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An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Health technology assessment (HTA) of smoking cessation interventions

Appendices

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List of abbreviations used in this report

BIOCHEM	biochemically validated abstinence
CBT	cognitive behavioural therapy
CAR	continuous abstinence rate
COPD	chronic obstructive pulmonary disease
EAG	Expert Advisory Group
EMA	European Medicines Agency
ENDS	electronic nicotine delivery system
ENNDS	electronic non-nicotine delivery system
FDA	Food and Drugs Authority
FTND	Fagerstrom Test for Nicotine Dependence
HIQA	Health Information and Quality Authority
HPRA	Health Products Regulatory Authority
HR	hazard ratio
HSE	Health Service Executive
HTA	health technology assessment
ICER	incremental cost-effectiveness ratio
NICE	National Institute for Health and Care Excellence
NRPA	nicotine receptor partial agonist
NRT	nicotine replacement therapy
OR	odds ratio
PCRS	Primary Care Reimbursement Scheme
PP	point prevalence abstinence
PTSD	Post-traumatic stress disorder
QALY	quality-adjusted life year
RCT	randomised controlled trial
RR	relative risk
SR	self reported
TQD	target quit date
UK	United Kingdom
WHO	World Health Organization

Appendices

Appendix 1 Search details for review of smoking cessation interventions among users of secondary mental health services

Figure 1.1 Flow diagram of included studies from the updated search

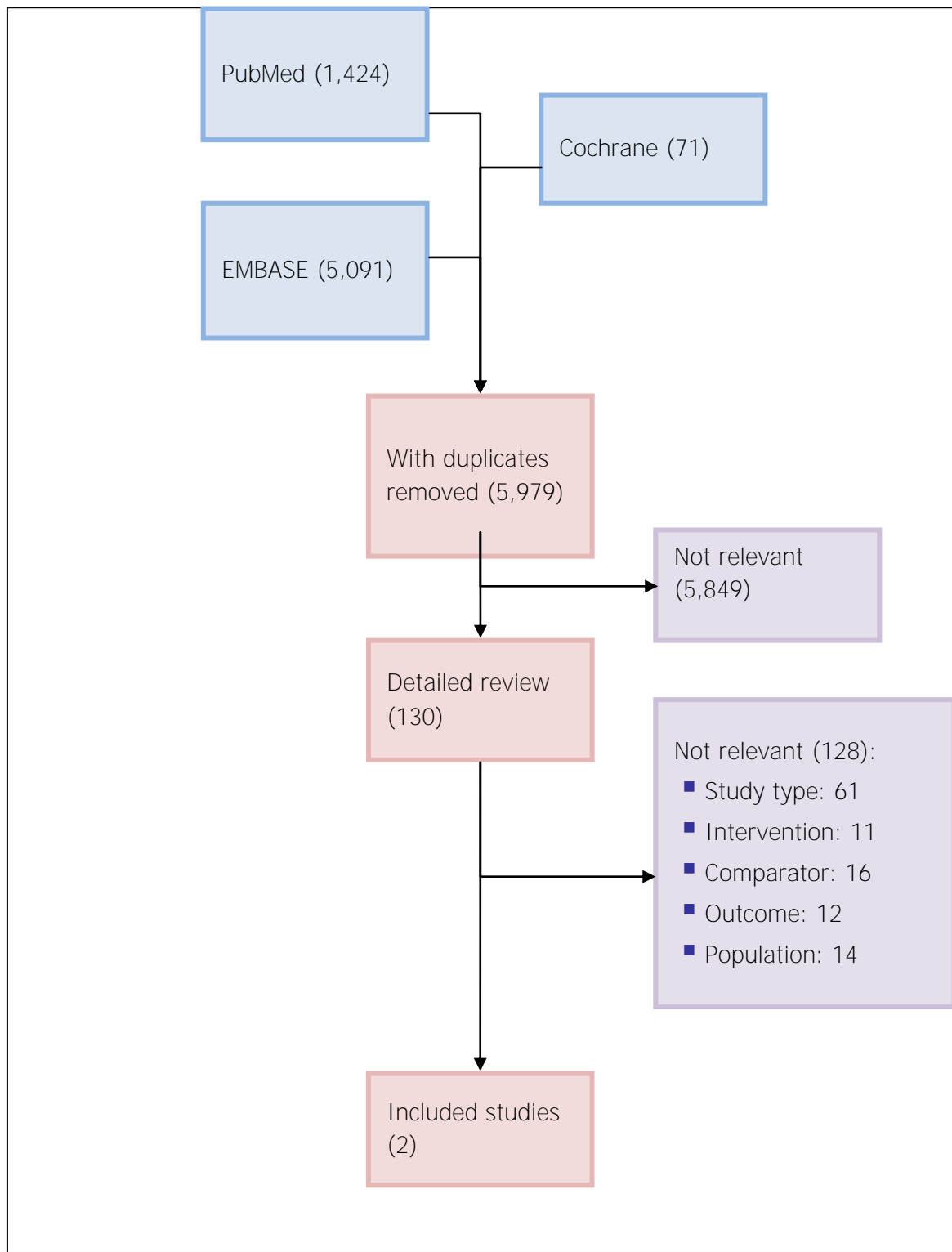


Table 1.1 Search string used in PubMed

Search string	Results
<pre> ((((((((bipolar[Title/Abstract]) OR depress*[Title/Abstract]) OR schizophren*[Title/Abstract]) OR mental health[Title/Abstract]) OR mental illness*) OR mental disorder*[Title/Abstract]) OR "Mental Health Services"[Mesh]) OR "Mental Disorders"[Mesh])) AND ((((("Tobacco Use Cessation products"[Mesh]) OR "Tobacco Use Cessation"[Mesh]) OR "Smoking"[Mesh]) OR ((((abstinence[Title/Abstract]) OR cessat*[Title/Abstract]) OR quit*[Title/Abstract]) OR stop*[Title/Abstract])) AND (((cigarette*[Title/Abstract]) OR tobacco[Title/Abstract]) OR smok*[Title/Abstract]))) AND ((Clinical Trial[ptyp] OR Randomized Controlled Trial[ptyp] OR Clinical Trial, Phase I[ptyp] OR Clinical Trial, Phase II[ptyp] OR Clinical Trial, Phase III[ptyp] OR Clinical Trial, Phase IV[ptyp] OR systematic[sb] OR Review[ptyp]) AND ("2012/01/01"[PDat] : "2016/12/31"[PDat]) AND Humans[Mesh]) </pre>	1,424

Appendix 2 Included studies for those with a diagnosis of schizophrenia or schizoaffective disorder

Table 2.1 Bupropion + behavioural intervention with/without NRT versus placebo + behavioural intervention with/without NRT

