculation performed.</p> <p><b>Intervention delivery:</b></p>	<p><b>Primary outcomes:</b> Self-reported days per week smoking; Self-reported CPD on smoking days; Smoking refusal self-efficacy</p> <p><b>Secondary outcomes:</b> Abstinence</p> <p><b>Follow-up periods:</b> 3 and 6 months</p> <p><b>Method of analysis:</b> Dependent variables evaluated using mixed model MANOVA, with intervention as between groups independent variable (I/C) and time as within groups variable (pre-intervention, 1-, 3-, and 6-month follow-up).</p>	<p><b>Primary:</b> At 6-months no significant difference in self-reported days per week, in CPD or smoking refusal self-efficacy.</p> <p><b>Secondary:</b> Between-group difference at 6 months not significant (no statistical values reported).</p> <p><b>Attrition:</b> Attrition at six months was 25%.</p>	<p><b>Limitations (author):</b> Small sample size Self-report data High rates of attrition</p> <p><b>Limitations (review team):</b> No power calculation. No information on allocation method.</p> <p><b>Evidence gaps:</b> None stated</p> <p><b>Funding sources:</b> NHMRC Career Development Award. NHMRC Project Award.</p> <p><b>Applicable to UK?</b> Yes</p>

		Delivered by second author; PhD candidate with four years experience in adolescent psychotherapy.			
<p><b>First author and year:</b> Kralikova 2009</p> <p><b>Aim of study:</b> To evaluate the efficacy and safety of nicotine gum or nicotine inhaler to help smokers reduce or quit smoking.</p> <p><b>Study Design :</b> Quasi RCT</p> <p><b>Quality score:</b> +</p> <p><b>External validity score:</b> +</p>	<p><b>Setting:</b> Czech Republic. Two medical centres (Prague and Kutna Hora).</p> <p><b>Participants:</b> 314 adult smokers recruited via advertisement in free newspaper (Prague) or leaflets (Kutna Hora). Gender: 42% male (I), 40% male (C) Age: 46.1 (I), 46.6 (C) CPD: 25.7 (I), 25.2 (C)</p> <p><b>Inclusion:</b> Age ≥ 18 years; smokers ≥ 15 CPD; smoked for ≥ 3 years; CO ≥10 ppm; motivated to reduce smoking; at least one failed quit attempt</p> <p><b>Exclusion:</b> Current use of NRT; current involvement in smoking cessation or reduction programs; unstable angina pectoris or MI within previous 3 months; pregnancy/lactation or intended pregnancy; psychiatric treatment or medication; co-existing alcohol or other drug problems.</p> <p><b>Motivation of participants:</b> Wanted to reduce smoking and had made ≥1 quit attempts. Did not have to be motivated to quit.</p>	<p><b>Method of allocation:</b> Not stated</p> <p><b>Intervention(s):</b> Choice of nicotine gum (4 mg) or nicotine inhaler (10 mg). Recommended doses: Gum: <i>ad libitum</i> use to maximum of 24 pieces/day; Inhaler: 6 -1 2 cartridges, not exceeding 12 in 24 hrs.</p> <p><b>Control:</b> Matched placebo.</p> <p>All subjects received brief behavioural smoking reduction/cessation support. All instructed to reduce smoking by replacing as many cigarettes as possible with inhaler or gum. Nine clinic visits (screening, baseline, weeks 2, 6 and 12, months 4, 6, 9 and 12). Six months full treatment was followed by ≤3 months voluntary tapering to prevent relapse.</p> <p><b>Sample sizes:</b> Eligible: 325 Intervention: 209 Control: 105</p> <p><b>Baseline comparisons:</b> Balanced across all measures.</p> <p><b>Study power:</b> For α=0.05 and power of 80% 210 subjects required (140 in</p>	<p><b>Primary outcomes:</b> Abstinence - short term (week 6 to month 4) and long term (month 6 to month 12): Sustained abstinence (self report, CO ≤10ppm at each visit) 7-day point prevalence abstinence, CO-verified (≤10ppm) <i>Reduction</i> (reduced smoking by ≥50% vs baseline; lower than baseline CO measurement) <i>Safety:</i> adverse events. <i>Intention to quit</i> Scale from 0 (definitely not intending to quit) to 4 (definitely intending to quit).</p> <p><b>Follow-up periods:</b> Months 9 and 12 (3 and 6 months post-full treatment).</p> <p><b>Method of analysis:</b> Intention-to-treat (drop-outs regarded as treatment failure). Wilcoxon rank sum test to test intra-individual differences from baseline to 4 and 12 months in each outcome group. Pearson's χ<sup>2</sup> test to analyse primary efficacy results. Factor analysis using logistic regression.</p>	<p><b>Primary:</b> Reduction: No statistically significant difference between groups, either at short term or long term follow-up. 12 months: I = 17.2%; C = 18.1% 4 months: I = 19.6%; C = 23.8%. Sustained abstinence: 12 months: I = 18.7%; C = 8.6% (p=0.019) 4 months: I = 20.1%; C = 8.6% (p=0.009) Point prevalence abstinence: 12 months: I = 21.5%; C = 10.5% (p=0.016); 4 months: I = 26.3%; C = 13.3% (p=0.009) Intention to quit: Long term reducers (n = 52) decreased mean score from 3.1 (0.9) at baseline to 2.3 (1.2) at month 12 (p&lt;0.001). Adverse events: none unexpected.</p> <p><b>Attrition:</b> At week 2: 196/209 (94%) of intervention and 95/105 (90%) of control group attended clinic visit At 9 months: 130/209 (62%) of intervention and 62/105 (59%) of control group attended clinic visit.</p> <p><b>Meta-analysis data:</b> 12 months ≥50% CPD reduction I = 36/209; C = 19/105 12 months sustained abstinence I = 39/209; C = 9/105 12 months point prevalence</p>	<p><b>Limitations (author):</b> Some participants reduced cigarette consumption in two weeks between screening and baseline visits with an impact on baseline measurement.</p> <p><b>Limitations (review team):</b> Significant attrition.</p> <p><b>Evidence gaps:</b> None stated</p> <p><b>Funding sources:</b> Study funded by McNeil AB, Sweden (the company manufacture NRT products). Two co-authors employees on McNeil AB.</p> <p><b>Applicable to UK?</b> Yes</p>

		intervention group and 70 in placebo group) <b>Intervention delivery:</b> University researchers		abstinence : I = 45/209; C = 19/105	
<p><b>First author and year:</b> McCambridge 2005 <i>Linked paper:</i> McCambridge 2004</p> <p><b>Aim of study:</b> To test whether a single session of motivational interviewing, discussing alcohol, tobacco, and illicit drug use, would lead successfully to reduction in use of these drugs or in perceptions of drug-related risk and harm among young people</p> <p><b>Study Design :</b> Cluster RCT</p> <p><b>Quality score:</b> +</p> <p><b>External validity score:</b> ++</p>	<p><b>Setting:</b> UK. Ten further education colleges across inner London</p> <p><b>Participants:</b> 200 young people aged 16-20 years who had current involvement with drug use.</p> <p><b>Inclusion:</b> Weekly cannabis use or stimulant drug use within previous three months</p> <p><b>Exclusion:</b> Opiate and injecting drug use</p> <p><b>Motivation of participants:</b> Not stated.</p>	<p><b>Method of allocation:</b> Non-computerised. A colleague, not involved in the study, allocated clusters (defined as all those recruited by each individual peer recruiter and used as the unit of randomisation) randomly with complete concealment. Stratification by college was applied to control for local variation in drug use.</p> <p><b>Intervention(s):</b> Intervention was adapted from the literature on motivational interviewing in the form of a topic-based 1-hour single session face-to-face interview.</p> <p><b>Control:</b> “Education as usual”. Those allocated to this condition completed baseline and follow-up assessments only.</p> <p><b>Sample sizes:</b> 200 participants recruited in 32 clusters. Clusters varied in size from 2 to 19. Randomisation: I= 105 C= 95.</p> <p><b>Baseline comparisons:</b> Differences between groups for ethnicity and use of stimulant drugs. When</p>	<p><b>Primary outcomes:</b> Self-reported cigarette, alcohol, cannabis and other drug use. Severity of drug, alcohol and tobacco dependence. Problems with drugs and problems caused by drug use. Health problems. Educational harms. Risk behaviours. Motivational stage of change. Satisfaction with drug use and other life areas. Attitudes to drug use.</p> <p><b>Follow-up periods:</b> 3 and 12 months</p> <p><b>Method of analysis:</b> Huber/White sandwich estimator of variance to control for clustered recruitment, using STATA. Linear or logistic regression used for continuous and binary outcomes respectively. In analyses of baseline data, ethnic group predictive of important differences in many measures. Intervention and control groups also non-equivalent in this variable. Therefore ethnic group controlled for in all outcome analyses. In addition to baseline measure of outcome in question and ethnic group, eight other potential confounders also investigated as covariates. These</p>	<p><b>Primary:</b> At 12 months: mean frequency of CPW in intervention group (<math>n=84</math>) increased to 27.7 (<math>p=0.07</math> for baseline/12-month mean comparison). When analysis restricted to smokers at study entry (<math>n=66</math>) mean CPW declined from 41.0 to 32.3 (<math>p=.02</math>). Mean CPW in control group decreased to 34.2 (<math>p&gt;0.1</math> for baseline/12-month mean comparison). Difference over time remained non-significant even when restricted to smokers at study entry (<math>n=60</math>): mean CPW declined from 47.7 to 38.9 (<math>p&gt;0.1</math>). Between-group difference not significant (<math>p &gt;.1</math>).</p> <p>At 3 months: CPW from baseline to follow-up decreased by 21% in intervention group and increased by 12% in control group. CPW post-intervention: 25.2 (I) and 39.4 (C). (<math>\beta=13.37</math> (95%CI 3.55-23.19, <math>p=0.009</math>). Of 139 smokers at baseline, 25% in the intervention group quit, vs 8% in the control group (<math>p=0.008</math>). After adjustment for ethnicity and other potential confounders, not statistically significant (OR=0.36 (95% CI: 0.13, 1.03), <math>p=0.056</math>). Little difference in the mean frequency of cigarette smoking for continuing smokers (smoking at study entry and follow-up, <math>n=115</math>): I = decrease from 47.7 to 41.7 CPW; C = increase from 44.9 to 51.0 CPW. Adjusted</p>	<p><b>Limitations (author):</b> Choice of a non-intervention education-as-usual control condition imposes limitations on inferences that may be drawn. Possible other interventions in same target population may secure similar benefits - no control of non-specific intervention factors was attempted. Not possible to completely exclude the possibility of a Hawthorn effect. Data were self-reported without biochemical validation.</p> <p><b>Limitations (review team):</b> None</p> <p><b>Evidence gaps:</b> Whether more MI sessions are needed.</p> <p><b>Funding sources:</b> Research training fellowship awarded by the NHS Executive (London/ South Thames). Additional funding from Action on Addiction for 12-month follow-up.</p> <p><b>Applicable to UK?</b> Yes – carried out in London</p>

		<p>adjusting for ethnicity randomisation deemed to have failed in four other variables: dependence on an illegal drug; interactional problems with parents/family; attitudinal positivity to drug use; previous decisions to cut down/stop.</p> <p><b>Study power:</b> No power calculation reported.</p> <p><b>Intervention delivery:</b> First author (university academic) delivered all intervention sessions.</p>	<p>were all considered for inclusion in final models using a stepwise backward elimination procedure with a value of <math>P=0.1</math>. Analyses primarily conducted in those for whom outcome data was available: 162 participants (81% contacted successfully after 12 months (158 of those providing 3-month data) and 179 followed-up after 3 months (89.5%).</p>	<p>difference between groups 11.25 (95% CI: 1.19, 21.32, <math>p=0.03</math>).</p> <p>Intervention group approx twice as likely to decide to stop or cut down smoking as control group, but difference not statistically significant (OR=2.1, <math>p=0.067</math>). In smokers at follow-up (<math>n=123</math>), difference between groups in adjusted mean nicotine dependence scores statistically significant (<math>\beta=1.34</math>, <math>p=0.006</math>). Those smoking at follow-up also rated importance of cigarette use. Adjusted mean difference between groups not significant (<math>\beta=0.63</math>, <math>p=.055</math>). Higher levels of motivational stage of change in relation to drug use in general were observed in the intervention group than in the control group, after controlling for baseline status and other potential confounders (<math>\beta=0.76</math>, <math>p=0.004</math>).</p> <p>To test impact of attrition on findings, ITT analysis undertaken; estimates of intervention effect very similar to those reported above (<math>\beta=12.96</math> (3.42–22.49), <math>p=0.009</math>) (Changes in drug use and alcohol consumption and associated outcomes were also reported.)</p> <p><b>Attrition:</b> 80% of the intervention group and 82% of the control group provided 12-month follow-up data. 92.4% of the intervention recipients and 86.3% of the controls were retained at 3 months.</p>	
<b>First author and year:</b>	<b>Setting:</b>	<b>Method of allocation:</b>	<b>Primary outcomes:</b>	<b>Primary:</b>	<b>Limitations (author):</b>

<p>Munday, 1993</p> <p><b>Aim of study:</b> To evaluate the effectiveness of written pre-operative advice to stop smoking before admission.</p> <p><b>Study Design :</b> Controlled clinical trial.</p> <p><b>Quality score:</b> -</p> <p><b>External validity score:</b> +</p>	<p>UK teaching hospital – location unknown.</p> <p><b>Participants:</b> Patients waiting for surgery. No demographic information provided.</p> <p><b>Inclusion:</b> Not provided.</p> <p><b>Exclusion:</b> Not provided.</p> <p><b>Motivation of participants:</b> Not provided.</p>	<p>Not provided.</p> <p><b>Intervention(s):</b> Participants received leaflet outlining reasons for stopping smoking prior to surgery. Advised to stop smoking ≥6 weeks prior to operation.</p> <p><b>Control:</b> No specific advice.</p> <p><b>Sample sizes:</b> I = 136 C = 97</p> <p><b>Baseline comparisons:</b> Cigarette consumption only. No significant difference between groups.</p> <p><b>Study power:</b> Not provided.</p> <p><b>Intervention delivery:</b> Through outpatient clinic</p>	<p>Pre-operative abstinence for ≥3 days. Alteration in cigarette consumption.</p> <p><b>Follow-up periods:</b> No follow-up. Assessments at admission for surgery only.</p> <p><b>Method of analysis:</b> χ<sup>2</sup> test with Yates' correction.</p>	<p>No significant difference for reported abstinence ≥3 days between groups. I = 10 (7.4%), (95% CI: 5.1, 9.6) C = 9 (9.3%), (95% CI 6.4, 12.2 (p&gt;0.5).</p> <p>More patients in the control group had increased CPD, I = 4, C = 11 (p&lt;0.025). Trend for decreased CPD, I = 40, C=20 (p&gt;0.1).</p> <p>15% reported smoking within an hour of surgery.</p> <p><b>Attrition:</b> Not clear. N=211 for abstinence immediately prior to surgery.</p>	<p>When advice given patients did not know date of surgery. Potentially not all patients understood leaflet. Self-reported outcomes.</p> <p><b>Limitations (review team):</b> No randomization. No comparison of baseline characteristics other than cigarette consumption. Self-reported outcomes only. Difficult to identify when patients were assessed as not clear if operations took place at same interval after receiving information.</p> <p><b>Evidence gaps:</b> None stated.</p> <p><b>Funding sources:</b> Health Education Authority.</p> <p><b>Applicable to UK?</b> Yes</p>
<p><b>First author and year:</b> Pickworth 1994</p> <p><b>Aim of study:</b> To evaluate the physiological, performance and subjective effects of a nicotine patch in 10 subjects who smoked <i>ad libitum</i> on a residential research ward for 30 days.</p> <p><b>Study Design :</b> Laboratory study to test various doses of nicotine patch</p>	<p><b>Setting:</b> Developed. Residential research ward in Addiction Research Centre, Baltimore, MA, USA</p> <p><b>Participants:</b> 10 male smokers. Mean age 33.1 (range 20-35), mean weight 76.2 kg (range 59.5-87.3), mean level of addiction by the Fagerstrom Tolerance Questionnaire 8.1 (7-10), mean CPD 23.3 (20-35). 5 had extensive histories of drug abuse.</p> <p><b>Inclusion:</b></p>	<p><b>Method of allocation:</b> 10 volunteer male smokers responding to newspaper advertisements.</p> <p><b>Intervention(s):</b> 30 day stay on residential research ward. Unlimited access to usual brand of cigarettes via computer controlled dispenser. Days 4-6 two patches delivering 0, 22 or 44 mg nicotine applied in ascending dose order to test tolerance. Dose patches (0, 22 or 44 mg) applied daily (at</p>	<p><b>Primary outcomes:</b> Expired CO, CPD, puff measures with single cigarette (puff duration, number of puffs, cigarette duration, interpuff interval), venous plasma sample (10 mins after smoking for puff sample) for cotinine and nicotine. Also performance tasks, subjective measures, physiologic measures, adverse events, concomitant medications.</p> <p><b>Follow-up periods:</b> Each day to 30 days.</p> <p><b>Method of analysis:</b> Repeated measures analysis of</p>	<p><b>Primary:</b> Compared to smoking rates in the placebo condition each of the nicotine conditions significantly reduced average CPD (placebo: 18.1±1, 22 mg: 15.3±1, 44 mg: 13.4±1)</p> <p>On the first day of all patch conditions, cigarette totals were the lowest of the 7 days. In the first 6 hours of patch application, <i>ad libitum</i> smoking decreased from 5.6 (placebo) to 5.1 and 4.4 (22 and 44 mg).</p> <p>Plasma nicotine levels in the baseline phase averaged 29.6±5.2 ng/ml</p>	<p><b>Limitations (author):</b> None stated</p> <p><b>Limitations (review team):</b> Close involvement of pharmaceutical company. Uncontrolled lab based study in tiny population group, some with extensive drug abuse history.</p> <p><b>Evidence gaps:</b> None stated</p> <p><b>Funding sources:</b> Elan pharmaceutical company - who also supplied the nicotine patches and carried out the</p>

<p><b>Quality score:</b> –</p> <p><b>External validity score:</b> –</p>	<p>Not stated</p> <p><b>Exclusion:</b> Not stated</p> <p><b>Motivation of participants:</b> No current interest in stopping smoking.</p>	<p>9am) for next three weeks. Doses varied in random double-blind order - same dose for each 7 days. Further 3 days on ward after last patch removed. Subjects were paid \$800 for participation.</p> <p><b>Control:</b> No control group</p> <p><b>Sample sizes:</b> 10</p> <p><b>Baseline comparisons:</b> No control group</p> <p><b>Study power:</b> Power calculation not reported</p> <p><b>Intervention delivery:</b> Addiction Research Centre researchers.</p>	<p>variance to examine effect of dose.</p>	<p>(SEM) compared to 18.8±3.3, 39.2±4.7 and 63.4±8.5 ng/ml in the placebo, 22mg and 44 mg conditions respectively.</p> <p>The only significant difference between expired CO (at 14.00 h) was between the 44 mg and baseline smoking conditions: 16±1 vs 22±1 ppm, compared to 18±1 ppm in both the placebo and 22 mg conditions.</p> <p>The nicotine content of the patch did not significantly affect the average or total puff duration on the daily cigarette.</p> <p><b>Secondary:</b></p> <p><b>Attrition:</b> None</p>	<p>plasma nicotine assay.</p> <p><b>Applicable to UK?</b> Too small a population to generalise.</p>
<p><b>First author and year:</b> Pisinger 2005a <i>Additional data from:</i> Pisinger 2005b</p> <p><b>Aim of study:</b> To evaluate a population-based smoking reduction intervention, the results after 1 year and the influence on motivation to quit within a large lifestyle change intervention to prevent cardiovascular disease and diabetes mellitus.</p> <p><b>Study Design :</b></p>	<p><b>Setting:</b> Denmark, Copenhagen.</p> <p><b>Participants:</b> Daily smokers within the broader lifestyle 'Inter99 study'. Mean age 46 years.</p> <p><b>Eligible sample for this review = 39 people participating in a smoking reduction group.</b> No details provided on participant characteristics for group.</p> <p><b>Inclusion:</b> Aged 30-60; Smokers (&gt;1g per day).</p> <p><b>Exclusion:</b> None stated.</p> <p><b>Motivation of participants:</b></p>	<p><b>Method of allocation:</b> Randomly selected subjects from a defined area of the Copenhagen suburb.</p> <p><b>Intervention(s):</b> High intensity (A): Lifestyle consultation (15-45 mins); and participation in 6 smoking cessation or smoking reduction groups (depending on motivation) over 6 months. Within smoking reduction group intervention, two strategies offered: slowly reduce smoking or immediate 50% reduction combined with NRT of participant's choice (patch, gum, inhaler,</p>	<p><b>Primary outcomes:</b> Mean CO reduction (for smoking reduction group)</p> <p>Remaining outcomes reported were aggregated with the wider Inter99 study for all smokers, and are therefore not eligible for inclusion in the review. These outcomes were: self-reported grams of tobacco per day; ≥50% reduction from baseline; motivation to quit.</p> <p><b>Follow-up periods:</b> 6 months. 1 year (persons at high risk of cardiovascular disease only were invited).</p> <p><b>Method of analysis:</b> Wilcoxon's signed rank test for</p>	<p><b>Primary outcomes:</b> At six months mean CO reduction was 10% for 39 eligible participants (no raw data presented). Authors state that data were too small to make more analyses. <i>Remaining results merged for all smokers (i.e. results are aggregated with those who attended smoking cessation, smoking reduction or refused to receive the intervention.)</i></p> <p><b>Attrition:</b> Smoking reduction group (intervention A) =51.3%. For main Inter99 study initial participation rate = 52.5%. Complete smoking data available for 1,086 (of 2,408 in the merged group) who</p>	<p><b>Limitations (author):</b> No validation of smoking status. Very poor compliance with smoking reduction groups.</p> <p><b>Limitations (review team):</b> Clear from Pisinger 2005b that smoking component was predominantly a cessation intervention and 2005a appears to be a secondary analysis. Very small sample size. No raw data for smoking reduction group. Smokers unwilling to quit within the low intensity group were provided with</p>

<p>Partially randomised controlled trial – 2005a possibly a secondary analysis</p> <p><b>Quality score:</b> –</p> <p><b>External validity score:</b> +</p>	<p>Smoking reduction attendees (N=39) unwilling or unable to quit smoking</p> <p>Broader Inter99 study: varied motivations - 43% wanted to reduce tobacco consumption rather than quitting.</p>	<p>tablet). Smoker defined reduction goal and strategy to use.</p> <p>Low intensity (B): Lifestyle consultation and complimentary nicotine product of choice for a ‘few days’, but no participation in smoking group(s).</p> <p><b>Control:</b> No intervention</p> <p><b>Sample sizes:</b> Smokers within wider Inter99 study: High intensity: 2,168 Low intensity: 240 Control: 1,276</p> <p>76 accepted smoking reduction group (intervention A), 39 participated.</p> <p><b>Baseline comparisons:</b> Not reported for smoking cessation attendees. Whole sample, some differences. Merged intervention group subjects had slightly higher socio-economic status (p=0.002) and more likely to be in preparation stage for quitting (10.8% vs 7.2%, p&lt;0.001).</p> <p><b>Study power:</b> Power calculation not reported..</p> <p><b>Intervention delivery:</b> Lifestyle consultation [motivational interview] delivered by trained health professionals (2 medical doctors, 4 nurses and a</p>	<p>tobacco consumption. Logistic regression to test predictors, adjusted for sex, age and socio-economic status.</p>	<p>attended at both baseline and 1 year (45.1%).</p> <p>ITT analysis carried out on 2,143 rather than 2,408 daily smokers (ie 89%).</p>	<p>smoking reduction advice, but results not presented separately.</p> <p>Lack of clarity. 2005b doesn’t mention smoking reduction intervention; 2005a describes difference between the smoking cessation and smoking reduction intervention in the high intensity group.</p> <p>The main outcomes not provided separately according to the initial motivations of subjects (wanting to quit vs unable or unwilling to quit)..</p> <p>At 1 year follow up only persons at high risk of CVD were invited to participate (thus ITT results reported). Some baseline differences.</p> <p><b>Evidence gaps:</b> None stated.</p> <p><b>Funding sources:</b> Danish Medical Research Council, Danish Centre for Evaluation and Health Technology Assessment, NovoNordisk, Copenhagen County, Danish Heart Foundation, Danish Pharmaceutical Association, Augustinus Foundation, Becket Foundation, Ib Henriksens Foundation.</p> <p><b>Applicable to UK?</b> Yes - community based</p>
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		dietician).			counselling study
<p><b>First author and year:</b> Polosa 2011</p> <p><b>Aim of study:</b> Proof of concept to monitor possible modifications in the smoking habits of regular smokers (unwilling to quit) experimenting using the 'Categoria' e-Cigarette with a focus on smoking reduction and smoking abstinence.</p> <p><b>Study Design :</b> Uncontrolled before and after</p> <p><b>Quality score:</b> –</p> <p><b>External validity score:</b> –</p>	<p><b>Setting:</b> Italy. Hospital in Catania, Italy.</p> <p><b>Participants:</b> 40 local hospital staff. Mean age 42.9 (±8.8 years), regular smokers (34.9±14.7 packs per year),</p> <p><b>Inclusion:</b> Healthy, aged 18-60, ≥15 factory-made CPD for ≥10 years, not attempting to quit or wishing to do so in next 30 days.</p> <p><b>Exclusion:</b> Recent myocardial infarction, angina pectoris, high blood pressure, diabetes, severe allergies, poorly controlled asthma or other airway diseases. No subjects reported a history of alcohol and illicit drug use, major depression or other psychiatric conditions.</p> <p><b>Motivation of participants:</b> Not wishing to quit</p>	<p><b>Method of allocation:</b> 40 recruited staff meeting inclusion criteria</p> <p><b>Intervention(s):</b> E-cigarette kit and cartridges supplied free for <i>ad libitum</i> use up to a maximum of 4 cartridges per day (manufacturer recommendation) plus study diary to record product use, CPD and adverse events. Further supplies and new diary at each study visit.</p> <p><b>Control:</b> No control.</p> <p><b>Sample sizes:</b> No control.</p> <p><b>Baseline comparisons:</b> No control</p> <p><b>Study power:</b> Calculated and imputed since first study of this type but authors note results could be by chance since a small study.</p> <p><b>Intervention delivery:</b> Authors are University researchers</p>	<p><b>Primary outcomes:</b> Product use; 30-day sustained 50% reduction; exhaled CO; adverse events.</p> <p><b>Secondary outcomes:</b> 30-day sustained 80% reduction; Sustained abstinence</p> <p><b>Follow-up periods:</b> 4, 8, 12, 24 weeks</p> <p><b>Method of analysis:</b> Wilcoxon signed rank test for non-parametric data. ITT analysis. Parametric and non-parametric data expressed as mean (±SD) and median (inter quartile range, IQR). Correlations using Spearman's Rho Correlation.</p>	<p><b>Primary:</b> At 24 weeks sustained (previous 30 days) self-report 50% CPD reduction in 13/40 (32.5%) participants, with a reduction from a median of 25 CPD (IQR 20,30) to 6 CPD (IQR 5,6)(p&lt;0.001). Results were validated by reduced CO levels. Product use varied greatly with a mean of 2.0 (±1.4) cartridges per day and a range of 0 to 4 per day over study period. No correlation between cartridges per day and those with sustained 50% reduction or abstinence. Most frequent adverse events: Mouth irritation (20.6%); throat irritation (32.4%); dry cough (32.4%).</p> <p><b>Secondary:</b> At 24 weeks sustained (previous 30 days) self-reported 80% CPD reduction in 5/40 (12.5%) participants, with a reduction from a median of 30 CPD (IQR 25,35) to 3 CPD (IQR 0,6)(p&lt;0.001). 9/40 (22.5%) quitters, with 6/9 using the e-cigarette at end of study. In both groups results were validated by reduced CO levels.</p> <p><b>Attrition:</b> 27 (67.5%) completed all study visits and returned at week 24.</p>	<p><b>Limitations (author):</b> Small uncontrolled study and findings could be a chance effect. Only 67.5% completed study.</p> <p><b>Limitations (review team):</b> Withdrawal symptoms mentioned in discussion but not reported in paper. Lead author is a consultant for the e-cigarette supplier.</p> <p><b>Evidence gaps:</b> None stated.</p> <p><b>Funding sources:</b> Polosa received lecture fees from Pfizer and from Feb 2011, has been a consultant for Arbi Group Srl (manufacturer and supplier of e-Cigarette used in trial.)</p> <p><b>Applicable to UK?</b> Feasible in the UK</p>
<p><b>First author and year:</b> Rennard 1990</p> <p><b>Aim of study:</b> To assess the beneficial effect of short-term smoking reduction in</p>	<p><b>Setting:</b> Developed. Unclear setting but researchers are from the University of Nebraska Medical Centre.</p>	<p><b>Method of allocation:</b> Volunteers – unclear how identified.</p> <p><b>Intervention(s):</b> ≥ 20 mg nicotine gum daily. Subjects were paid (amount</p>	<p><b>Primary outcomes:</b> CPD, expired CO, respiratory tract inflammation (various measures).</p> <p><b>Follow-up periods:</b> One, two months</p>	<p><b>Primary:</b> At two months, self reported CPD decreased from 50.7±2.3 to 18.8±1.5 (p&lt;0.001) and expired CO decreased from 48.5±2.5 to 27.3±2.5 ppm (p&lt;0.001).</p>	<p><b>Limitations (author):</b> Study designed to look at lower respiratory tract inflammation, not at efficacy for smoking reduction.</p>

<p>reducing lower respiratory tract inflammation</p> <p><b>Study Design :</b> Uncontrolled before and after</p> <p><b>Quality score:</b> –</p> <p><b>External validity score:</b> –</p>	<p><b>Participants:</b> 15 healthy volunteers, 60% male</p> <p><b>Inclusion:</b> Aged 21-44, consuming at least 40 CPD, normal results on physical examination, ECG, chest radiograph, and blood chemistries.</p> <p>Comparison group for respiratory tract inflammation measures: (n=15) non smoking, aged 18-36, normal result as above.</p> <p><b>Exclusion:</b> None stated</p> <p><b>Motivation of participants:</b> Not currently interested in quitting</p>	<p>unstated). All agreed to reduce their CPD by 50%.</p> <p><b>Control:</b> No control group but respiratory tract measures were compared with a group of 15 normal non-smoking volunteer.</p> <p><b>Sample sizes:</b> 15</p> <p><b>Baseline comparisons:</b> No control group</p> <p><b>Study power:</b> Power calculation not reported</p> <p><b>Intervention delivery:</b> Authors are university researchers.</p>	<p><b>Method of analysis:</b> Unpaired Wilcoxon test to compare smoker and normal subject measures. Student's paired t-test for changes in CO and CPD.</p>	<p>After two months, measures of respiratory tract inflammation had improved significantly.</p> <p><b>Attrition:</b> None</p>	<p><b>Limitations (review team):</b> Part pharmaceutical company supported. No control group, small population and not described, short term follow-up.</p> <p><b>Evidence gaps:</b> Need for a prospective double-blind intervention study</p> <p><b>Funding sources:</b> Part supported by a grant from Merrell Dow Pharmaceuticals, supplier of the nicotine gum.</p> <p><b>Applicable to UK?</b> Too small a sample to generalise</p>
<p><b>First author and year:</b> Rennard 2006</p> <p><b>Aim of study:</b> To evaluate the nicotine inhaler as a smoking reduction aid and to determine the effect of the inhaler on quit attempts and motivation to quit among smokers unwilling to quit.</p> <p><b>Study Design :</b> Quasi- RCT</p> <p><b>Quality score:</b> +</p> <p><b>External validity score:</b> ++</p>	<p><b>Setting:</b> USA Three sites (Tucson, Arizona; Morgantown, W Virginia; Omaha, Nebraska)</p> <p><b>Participants:</b> 429 healthy adult smokers recruited via newspaper adverts. Gender: 88 (41%) male (I), 104 (49%) (C); Age: 45.9 (I), 44.8 (C) CPD: 29.3 (I). 30.4 (C).</p> <p><b>Inclusion:</b> Age ≥ 18 years; smoking ≥20 CPD; Smoked for ≥ 3 years; CO ≥15 ppm after 15 smoke free minutes; ≥ 1 failed quit attempt in last 2 years; desire to reduce cigarette consumption.</p> <p><b>Exclusion:</b> Planning to quit smoking within</p>	<p><b>Method of allocation:</b> Not stated</p> <p><b>Intervention(s):</b> Nicotine inhaler 10 mg</p> <p><b>Control:</b> Placebo inhaler</p> <p>Both groups used the inhaler <i>ad libitum</i> (recommended dose 6-12 cartridges/day) for up to 12 months. Participants instructed to reduce smoking as much as possible. Smoking cessation recommended (but not mandatory) from month 6.</p> <p>Nine clinic visits: baseline; weeks 2, 6 and 10; and months 4, 6, 9, 12 and 15)</p> <p><b>Sample sizes:</b></p>	<p><b>Primary outcomes:</b> Reduction in CPD by at least 50% compared with baseline (self report verified by reduced CO of ≥ 1 ppm compared to baseline). Smoking status and expired CO recorded at regular intervals:</p> <p><b>Secondary outcomes:</b> Effect of smoking reduction on smoking cessation (point prevalence abstinence for ≥ 7 days verified by CO &lt; 10 ppm) Intention to quit smoking Quality of life (RAND 36 item health survey) and smoking related symptoms (cough, phlegm, shortness of breath and senses of smell and taste): assessed at baseline and after 4, 12 and 15 months.</p>	<p><b>Primary:</b> Mean CPD reduction from baseline: 12 months: I = 14.5; C = 12.6 9 months: I = 14.2; C = 11.8 6 months: I = 14.6; C = 13.4 CO, month 15: mean CPD reduction &gt;75%: mean decrease in CO from baseline 25.2 ppm: 50% to ≤ 75% reduction: 8.3 ppm: 25% to &lt;50% reduction: 8.0 ppm: &lt;25% reduction: 4.6 ppm.</p> <p>At 4 months: 18% of subjects in the active group had reduced their daily smoking by at least 50% from baseline, compared with 8% in the placebo group (p=0.004)</p> <p><b>Secondary:</b> Point prevalence abstinence: 15 months: I = 7.9%; C = 1.4%</p>	<p><b>Limitations (author):</b> High dropout rate (64%)</p> <p><b>Limitations (review team):</b> No information on study funding. Four authors were pharmaceutical company employees.</p> <p><b>Evidence gaps:</b> None stated</p> <p><b>Funding sources:</b> Not stated. Four authors are employees of Pfizer Consumer Healthcare, Sweden.</p> <p><b>Applicable to UK?</b> Yes – community based study.</p>