Study	Country	Setting	Participants	Mean age	Female	Population	Intervention	Control	Support	Outcome	Risk of bias
Evins 2001 ⁽¹⁾	USA	Community volunteers	19	44.1	42%	DSM-IV diagnosis of schizophrenia	Bupropion 150mg/day for 12 wks	Placebo for 12 wks	Both groups received brief advice and 9 wkly 1-hour sessions of group CBT	6m (biochem, PP)	High
Evins 2005 ⁽²⁾	USA	Community volunteers	57	45.7	31.6%	DSM-IV diagnosis of schizophrenia or schizoaffective disorder, depressed type	Bupropion 300mg/day for 12 wks (150mg/day for first wk)	Placebo for 12 wks	Both groups received 12 wkly 1-hour sessions of group CBT	6m (biochem and self-reported, CAR, PP)	High
Evins 2007 ⁽³⁾	USA	Community volunteers	51	44.2	NR	DSM-IV diagnosis of schizophrenia	Bupropion SR 300mg/day for 12 wks. (150mg/day for first 7 days)	Placebo for 12 wks	Both received 1) 12 wkly 1-hour sessions of group CBT; (2) TNP (from wk 4) 21 mg/day for 4 wks, then 14 mg/day for 2 wks, 7 mg/day for 2 wks + up to 18 mg per day NG as required	6m, 12m (biochem, PP)	Low
George 2002 ⁽⁴⁾	USA	Community volunteers	32	43.2	43.8%	DSM-IV diagnosis of schizophrenia or schizoaffective disorder. 20 had	Bupropion 300mg/day for 10 wks (150mg/day for first 3	Placebo for 10 wks	Both groups received 10 wkly 1-hour sessions of group therapy for motivational	6m (biochem, CA)	Unclear

						a diagnosis of schizophrenia	days)		enhancement, psychoeducation and relapse prevention		
George 2008 ⁽⁵⁾	USA	Community volunteers	59	40.3	40.7%	DSM-IV diagnosis of schizophrenia or schizoaffective disorder. 32 had a diagnosis of schizophrenia	Bupropion 300mg/day for 10 wks (150mg/day for first 3 days)	Placebo for 10 wks	Both groups received 10 wkly 50-minute sessions of GBT and TNP (21mg per 24 hours) from day 15 to day 70	6m (PP, biochem CA)	Unclear

Table 2.2 Varenicline + behavioural intervention versus placebo + behavioural intervention

Study	Country	Setting	Participants	Mean age	Female	Population	Intervention	Control	Support	Outcome	Risk of bias
Williams 2012 ⁽⁶⁾	USA, Canada	Community volunteers	128	41.1	23.4%	DSM-IV TR diagnosis of schizophrenia or schizoaffective disorder. 91 had schizophrenia. 109 pts on atypical antipsychotic	Varenicline (0.5mg daily for 3 days then twice daily for 4 days then 1mg twice daily) for 12 wks	Placebo for 12 wks	Both groups received wkly counselling (less than 30 minutes)	6m (biochem, PP)	Unclear

Table 2.3 Individual counselling + NRT versus routine care

Study	Country	Setting	Participants	Mean age	Female	Population	Intervention	Control	Additional support	Outcome	Risk of bias
Baker 2006 ⁽⁷⁾	Australia	Community volunteers	298	37.2	48%	ICD-10 diagnosis of psychotic disorder. 126 had a diagnosis of schizophrenia and 43 a diagnosis of schizoaffective disorder	Individually administered SC intervention (6 wky sessions & 2 boosters at wks 8 and 10, 1 hour each): based on MI and CBT + TNP (21mg from wk 3 (quit date set) to 8; 14mg from week 9 to 10; 7mg from wk 11 to 12)	Routine care	Both groups received booklets on smoking cessation	6m, 12m, 4yrs (CA, biochem, PP)	High

Table 2.4 High-intensity individual counselling + NRT versus lower-intensity individual counselling + NRT

Study	Country	Setting	Participants	Mean age	Female	Population	Intervention	Control	Additional support	Outcome	Risk of bias
Williams 2010 ⁽⁸⁾	USA	Community volunteers	100	45.2	45%	DSM-IV diagnosis of schizophrenia or schizoaffective disorder	High intensity: TANS (treatment of nicotine addiction in schiz): 24 individual sessions of 45 minutes psychological intervention over 26 wks (MI, social skills training, use of NRT, relapse prevention technique)	Medication Management: 9 individual sessions of 20 minutes psychological intervention over 26 wks (medication compliance, education about NRT)	Both groups also received TNP for 16 wks after quit date (21mg for 12 wks then 14mg for remaining 4 wks)	6, 12m (PP, biochem)	High

Table 2.5 Group behavioural intervention (generic) + NRT versus group behavioural intervention (tailored to schizophrenia) + NRT

Study	Country	Setting	Participants	Mean age	Female	Population	Intervention	Control	Additional support	Outcome	Risk of bias
George 2000 ⁽⁹⁾	USA	Unclear	45	39.7	33.3%	DSM-IV diagnosis of schizophrenia (n=19) or schizoaffective disorder	Specialised smoking cessation group therapy designed for pts with schizophrenia, wkly for 10 wks (60 minutes each session): first 3 wks motivational enhancement therapy + last 7 wks psycho-education, social skills training and relapse prevention strategy	American Lung Assoc. (ALA) programme wkly for 10 wks (60 minutes each session): first 7 wks behavioural group therapy + final 3 wks supportive group counselling	Both groups received nicotine patch (21mg/day for first 6 wks then 14mg/day for another 2 wks and 7mg/day for final 2 wks)	6m (CA, biochem + SR)	High

Appendix 3 Included studies for those with a diagnosis of bipolar disorder

Table 3.1 Varenicline + brief advice versus placebo + brief advice

Study	Country	Setting	Participants	Mean age	Female	Population	Intervention	Control	Additional support	Outcome	Risk of bias
Chengappa 2014 ⁽¹⁰⁾	USA	Outpatient clinics	60	46	37%	DSM-IV bipolar disorder	Varenicline	Placebo	Smoking cessation counselling provided to all patients	6m (PP, biochem at 12 weeks only)	Low

Appendix 4 Studies from the UK Centre for Tobacco Control Studies (UKCTCS) report that were excluded from this review

	Study (year)	Reason	Reason for exclusion
1	Akbarpour 2010	Outcome	Outcome not applicable (reduction in smoking - abstinence not defined or measured).
2	Axtmayer 2011	Outcome	Outcome not applicable ('number of cigarettes smoked per day' - not smoking cessation).
3	Baker 2009	Study design	Study design not applicable (uncontrolled before and after study).
4	Barnett 2008	Intervention	Intervention not applicable (participants received \$25 payment for each research assessment).
5	Bloch 2010	Outcome	Outcome not applicable (reduction in smoking - abstinence not defined or measured).
6	Batra 2010	Population	Current depression population - not clear if all attending secondary mental health services.
7	Brown 2003	Population	Population not applicable (people aged less than 18 years old).
8	Brown 2007	Population	Current depression population - not clear if all attending secondary mental health services.
9	Catley 2005	Population	Current depression population - not clear if all attending secondary mental health services.
10	Chen 2002	Short-term	Short-term only (7 day point prevalence quit rates at 4 and 8 weeks). No 6-month cessation data.
11	Chou 2004	Short-term	Short-term only (cessation measured at 8 weeks only).
12	Cornelius 1997	Intervention	Intervention not applicable (fluoxetine).
13	Culhane 2008	Short-term	Short-term only (12 weeks only).
14	Currie 2008	Study design	Study design not applicable (not random assignment).
15	Dalack 1999	Outcome	Outcome not applicable (reduction in smoking, abstinence not defined or measured).
16	de Leon 2005b	Intervention	Intervention not applicable (clozapine).
17	Dixon 2009	Study design	Patients not randomised.
18	Dutra 2012	Comparator	No comparison group. Uncontrolled before-and-after study.
19	Fatemi 2005	Outcome	Outcome not applicable (reduction in smoking, abstinence not defined or measured).
20	Gallagher 2007	Intervention	Intervention not applicable (includes contingency payments).
21	Hall 2006	Population	Current depression population - not clear if all attending secondary mental health services.
22	Hartman 1991	Outcome	Outcome not applicable (reduction in smoking, abstinence not defined or measured).
23	Hertzberg 2001	Population	Population not applicable (PTSD in male combat veterans).
24	Hill 2007	Short-term	Non-randomised pilot study, outcomes measured at 3 months only.

25	Kelly 2008	Intervention	Intervention not applicable (galantamine).
26	Kinnunen 2008	Population	Current depression population - not clear if all attending secondary mental health services.
27	Kisely 2003	Study design	Study design not applicable, non-randomised cross-over study.
28	Levine 2010	Population	Current depression, but not clear if all attending secondary mental health services.
29	Li 2009	Short-term	Short-term only, cessation measured at 1, 2, 4 and 8 weeks.
30	McEvoy 2005	Intervention	Intervention not applicable (clozapine).
31	McFall 2005	Population	Population not applicable, (PTSD in veterans).
32	McFall 2010	Population	Population not applicable, (PTSD).
33	Morris 2011	Outcome	Outcomes not applicable (50% reduction and not cessation).
34	Panchas 2012	Study design	Study design not applicable - before-and-after study without randomisation.
35	Rabius 2007a	Population	Current depression population - not clear if all attending secondary mental health services.
36	Rabius 2007b	Population	Current depression population - not clear if all attending secondary mental health services.
37	Roll 1998	Intervention	Intervention not applicable (contingency payments).
38	Saxon 2003	Population	Population and intervention not applicable: veterans in treatment for alcohol or drug dependency.
39	Smith 2009	Short-term	Short-term follow-up (9 weeks only).
40	Steinberg 2003	Outcome	Outcome not applicable (reduction in smoking, abstinence not defined or measured).
41	Szombathyne 2010	Outcome	Outcome (abstinence not defined or measured) and intervention (altrexone) not applicable.
42	Thorsteinsson 2001	Short-term	Short-term follow-up period (29 days).
43	Tidey 2002	Intervention	Intervention not applicable (contingency payments).
44	Tidey 2011	Outcome	Outcome not applicable (reduction in smoking, abstinence not defined or measured).
45	Van der Meer 2010	Population	Current depression population - not clear if all attending secondary mental health services.
46	Weinberger 2008a	Study design	Study design not applicable (pilot study of 5 people).
47	Weiner 2001	Comparator	No comparison group.
48	Weiner 2011 a	Short-term	Short-term only (cessation measured at 4 and 12 weeks only).
49	Weiner 2011 b	Short-term	Short-term only (cessation measured at 12 weeks only).
50	Williams 2007	Short-term	Short-term only (cessation measured at 8 weeks only).
51	Wotjna 2009	Study design	Study design (lack of randomisation).

Appendix 5 Studies from the Cochrane review of smoking cessation in schizophrenia that were excluded from this review

	Study (year)	Reason	Reason for exclusion
1	Akbarpour 2010	Outcome	Outcome is reduction in smoking; abstinence not defined or measured.
2	Bloch 2010	Outcome	Outcome is reduction in smoking; abstinence not defined or measured.
3	Brown 2003	Population	Population less than 18 years old.
4	Chen 2012	Short-term	Abstinence reported at 8 weeks only.
5	Dalack 1999	Outcome	Outcome is reduction in smoking; abstinence not defined or measured.
6	de Leon 2005b	Intervention	Use of Clozapine.
7	Dutra 2012	Comparator	No comparison group. Uncontrolled before-and-after study.
8	Fatemi 2005	Outcome	Outcome is reduction in smoking, abstinence not defined or measured.
9	Gallagher 2007	Intervention	Includes contingency payments.
10	Gelkopf 2012	Outcome	Outcome is reduction in smoking; abstinence not defined or measured.
11	Hartman 1991	Outcome	Outcome is reduction in smoking; abstinence not defined or measured.
12	Hong 2011	Outcome	Effect of varenicline on neurobiological and cognitive biomarkers in schizophrenia. Abstinence not defined or measured.
13	Horst 2005	Outcome	Relapse prevention after smoking cessation. Abstinence not defined or measured.
14	Kelly 2008	Intervention	Use of Galantamine.
15	Li 2009	Short-term	Cessation measured at 1, 2, 4 and 8 weeks only.
16	McEvoy 1995	Intervention	Use of Clozapine.
17	McEvoy 1999	Intervention	Use of Clozapine.
18	Meszaros 2012	Outcome	Effect of varenicline on alcohol dependence (as primary outcome according to protocol). Abstinence not defined or measured.
19	Pachas 2012	Study design	Before and after study without randomisation.
20	Roll 1998	Intervention	Contingency payments.
21	Sacco 2009	Intervention	Use of Atomoxetine.
22	Shim 2012	Outcome	Outcome is reduction in smoking; abstinence not defined or measured.

23	Steinberg 2003	Outcome	Outcome is reduction in smoking; abstinence not defined or measured.
24	Szombathyne 2010	Outcome Intervention	Outcome is reduction in smoking; abstinence not defined or measured. Use of Naltrexone.
25	Tidey 2002	Intervention	Contingency payments.
26	Tidey 2011	Outcome	Outcome is reduction in smoking; abstinence not defined or measured.
27	Weinberger 2008	Intervention	Use of Topiramate.
28	Weiner 2001	Comparator	No comparison group.
29	Weiner 2011 a (var)	Short-term	Cessation measured at 4 and 12 weeks only.
30	Weiner 2012	Short-term	Cessation measured at 12 weeks only.
31	Williams 2007	Short-term	Cessation measured at 8 weeks only.
32	Wing 2012	Intervention	Active Repetitive Transcranial Magnetic Stimulation (rTMS) - bilateral to dorsolateral prefrontal cortex v Sham rTMS.

Appendix 6 Studies from the Cochrane review of smoking cessation in current and past depression that were excluded from this review

	Study (year)	Reason	Reason for exclusion
1	Batra 2010	Population	Current depression population; not clear if all attending secondary mental health services.
2	Blondal 1999	Intervention	Use of Fluoxetine.
3	Brown 2001	Population	Past depression.
4	Brown 2007	Population	Current depression population; not clear if all attending secondary mental health services.
5	Carmody 2008	Intervention	Includes hypnosis.
6	Catley 2003	Intervention	Culturally-sensitive self-help materials.
7	Catley 2005	Population	Current depression population; not clear if all attending secondary mental health services.
8	Cinciripini 2010	Population	Pregnant smokers.
9	Covey 1999	Intervention	Use of Naltrexone.
10	Covey 2002	Intervention	Use of Sertraline.
11	Duffy 2006	Population	Smokers with head and neck cancer.
12	Hall 1994	Population	Past depression.
13	Hall 1996	Population	Subgroup of past depression only.
14	Hall 1998	Population	Past depression.
15	Hall 2002	Population	Past depression. Only information available which compared nortriptyline versus bupropion (CR).
16	Hall 2006	Population	Current depression population; not clear if all attending secondary mental health services.
17	Hall 2009	Population	Subgroup of past depression only.
18	Hayes 2010	Population	Medically ill smokers using home healthcare nursing services with current depressive symptoms.
19	Hayford 1999	Population	Past depression.
20	Kahler 2008	Population	Heavy drinking and smoking adults.
21	Killen 2000	Intervention	Use of Paroxetine.
22	Killen 2008	Population	Current depression population; not clear if all attending secondary mental health services.
23	Kinnunen 2008	Population	Current depression population; not clear if all attending secondary mental health services.