	<p>next 4 weeks; scores of 9 or 10 on Contemplation Ladder; concurrent use of NRT or any behavioural/pharmacological smoking cessation/reduction program; use of other NCPs; unstable angina pectoris or MI within last 3 months; pregnancy or lactation; psychiatric care or taking psychiatric medication; alcohol or drug abuse</p> <p><b>Motivation of participants:</b> Subjects wanted to reduce their cigarette consumption but were unwilling to quit.</p>	<p>Screened: 2,306 Intervention: 215 Control: 214</p> <p><b>Baseline comparisons:</b> Generally comparable but differences in gender.</p> <p><b>Study power:</b> Authors estimated at 4 months 20% of the active group and 10% of the placebo group would have reduced smoking by at least 50% compared to baseline: 197 subjects in each group required to have a power of 80% to detect a difference at a significance level of 0.05.</p> <p><b>Intervention delivery:</b> Authors are university researchers.</p>	<p>Risk markers for cardiovascular disease: white blood cells, cholesterol (HDL, LDL), fibrinogen, C reactive protein): at baseline, 4, 12 and 15 months.</p> <p>Adverse events (self reported): assessed by open ended questions at each visit.</p> <p><b>Follow-up periods:</b> One follow up visit at 15 months (3 months post intervention)</p> <p><b>Method of analysis:</b> Intention to treat (subjects who withdrew early or were lost to follow up were classified as failures). Fisher's exact test to analyse binary variables. Kruskal-Wallis test to analyse continuous variables. Wilcoxon signed rank test to investigate changes from baseline for continuous variables.</p>	<p>(p=0.002) 12 months: I = 7.9%; C = 2.3% (p=0.014).</p> <p>Intention to quit smoking: 17% (I) and 18% (C) intended to quit at month 15 compared to 1% (I) and none (C) at baseline.</p> <p>Safety: Adverse events reported by 159 subjects (I) and 147 subjects (C). Serious adverse events: 15 events reported by 9 subjects (I) and 13 events reported by 11 subjects (C).</p> <p>Markers of Exposure Cardiovascular risk markers (4 month results only): For participants achieving ≥50% reduction, statistically significant differences in HDL (mean increase 2.11 mg/dl, p =.003) and white blood cells (mean decrease 0.34 x 10<sup>9</sup>/l, p=0.03) and C reactive protein (mean decrease 0.09 mg/dl, p=0.04) Results for LDL and fibrogen were non-significant.</p> <p>Quality of Life: At 15 months statistically significant improvements in self-control (p&lt;0.001) recorded for subjects who had reduced their mean cigarette consumption by ≥50%.</p> <p><b>Attrition:</b> 154/429 (36%) completed the 15 month study (89/215 (41%) intervention and 65/214 (30%) placebo)</p> <p><b>Meta-analysis data:</b> CPD reduction from baseline: 12 months: I = mean 14.5 (SD 10.2); C = mean 12.6 (SD 10.2)</p>	
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<p><b>First author and year:</b> Riggs 2001</p> <p><b>Aim of study:</b> To compare two behavioural treatments (hierarchical reduction and increased inter-cigarette interval) for their efficacy and acceptability in reducing smoking among smokers who were interested in reducing but not quitting their smoking.</p> <p><b>Study Design :</b> Quasi-RCT (within-subject, crossover design with random assignment to treatment order</p> <p><b>Quality score:</b> -</p> <p><b>External validity score:</b> +</p>	<p><b>Setting:</b> USA. Vermont.</p> <p><b>Participants:</b> 20 smokers recruited through newspaper advertisements. Age: 44 (±14.2) years; gender: 14 (70%) female.</p> <p><b>Inclusion:</b> ≥ 18 years; Smoking 15 – 40; CPD; afternoon CO ≥20 ppm; able to chew nicotine gum.</p> <p><b>Exclusion:</b> Planning to quit smoking in next 2 months; increase or decrease in CPD of ≥25% in last 2 months; use of any other forms of tobacco in last 6 months.</p> <p><b>Motivation of participants:</b> Not currently interested in smoking, but wishing to reduce the number of cigarettes smoked.</p>	<p><b>Method of allocation:</b> Not stated</p> <p><b>Intervention(s):</b> 1 week baseline period (smoking as normal) followed by one behavioural treatment (of 2 weeks duration). Then second baseline period (normal smoking for 2 weeks) and second treatment (2 weeks)</p> <p><i>Increased Inter-cigarette interval (ICI):</i> Mean baseline inter-cigarette interval calculated. During first week interval increased by 25%. In second week interval doubled; giving 50% decrease in CPD.</p> <p><i>Hierarchical Reduction (HR):</i> Eliminating cigarettes rated easiest to give up. During first week participants attempt to eliminate easiest 25%. During second, counselled to eliminate easiest 50% of remaining CPD.</p> <p>All participants given nicotine gum to be used ad libidum during treatments (&lt;25CPD: 2mg; ≥25 CPD: 4mg) and</p>	<p><b>Primary outcomes:</b> Self-reported CPD; CO, salivary thiocyanate and cotinine twice weekly. Ease of reduction (1-10 Likert scale ); Adverse events Motivation to quit smoking (0-10 Contemplation ladder; 0 = not thinking of quitting) Preference rating for behavioural treatment.</p> <p><b>Follow-up periods:</b> None</p> <p><b>Method of analysis:</b> T-tests (paired samples)</p>	<p><b>Primary:</b> Self reported CPD: 10/20 (50%) of participants reduced their smoking by ≥50% by the end of ICI treatment. 6/20 (30%) of participants reduced their smoking by ≥50% by the end of HR treatment. Reduction in self reported CPD significant for both treatments (HR p&lt;0.0001; ICI p&lt;0.0001) Average CPD reduction: ICI = 45%; HR = 38% p&lt;0.02) Significant reduction in CO for both treatments – 20% ICI vs 19% HR (p&lt;0.0001) with no difference between treatments. Neither treatment produced significant reduction in thiocyanate or cotinine. No difference in measures between treatments. 2/20 subjects reported adverse events. Neither event led to the subject discontinuing nicotine gum and symptoms resolved spontaneously. Motivation to quit smoking: Contemplation ladder scores increased from 5.8 (±3.0) at baseline to 7.9 (±2.4) at final visit (p&lt;0.001).</p>	<p><b>Limitations (author):</b> Small, self selected sample. Short duration and no follow-up. No information on whether participants followed behavioural insufficient encouragement for use of NRT gum.</p> <p><b>Limitations (review team):</b> CO and saliva measures are reported separately from CPD – does not appear to be used to validate self-report.</p> <p><b>Evidence gaps:</b> Larger studies with longer duration of treatment and more effective measures.</p> <p><b>Funding sources:</b> Grants from Pinney Associates, Smith Kline Beecham Consumer Healthcare and Pharmacia and Upjohn. NIDA Institutional Training Grant T–22032 (Riggs and Pillitteri). NIDA Research Scientist Development Award DA–00109 (Hughes).</p> <p><b>Applicable to UK?</b></p>

		<p>encouraged to chew one piece for each cigarette eliminated.</p> <p>Daily diary used to record time of each cigarette with an associated difficulty rating.</p> <p><b>Control:</b> Cross-over, subjects act as their own control.</p> <p><b>Sample sizes:</b> n=20</p> <p><b>Baseline comparisons:</b> Not applicable (cross-over study)</p> <p><b>Study power:</b> Power calculation not reported</p> <p><b>Intervention delivery:</b> University researchers</p>		<p>17/20 (85%) of subjects showed increased motivation to quit, 1/20 had decreased motivation.</p> <p>Ease of reduction. No significant difference: ICI: 5.8 (<math>\pm</math>2.7); HR: 5.0 (<math>\pm</math>2.4)</p> <p><b>Attrition:</b> Not reported.</p>	Yes
<p><b>First author and year:</b> Riley 2002</p> <p><b>Aim of study:</b> To test the feasibility of two self-help behavioural treatments for smoking reduction</p> <p><b>Study Design :</b> Quasi-randomised trial.</p> <p><b>Quality score:</b> +</p> <p><b>External validity score:</b> ++</p>	<p><b>Setting:</b> USA. Greater Washington DC area.</p> <p><b>Participants:</b> 93 adult smokers interested in reducing smoking recruited via TV adverts Gender: 56% male; age: 44.8 (SD 11.7; ethnicity: 74% white, 23% African American, 3% other; educational attainment: 14.9 (SD 2.4) years; CPD: 27.3 (SD 10.4); Smoking for 24.4 (SD 11.5) years. No breakdown provided for comparator groups.</p> <p><b>Inclusion:</b> Regular smoking (15–50 CPD</p>	<p><b>Method of allocation:</b> Not stated</p> <p><b>Intervention(s):</b> <i>Computerized Schedule Gradual Reduction (CSGR)</i> Baseline (1 week): subjects recorded normal smoking, pressing a ‘smoke’ button when they smoked. Reduction (2 weeks): computer program scheduled a reduction to 50% of baseline, prompting cigarettes at intervals to achieve this. Could be adjusted if subjects having difficulties. Maintenance (2 weeks): fixed</p>	<p><b>Primary outcomes:</b> Self-report CPD reduction <math>\geq</math> 50% at baseline, 7 weeks, 6 and 12 months. CO pre- and post- treatment (7 weeks) 7-day point-prevalence abstinence (self report validated by CO &lt; 10ppm) recorded at post assessment and 6 and 12 months.</p> <p><b>Follow-up periods:</b> 6 and 12 months from baseline.</p> <p><b>Method of analysis:</b> T-test or <math>\chi^2</math> analyses conducted as appropriate on all pre-test measures. Repeated measures ANOVA :</p>	<p><b>Primary:</b> <math>\geq</math>50% reduction CPD (completers only): 12 months: CSGR = 18.2%, SER = 18.4% (ns); 6 months: CSGR = 18.2%; SER = 12.2% (ns). Difference in mean percent reduction in smoking from baseline (pre-treatment) not statistically significant at 12 months (38% for CSGR vs 35% for SER) or at 6 months (32% for CSGR vs 25% for SER). Compliance: 66% CSGR and 60% SER subjects reported using assigned program every day. 13% CSGR and 10% SER subjects used it most days. For 45 participants who completed all time points, mean reduction of <math>\sim</math>10 CPD from pre-treatment to post</p>	<p><b>Limitations (author):</b> Smoking rates determined by self report only. Absence of control Possible for SER subjects to continue past the 7 week treatment period. CSGR subjects had to return the computer system at the end of the treatment period.</p> <p><b>Limitations (review team):</b> Significant attrition. No power calculation. No information on allocation method. Authors worked for organisation with a commercial interest in</p>