24	Kodl 2008	Population	Adult alcohol-dependent smokers.
25	Levine 2003	Population	Current depression population; not clear if all attending secondary mental health services.
26	Levine 2010	Population	Current depression population; not clear if all attending secondary mental health services.
27	MacPherson 2010	Population	Mildly elevated depressive symptoms (BDIII ≥ 10). Recruited through community and University, so not clear if attending secondary health. Intervention=BATS.
28	McAlister 2004	Population	Mild depression: depression according to a single self-report question: 'Have you felt sad or blue every day for the last two weeks?' Recruited through community and quitline so not clear if attending secondary mental health.
29	McFall 2010	Population	PTSD related to military service.
30	Muñoz 1997	Intervention	Quit smoking guide (Spanish: Guía) + mood management.
31	Muñoz 2006a	Intervention	Guía + Individually Timed Educational Messages + mood management course versus Guía + Individually Timed Educational Messages.
32	Muñoz 2006b	Intervention	Guía + Individually Timed Educational Messages + mood management course versus Guía + Individually Timed Educational Messages.
33	Muñoz 2009	Intervention	Guía + Individually Timed Educational Messages + mood management course versus Guía + Individually Timed Educational Messages versus Guía + Individually Timed Educational Messages + mood management course + virtual group versus Guía alone.
34	Patten 1998	Population	Abstinent alcoholics.
35	Piper 2009	Population	Not clear if attending secondary mental health services.
36	Rabius 2007a	Population	Current depression population; not clear if all attending secondary mental health services.
37	Rabius 2007b	Population	Current depression population; not clear if all attending secondary mental health services.
38	Rabius 2008	Intervention	Tailored interactive site versus control (minimally interactive) site.
39	Sauls 2004	Intervention	Use of Fluoxetine.
40	Schnoll 2010	Population	Cancer and depressive symptoms.
41	Smith 2003	Population	Subgroup of past depression only.
42	Spring 2007	Intervention	Use of Fluoxetine.
43	Swan 2010	Population	Not clear if attending secondary mental health services.
44	Thorndike 2008	Population	Acute cardiovascular disease.
45	Van der Meer	Population	Current depression population; not clear if all attending secondary mental health services.

	2010		
46	Vickers 2009	Intervention	Exercise counselling.
47	Walsh 2008	Intervention	Use of Naltrexone.
48	Weinberger 2010b	Intervention	Use of Selegiline hydrochloride (antidepressant).
49	Wewers 2009	Population	Primary care and women's health clinics that served a socio-economically diverse population and reported >200 Pap smears per month were invited to participate in the study. Not clear if attending secondary mental health.

Appendix 7 Search details for review of smoking cessation interventions among unselected adults

Figure 7.1 Flow diagram of included studies from the updated search

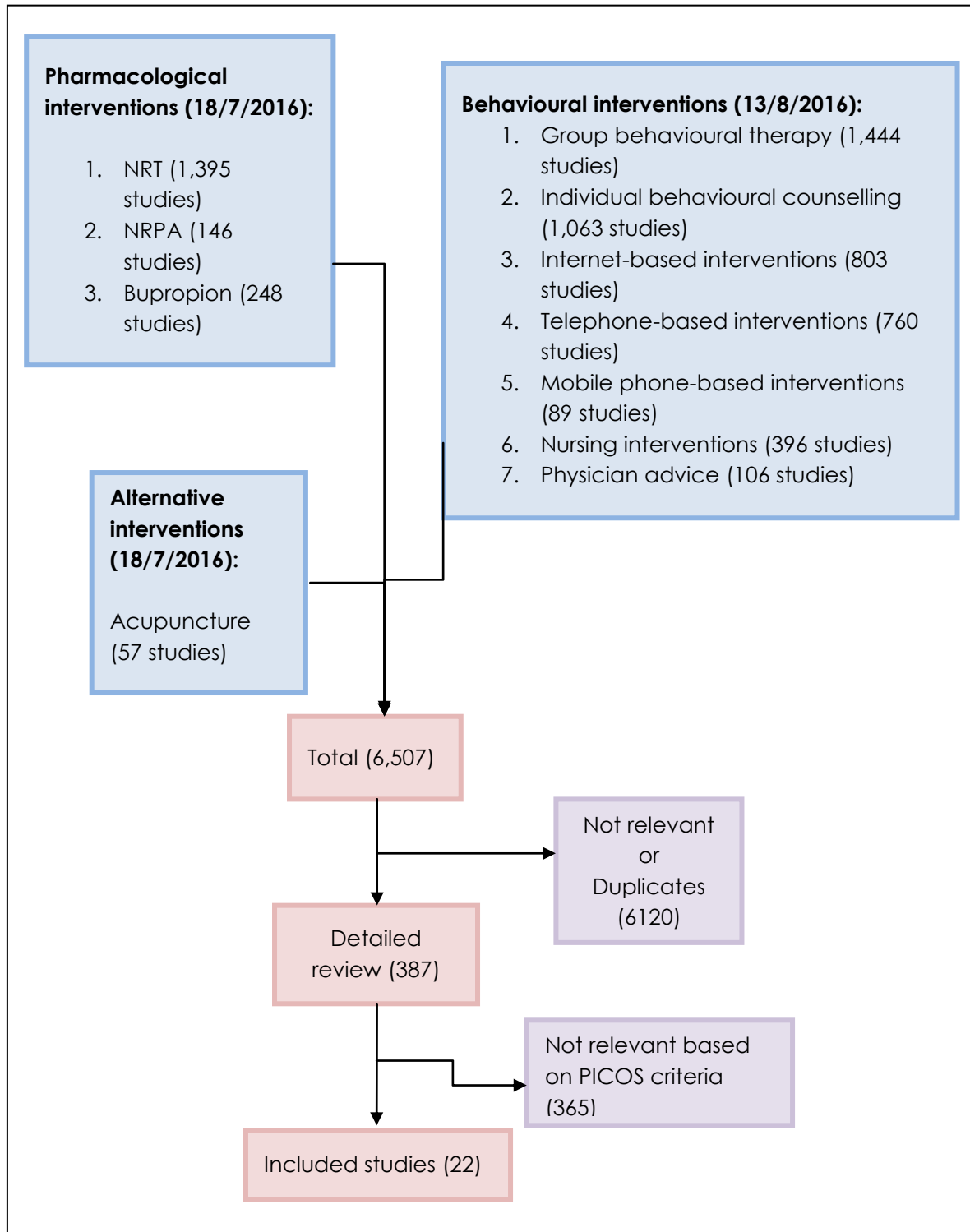


Table 7.1 Sample search strategy: Updated review for NRT (Medline)

Pubmed 18/07/2016		Search strings	Results
Searches	#1	((("Smoking Cessation"[Mesh]) OR ("Tobacco Use Cessation"[Mesh]) OR (Stop* smoking) OR (Quit* smoking)))	31023
	#2	((((((((((NRT) OR (nicotine AND patch*)) OR (nicotine AND gum)) OR (nicotine AND nasal AND spray)) OR (nicotine AND lozenge*)) OR (nicotine AND tablet*)) OR (nicotine AND sublingual)) OR (nicotine AND inhal*)) OR (nicotine AND replacement)) OR (nicotine AND therap*))	10421
	#3	#1 AND #2	4353
	#4	#3 AND Filters: <ul style="list-style-type: none"> • <u>From 2012/05/01 to 2016/07/18</u> • Clinical Trial; Randomized Controlled Trial; Review; Systematic Reviews; Meta-Analysis • Humans 	451

Search string: (((((((((((NRT) OR (nicotine AND patch*)) OR (nicotine AND gum)) OR (nicotine AND nasal AND spray)) OR (nicotine AND lozenge*)) OR (nicotine AND tablet*)) OR (nicotine AND sublingual)) OR (nicotine AND inhal*)) OR (nicotine AND replacement)) OR (nicotine AND therap*)) AND (((("Smoking Cessation"[Mesh]) OR ("Tobacco Use Cessation"[Mesh]) OR (Stop* smoking) OR (Quit* smoking))))

Appendix 8 Included studies: Unselected adults

Table 8.1 Included studies from systematic review: nicotine gum versus placebo

Study	Country	Setting	Participants	Mean age	Female	Intervention	Control	Support	Outcome	Risk of bias
Ahluwalia 2006 ⁽¹¹⁾	USA	Community volunteers	755	45	67%	Nicotine gum (2mg), recommended use tailored to cpd. Highest 10/day for 4 wks, tapering for 4 wks	Placebo gum, 8 wks	3 in-person visits at randomisation, wk 1, wk 8, and phone contact at wk 3, wk 6, wk 16, content based on either motivational interviewing or health education principles	6m (biochem, pp)	Low
Areechon 1988 ⁽¹²⁾	Thailand	Community volunteers	200	39	6%	Gum (2mg) x 8 boxes	Placebo gum x 8 boxes	Weekly visits with physician	6m (biochem, pp)	High
Blondal 1989 ⁽¹³⁾	Iceland	Community volunteers	182	42	57%	Gum (4mg) for at least 1 month	Placebo gum (containing pepper) for 1m or more	Group therapy, 5x1hr sessions, TQD at session 1	12m (biochem, car)	Unclear
Campbell 1987 ⁽¹⁴⁾	UK	Primary care	836	39	61%	Nicotine gum (2mg) x 6 boxes	Placebo gum x 6 boxes	No further face-to-face contact, 2/3rds received a letter after 1m	12m (biochem, car)	Unclear
Campbell 1991 ⁽¹⁵⁾	UK	Hospital inpatients	212	53% 50+	44%	Gum 2-4mg (3m)	Placebo gum	Support at 2, 3, 5 wks, 3m, 6m	12m (biochem, sustained)	Unclear
Clavel 1985 ⁽¹⁶⁾	France	Community volunteers	427	34	51%	Nicotine gum (2mg) x 1 box	Control group (time lock controlled cigarette case)	3x1hr group therapy sessions in first month	13m (biochem, car)	High

Clavel-Chapelon 1992 ⁽¹⁷⁾	France	Community volunteers	996	34	45%	Nicotine gum (2mg) for up to 6m, max 30/day	Placebo gum (contained 1mg unbuffered nicotine)	3 acupuncture session at 0, 7, 28 days	13m (self, NR)	High
Cooper 2005 ⁽¹⁸⁾	USA	Community volunteers	439	38	100%	Nicotine gum (2mg), 10-12 pieces/day recommended, for 9 wks, weaning last 3 wks	Placebo gum	13x1hr weekly cognitive behavioural group sessions. Reduction prior to TQD wk 5	12m (biochem, pp)	Unclear
Fagerstrom 1982 ⁽¹⁹⁾	Sweden	Smoking cessation clinic	100	NS	59%	Nicotine gum (2mg) for at least 4 wks	Placebo gum for at least 4 wks	Individual counselling, average 7.7 sessions	6m (biochem, pp)	Unclear
Fagerstrom 1984 ⁽²⁰⁾	Sweden	Primary care	145	40	56%	Nicotine gum (2 or 4mg) + long or short follow-up	Advice + long or short follow-up	Low	12m (self, car)	High
Fee 1982 ⁽²¹⁾	UK	Smoking cessation clinic	352	NS	NS	Gum (2mg) given for 5 wks	Placebo gum given for 5 wks	10 group therapy sessions	12m (biochem, pp)	Unclear
Fortmann 1995 ⁽²²⁾	USA	Community volunteers	1044	40	42%	Nicotine gum (2mg, 1 per hr, at least 10/day and not more than 30/day)	Incentive alone	Low	12m (biochem, pp)	Unclear
Garcia 1989 ⁽²³⁾	Spain	Primary care	106	36	65%	Gum (2mg) for 3-4m	Placebo gum for 3-4m		6m (biochem, car)	Unclear
Garvey 2000 ⁽²⁴⁾	USA	Community volunteers	608	NS	51%	4mg nicotine gum (recommended 9-15 pieces),	Placebo gum	Brief counselling (5-10 mins) at each study visit (1, 7, 14, 30 days, 2, 3,	12m (biochem, car)	High

						weaning from 2m; 2mg nicotine gum, use as 1		6, 9, 12m)		
Gilbert 1989 ⁽²⁵⁾	Canada	Primary care	223	NR	NS	Support from physician plus offer of nicotine gum prescription (2mg)	Support from physician (no placebo)	Enrolment, quit day, offer of 4 support visits, 2 in wk 1, 1m, 2m	12m (biochem, car)	High
Gross 1995 ⁽²⁶⁾	USA	Community volunteers	177	42	51%	Nicotine gum (2mg), tapered from wk 12. Active gum groups further randomised to chew 7, 15 or 30 pieces of gum	No gum	1 pre-quit group counselling session, 14 clinic visits in 10 wks	6m (biochem, car)	High
Hall 1985 ⁽²⁷⁾	USA	Community volunteers + physician referrals	120	38	47%	Combined - 2mg nicotine gum (period of use not specified) and intensive behavioural treatment	Intensive behavioural treatment (14 group sessions over an 8 wk period)	High	12m (biochem, NR)	High
Hall 1987 ⁽²⁸⁾	USA	Community volunteers	139	39	47%	Nicotine gum (2mg) up to 12m	Placebo gum up to 12m	Both group-based, 14x75 min sessions, or 5x60 min sessions	12m (biochem, pp)	Unclear
Hall 1996 ⁽²⁹⁾	USA	Community volunteers	207	40	52%	Nicotine gum (2mg) for 8 wks, 1 piece/hr for 12 hrs/day	Placebo gum, same schedule	Group-based, 10 sessions over 8 wks, TQD session 3	12m (biochem, car)	Unclear