	<p>for <math>\geq 1</math> year); willing to attempt reduction as a short-term goal. Unable to quit in the past and unwilling to quit at present (no plans to quit in next 30 days). Participants given opportunity to participate in cessation study as an alternative (to select only those subjects who were not interested in quitting)</p> <p><b>Exclusion:</b> Regular use of other tobacco products; Current use of NRT; use of Zyban (bupropion) in past 2 weeks; treatment for alcohol/drug abuse in the past year; pregnancy.</p> <p><b>Motivation of participants:</b> Subjects willing to attempt smoking reduction as a short-term goal. Unable to quit previously and unwilling to quit at the time of recruitment.</p>	<p>schedule to maintain 50% reduction</p> <p><i>Selective Elimination Reduction via manual instruction (SER):</i> Baseline (1 week): subjects recorded CPD manually (in smoking diary) Reduction (2 weeks): subjects determined the daily reduction for each day by using a table in the manual. Maintenance (2 week): once the goal of 50% reduction was obtained, subjects completed a 2 week period at which this smoking level was maintained.</p> <p>-----</p> <p>Both conditions received a manual providing equivalent information - advice on relapse prevention techniques and condition-specific information.</p> <p><b>Control:</b> No control. Comparison of two interventions.</p> <p><b>Sample sizes:</b> CSGR = 44 SER = 49</p> <p><b>Baseline comparisons:</b> Figures not provided. Authors report only significant difference was experience with group cessation counselling (CSGR= 27%, SER=6.1%, <math>\chi^2 = 7.44</math>, <math>p &lt; 0.05</math>)</p> <p><b>Study power:</b> Power calculation not</p>	<p>weekly mean smoking rate, self-reported smoking rate</p> <p>One way ANOVAs to compare conditions on percent in smoking at all time points.</p> <p>Participants who dropped out or were lost to follow-up were coded as treatment failures.</p>	<p>treatment occurred in both groups and was maintained over 1 year.</p> <p>Effect of reduction on subsequent quitting at 12 months: 11.4% of CSGR subjects vs 6.1% of the SER subjects were abstinent.</p> <p>32% of CSGR subjects vs 18% of SER subjects reported a quit attempt lasting 24 hours or longer between the 6 and 12 month follow up (not statistically significant).</p> <p><b>Attrition:</b> Completers: Post-treatment assessment (7 weeks): CSGR: 38/44 (89%); SER 39/49 (78%) At 6 months: CSGR 75%; SER 55% At 12 months: CSGR: 68%; SER: 55%</p>	<p>computerised smoking reduction products</p> <p><b>Evidence gaps:</b> Need for adequately powered studies.</p> <p><b>Funding sources:</b> Grant from National Cancer Institute. Work was carried out at Personal Improvement Computer Systems (PICS). All authors were employees of PICS which had a commercial interest in developing computerized smoking reduction products.</p> <p><b>Applicable to UK?</b> Yes</p>
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		reported. <b>Intervention delivery:</b> Authors are university researchers.			
<p><b>First author and year:</b> Roll 1998</p> <p><b>Aim of study:</b> Can short-term abstinence from cigarette smoking in a schizophrenic population be increased by contingent positive reinforcement?</p> <p><b>Study Design :</b> Uncontrolled before and after</p> <p><b>Quality score:</b> –</p> <p><b>External validity score:</b> –</p>	<p><b>Setting:</b> USA. Mental health setting (no information on location)</p> <p><b>Participants:</b> 11 adults; 5=Male.  For 10 completers, average: age 40.4 years (25-52); CPD 28 (range 15-42); CO level 37ppm (range 18-81); Fagerstrom score 8 (3-10).</p> <p><b>Inclusion:</b> Current cigarette smoker; ≥18 years; diagnosis of schizophrenia or schizoaffective disorder confirmed by a board certified psychiatrist using DSM-IV criteria; baseline CO reading of ≥18ppm, able to provide informed consent.</p> <p><b>Exclusion:</b> None stated</p> <p><b>Motivation of participants:</b> None of the participants were considering quitting smoking on entry into the study</p>	<p><b>Method of allocation:</b> No randomisation.</p> <p><b>Intervention(s):</b> Week 1 and 3 baseline phase and Week 2 intervention phase. During weeks 1 and 3 participants visited Mon-Fri afternoons at a private location selected by them. CO collected at every visit and \$5 paid per sample regardless of ppm level. Weekly urine sample to test for illegal drugs and other drug use monitored.  During week 2, visits increased to three per day (morning, afternoon, evening) and CO samples collected. Abstinence was operationalised at ≤11ppm. Participants received immediate cash payments contingent on achieving CO levels of ≤11ppm. Starting at \$3 and increasing by \$0.50 for each subsequent sample ≤11ppm to a maximum of \$10. Three consecutive samples ≤11ppm earned an additional \$10 bonus. CO readings &gt;11ppm reset the value of reinforcement back to \$3. Total available across the week was \$147.</p>	<p><b>Primary outcomes:</b> CO measures</p> <p><b>Follow-up periods:</b> During weeks 1-3 and an average of 8 weeks post-participation.</p> <p><b>Method of analysis:</b> One-way repeated measure ANOVAs. Pairwise comparisons with Fisher’s least significant difference <math>p &lt; 0.05</math> for baseline, intervention and follow-up phases. Two way repeat measures ANOVA for data collected during intervention to examine possible effects of days of week or time of day on CO level. Missing samples treated as positives.</p>	<p><b>Primary:</b> Mean CO levels: Week 1 35.9ppm Week 2 (intervention) 15.9ppm Week 3 25.9ppm 8 weeks post-participation 36.8ppm (no significant difference from the baseline level)</p> <p><b>Attrition:</b> 10 patients completed study. 1 male dropped out in week 1.</p>	<p><b>Limitations (author):</b> Short term study  Possible that reductions during the intervention phase resulted from instructions to reduce rather than contingency payments.</p> <p><b>Limitations (review team):</b> Small scale study . Possible that increased attention during intervention phase may have had an effect. Information provided only as statistically significant or not (<math>p &lt; 0.05</math> or <math>p &gt; 0.05</math>).</p> <p><b>Evidence gaps:</b> Are other forms of substance use by persons with schizophrenia sensitive to contingency management interventions?</p> <p><b>Funding sources:</b> Research grants DA0613, DA08076, DA09278 and training grant DA07267 from NIDA (National Institute on Drug Abuse)</p> <p><b>Applicable to UK?</b> Unclear but project team’s expert advisory group advise that payments are unlikely in the UK context.</p>

		<p>All participants were maintained on their usual medication during the study.</p> <p>8 weeks post-study, participants contacted for a CO sample. Paid \$5 regardless of ppm level.</p> <p>\$150 bonus for completing the study.</p> <p><b>Baseline comparisons:</b> No control group</p> <p><b>Study power:</b> Not provided</p> <p><b>Intervention delivery:</b> Authors are university researchers</p>			
<p><b>First author and year:</b> Schleicher 2010</p> <p><b>Aim of study:</b> To examine smoking reduction and cessation among college smokers with elevated depressive symptoms participating in a group-based multi-component intervention including mood management, behavioural counselling, and motivational enhancement (CBT).</p> <p><b>Study Design :</b> RCT</p> <p><b>Quality score:</b> +</p> <p><b>External validity score:</b></p>	<p><b>Setting:</b> USA – University of Montana</p> <p><b>Participants:</b> 58 university students Age 21; 51% female; white 84.6%</p> <p><b>Inclusion:</b> Age ≥18 years; smoked on ≥6 in past 30 days; CES-D Sum ≥16; Contemplation Ladder score ≥3; undergraduate at University of Montana; willing to participate in all study components</p> <p><b>Exclusion:</b> No current major depressive disorder; no current suicidal intent or plan; no participation in another structured cessation program in the past 30 days</p> <p><b>Motivation of participants:</b> Did not recruit students seeking</p>	<p><b>Method of allocation:</b> Random number table and blocked random assignment of subjects who had been screened at the University during 2007-8 and agreed to participate.</p> <p><b>Intervention(s):</b> Six group-based 2-hour CBT sessions over 8 weeks combining mood management, behavioural counselling and motivational enhancement.</p> <p><b>Control:</b> 6 group sessions designed to increase the consumption of fruit and vegetables.</p> <p><b>Sample sizes:</b> I = 29 C = 29</p> <p><b>Baseline comparisons:</b></p>	<p><b>Primary outcomes:</b> Self-reported 30-day point prevalence abstinence and 50% smoking reduction at end of treatment, CPD, salivary nicotine (results not reported), motivation and confidence, depressive and other psychological measures, pharmacotherapy use</p> <p><b>Secondary outcomes:</b> Self-reported 30-day point prevalence abstinence and 50% smoking reduction at 1-month follow-up Treatment attendance, treatment satisfaction.</p> <p><b>Follow-up periods:</b> End of treatment (week 8) and 1 month post treatment (3 months post baseline).</p> <p><b>Method of analysis:</b> Two-tailed tests with <math>p &lt; 0.05</math> significance. Group differences</p>	<p><b>Primary:</b> At end of treatment no significant differences between groups on 30-day point prevalent abstinence (I: 6.9%, C: 3.4%) though the proportion of intervention subjects reducing their smoking by 50% compared to control was just significant (34.5% vs 10.3%, <math>p = 0.028</math>).</p> <p><b>Secondary:</b> At one month post-intervention follow-up no significant differences between groups on the proportion of participants that reduced their smoking by 50% (I: 24.1%; C: 17.2%); <math>p = 0.747</math>) or 30-day point prevalence abstinence (10.3% in both groups, <math>p = 1.0</math>).</p> <p><b>Attrition:</b> Unclear but approx 59%</p>	<p><b>Limitations (author):</b> Small scale pilot evaluation. Limited follow-up period.</p> <p><b>Limitations (review team):</b> Self-report only; not verified by CO or cotinine. Significant attrition, although an ITT analysis was conducted. No confidence intervals.</p> <p><b>Evidence gaps:</b> None stated</p> <p><b>Funding sources:</b> Grant Number F31DA023738 from NIDA and by The University of Montana.</p> <p><b>Applicable to UK?</b> Yes</p>



+	treatment for smoking	<p>No significant differences on any measure</p> <p><b>Study power:</b> An a priori power analysis indicated sufficient power (0.80) for n=50 participants to detect a difference in abstinence rates at end of treatment between treatment and control groups. The abstinence rates for the control group (4% &amp; 6%) were based on estimates of spontaneous and minimal intervention quit rates in the general population.</p> <p><b>Intervention delivery:</b> Two supervised clinical psychology graduate students.</p>	<p>were assessed using independent t-tests for continuous variables and Pearson's <math>\chi^2</math> test for categorical variables (Fischer's Exact when noted). Outcomes analysed on an ITT basis.</p>		
<b>Thomsen see p 128</b>					
<p><b>First author and year:</b> Tidey 2002</p> <p><b>Aim of study:</b> To examine the effects of contingent monetary reinforcement (CM) for smoking reduction, with and without transdermal nicotine.</p> <p><b>Study Design :</b> Within subjects, repeated measures</p> <p><b>Quality score:</b> -</p> <p><b>External validity score:</b> -</p>	<p><b>Setting:</b> US (Vermont).</p> <p><b>Participants:</b> 14 adults recruited from an outpatient mental health centre. Age: 37.8 (SEM = 3.1); Gender: 5 female, 9 male; FTQ: 8.1 (SEM = 0.4); Average CPD: 31.4 (SEM 3.7); CO: 34.2ppm (SEM=3.1). All taking prescribed antipsychotic drugs.</p> <p><b>Inclusion:</b> Regular smokers Diagnoses of schizophrenia or schizoaffective disorder (confirmed by psychiatrist) CO <math>\geq</math> 18 ppm</p>	<p><b>Method of allocation:</b> Order of conditions counterbalanced across participants. No mention of using randomisation methods to determine order.</p> <p><b>Intervention(s):</b> All subjects received all interventions, order unclear. Conditions separated by washout weeks (smoking <i>ad libitum</i>). CM for smoking reduction + 21 mg nicotine patch (C+NIC) CM + placebo patch (C+P) designed to look and feel the same as the active patch.</p>	<p><b>Primary outcomes:</b> For each condition: Smoking reduction (expired air CO level <math>\leq</math> 11 ppm). Breath sample at baseline, three times daily for the five day study period and two weeks after the end of the study. Nicotine withdrawal scores and smoking urges: Minnesota Nicotine Withdrawal Scale (MNWS) and Questionnaire on Smoking Urges (QSU) measures. Questionnaires completed at baseline and daily for five days. Saliva cotinine levels daily for five days. Other drug use: urine sample</p>	<p><b>Primary:</b> Two week-follow up CO levels: Average = 28.5 ppm (SEM = 3.6); vs baseline (34.2 (SEM = 3.4), p=0.25). During study: Average CO levels during NC condition were significantly higher than during C+P and C+NIC conditions; respectively 28.0 (SEM = 2.9), 20.5 (SEM = 3.7) and 19.4 (SEM = 2.9) ppm (p&lt;0.05). Participants submitted average of 1.3 (SEM =0.7), 5.4 (SEM=1.6) and 6.4 (SEM=1.6) CO samples below cut-off during NC, C+P and C+NIC conditions (p&lt;0.001). Nicotine withdrawal and smoking</p>	<p><b>Limitations (author):</b> Suspect 21 mg patch may not have provided sufficient level of nicotine replacement. Motivation by monetary reward rather than health and social reasons.</p> <p><b>Limitations (review team):</b> Study doesn't report CPD, using CO as a measure of smoking. Small sample study. Lack of randomisation</p> <p><b>Evidence gaps:</b> Suggest studying higher doses or drug such as bupropion to study effect</p>

	<p>FTQ ≥ 6</p> <p><b>Exclusion:</b> None stated.</p> <p><b>Motivation of participants:</b> Participants not actively trying to quit smoking.</p>	<p>Non-contingent monetary reinforcement + placebo patch(NC)</p> <p>Patches changed by research assistant each evening.</p> <p>CM participants received cash payments if they met CO reduction criteria (CO ≤ 11 ppm): \$3 for the 1<sup>st</sup> sample below cutoff, \$3.50 for the second etc with a \$10 bonus for every third consecutive sample below cutoff.</p> <p>NC participants received \$9.80 per visit regardless of breath CO level.</p> <p><b>Sample sizes:</b> 14</p> <p><b>Baseline comparisons:</b> Not applicable - all subjects exposed to all conditions.</p> <p><b>Study power:</b> Not reported</p> <p><b>Intervention delivery:</b> Authors are university researchers.</p>	<p>tested on day 5.</p> <p>Adverse effects - open ended question daily for 5 days.</p> <p>Washout weeks: Expired air sample for CO, completion of QSU and MNWS, and urine and saliva samples at the end of each week (Friday).</p> <p><b>Follow-up periods:</b> 2 weeks post study.</p> <p><b>Method of analysis:</b> Two way repeated measures ANOVA to examine effects of within subject factors condition and day of condition on average daily CO values, QSU factor 1 and factor 2 scores. One way ANOVAs to examine effects of condition on total number of samples below CO cut-off per condition and salivary cotinine levels per condition.</p>	<p>urges:</p> <p>Mean MNWS scores increased during contingent reinforcement conditions, averaging 0.96 (SEM = 0.15), 1.26 (SEM = 0.18) and 1.25 (SEM = 0.16) during NC, C+P and C+NIC conditions (p&lt;0.05).</p> <p>No evidence of nicotine toxicity with concurrent smoking.</p> <p><b>Attrition:</b> 3/14 participants did not complete study. 9/714 scheduled samples missed (1.3%)</p>	<p>on efficacy of CM.</p> <p><b>Funding sources:</b> Funded by National Institute on Drug Abuse grants and Senator Proctor Award from American Lung Association of Vermont.</p> <p><b>Applicable to UK?</b> Unclear</p>
<p><b>First author and year:</b> Wakefield 2002</p> <p><b>Aim of study:</b> Whether an intervention that gave parents objective feedback about their child's level of exposure to ETS and provided practical advice about restricting smoking at home</p>	<p><b>Setting:</b> South Australia. Paediatric outpatients clinic</p> <p><b>Participants:</b> 292 families with children aged 1-11 years with a doctor-confirmed diagnosis of asthma 58% low income (household income &lt;Au\$20,000); employment rate of fathers relatively low (80% vs 90-95% of general population)</p>	<p><b>Method of allocation:</b> Alternatively by week of attendance at clinic</p> <p><b>Intervention(s):</b> Formal letter on hospital stationary to parents Information on child's urinary cotinine-to-creatinine ratio along with minimally tailored feedback level and booklets on reducing ETS exposure and smoking cessation.</p>	<p><b>Primary outcomes:</b> Smoking ban in home (no exceptions)*</p> <p><b>Secondary outcomes:</b> Reduction from baseline in total daily CPD Smoking cessation Smoking ban in the car * Reduction in consumption in front of the child * Child urinary cotinine *</p> <p><b>Follow-up periods:</b></p>	<p><b>Primary:</b> * Results not reported – not relevant to this review.</p> <p><b>Secondary:</b> Reduction from baseline in total daily CPD: Fathers: (I) -1.51 (95%CI: -3.61, 0.59); (C) -1.20 (95%CI: -3.28, 0.88) p= .80. Mothers (I) -0.17 (95%CI: -1.62, 1.27); (C) -0.94 (95%CI: -1.90, 0.02) p= .40. Smoking cessation. No parents in intervention group; 1 father and 2</p>	<p><b>Limitations (author):</b> Lack of random allocation. Statistical power to detect a difference was low (24%)</p> <p><b>Limitations (review team):</b> As above.</p> <p><b>Evidence gaps:</b> More intensive interventions to encourage and maintain change among parents with chronically ill children.</p>

<p>would encourage them to impose bans on smoking in the home or otherwise change their smoking habits.</p> <p><b>Study Design :</b> Non-randomised controlled trial</p> <p><b>Quality score:</b> +</p> <p><b>External validity score:</b> ++</p>	<p><b>Inclusion:</b> At least one resident English-speaking smoker parent.</p> <p><b>Exclusion:</b> None stated</p> <p><b>Motivation of participants</b> Not stated but it does not appear that parents needed to be committed to quit.</p>	<p><b>Control:</b> Usual care - minimal ad hoc and variable advice on smoking from doctors and nurses.</p> <p><b>Sample sizes:</b> Eligible: 378 families Intervention: 143 (101 fathers and 127 mothers were smokers) Control: 149 (105 fathers and 135 mothers were smokers)</p> <p><b>Baseline comparisons:</b> Groups did not differ</p> <p><b>Study power:</b> With 80% power and a 5% level of significance, required a sample size of 100 in each group, assuming no control group change. However, indicates that statistical power to detect a difference was low (24%)</p> <p><b>Intervention delivery:</b> Hospital-based researchers</p>	<p>Appears to be 6 months from baseline.</p> <p><b>Method of analysis:</b> Baseline comparison using <math>\chi^2</math> tests and t tests using <math>p=0.05</math> for statistical significance. Difference scores were computed for parents' reported daily cigarette consumption between baseline and follow-up and compared differences between groups using t tests.</p>	<p>mothers in control group.</p> <p><b>Attrition:</b> Retention rate 90.4% (264/292)</p>	<p><b>Funding sources:</b> Australian National Health and Medical Research Council Grant 980608</p> <p><b>Applicable to UK?</b> Yes</p>
<p><b>First author and year:</b> Walker 2009</p> <p><b>Aim of study:</b> To quantify the effect of pre-operative counselling prior to elective forefoot surgery in smokers.</p> <p><b>Study Design :</b> Uncontrolled before &amp; after</p> <p><b>Quality score:</b> -</p>	<p><b>Setting:</b> UK hospital (location not specified).</p> <p><b>Participants:</b> 25 smokers from 98 patients for forefoot surgery by a single orthopaedic surgeon.</p> <p><b>Inclusion:</b> Smokers booked in for forefoot osteotomy or arthrodesis in 2005-2006.</p> <p><b>Exclusion:</b> None stated</p>	<p><b>Method of allocation:</b> All smokers booked in for forefoot surgery over a two year period.</p> <p><b>Intervention(s):</b> Outline of risks associated with forefoot surgery, and advice to stop smoking prior to surgery, given to patients approximately 6 months before elective forefoot osteotomy or arthrodesis surgery. Advice reiterated at pre-operative clinic.</p>	<p><b>Primary outcomes:</b> Smoking abstinence, smoking reduction (not defined).</p> <p><b>Follow-up periods:</b> One and two weeks post-operatively and (by telephone interview) at 12 months.</p> <p><b>Method of analysis:</b> Self report of abstinence or reduction (no data). No confidence intervals.</p>	<p><b>Primary:</b> 16 (64%) smokers stopped smoking prior to surgery, 4 (16%) reduced smoking (no data given), 2 (8%) were not influenced.</p> <p>12 months post surgery 12/16 (75%) of the abstinent patients at time of surgery had maintained their non-smoking status (48% of the original cohort).</p> <p><b>Attrition:</b> None</p>	<p><b>Limitations (author):</b> No biochemical validation.</p> <p><b>Limitations (review team):</b> Single surgeon's intake only, no control group, could be chance result.</p> <p><b>Evidence gaps:</b> None stated.</p> <p><b>Funding sources:</b> No information given</p> <p><b>Applicable to UK?</b> Yes, UK based, though single site (single surgeon)</p>

<p><b>External validity score:</b> +</p>	<p><b>Motivation of participants:</b> No information provided</p>	<p><b>Control:</b> No control group</p> <p><b>Sample sizes:</b> 25</p> <p><b>Baseline comparisons:</b> No control group</p> <p><b>Study power:</b> Not provided</p> <p><b>Intervention delivery:</b> Single orthopaedic surgeon. Authors are UK NHS Trust based.</p>			<p>only) limits generalisability.</p>
<p><b>First author and year:</b> Warner 2005</p> <p><b>Aim of study:</b> If NRT for cigarette smokers scheduled for elective surgery affects post-operative smoking behaviour.</p> <p><b>Study Design :</b> RCT</p> <p><b>Quality score:</b> ++</p> <p><b>External validity score:</b> +</p>	<p><b>Setting:</b> USA. Mayo Clinic Rochester NY.</p> <p><b>Participants:</b> 116 patients undergoing elective surgery recruited from those evaluated at the Clinic's Preoperative Evaluation Center. Male: I=50%, C = 52%; age [median, (range)]: I = 52 (26-73), C = 47.5 (18-80).</p> <p><b>Inclusion:</b> ≥18years; history of smoking ≥1 CPD during past week with average consumption of ≥10 CPD during past 30 days.</p> <p><b>Exclusion:</b> None stated.</p> <p><b>Motivation of participants:</b> Mixed population with I = 88% and C = 81% at action stage of change.</p>	<p><b>Method of allocation:</b> Randomisation schedule.</p> <p><b>Intervention(s):</b> Provision of NRT patch on morning of surgery with dose either of 21, 35 or 42mg/day, then 30 day supply post-op. Dose based on average CPD.</p> <p><b>Control:</b> Placebo patch</p> <p><b>Sample sizes:</b> Eligible: 1327 Randomised : 121 Treated: 116: I = 60; C = 56.</p> <p><b>Baseline comparisons:</b> Intervention group older and less likely to have a history of lung disease. Otherwise similar.</p> <p><b>Study power:</b> Required 60/group for power of approx. 80% to detect 0.5 SD units difference between groups.</p> <p><b>Intervention delivery:</b> By study personnel.</p>	<p><b>Primary outcomes:</b> Nicotine withdrawal symptoms, psychological stress, pain, self-reported smoking and patch adherence.</p> <p><b>Follow-up periods:</b> Post-operative day (POD) 1, time of discharge &amp; 2, 3, 8, 30 and 180 days post-operatively</p> <p><b>Method of analysis:</b> Comparison of outcomes between groups using <math>\chi^2</math> test or Fisher exact test. Two-sided tests used in all cases.</p>	<p><b>Outcomes</b> 115/116 participants maintained abstinence during hospitalisation.</p> <p>No significant difference between groups in stress, pain or withdrawal during week after surgery.</p> <p>6 months post-op self report: Continuous abstinence I = 5 (9%); C = 9 (15%) (p=0.32); 7-day point prevalence abstinence I = 10 (18%); C = 11 (18%) (p=0.95). Change in CPD from baseline among smokers; mean <math>\pm</math> SD: I = -5.3 <math>\pm</math> 6.9, C = -5.0 <math>\pm</math> 7.4 (p=0.44).</p> <p>30 days post-op self report: Continuous abstinence I = 16 (29%); C = 15 (15%) (p=0.66); 7-day point prevalence abstinence I = 22 (39%), C = 18 (30%) (p=0.29); Change in CPD from baseline among smokers POD 30; mean <math>\pm</math> SD: I = -9.7 <math>\pm</math> 7.8, C = -6.1 <math>\pm</math> 7.0 (p=0.027).</p> <p>Patch discontinuation before POD 30: I = 64%; C = 83.</p> <p>Active patch subjects significantly more likely to have used additional</p>	<p><b>Limitations (author):</b> Participants not representative as were more motivated to modify behaviour.</p> <p><b>Limitations (review team):</b> Limited time for patients to accept the use of patch prior to surgery. High percentage discontinued use before POD 30.</p> <p><b>Evidence gaps:</b> Explore NRT as component of interventions to maintain prolonged post-operative abstinence.</p> <p><b>Funding sources:</b> Minnesota Partnership for Action Against Tobacco, Mayo Foundation. GlaxoSmithKline provided patches.</p> <p><b>Applicable to UK?</b> Yes</p>

				<p>pharmacotherapy since discontinuing study patches: I = 23%, C = 7% (p=0.04).</p> <p><b>Attrition:</b> At POD 30 C = 15% &amp; I = 14%.</p>	
<p><b>First author and year:</b> Wennike, 2003</p> <p><b>Aim of study:</b> To test the effect of nicotine gum (NRT) and placebo (P) in smokers not motivated or not able to quit smoking with regard to smoking reduction and smoking cessation.</p> <p><b>Study Design :</b> Individual quasi-RCT</p> <p><b>Quality score:</b> +</p> <p><b>External validity score:</b> +</p>	<p><b>Setting:</b> Denmark, Copenhagen.</p> <p><b>Participants:</b> 411 adults recruited through newspaper advertisements. Female (%) 65% (I) , 59% (C); Mean baseline consumption 24 CPD; mean CO 28ppm; high degree of nicotine dependence. 61% of participants had made 2-5 previous quit attempts. 68% high FTND scores. 42% previous use of NRT gum.</p> <p><b>Inclusion:</b> Age ≥ 18 years, currently smoking ≥15 CPD; smoked regularly ≥3 years, CO ≥15 ppm after ≥15 smoke-free minutes, failed at least one serious quit attempt within the last 24 months, wanted to reduce smoking with nicotine gum.</p> <p><b>Exclusion:</b> Current use of NRT or any other behavioural or pharmacological smoking cessation/reduction programme; use of other nicotine-containing products; having unstable angina pectoris, myocardial infarction within the last 3 months; under psychiatric care or medication; alcohol or other drug problem;</p>	<p><b>Method of allocation:</b> Not stated.</p> <p><b>Intervention(s):</b> Subjects with FTND scores ≤5 allocated NRT 2 mg gum. Those scoring 6–10 allocated NRT 4mg gum. Gum provided for ≤12 months.</p> <p><b>Control:</b> Placebo gum</p> <p>All participants received moderate behavioural smoking reduction information. General implications of smoking and effects on health discussed. Participants asked to reduce CPD as much as possible. All given info about possible ways to achieve this: increased interval between cigarettes; longer time to first cigarette; removing habitual cigarettes. Smoking cessation recommended as ultimate goal throughout study, but not mandatory.</p> <p><b>Sample sizes:</b> Intervention = 205 Control = 206</p> <p><b>Baseline comparisons:</b></p>	<p><b>Primary outcomes:</b> Self reported ≥50% reduction in CPD maintained from week 6 compared to baseline. CO verified by reduction from baseline of ≥1ppm.</p> <p>Point prevalence ≥50% reduction – length of time not stated.</p> <p><b>Secondary outcomes:</b> Smoking cessation (confirmed by CO &lt;10ppm.) Changes in attitudes to quitting.</p> <p><b>Follow-up periods:</b> From week 6 to 4, 12, and 24 months.</p> <p><b>Method of analysis:</b> Two-tailed at 5% significance level. No formal adjustments for multiplicity performed. <math>\chi^2</math> test for categorical or binary variables, and two-sided Mann–Whitney test for small or not normally distributed data. Used ITT in outcome analysis.</p>	<p><b>Primary:</b> Sustained reduction: Month 24 I = 13 (6.3%) C = 1 (0.5%) OR 13.9 (95% CI: 1.80, 107; p&lt;0.001) Month 12 I = 18 (8.8%) C = 3 (1.5%) OR 6.51 (95% CI 1.89, 22.5; p&lt;0.001)</p> <p>≥50% reduction Month 24 I = 30 (14.6%) C = 20 (9.7%) OR 1.59 (95% CI 0.87, 2.91 0.13; p=0.13) Month 12 I = 43 (21.0%) C = 27 (13.1%) OR 1.76 (95% CI 1.04, 2.98; p=0.036)</p> <p>NNT for reduction in smoking by at least 50% from week 6 to months 12 and 24 are 14 (95% CI 9, 32) and 17 (95% CI 11, 42), respectively.</p> <p><b>Secondary:</b> Point prevalence cessation Month 24 I = 19 (9.3%) C = 7 (3.4%) OR 2.90 (95% CI 1.19, 7.07; p=0.015) Month 12 I = 23 (11.2) C = 8 (3.9%) OR 3.13 (95% CI 1.36, 7.7; p=0.005)</p> <p>NNTs for point prevalence abstinence at 12 and 24 months are: 14 (95% CI 8, 44) and 17 (95% CI 9, 84) respectively.</p> <p>Motivation to stop smoking, via 10-point VAS scale: mean (SD) Baseline: I = 49, 6.5 (3.2); C = 49, 6.1 (2.8) 24 mths: I = 4.7 (2.8); C = 5.2 (3.2).</p>	<p><b>Limitations (author):</b> High premature dropout rate with a 41% 1-year attendance rate</p> <p><b>Limitations (review team):</b> As above – high attrition rate.</p> <p><b>Evidence gaps:</b> None stated</p> <p><b>Funding sources:</b> Study supported by grant from Pharmacia AB.</p> <p><b>Applicable to UK?</b> Yes</p>

	<p>intention to quit smoking within the next month.</p> <p><b>Motivation of participants:</b> Want to reduce smoking with NRT gum.</p>	<p>No significant differences</p> <p><b>Study power:</b> States that "based on previous smoking reduction studies, assumed 200 subjects in each group needed for a power of 80% and a two-tailed significance level of 0.05", but no power calculation provided.</p> <p><b>Intervention delivery:</b> Authors are academics at a university hospital and pharmaceutical company employees.</p>		<p>Adverse events: at 24 months I = 166, C = 147. 21 SAEs not attributed to treatment.</p> <p><b>Attrition:</b> Loss to follow up not clearly stated, Results from primary analysis suggest higher drop out in control group, and response rates were poor &lt; 50%.</p> <p><b>Meta-analysis data:</b> Sustained reduction: Month 24 I = 13/205; C = 1/206 Month 12 I = 18/205; C = 3/206 ≥50% reduction Month 24: I = 30/205; C = 20/206 Month 12: I = 43/205; C = 27/206 CPD (percentage of baseline) 24 months: I = 82 mean = 54 (SD 42) C = 71; mean=61 (SD 34), (p=0.20) 12 months I = 96; mean=46 (SD 36) C:n=73; mean=57 (SD 31), (p=0.05) Point prevalence cessation Month 24 I = 19/205; C = 7/206 Month 12 I = 23/205; C = 206</p>	
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**SYSTEMATIC REVIEW**

Review details	Search Parameters	Population and setting	Intervention/s	Outcomes and method of analysis	Results	Notes
<p><b>First author and year:</b> Thomsen 2010</p> <p><b>Aim of review:</b> To assess the effect of preoperative smoking intervention on smoking cessation at the time of surgery and post-operatively.</p> <p><b>Review Design :</b> Systematic</p> <p><b>Quality score:</b> +</p>	<p><b>Databases and websites searched:</b> Cochrane Tobacco Addiction Group specialized register, Medline, Embase &amp; Cinahl</p> <p><b>Other search methods undertaken (e.g. reference checking):</b> None reported</p> <p><b>Years searched:</b> Not clear from when but last search April 2010</p> <p><b>Study type inclusion criteria:</b> RCTs</p> <p><b>Study type exclusion criteria:</b> All non-RCTs</p> <p><b>Number of studies included:</b> 8</p> <p><b>Method of synthesis:</b> Narrative and meta-analysis</p>	<p><b>Included population/s:</b> Smokers of any age, who are scheduled for elective surgery.</p> <p><b>Excluded populations:</b> Not reported</p> <p><b>Setting of included studies:</b> Hospital; Australia, Canada, Denmark, Sweden &amp; UK</p> <p><b>External validity score:</b></p>	<p><b>Intervention/s description:</b> Any pre-operative brief or intensive intervention to help patients awaiting surgery to stop smoking including both behavioural and pharmacological strategies, with/without face-to-face contact, at least 48 hours before the operation. Interventions formed into 2 sub-groups: intensive consisted of weekly counselling sessions over a period of four to eight weeks; brief provided in relation to routine preoperative evaluation and consisting of one face-to-face and/or telephone counselling session and/or interactive computer counselling or one letter about the risks of smoking in relation to surgery before surgery.</p> <p><b>Control/comparison/s description:</b> Included: booklet and nurse advice; standard/usual care; told to continue to smoke; staff could provide advice and NRT at their discretion.</p>	<p><b>Outcomes:</b> Prevalence of smoking cessation at the time of surgery and 12 months post-operatively. Preferred self-reported continuous abstinence rather than self-reported point prevalence.</p> <p><b>Follow-up periods:</b> Four papers assessed cessation at 12 months</p> <p><b>Methods of analysis:</b> Outcomes expressed as risk ratios using intention-to-treat and available case analysis. Where appropriate to pool Mantel-Haenszel fixed-effect method was used.</p>	<p><b>Outcomes</b> Two trials initiated multi-session face to face counselling <math>\geq 6</math> weeks before surgery whilst six used a brief intervention. NRT offered or recommended to some or all participants in seven trials. Five trials detected significantly increased smoking cessation at time of surgery, and one approached significance. Subgroup analyses showed both intensive and brief intervention significantly increased smoking cessation at time of surgery; pooled RR 10.76 (95% CI 4.55, 25.46, two trials) and RR 1.41 (95% CI 1.22, 1.63, five trials) respectively.</p> <p>Four trials found significant effect on long-term smoking cessation; pooled RR 1.61 (95% CI 1.12, 2.33). However, when pooling intensive and brief interventions separately, only intensive retained significant effect on long-term smoking cessation; RR 2.96 (95% CI 1.57, 5.55 - two trials).</p> <p><b>Attrition:</b> Drop rates ranged from 1% to 29%.</p>	<p><b>Limitations (author):</b> Implementation of various smoking policies during time range of included studies may have lessened effect of brief interventions. Small sample sizes. Inconsistency in way trials defined “at the time of surgery” and variations in intensity of support provided.</p> <p><b>Limitations (review team):</b> Limited information on search strategy. Limited consideration of participant motivations.</p> <p><b>Evidence gaps:</b> Analysis of long-term smoking abstinence rates (<math>\geq 12</math> months) and effect of different methods of smoking intervention</p> <p><b>Funding sources:</b> Not stated. Authors are also authors of two of the included trials.</p> <p><b>Applicable to UK?</b> Yes</p>