Harackiewicz 1988 ⁽³⁰⁾	USA	Primary care	197	36	63%	Nicotine gum (2mg, 6 wks initial supply, suggested tapering after 3m, available for 6m) plus self-help manual	Self-help manual; Control (booklet)	Single appointment with doctor or nurse, length not specified	12m (biochem, car)	High
Herrera 1995 ⁽³¹⁾	Venezuela	Community volunteers	322	38	43%	2mg nicotine gum (low dependence)	Placebo gum (low dependence)	12 group sessions over 6 wks + 6 weekly maintenance sessions	24m (biochem, car)	Unclear
Hjalmarson 1984 ⁽³²⁾	Sweden	Smoking cessation clinic	206	42	56%	Nicotine gum (2mg) (no restrictions on amount or duration of use)	Placebo gum	6 group sessions in 6 wks	12m (biochem, car)	Unclear
Huber 1988 ⁽³³⁾	Germany	Community volunteers	225	NS	NS	Nicotine gum (no details of dose) and behaviour therapy	Behaviour therapy, 5 weekly group meetings	High	12m (self, NR)	Unclear
Hughes 1989 ⁽³⁴⁾	USA	Primary care	315	37	56%	Nicotine gum (2mg for 3- 4m)	Placebo gum	29-35 min at first visit including nurse & physician advice, and materials, follow-up appointment 1-2 wks later	12m (biochem, car)	Low
Hughes 1990 ⁽³⁵⁾	USA	Community volunteers	78	40	54%	Nicotine gum - 1mg/2mg/4mg	Placebo gum	29-35 min at 1st visit including nurse and physician advice, and	6m (self, car)	Unclear

								materials, follow-up appointment 1-2 wks later		
Jamrozik 1984 ⁽³⁶⁾	UK	Primary care	200	NS	NS	Nicotine gum (2mg) for 3m+	Placebo gum	Follow-up visits at 2, 4, 12 wks for data collection	6m (biochem, pp)	Unclear
Jarvis 1982 ⁽³⁷⁾	UK	Smoking cessation clinic	116	40	55%	Nicotine gum (2mg) unrestricted amount for at least 3m	Placebo gum (1mg unbuffered nicotine)	Group therapy 6x1hr weekly	12m (biochem, car)	High
Jensen 1991 ⁽³⁸⁾	Denmark	Smoking cessation clinic	293	42	54%	Nicotine gum (2mg for 3m)	Standard chewing gum	9 group meetings over a year, weekly to wk 4	12m (biochem, car)	High
Killen 1984 ⁽³⁹⁾	USA	Community volunteers	64	44	72%	Nicotine gum (2mg) for 7 wks; Skills training plus nicotine gum	Skills training	Group therapy	10.5m (biochem, car)	High
Killen 1990 ⁽⁴⁰⁾	USA	Community volunteers	1218	43	52%	Nicotine gum (2mg, 8 wks) ad lib dosing; Nicotine gum on a fixed dose	Placebo gum; No gum	Randomised to 1 of 3 psychological interventions	12m (biochem, pp)	Unclear
Llivina 1988 ⁽⁴¹⁾	Spain	Smoking cessation clinic	216	NR	NR	Nicotine gum (dose not stated) for 1m	Placebo gum	Group support	12m (biochem, car)	Unclear
Malcolm 1980 ⁽⁴²⁾	UK	Community volunteers	194	45	41%	Nicotine gum (2mg) at least 10/day for at least 3m	Placebo gum; Control	Weekly individual counselling for 1m	6m (biochem, car)	Unclear
McGovern 1992 ⁽⁴³⁾	USA	Community volunteers	293	NS	NS	American Lung Assoc. Freedom from Smoking clinic	ALA Freedom from Smoking clinic programme	Group support	12m (biochem, pp)	Unclear

						programme plus nicotine gum (2mg for 3m)	alone (no placebo gum)			
Mori 1992 ⁽⁴⁴⁾	Japan	Hospital	364	NR	NR	Nicotine gum 2mg for 3m	Placebo gum		6m (NR, biochem)	Unclear
Nakamura 1990 ⁽⁴⁵⁾	Japan	Community volunteers	60	NS	NS	Nicotine gum (2mg for 2m or longer)	Non-placebo control group received counselling	High	6m (biochem, car)	High
Nebot 1992 ⁽⁴⁶⁾	Spain	Primary care	425	NS	NS	Physician counselling plus nicotine gum	Brief counselling from physician; health education from nurse	Low	12m (biochem, pp)	High
Niaura 1994 ⁽⁴⁷⁾	USA	Outpatients	173	42	50%	Nicotine gum 2mg, ad lib for up to 4m (participants given prescription for gum, not free)	No gum	4 individual counselling sessions and ALA self-help treatment manuals	12m (biochem, car)	Unclear
Niaura 1999 ⁽⁴⁸⁾	USA	Community volunteers	62	28	50%	Intensive cognitive behavioral relapse prevention (CBRP) with cue exposure + nicotine gum	Intensive CBRP with cue exposure	5 group sessions within 3 wks of TQD	12m (biochem, car)	Unclear
Ockene 1991 ⁽⁴⁹⁾	USA	Primary care	1223	35	57%	Patient-centred counselling	Patient-centred counselling	Mixed	12m (self, car)	Unclear

						and offer of nicotine gum(2mg) plus minimal or intensive follow-up by telephone				
Page 1986 ⁽⁵⁰⁾	Canada	Primary care	275	NS	NS	Advice to quit plus offer of nicotine chewing gum prescription (2mg)	No advice; Advice to quit	Low	6m (self, car)	High
Pirie 1992 ⁽⁵¹⁾	USA	Community volunteers	417	NS	100%	Group therapy plus nicotine gum; Group therapy plus weight control programme and nicotine gum	Group therapy; Group therapy plus weight control programme	High	12m (biochem, car)	Unclear
Puska 1979 ⁽⁵²⁾	Finland	Community volunteers	229	NS	NS	Nicotine gum (4mg) for 3 wks	Placebo gum for 3 wks	Group therapy	6m (self, pp)	Unclear
Richmond 1993 ⁽⁵³⁾	Australia	Primary care	450	NS	NS	Smokescreen programme plus nicotine gum, dose and duration not stated	Smokescreen programme alone	5 visits during first 3m	12m (biochem, car)	High
Roto 1987 ⁽⁵⁴⁾	Finland	Primary care	121	NS	43%	Nicotine gum (2mg and 4mg), + advice	Advice only (no placebo)	Low	6m (NR, NR)	Unclear
Russell 1983 ⁽⁵⁵⁾	UK	Primary care	2106	NS	NS	As group 2, plus offer of	No intervention;	Low	12m (biochem,	High

						nicotine gum prescription, Individual therapy, Single visit 1 minimal content, 1 more intensive content, untrained therapist	Advised to stop smoking plus provided with a 'give up smoking' booklet		car)	
Schneider 1985A ⁽⁵⁶⁾	USA	Community volunteers	60	38	60%	Nicotine gum, (2mg duration not stated)	Placebo gum	Individual support at multiple clinic assessment visits, daily during week 1, weekly to wk 5	12m (biochem, car)	Unclear
Schneider 1985B ⁽⁵⁶⁾	USA	Community volunteers	36	NS	NS	Nicotine gum, (2mg duration not stated)	Placebo gum	Weekly laboratory visits for 5 wks but no support provided	12m (biochem, car)	Unclear
Segnan 1991 ⁽⁵⁷⁾	Italy	Primary care	923	NS	NS	Repeated counselling plus prescription for nicotine gum unless contraindicated, dose not stated, up to 3m	Advice and leaflet; Repeated counselling (follow-up at 1, 3, 6, 9m); Repeated counselling plus spirometry	High	12m (biochem, car)	Low
Shiffman 2009 (2mg) ⁽⁵⁸⁾	USA	Community volunteers	1636	42	64%	Nicotine gum 2mg. Instructed to gradually reduce smoking while increasing gum	Placebo gum, same schedule as above	Designed to simulate over the counter (OTC) setting	6m (biochem, car)	Unclear