**APPENDIX B: SUMMARY OF QUALITY APPRAISAL – INCLUDED STUDIES**

**Key to headings (brief summary from Appendix F, NICE 2009):** 1.1 Source population described; 1.2 Eligible population representative of source ; 1.3 Selected population representative of eligible; 2.1 Population described; 2.2 Intervention/comparison described; 2.3 Allocation concealed; 2.4 Blinded; 2.5 Exposure adequate; 2.6 Contamination low; 2.7 Other interventions similar in groups; 2.8 All participants accounted for; 2.9 Setting reflects UK practice; 2.10 Intervention reflects UK practice; 3.1 Reliable outcomes; 3.2 Complete outcomes; 3.3 Important outcomes assessed; 3.4 Relevant outcomes; 3.5 Similar follow up times; 3.6 Meaningful follow up; 4.1 Groups similar at baseline; 4.2 ITT used; 4.3 Sufficient power; 4.4 Estimates of effect size given; 4.5 Appropriate analysis; 4.6 Precision; 5.1 Internally valid; 5.2 Externally valid; ++ Minimal bias; +Bias unclear; - Risk of bias; nr Not reported; na Not applicable

Author Year	Study design	Population			Method of allocation to intervention (or comparison)										Outcomes						Analyses						Summary		
		1.1	1.2	1.3	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	2.9	2.10	3.1	3.2	3.3	3.4	3.5	3.6	4.1	4.2	4.3	4.4	4.5	4.6	5.1	5.2	
Audrain-McGovern 2011	Quasi-RCT	+	++	++	+	++	nr	nr	++	+	++	++	+	+	+	++	++	++	++	+	+	-	nr	+	+	+	+	+	
Batra 2005	Quasi-RCT	+	+	++	+	++	nr	++	++	++	++	+	+	++	++	+	++	++	++	++	++	++	+	++	++	++	+	++	
Beard 2012	UBA	-	nr	nr	na	++	na	na	++	na	na	++	++	+	+	++	++	++	na	-	na	nr	nr	++	++	+	-	-	
Benowitz 1998	Non-RCT	+	+	-	nr	+	nr	+	-	+	-	++	-	-	++	+	++	++	++	-	nr	-	nr	+	++	+	-	-	
Bolliger 2000	RCT	+	+	+	++	++	++	++	nr	++	nr	+	++	++	++	++	++	++	++	++	+	++	+	++	++	++	++	+	
Borland 1999	Quasi RCT	+	+	+	+	++	nr	nr	-	++	++	-	++	++	-	nr	++	++	++	++	-	+	-	++	++	++	+	+	
Carpenter 2004	Quasi-RCT	+	+	++	+	++	nr	-	+	++	+	++	+	+	-	nr	+	++	++	-	-	++	nr	++	++	++	+	+	
Carpenter 2007	SA	+	+	+	na	++	na	-	na	na	na	na	+	-	-	-	-	++	na	-	na	nr	nr	+	+	-	-	-	
Chan 2011	RCT	-	-	-	++	++	++	+	++	nr	+	++	++	+	++	+	++	++	++	++	+	++	++	++	++	+	+	++	+
Cunningham 2006	Quasi-RCT	-	+	-	+	++	nr	nr	++	+	+	++	++	+	-	nr	+	++	++	-	++	-	nr	+	++	+	+	+	
Davis 2011	Quasi-RCT	-	-	-	+	+	nr	nr	++	++	++	-	-	+	++	-	++	++	++	++	++	++	-	++	++	++	+	-	
Etter 2007	RCT	++	++	++	++	++	++	+	nr	nr	nr	++	+	+	-	+	++	++	++	++	++	++	++	++	++	++	+	++	
Fagerstrom 1997	PartialRCT	+	-	+	+	-	nr	-	nr	-	++	++	+	+	++	+	++	++	++	-	++	-	nr	++	-	-	-	+	
Fossum 2004	CBA	+	nr	+	-	-	-	+	++	++	++	-	++	+	++	-	+	++	++	-	+	-	nr	+	+	-	-	+	
Foulds 1992	Quasi-RCT	-	-	-	+	++	nr	++	-	+	++	++	-	-	+	++	++	++	+	-	nr	++	+	++	++	+	+	-	
Glasgow 2009	RCT	++	+	+	++	++	++	+	++	nr	nr	-	++	++	++	++	++	++	++	+	++	++	nr	++	++	++	++	++	
Gray 2005	CBA	+	-	+	na	-	na	-	+	++	nr	++	+	+	-	++	+	++	++	-	-	-	nr	++	++	-	-	+	
Griffiths 2010	UBA	-	-	+	na	++	na	na	+	na	na	-	+	-	-	-	+	++	na	-	-	-	nr	++	++	+	-	-	



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Gulliver 2008	Quasi-RCT	+	+	+	+	++	nr	nr	+	+	++	-	++	+	+	-	++	++	++	++	++	++	++	++	++	++	+	+
Hanson 2008	Quasi-RCT	++	+	+	+	++	nr	-	++	++	++	+	++	+	++	++	++	++	++	++	++	nr	-	++	++	++	+	++
Hatsukami 2005	Quasi-RCT	+	++	+	+	+	nr	nr	nr	nr	+	+	+	-	-	nr	+	++	++	-	nr	-	nr	+	+	-	-	+
Hatsukami 2007	UBA	+	++	+	na	++	na	na	++	na	na	-	+	+	++	-	++	++	na	-	na	-	nr	++	++	-	-	-
Horn 2007	RCT	++	++	+	++	++	++	++	++	++	++	-	+	++	-	-	++	++	++	++	++	+	nr	++	++	++	+	++
Hovell 2000	RCT	+	++	+	++	++	++	++	++	++	+	+	+	++	++	+	++	++	++	++	++	++	++	++	++	++	++	++
Hurt 2000	UBA	-	+	-	na	+	na	na	-	na	na	+	-	-	++	+	++	++	na	-	na	nr	nr	++	++	-	-	-
Irvine 1999	Quasi-RCT	+	++	++	+	++	nr	+	++	++	++	++	++	++	+	-	++	++	++	++	++	-	-	++	++	+	+	++
Jimenez-Ruiz 2002	UBA	+	+	+	na	++	na	na	+	na	na	++	+	+	++	++	++	++	na	++	na	nr	-	++	++	++	-	+
Joseph 2008	RCT	+	++	++	++	+	++	-	++	++	+	+	++	+	-	+	+	++	++	-	++	nr	+	++	++	++	+	+
Kelly 2006	Quasi-RCT	++	++	-	+	++	nr	nr	++	++	++	+	++	+	-	+	++	++	++	++	+	++	-	++	++	++	+	++
Kralikova 2009	Quasi-RCT	+	+	++	+	++	nr	++	++	nr	++	+	++	+	++	nr	++	++	++	+	++	++	++	++	++	++	+	+
McCambridge 2005	RCT	++	++	+	++	++	++	-	++	++	++	++	++	++	-	++	++	++	++	++	++	-	nr	++	++	++	+	++
Munday 1993	Non-RCT	+	-	-	na	+	na	+	+	+	nr	nr	++	++	-	nr	+	++	-	++	-	nr	nr	++	++	+	-	+
Pickworth 1994	UBA	-	+	-	na	++	na	na	++	na	na	++	-	-	++	++	++	++	na	-	na	nr	nr	++	++	+	-	-
Pisinger 2005	Partial RCT/SA	++	++	+	+	-	-	-	-	+	+	-	+	+	-	-	-	+	+	+	+	+	+	++	++	++	-	+
Polosa 2011	UBA	+	-	+	na	++	na	na	+	na	na	+	-	-	++	+	++	++	na	+	na	+	-	++	++	+	-	-
Rennard 1990	UBA	-	-	-	na	+	na	na	+	na	na	++	nr	nr	++	++	++	++	na	-	na	nr	nr	++	++	+	-	-
Rennard 2006	Quasi-RCT	+	++	++	+	++	nr	+	+	nr	++	-	++	+	++	nr	++	++	++	+	-	++	-	++	++	++	+	+
Riggs 2001	Quasi-RCT	+	++	++	+	++	nr	na	+	++	++	nr	+	-	++	nr	++	++	na	-	na	nr	nr	++	++	++	-	+
Riley 2002	Quasi-RT	+	++	++	+	++	nr	nr	++	++	++	+	++	+	+	+	+	++	++	++	+	++	nr	++	++	++	+	++
Roll 1998	UBA	+	-	-	na	++	na	na	na	na	na	++	nr	-	++	++	-	+	na	-	na	nr	-	++	++	-	-	-
Schleicher 2010	RCT	++	+	+	++	+	++	-	+	+	++	-	+	+	-	-	+	++	++	-	++	++	++	++	+	-	+	+
Tidey 2002	UBA	+	-	+	-	++	-	+	-	nr	++	++	++	-	+	++	-	+	na	-	na	-	nr	++	++	++	-	-
Wakefield 2002	Non-RCT	++	+	++	-	++	-	nr	++	++	++	++	++	++	+	++	++	++	++	+	+	-	-	++	++	++	+	++

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Walker 2009	UBA	+	+	++	na	++	na	na	++	na	na	++	++	++	-	++	++	+	na	++	na	nr	nr	+	-	-	-	+
Warner 2005	RCT	+	+	-	++	++	++	++	-	++	++	++	++	++	-	++	++	++	++	+	+	++	++	++	++	++	++	+
Wennike 2003	Quasi-RCT	+	+	+	+	+	nr	+	+	+	++	-	++	++	++	++	++	++	++	++	++	++	++	++	++	+	+	+

## APPENDIX C: EXPERT ADVISORY GROUP

Dr Julie Bishop	Consultant in Public Health and currently Acting Director of Health Improvement for Public Health Wales.
Ms Elen de Lacy	Chief Executive of ASH Wales, formerly Research and Policy Manger.
Dr Keir Lewis	Senior Lecturer at Swansea University and Honorary Respiratory Consultant to the Hywel Dda Health Board, Wales, UK.
Professor Laurence Moore	Professor of Public Health Improvement at Cardiff University, and Director of DECIPHer, a UKCRC Centre Public Health Research Excellence
Ms Helen Poole	Secondary care smoking cessation counsellor at the University Hospital of Wales.
Dr Marianne van den Bree	Reader at Cardiff University in the Department of Psychological Medicine and Neurology.

**APPENDIX D: REVIEW TEAM**

<b>Staff/Resource Description</b>	<b>Role</b>
Ms Ellie Byrne, CISHE, Cardiff University	Study selection
Dr Ben Carter, North Wales Clinical School, Cardiff University	Statistical analysis including meta-analysis and advice; quality assessment and data extraction
Mr Stephen Jones, CEDAR	Technical advice, quality assessment and data extraction
Ms Fiona Morgan, SURE, Cardiff University	Project management, searching, study selection, quality assessment, data extraction, narrative synthesis and report writing.
Dr Helen Morgan, SURE, Cardiff University	Project management, searching study selection, quality assessment, data extraction, narrative synthesis and report writing.
Ms Ruth Turley, SURE, Cardiff University	Quality assessment, data extraction
Dr Alison Weightman, SURE, Cardiff University	Project Director. Searching, study selection, quality assessment, data extraction, narrative synthesis and report writing.
Dr Sarah Whitehead, CISHE, Cardiff University	Study selection, quality assessment, data extraction and report writing.

## APPENDIX E: SEARCH STRATEGY

The search strategy below was used for effectiveness and barrier/facilitator reviews. It was designed for the Ovid MEDLINE(R) database 1966 to August Week 1 2011 and was adapted for use in the other databases listed in section 2.1.1.

1. Smoking Cessation/ or exp Smoking/ 112950
2. ((Nicotine adj4 (therapy or gum\* or inhal\* or replace\* or lozenge\* or tablet\* or microtab\* or nasal spray\* or patch\* or delivery device\* or delivery system\* or gel\*)) or ((smok\* or tobacco or nicotine or cigarette\*) adj10 NRT)).ti,ab. 3472
3. 1 and 2 2800
4. (exp smoking/ or smoking cessation/) and harm reduction/ 156
5. nicotine/th 2
6. (Cigarette\* adj2 substitut\*).ti,ab. 40
7. ("electronic cigarette\*" or e-cigarette\* or ecigarette\* or ecig\* or e-cig\* or Intellcig).ti,ab.27
8. (vaping or (personal adj4 vaporizer)).ti,ab. 3
9. (Nicotine adj4 (therapy or gum\* or inhal\* or replace\* or lozenge\* or tablet\* or microtab\* or nasal spray\* or patch\* or delivery device\* or delivery system\* or gel\*)).ti,ab. 3465
10. (Pastille\* and (smok\* or tobacco or nicotine or cigarette\*)).ti,ab. 0
11. (Nicorette or Nicotinell or Niconil or NiQuitin or Polacrilex or Habitrol or Nicabate or NicoDerm or Nicotex or Nicotrol or ProStep or Quickmist).ti,ab. 195
12. ((Stoppers or Commit or pharmacotherap\*) adj3 (smok\* or tobacco or nicotine or cigarette\*)).ti,ab. 372
13. (Stubit or super-25).ti,ab. 0
14. (pharmacotherapy/ or drug therapy/) and (smok\* or tobacco or nicotine or cigarette\*).ti,ab. 198
15. (((pre-quit or prequit or "Stop/start" or abstain\* or abstinence or reduc\* or declin\* or quit\* or stop\* or cess\* or cease\* or cut down or giv\* up) adj4 (smok\* or tobacco or cigarette\*)) and nicotine).ti,ab. 5085
16. or/3-15 6746
17. \*counseling/ or \*directive counseling/ or behavior therapy/ or cognitive therapy/ or Self help groups/ 50185
18. (advis\* or advic\* or counsel\* or help line\* or helpline\* or self help or selfhelp or ((behavio?r\* or group or cognitive) adj (support or therap\*))).ti,ab. 128768
19. (((mobile or cell\*) adj (phone\*1 or telephone\*1)) or (SMS or short message service or text messag\* or instant messag\* or videomessag\* or video messag\* or multimedia messag\* or web or internet or computer\* or e-mail\* or email\* or electronic mail\* or mailing list\*)).ti,ab. 239196
20. \*internet/ or \*cellular phone/ or \*User-computer interface/ or Therapy, Computer-assisted/mt 33263
21. or/17-20 408269
22. smoking cessation/ or ((pre-quit or prequit or "Stop/start" or abstain\* or abstinence or reduc\* or declin\* or quit\* or stop\* or cess\* or cease\* or cut down or giv\* up) adj4 (smok\* or tobacco or cigarette\*)).ti,ab. 29968
23. 21 and 22 5821
24. 16 or 23 10954
25. randomized controlled trial.pt. 313813
26. controlled clinical trial.pt. 83155
27. clinical trial.pt. 466468
28. trial.ti,ab. 272946
29. randomi?ed.ti,ab. 279552
30. Random allocation/ or ((randomly adj1 (allocat\$ or assign\$)) or placebo-controlled or placebo group).ti,ab. 185061
31. "controlled before and after".ti,ab. 331

32. (time adj series).ti,ab. 10470
33. quasi-experiment\*.ti,ab. 3683
34. Control groups/ or Evaluation studies as topic/ or ((evaluation or intervention) adj3 (control group or controlled or study or program\* or comparison or "before and after" or comparative)).ti,ab. 164284
35. (pre test or pretest or pre-intervention or post-intervention or posttest or post test).ti,ab. 14740
36. ((systematic\* adj1 review) or meta analys\*).ti,ab. or meta-analysis/ 60586
37. "mixed methods".ti,ab. 999
38. or/25-37 1034277
39. 24 and 38 3685
40. (interviews or interview or interviewed or qualitative or ethnograph\* or thematic analysis or grounded theory).ti,ab. 233563
41. ((perception\* or perceive\* or attitude\* or view\*1 or viewpoint\* or standpoint\* or encounter\* or experience\* or story or stories or narrative\*1 or description\* or theme\* or opinion\* or need\*1) adj3 (survey\* or questionnaire\*)).ti,ab. 12123
42. ((field or case) adj (stud\* or research)).ti,ab. 46844
43. Focus groups/ or Qualitative research/ or Interviews as topic/ or Questionnaires/ or Interview, Psychological/ or ((focus or discussion) adj group\*1).ti,ab. 293785
44. process evaluation/ or process evaluation.ti,ab. 871
45. or/40-44 509964
46. 24 and 45 2094
47. 39 or 46 5125
48. animal/ not (animal/ and human/) 3568174
49. 47 not 48 5112
50. (letter or editorial or historical article).pt. 1269683
51. 49 not 50 5082
52. limit 51 to (english language and yr="1990 - Current") 4468