						use for up to 8 wks. Post-quit; instructed to use 1 piece every 1-2hrs for first 6 wks; 1 every 2-4hrs for next 3 wks; 1 every 4-8hrs for final 3 wks				
Shiffman 2009 (4mg) ⁽⁵⁸⁾	USA	Community volunteers	1661	46	50%	Nicotine gum 4mg. Instructed to gradually reduce smoking while increasing gum use for up to 8 wks. Post-quit; instructed to use 1 piece every 1-2hrs for first 6 wks; 1 every 2-4hrs for next 3 wks; 1 every 4-8hrs for final 3 wks	Placebo gum, same schedule as above	Designed to simulate OTC setting	6m (biochem, car)	Unclear
Tonnesen 1988 ⁽⁵⁹⁾	Denmark	Primary care	113	45	56%/58%	Nicotine Gum (2mg) for 16 wks	Placebo	Informal group support, 6 sessions	12m (biochem, car)	Unclear
Villa 1999 ⁽⁶⁰⁾	Spain	Worksite volunteers	47	36	72%	Nicotine gum (2mg)	No gum	8 weekly group sessions, 5 before TQD. Reduction prior to quitting	12m (self, NR)	Unclear
Zelman 1992 ⁽⁶¹⁾	USA	Community volunteers	116	32	54%	Nicotine gum 2mg, average	Rapid smoking + support	6x60-75 min group sessions over 2	12m (self, car)	High

						10 pieces/day, duration not stated + skills training; Nicotine gum + support counselling	counselling; Rapid smoking + skills training	wks, starting on quit day		
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Table 8.2 Included studies from systematic review: NRT patches versus placebo

Study	Country	Setting	Participants	Mean age	Female	Intervention	Control	Support	Outcome	Risk of bias
Abelin 1989 ⁽⁶²⁾	Switzerland	Primary care	199	41	40%	Nicotine patch, 24hr, 12 wks with weaning; 21mg smokers of >20 cpd, 14mg for <20 cpd	Placebo patch	Unclear	12m (biochem, car)	High
Buchkremer 1988 ⁽⁶³⁾	Germany	Community volunteers	131	35	50%	Nicotine patch (24hr/day, 8 wks, 15cm with weaning) + behavioural therapy	Placebo patch + behavioural therapy; Behavioural therapy alone	9 weekly group sessions	12m (self, NR)	Unclear
Campbell 1996 ⁽¹⁰⁾	UK	Hospital inpatients and outpatients	234	49	54%	Patch (21mg, 24hr, 12 wks with dose tapering)	Placebo patch	Counselling at 2, 4, 8, 12 wks	12m (biochem, continuous)	Unclear
CEASE 1999 ⁽⁶⁴⁾	Europe	Community volunteers	3575	41	48%	Nicotine patch 15/25mg (16hr), duration of active treatment 12/28 wks (incl 4 wk	Placebo	Brief advice & self-help brochure, visits at enrolment, TQD, wk 1, 2,	12m (biochem, car)	Low

						fading)		4, 8, 12, 22, 26		
Daughton 1991 ⁽⁶⁵⁾	USA	Community volunteers	158	42	53%	Nicotine patch (15cm ² , 4 wks) worn for 16 or 24hr/day	Placebo patch, 4 wks	Unclear & differed between sites	6m (self, car)	Unclear
Daughton 1998 ⁽⁶⁶⁾	USA	Community volunteers	158	42	53%	Nicotine patch (21mg, 16hr, 10 wks with weaning)	Placebo patch	Nicoderm Committed Quitters Programme support booklet + follow-up visit 1 wk after quit day	12m (biochem, car)	Low
Davidson 1998 ⁽⁶⁷⁾	USA	Community volunteers	802	39	54%	Nicotine patch (22mg, 24hr, for up to 6 wks)	Placebo patch	Self-help book provided. Participants visited mall weekly to obtain patches. CO levels were monitored	6m (self, car)	Low
Ehram 1991 ⁽⁶⁸⁾	Switzerland	Primary care	112	26	NS	Nicotine patch (21 or 14mg/24hr, 9 wks, tapered)	Placebo patch	High (no counselling)?	12m (biochem, car)	Unclear
Fiore 1994A ⁽⁶⁹⁾	USA	Community volunteers	88	NS	NS	Nicotine patch (22mg/24hr, 8 wks, no weaning)	Placebo patch	Intensive group counselling	6m (biochem, pp)	Low
Fiore 1994B ⁽⁶⁹⁾	USA	Community volunteers	112	NS	NS	Nicotine patch (22mg/24hr, 6 wks incl weaning)	Placebo patch	8 weekly 10-20 min individual counselling	6m (biochem, pp)	Unclear
Glavas 2003a ⁽⁷⁰⁾	Croatia	NS	112	34	66%	Nicotine patch, 24hr, 25mg/15 mg/8mg starting dose depending on baseline cpd 3 wks	Placebo patch	Visits to pick up patch at 7, 14, 21 days, no details about advice given	12m (biochem, car)	Unclear

Glavas 2003b ⁽⁷¹⁾	Croatia	Community volunteers	160	NS	NS	Nicotine patch, 24hr, 25mg/15mg/8mg starting dose depending on baseline cpd. 6 wks; Nicotine patch, 24hr, 25mg/15mg starting dose depending on baseline cpd 3 wks	Placebo patch. 6 wks; Placebo patch 3 wks		6m (biochem, NR)	Unclear
Hand 2002 ⁽⁷²⁾	UK	Hospital inpatient/ou tpatient	245	NR	54%	Nicotine patch (initially 30 or 20mg based on smoking rate) and inhaler for 3 wks including patch tapering. Same counselling as control	Individual counselling, 4 sessions in 4 wks. No placebo		12m (biochem, sustained)	High
Hays 1999 ⁽⁷³⁾	USA	Community volunteers	958	44	50%	Nicotine patches (22mg, 24hr for 6 wks) purchased by participants, open label; Nicotine patches (22mg, 24hr for 6 wks) provided, double blind	Placebo patches provided	No advice, counselling or interaction with medical personnel	6m (biochem, pp)	Low
Hughes 1999 ⁽⁷⁴⁾	USA & Australia	Community volunteers	1039	43	50%	42mg nicotine patch (24hr, 6 wks + 10 wks tapering); 35mg nicotine patch; 21mg nicotine patch	Placebo patch	Group behaviour therapy for 7 wks, brief individual counselling at 5-dose tapering meetings. Self-	6m (biochem, car)	High

								help booklet		
Hughes 2003 ⁽⁷⁵⁾	US	Community volunteers	115	NR	32%	Nicotine patch (21mg, 24hr, 6 wks + 4 wks tapering + 2 wks placebo)	Placebo patch 12 wks	Group behaviour therapy x 6, brief individual counselling x 3	6m (biochem, sustained)	Unclear
Hurt 1990 ⁽⁷⁶⁾	USA	Community volunteers	62	39	53%	Nicotine patch (30mg 24hrs, 6 wks + option of further 12 wks +/- tapering)	Placebo patch (continuing smokers at 6 wks were offered active patch)	Brief advice from nurse co-ordinator at 6 weekly visits	12m (biochem, car)	Unclear
Hurt 1994 ⁽⁷⁷⁾	USA	Community volunteers	240	43	53%	Nicotine patch (22mg/24hr, 8 wks, no tapering)	Placebo patch	Nurse counselling at 8 weekly visits, weekly phone calls to wk 12	12m (biochem, car)	Unclear
ICRF 1994 ⁽⁷⁸⁾	UK	Primary care	1686	43	55%	Nicotine patch (21mg/24hr, 12 wks incl tapering)	Placebo patch	Brief advice from nurse at 4 study visits	12m (biochem, car)	Low
Jorenby 1999 ⁽⁷⁹⁾	USA	Community volunteers	893	43	52%	Nicotine patch and placebo tablets	Placebo patch and placebo tablets	<15min individual counselling session at each weekly assessment. One phone call 3 days after quit day	12m (biochem, car)	Unclear
Joseph 1996 ⁽³⁾	US	VA medical centres	584	60	~100%	Nicotine patch, (21mg/24hr for 6 wks, 14mg for 2 wks, 7mg for 2 wks)	Placebo patch	Self-help pamphlets and brief behavioural counselling on	12m (biochem, pp)	Unclear