**APPENDIX F: LIST OF INCLUDED STUDIES**

- Andrews, K., Bale, P., Chu, J., Cramer, A., & Aveyard, P. 2006. A randomized controlled trial to assess the effectiveness of a letter from a consultant surgeon in causing smokers to stop smoking pre-operatively. *Public Health*, 120, (4) 356-358 [Included in systematic review by Thomsen et al]
- Audrain-McGovern, J., Stevens, S., Murray, P.J., Kinsman, S., Zuckoff, A., Pletcher, J., Moss, D., Baumritter, A., Kalkhuis-Beam, S., Carlson, E., Rodriguez, D., & Wileyto, E.P. 2011. The efficacy of motivational interviewing versus brief advice for adolescent smoking behavior change. *Pediatrics*, 128, (1) e101-e111
- Batra, A., Klingler, K., Landfeldt, B., Friederich, H.M., Westin, A., & Danielsson, T. 2005. Smoking reduction treatment with 4-mg nicotine gum: a double-blind, randomized, placebo-controlled study. *Clinical Pharmacology & Therapeutics*, 78, (6) 689-696
- Beard, E., & West, R. 2012 Pilot study of the use personal carbon monoxide monitoring to achieve radical smoking reduction. In press.
- Benowitz, N.L., Zevin, S., & Jacob, P., III 1998. Suppression of nicotine intake during ad libitum cigarette smoking by high-dose transdermal nicotine. *Journal of Pharmacology & Experimental Therapeutics*, 287, (3) 958-962
- Bolliger, C.T., Zellweger, J.P., Danielsson, T., van, B., X, Robidou, A., Westin, A., Perruchoud, A.P., & Sawe, U. 2000. Smoking reduction with oral nicotine inhalers: double blind, randomised clinical trial of efficacy and safety. *BMJ*, 321, (7257) 329-333
- Bolliger, C.T., Zellweger, J.P., Danielsson, T., van, B., X, Robidou, A., Westin, A., Perruchoud, A.P., & Sawe, U. 2002. Influence of long-term smoking reduction on health risk markers and quality of life. *Nicotine & Tobacco Research*, 4, (4) 433-439
- Borland, R., Owen, N., Tooley, G., Treijs, I., Roberts, L., & Hill, D. 1999. Promoting reduced smoking rates in the context of workplace smoking bans. *American Journal of Health Promotion*, 14, (1) 1-3
- Carpenter, M.J., Hughes, J.R., & Keely, J.P. 2003. Effect of smoking reduction on later cessation: a pilot experimental study. *Nicotine & Tobacco Research*, 5, (2) 155-162
- Carpenter, M.J., Hughes, J.R., Solomon, L.J., & Callas, P.W. 2004. Both smoking reduction with nicotine replacement therapy and motivational advice increase future cessation among smokers unmotivated to quit. *Journal of Consulting & Clinical Psychology*, 72, (3) 371-381
- Carpenter, M.J., Strange, C., Jones, Y., Dickson, M.R., Carter, C., Moseley, M.A., & Gilbert, G.E. 2007. Does genetic testing result in behavioral health change? Changes in smoking behavior following testing for alpha-1 antitrypsin deficiency. *Annals of Behavioral Medicine*, 33, (1) 22-28
- Chan, S.S., Leung, D.Y., Abdullah, A.S., Wong, V.T., Hedley, A.J., & Lam, T.H. 2011. A randomized controlled trial of a smoking reduction plus nicotine replacement therapy intervention for smokers not willing to quit smoking. *Addiction*, 106, (6) 1155-1163
- Cunningham, J.A., Faulkner, G., Selby, P., & Cordingley, J. 2006. Motivating smoking reductions by framing health information as safer smoking tips. *Addictive Behaviors*, 31, (8) 1465-1468
- Dar, R., Stronguin, F., & Etter, J.F. 2005. Assigned versus perceived placebo effects in nicotine replacement therapy for smoking reduction in Swiss smokers. *Journal of Consulting & Clinical Psychology*, 73, (2) 350-353
- Davis, M.F., Shapiro, D., Windsor, R., Whalen, P., Rhode, R., Miller, H.S., & Sechrest, L. 2011. Motivational interviewing versus prescriptive advice for smokers who are not ready to quit. *Patient Education & Counseling*, 83, (1) 129-133
- Etter, J.F., Laszlo, E., Zellweger, J.P., Perrot, C., & Perneger, T.V. 2002. Nicotine replacement to reduce cigarette consumption in smokers who are unwilling to quit: a randomized trial. *Journal of Clinical Psychopharmacology*, 22, (5) 487-495

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- Foulds, J., Stapleton, J., Feyerabend, C., Vesey, C., Jarvis, M., & Russell, M.A. 1992. Effect of transdermal nicotine patches on cigarette smoking: a double blind crossover study. *Psychopharmacology*, 106, (3) 421-427
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- Griffiths, M., Kidd, S.A., Pike, S., & Chan, J. 2010. The Tobacco Addiction Recovery Program: initial outcome findings. *Archives of Psychiatric Nursing*, 24, (4) 239-246
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- Hanson, K., Zylla, E., Allen, S., Li, Z., & Hatsukami, D.K. 2008. Cigarette reduction: an intervention for adolescent smokers. *Drug & Alcohol Dependence*, 95, (1-2) 164-168
- Hatsukami, D., Mooney, M., Murphy, S., LeSage, M., Babb, D., & Hecht, S. 2007. Effects of high dose transdermal nicotine replacement in cigarette smokers. *Pharmacology Biochemistry and Behavior*, 86, (1) 132-139
- Hatsukami, D.K., Kotlyar, M., Allen, S., Jensen, J., Li, S., Le, C., & Murphy, S. 2005. Effects of cigarette reduction on cardiovascular risk factors and subjective measures. *Chest*, 128, (4) 2528-2537
- Hecht SS, Murphy SE, Carmella SG, Zimmerman CL, Losey L, Kramarczuk I, Roe MR, Puumala SS, Li YS, Le C, Jensen J, & Hatsukami DK 2004. Effects of reduced cigarette smoking on the uptake of a tobacco-specific lung carcinogen. *Journal of the National Cancer Institute*, 96, (2) 107-115
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- McCambridge, J. & Strang, J. 2005. Deterioration over time in effect of Motivational Interviewing in reducing drug consumption and related risk among young people. *Addiction*, 100, (4) 470-478
- Moller, A.M., Villebro, N., Pedersen, T., & Tonnesen, H. 2002. Effect of preoperative smoking intervention on postoperative complications: a randomised clinical trial. *Lancet*, 359, (9301) 114-117 [Included in systematic review by Thomsen et al]
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- Pisinger, C., Vestbo, J., Borch-Johnsen, K., & Jorgensen, T. 2005. Smoking reduction intervention in a large population-based study. The Inter99 study. *Preventive Medicine*, 40, (1) 112-118
- Pisinger C, Vestbo J, Borch-Johnsen K, Thomsen T, & Jorgensen T 2005. Acceptance of the smoking cessation intervention in a large population-based study: the Inter99 study. *Scandinavian Journal of Public Health*, 33, (2) 138-145
- Polosa R, Caponnetto P, Morjaria JB, Papale G, Campagna D, & Russo C 2011. Effect of an Electronic Nicotine Delivery Device (e-Cigarette) on Smoking Reduction and Cessation: A Prospective 6-Month Pilot Study. *BMC Public Health*, Oct 11;11(1):786. [Epub ahead of print],
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- Rennard, S.I., Glover, E.D., Leischow, S., Daughton, D.M., Glover, P.N., Muramoto, M., Franzon, M., Danielsson, T., Landfeldt, B., & Westin, A. 2006. Efficacy of the nicotine inhaler in smoking reduction: A double-blind, randomized trial. *Nicotine & Tobacco Research*, 8, (4) 555-564

Rennard, S.I., Daughton, D., Fujita, J., Oehlerking, M.B., Dobson, J.R., Stahl, M.G., Robbins, R.A., & Thompson, A.B. 1990. Short-term smoking reduction is associated with reduction in measures of lower respiratory tract inflammation in heavy smokers. *Eur Respir.J.*, 3, (7) 752-759

Riggs, R.L., Hughes, J.R., & Pillitteri, J.L. 2001. Two behavioral treatments for smoking reduction: a pilot study. *Nicotine & Tobacco Research*, 3, (1) 71-76

Riley, W., Jerome, A., Behar, A., & Weil, J. 2002. Computer and manual self-help behavioral strategies for smoking reduction: initial feasibility and one-year follow-up. *Nicotine & Tobacco Research*, 4 Suppl 2, S183-S188

Roll, J.M., Higgins, S.T., Steingard, S., & McGinley, M. 1998. Use of monetary reinforcement to reduce the cigarette smoking of persons with schizophrenia: a feasibility study. *Exp.Clin Psychopharmacol.*, 6, (2) 157-161

Schleicher, H. 2010. Evaluation of a cognitive-behavioral mood management intervention for depressed college smokers. *Dissertation Abstracts International: Section B: The Sciences and Engineering* (6-B) 3946

Sorensen, L.T., Hemmingsen, U., & Jorgensen, T. 2007. Strategies of smoking cessation intervention before hernia surgery—effect on perioperative smoking behavior. *Hernia*, 11, (4) 327-333

Tidey, J.W., O'Neill, S.C., & Higgins, S.T. 2002. Contingent monetary reinforcement of smoking reductions, with and without transdermal nicotine, in outpatients with schizophrenia. *Experimental & Clinical Psychopharmacology*, 10, (3) 241-247

Wakefield, M., Banham, D., McCaul, K., Martin, J., Ruffin, R., Badcock, N., & Roberts, L. 2002. Effect of feedback regarding urinary cotinine and brief tailored advice on home smoking restrictions among low-income parents of children with asthma: a controlled trial. *Preventive Medicine*, 34, (1) 58-65

Walker, N.M., Morris, S.A., & Cannon, L.B. 2009. The effect of pre-operative counselling on smoking patterns in patients undergoing forefoot surgery. *Journal of Foot & Ankle Surgery*, 15, (2) 86-89

Warner, D.O., Patten, C.A., Ames, S.C., Offord, K.P., & Schroeder, D.R. 2005. Effect of nicotine replacement therapy on stress and smoking behavior in surgical patients. *Anesthesiology*, 102, (6) 1138-1146

Wennike, P., Danielsson, T., Landfeldt, B., Westin, A., & Tonnesen, P. 2003. Smoking reduction promotes smoking cessation: results from a double blind, randomized, placebo-controlled trial of nicotine gum with 2-year follow-up. *Addiction*, 98, (10) 1395-1402

#### **SYSTEMATIC REVIEWS (included)**

Thomsen, T., Villebro, N., & Moller, A.M. 2010. Interventions for preoperative smoking cessation. *Cochrane Database of Systematic Reviews* (7) CD002294

#### **SYSTEMATIC REVIEWS (discussed comparatively)**

Stead, L.F., & Lancaster, T. Interventions to reduce harm from continued tobacco use. *Cochrane Database of Systematic Reviews* 2007, Issue 3. Art. No.: CD005231.

Moore, D., Aveyard, P., Connock, M., Wang, D., Fry-Smith, A., Barton, P., Moore, D., Aveyard, P., Connock, M., Wang, D., Fry-Smith, A., & Barton, P. 2009. Effectiveness and safety of nicotine replacement therapy assisted reduction to stop smoking: systematic review and meta-analysis. *BMJ*, 338, b1024

Wang, D., Connock, M., Barton, P., Fry-Smith, A., Aveyard, P., & Moore, D. 2008. 'Cut down to quit' with nicotine replacement therapies in smoking cessation: A systematic review of effectiveness and economic analysis. *Health Technology Assessment* 12[2].

[Note: Moore 2009 is a publication from Wang 2008.]

**APPENDIX G: EXCLUDED STUDIES WITH REASONS FOR EXCLUSION**

Reference	Reason for exclusion
Amos, A., White, D.A., & Elton, R.A. 1995. Is a telephone helpline of value to the workplace smoker? <i>Occupational Medicine (Oxford)</i> , 45, (5) 234-238	Survey of smoking cessation quitline
Arborelius, E. & Bremberg, S. 2001. Child health-centre-based promotion of a tobacco-free environment--a Swedish case study. <i>Health Promotion International</i> , 16, (3) 245-254	No data on parental smoking reduction
Ashton, M., Miller, C.L., Bowden, J.A., & Bertossa, S. 2010. People with mental illness can tackle tobacco. <i>Australian and New Zealand Journal of Psychiatry</i> , 44, (11) 1021-1028	Only 3.8% of participants were not motivated to quit
Baheiraei, A., Kharaghani, R., Mohsenifar, A., Kazemnejad, A., Alikhani, S., Milani, H.S., Mota, A., & Hovell, M.F. 2011. Reduction of secondhand smoke exposure among healthy infants in Iran: randomized controlled trial. <i>Nicotine &amp; Tobacco Research</i> , 13, (9) 840-847	Reduction in smoking around children is measured but not reduction overall
Baker, A., Richmond, R., Castle, D., Kulkarni, J., Kay-Lambkin, F., Sakrouge, R., Fila, S., & Lewin, T.J. 2009. Coronary heart disease risk reduction intervention among overweight smokers with a psychotic disorder: Pilot trial. <i>Australian and New Zealand Journal of Psychiatry</i> , 43, (2) 129-135	Intervention focused on quitting
Baxter, S., Blank, L., Everson-Hock, E.S., Burrows, J., Messina, J., Guillaume, L., & Goyder, E. 2011. The effectiveness of interventions to establish smoke-free homes in pregnancy and in the neonatal period: a systematic review. <i>Health Education Research</i> , 26, (2) 265-282	No interventions to reduce parental smoking.
Beard, E., McNeill, A., Aveyard, P., Fidler, J., Michie, S., & West, R. 2011. Use of nicotine replacement therapy for smoking reduction and during enforced temporary abstinence: a national survey of English smokers. <i>Addiction</i> , 106, (1) 197-204	Observational study. <b>For possible inclusion in Review 4</b>
Bolliger, C.T. 2000. Practical experiences in smoking reduction and cessation. <i>Addiction</i> , 95 Suppl 1, S19-S24	Discussion paper. Data covered in included study (Bolliger 2000). <b>For possible inclusion in Review 4</b>
Bond, L., Patton, G., Glover, S., Carlin, J.B., Butler, H., Thomas, L., & Bowes, G. 2004. The Gatehouse Project: can a multilevel school intervention affect emotional wellbeing and health risk behaviours? <i>Journal of Epidemiology &amp; Community Health</i> , 58, (12) 997-1003	Outcome was reduction in numbers of students reporting any and regular smoking as opposed to reductions in number of cigarettes at the individual level
Botvin, G.J., Baker, E., Filazzola, A.D., & Botvin, E.M. 1990. A cognitive-behavioral approach to substance abuse prevention: one-year follow-up. <i>Addictive Behaviors</i> , 15, (1) 47-63	Smoking prevention, not reduction programme
Brigham, J., Gross, J., Stitzer, M.L., & Felch, L.J. 1994. Effects of a restricted work-site smoking policy on employees who smoke. <i>American Journal of Public Health</i> , 84, (5) 773-778	Workplace smoking ban
Butz, A.M., Matsui, E.C., Breyse, P., Curtin-Brosnan, J., Eggleston, P., Diette, G., Williams, D., Yuan, J., Bernert, J.T., Rand, C. 2011. A randomized trial of air cleaners and a health coach to improve indoor air quality for inner-city children with	Looks at children's second hand smoke exposure with no outcomes relating to parental CPD or reductions in CPD

asthma and secondhand smoke exposure.	
Chan, Y.F., Nagurka, R., Richardson, L.D., Zaets, S.B., Brimacombe, M.B., & Levine, S.R. 2010. Effectiveness of stroke education in the emergency department waiting room. <i>Journal of Stroke &amp; Cerebrovascular Diseases</i> , 19, (3) 209-215	Insufficient data on smoking component of intervention
Dalack, G.W. & Meador-Woodruff, J.H. 1999. Nicotine replacement and smoking reduction in smokers with schizophrenia - Conference Abstract. <i>Schizophrenia Research</i> , 1-3, 276	Conference abstract with no outcomes reported
Dalack, G.W. & Meador-Woodruff, J.H. 1999. Acute feasibility and safety of a smoking reduction strategy for smokers with schizophrenia. <i>Nicotine &amp; Tobacco Research</i> , 1, (1) 53-57	Conference abstract with no outcomes reported
Emmons, K.M., Hammond, S.K., Fava, J.L., Velicer, W.F., Evans, J.L., & Monroe, A.D. 2001. A randomized trial to reduce passive smoke exposure in low-income households with young children. <i>Pediatrics</i> , 108, (1) 18-24	No data on parental smoking reduction
Etter, J.-F. 2011. Comparing abrupt and gradual smoking cessation: A randomized trial. <i>Drug and Alcohol Dependence</i> , 118 (2-3) 360-365	Cut down to quit study included in Review 2
Etter, J.F., Le, H.J., & Landfeldt, B. 2003. Impact of messages on concomitant use of nicotine replacement therapy and cigarettes: a randomized trial on the Internet. <i>Addiction</i> , 98, (7) 941-950	Impact of e-mailed messages on motivation to quit. <b>For possible inclusion in Review 4</b>
Fagerstrom, K.O., Hughes, J.R., & Callas, P.W. 2002. Long-term effects of the Eclipse cigarette substitute and the nicotine inhaler in smokers not interested in quitting. <i>Nicotine &amp; Tobacco Research</i> , 4 Suppl 2, S141-S145	Eclipse (a tobacco-containing product) was provided to both treatment arms
Garcia, M., Fernandez, E., Schiaffino, A., Peris, M., & Borrás, J.M. 2005. Smoking reduction in a population-based cohort. <i>Preventive Medicine</i> , 40, (6) 679-684	Study design – observational study. <b>For possible inclusion in Review 4</b>
Glasgow, R.E., Gaglio, B., France, E.K., Marcus, A., Riley, K.M., Levinson, A., & Bischoff, K. 2006. Do behavioral smoking reduction approaches reach more or different smokers? Two studies; similar answers. <i>Addictive Behaviors</i> , 31, (3) 509-518	No outcomes data
Godtfredsen, N.S., Prescott, E., Vestbo, J., & Osler, M. 2006. Smoking reduction and biomarkers in two longitudinal studies. <i>Addiction</i> , 101, (10) 1516-1522	Study design – observational study with cross-sectional data
Gunther, V., Gritsch, S., & Meise, U. 1992. Smoking cessation--gradual or sudden stopping? <i>Drug &amp; Alcohol Dependence</i> , 29, (3) 231-236	Cut down to quit study included in Review 2
Haddock, J. & Burrows, C. 1997. The role of the nurse in health promotion: an evaluation of a smoking cessation programme in surgical pre-admission clinics. <i>Journal of Advanced Nursing</i> , 26, 1098-1110	Participants intending to reduce were grouped with those intending to quit so data cannot be extracted for reducers
Hamilton, G., Cross, D., Resnicow, K., & Hall, M. 2005. A school-based harm minimization smoking intervention trial: outcome results. <i>Addiction</i> , 100, (5) 689-700	Prevention of transition from experimental to habitual smoking
Hoepfner, B.B., Goodwin, M.S., Velicer, W.F., Mooney, M.E., & Hatsukami, D.K. 2008. Detecting longitudinal patterns of daily smoking following drastic cigarette reduction. <i>Addictive</i>	Secondary analysis of Hatsukami 2005 with subset of data relating to maintenance phase. (Hatsukami 2005

Behaviors, 33, (5) 623-639	has post-maintenance phase follow-up).
Hovell, M.F., Zakarian, J.M., Matt, G.E., Liles, S., Jones, J.A., Hofstetter, C.R., Larson, S.N., & Benowitz, N.L. 2009. Counseling to reduce children's secondhand smoke exposure and help parents quit smoking: a controlled trial. <i>Nicotine &amp; Tobacco Research</i> , 11, (12) 1383-1394	No data on parental smoking reduction
Hovell, M.F., Wahlgren, D.R., Liles, S., Jones, J.A., Hughes, S.C., Matt, G.E., Ji, M., Lessov-Schlaggar, C.N., Swan, G.E., Chatfield, D., & Ding, D. 2011. Providing coaching and cotinine results to preteens to reduce their secondhand smoke exposure: A randomized trial. <i>Chest</i> , 140, (3) 681-689	Looks at reducing children's exposure to second hand smoke with no measure of parental smoking reduction
Keizer, I., Descloux, V., & Eytan, A. 2009. Variations in smoking after admission to psychiatric inpatient units and impact of a partial smoking ban on smoking and on smoking-related perceptions. <i>International Journal of Social Psychiatry</i> , 55, (2) 109-123	Study design - observational study. It does not appear that either patients or staff were the same in 2001 (pre-ban) as they were in 2005 (post-ban).
Macgregor, I.D. 1996. Efficacy of dental health advice as an aid to reducing cigarette smoking. <i>British Dental Journal</i> , 180, (8) 292-296	Not possible to extract relevant data for any time point. Some information on reduction but not allied to follow-up time or to allocated groups
Marks, D.F. & Sykes, C.M. 2002. Randomized controlled trial of cognitive behavioural therapy for smokers living in a deprived are of London: Outcome at one-year follow-up. <i>Psychology, Health and Medicine</i> , 7, (1) 17-24	Cut down to quit paper included in Review 2.
O'Connor, R.J., Norton, K.J., Bansal-Travers, M., Mahoney, M.C., Cummings, K.M., & Borland, R. 2011. US smokers' reactions to a brief trial of oral nicotine products. <i>Harm Reduction Journal</i> , 8, (1) 1	Participants provided with both smokeless tobacco and NRT. Not possible to extract NRT-only data.
Perkins, K.A., Grobe, J.E., Stiller, R.L., Fonte, C., & Goettler, J.E. 1992. Nasal spray nicotine replacement suppresses cigarette smoking desire and behavior. <i>Clinical Pharmacology &amp; Therapeutics</i> , 52, (6) 627-634	Lab study of nicotine nasal spray on desire to smoke measured over 2.5 hours
Pulley, K.R. & Flanders-Stepans, M. 2002. Smoking hygiene: an educational intervention to reduce respiratory symptoms in breastfeeding infants exposed to tobacco. <i>Journal of Perinatal Education</i> , 11, (3) 28-37	Not possible to identify how many mothers were smoking post-partum and no parental smoking outcomes
Sallit, J., Ciccazzo, M., & Dixon, Z. 2009. A cognitive-behavioral weight control program improves eating and smoking behaviors in weight-concerned female smokers. <i>Journal of the American Dietetic Association</i> , 109, (8) 1398-1405	Intervention is nutrition and eating behaviour education and does not specifically target smoking
Scheier, L.M., Botvin, G.J., & Griffin, K.W. 2001. Preventive intervention effects on developmental progression in drug use: structural equation modeling analyses using longitudinal data. <i>Prevention Science</i> , 2, (2) 91-112	Smoking prevention, not reduction programme
Selby, P., Voci, S.C., Zawertailo, L.A., George, T.P., & Brands, B. 2010. Individualized smoking cessation treatment in an outpatient setting: Predictors of outcome in a sample with psychiatric and addictions co-morbidity. <i>Addictive Behaviors</i> , 35, (9) 811-817	retrospective chart review – excluded study design
Shelef, K., Diamond, G.S., Diamond, G.M., & Myers, M.G. 2009. Changes in tobacco use among adolescent smokers in	Secondary analysis of the Cannabis Youth Treatment study - not related to

substance abuse treatment. <i>Psychology of Addictive Behaviors</i> , 23, (2) 355-361	cigarette use
Simmons, V.N. & Brandon, T.H. 2007. Secondary smoking prevention in a university setting: a randomized comparison of an experiential, theory-based intervention and a standard didactic intervention for increasing cessation motivation. <i>Health Psychology</i> , 26, (3) 268-277	Prevention of transition from experimental to habitual smoking.
Smith, K.H. & Stutts, M.A. 2003. Effects of short-term cosmetic versus long-term health fear appeals in anti-smoking advertisements on the smoking behaviour of adolescents. <i>Journal of Consumer Behaviour</i> (2) Dec-177	Reduction in smoking prevalence only
Taylor, A. & Katomeri, M. 2007. Walking reduces cue-elicited cigarette cravings and withdrawal symptoms, and delays ad libitum smoking. <i>Nicotine &amp; Tobacco Research</i> , 9, (11) 1183-1190	Three hour laboratory study. No useable data on smoking reduction
Tonnesen, P., Pisinger, C., Hvidberg, S., Wennike, P., Bremann, L., Westin, A., Thomsen, C., & Nilsson, F. 2005. Effects of smoking cessation and reduction in asthmatics. <i>Nicotine &amp; Tobacco Research</i> , 7, (1) 139-148	Authors looked at the effect of cessation, reduction or continuing at the same level (with participants merged from all three groups) on asthma symptoms. No data on the effect of the designated group on smoking behaviour
Tzelepis, F., Paul, C.L., Wiggers, J., Walsh, R.A., Knight, J., Duncan, S.L., Lecathelinais, C., Girgis, A., & Daly, J. 2011. A randomised controlled trial of proactive telephone counselling on cold-called smokers' cessation rates. <i>Tobacco Control</i> , 20, (1) 40-46	Study does not distinguish between those ready to quit and offered cessation advice and those not yet ready to quit
Williams, G.C., Patrick, H., Niemiec, C.P., Ryan, R.M., Deci, E.L., & Lavigne, H.M. 2011. The Smoker's Health Project: A self-determination theory intervention to facilitate maintenance of tobacco abstinence. <i>Contemporary Clinical Trials</i> , 32, (4) 535-543	Study protocol only
Williams, J.M., Dwyer, M., Verna, M., Zimmermann, M.H., Gandhi, K.K., Galazyn, M., Szkodny, N., Molnar, M., Kley, R., & Steinberg, M.L. 2011. Evaluation of the CHOICES program of peer-to-peer tobacco education and advocacy. <i>Community Mental Health Journal</i> , 47, (3) 243-251	Not a smoking reduction intervention
Wilson, S.R., Farber, H.J., Knowles, S.B., & Lavori, P.W. 2011. A randomized trial of parental behavioral counseling and cotinine feedback for lowering environmental tobacco smoke exposure in children with asthma: results of the LET'S Manage Asthma trial. <i>Chest</i> , 139, (3) 581-590	Study of environmental tobacco smoke exposure in asthmatic children. No measure of reduction of parental cigarette consumption
Wiseman, E.J., Williams, D.K., & McMillan, D.E. 2005. Effectiveness of payment for reduced carbon monoxide levels and noncontingent payments on smoking behaviors in cocaine-abusing outpatients wearing nicotine or placebo patches. <i>Experimental &amp; Clinical Psychopharmacology</i> , 13, (2) 102-110	Not a reduction study - only counselling recommendation given that subjects should quit
Woodruff, S.I., Conway, T.L., Elder, J.P., & Hovell, M.F. 2007. Pilot study using hair nicotine feedback to reduce Latino children's environmental tobacco smoke exposure. <i>American Journal of Health Promotion</i> , 22, (2) 93-97	Only reports results for child (hair nicotine). Nothing to indicate that the parents reduced smoking
Yi, R., Johnson, M.W., Giordano, L.A., Landes, R.D., Badger,	Reduction presented graphically

G.J., & Bickel, W.K. 2008. The effects of reduced cigarette smoking on discounting future rewards: An initial evaluation. <i>The Psychological Record</i> (2) Spr-174	displaying means of group, no ranges presented - no useable data.
Zakarian, J.M., Hovell, M.F., Sandweiss, R.D., Hofstetter, C.R., Matt, G.E., Bernert, J.T., Pirkle, J., & Hammond, S.K. 2004. Behavioral counseling for reducing children's ETS exposure: implementation in community clinics. <i>Nicotine &amp; Tobacco Research</i> , 6, (6) 1061-1074	Child's second hand smoke exposure with no information on parental reductions in CPD
Ziedonis, D., Williams, J., Zimmermann M, Krejci J, Steinbery M, Foulds J, Violette N, Agatep B, Sawh L, & Gaffney J Behavioral therapy development for smokers with schizophrenia., <i>In 13th World Conference on Tobacco OR Health</i> . Available at <a href="http://2006.confex.com/uicc/wctoh/techprogram/P8678.HTM">http://2006.confex.com/uicc/wctoh/techprogram/P8678.HTM</a>	Conference abstract only; insufficient data

The following were excluded as they were designed as smoking cessation studies.

Ahijevych, K. & Wewers, M.E. 1995. Low-Intensity Smoking Cessation Intervention Among African-American Women Cigarette Smokers - A Pilot-Study. <i>American Journal of Health Promotion</i> , 9, (5) 337-339.
Ahijevych, K.L.M. 1992. <i>Cigarette smoking behavior among African American women and the feasibility of a low-intensity smoking cessation intervention</i> . PH.D. OHIO STATE UNIVERSITY.
Armitage, C.J. 2008. A volitional help sheet to encourage smoking cessation: a randomized exploratory trial. <i>Health Psychology</i> , 27, (5) 557-566
Baker, A., Richmond, R., Haile, M., Lewin, T.J., Carr, V.J., Taylor, R.L., Jansons, S., & Wilhelm, K. 2006. A randomized controlled trial of a smoking cessation intervention among people with a psychotic disorder. <i>American Journal of Psychiatry</i> , 163, (11) 1934-1942
Baker, A., Richmond, R., Lewin, T.J., & Kay-Lambkin, F. 2010. Cigarette smoking and psychosis: naturalistic follow up 4 years after an intervention trial. <i>Australian &amp; New Zealand Journal of Psychiatry</i> , 44, (4) 342-350
Barnfather, K.D., Cope, G.F., & Chapple, I.L. 2005. Effect of incorporating a 10 minute point of care test for salivary nicotine metabolites into a general practice based smoking cessation programme: randomised controlled trial. <i>BMJ</i> , 331, (7523) 999
Becona, E. & Vazquez, F.L. 2001. Effectiveness of personalized written feedback through a mail intervention for smoking cessation: a randomized-controlled trial in Spanish smokers. <i>Journal of Consulting &amp; Clinical Psychology</i> , 69, (1) 33-40
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Borrelli, B., Novak, S., Hecht, J., Emmons, K., Papandonatos, G., & Abrams, D. 2005. Home health care nurses as a new channel for smoking cessation treatment: Outcomes from project CARES (Community-nurse Assisted Research and Education on Smoking). <i>Preventive Medicine</i> , 41, (5-6) 815-821
Burling, T.A., Marshall, G.D., & Seidner, A.L. 1991. Smoking cessation for substance abuse inpatients. <i>Journal of Substance Abuse</i> , 3, (3) 269-276

Butler, C.C., Rollnick, S., Cohen, D., Bachmann, M., Russell, I., & Stott, N. 1999. Motivational consulting versus brief advice for smokers in general practice: A randomized trial. <i>British Journal of General Practice</i> , 49, (445) 611-616
Candido, R., Tommasi, E., Jagodnik, G., Alberti, R., Baskar, B., Stuper, M., Daris, N., Presti, E., Caroli, E., Manca, E., Petrucco, A., Vegliach, A., Purich, R., Fabris, B., & Tominz, R. 2010. Effects of a systematic smoking cessation intervention in diabetic patients. <i>Diabetologia</i> , 46th EASD Congress, Stockholm
Canga, N., De, I.J., Vara, E., Duaso, M.J., Ferrer, A., & Martinez-Gonzalez, M.A. 2000. Intervention study for smoking cessation in diabetic patients: a randomized controlled trial in both clinical and primary care settings. <i>Diabetes Care</i> , 23, (10) 1455-1460
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Chan, S.S., Leung, G.M., Wong, D.C., & Lam, T.H. 2008. Helping Chinese fathers quit smoking through educating their nonsmoking spouses: a randomized controlled trial. <i>American Journal of Health Promotion</i> , 23, (1) 31-34
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