								3 occasions		
Killen 1997 ⁽⁸⁰⁾	USA	Community volunteers	424	45	50%	Nicotine patch (21mg/24hr) for 8 wks, 14mg for 4 wks, 7mg for 4 wks; Nicotine patch and video	Placebo patch; Placebo patch and video	All treatment groups received a self-help treatment manual designed to develop self-regulatory skills	12m (biochem, car)	Unclear
Kornitzer 1995 ⁽⁸¹⁾	Belgium	Worksite volunteers	374	40	39%	Nicotine patch (12 wks 15mg/16hr, 6 wks 10mg, 6 wks 5mg) and placebo gum	Placebo patch and placebo gum	Nurse counselling	12m (biochem, car)	Low
Lewis 1998 ⁽⁴⁾	US	Hospital in-patients	185	44	46%	Nicotine patch (22mg/ 24hrs for 3 wks, tapered to 11mg for 3 wks)	Placebo patch.	Nurse provided brief telephone counselling at 1, 3, 6 and 24 wks	6m (biochem, PP)	Low
Molyneux 2003 ⁽⁵⁾	UK	Hospital	274	60	40%	Choice of NRT products (15mg 16hr patch/2mg or 4mg gum, 10mg inhalator/2mg sublingual tablet, 0.5mg spray)	Brief counselling only; Usual Care, no smoking advice		12m (biochem, car)	Unclear
Oncken 2007 ⁽⁸²⁾	USA	Community volunteers	152	55	100%	Nicotine patch (21mg for 13 wks incl 4 wks tapering)	Placebo patch	7 visits incl 4 x 2hr group counselling, 1 pre-TQD	16m (biochem, pp)	Unclear
Paoletti 1996 ⁽⁸³⁾	Italy	Community volunteers	297	43	40%	Nicotine patch (15mg/16hr, 18 wks incl taper); Nicotine patch 25 mg	Placebo patch	Low	12m (biochem, pp)	Unclear
Perng	Taiwan	Outpatient	62	62	6%	Nicotine patch	Placebo	Weekly visit to	12m (NR)	Unclear

1998 ⁽⁸⁴⁾		chest clinics				(24mg/24 hr for 6 wks, no weaning)	patch	outpatient department for assessment		
Piper 2009 ⁽⁸⁵⁾	USA	Community volunteers	1504	45	58%	Nicotine patch (24hr, 21, 14, and 7mg titrated down over 8 wk period post quit)	Placebo (5 groups matched to above 5 interventions)	7 one-to-one 10-20min counselling sessions	6m (biochem, pp)	Unclear
Richmond 1994 ⁽⁸⁶⁾	Australia	Community volunteers	315	NS	NS	Nicotine patch (24 hr, 22mg/24 hr, 10 wks incl tapering)	Placebo patch	Group therapy	12m (biochem, car)	Low
Sachs 1993 ⁽⁸⁷⁾	USA	Community volunteers	220	NS	NS	Nicotine patch (15mg/16hr, 12 wks + 6 wks tapering)	Placebo patch	Physician advice, 8 visits during treatment period	12m (biochem, car)	Unclear
Sonderskov 1997 ⁽⁸⁸⁾	Denmark	Pharmacy customers	522	39	50%	Nicotine patch (24 hr). >20/day smokers used 21mg for 4 wks, 14mg for 4 wks, 7mg for 4 wks. Smokers of <20/day used 14mg for first 8 wks, 7mg for 4 wks	Placebo patches	Brief instructions on patch use at baseline, visit to collect further patches at 4 and 8 wks, no behavioural support	6m (self, pp)	Low
Stapleton 1995 ⁽⁸⁹⁾	UK	Primary care	1200	NS	NS	Nicotine patch standard dose (15mg/16hr for 18 wks); Nicotine patch with dose increase to 25mg at 1 wk, if required	Placebo patch group	Physician advice & brief support at 1, 3, 6, 12 wks	12m (biochem, car)	Low
TNSG 1991 ⁽⁹⁰⁾	USA	Community volunteers	808	43	60%	Nicotine patch (21mg /24 hr, 6 wks+); Nicotine	Placebo patch	Group therapy, 6+ sessions	6m (biochem, car)	Unclear

						patch 14mg				
Tonnesen 1991 ⁽⁹¹⁾	Denmark	Community volunteers	289	45	70%	Nicotine patch (15mg/16hr for 12 wks with tapering)	Placebo patch	7 clinic visits including a few minutes of advice	12m (biochem, car)	Low
Tonnesen 2000 ⁽⁹²⁾	Denmark	Lung clinic referrals	446	49	52%	15mg (16hr) nicotine patch for 12 wks (up to 9m on request)	5mg nicotine patch (placebo)	Physician advice at baseline, brief (15min) nurse counselling at 2, 6 wks	12m (biochem, sustained)	Unclear
Westman 1993 ⁽⁹³⁾	USA	Community volunteers	158	41	57%	Nicotine patch (25mg/24hr, 6 wks incl weaning)	Placebo patches	Brief counsellor support at 3 clinic visits, 4 telephone counselling sessions, self-help materials	6m (biochem, car)	Unclear
Otero 2006 ⁽⁹⁴⁾	Brazil	Community volunteers	1199	42	63%	Nicotine patch (21mg, 14mg for FTND<5) 8 wks incl tapering + behavioural support	Cognitive behavioural support only	Mixed (Low=single 20 min session. High= 1, 2, 3 or 4 weekly 1hr sessions. Maintenance or recycling sessions provided at 3, 6, 12 months)	12m (self, pp)	High
Cinciripini 1996 ⁽⁹⁵⁾	USA	Community volunteers	64	NR	70%	Nicotine patch (21mg, 12 wks incl weaning)	Behaviour therapy only (no placebo)	Group therapy weekly for 9 wks	12m (biochem, car)	Unclear
Prapavessis 2007 ⁽⁹⁶⁾	New Zealand	Community volunteers	121	NR	100%	Nicotine patch (21mg/24hr for 10 wks, no weaning)	No patch	36x45 min session over 12 wks of group	12m (biochem, car)	Unclear

								CBT or supervised vigorous exercise, starting 6 wks before TQD		
Wong 1999 ⁽⁹⁷⁾	USA	Community volunteers	100	42	53%	Nicotine patch: 21mg (24hr) for 8 wks, tapering to 14mg for 4 wks	Naltrexone: 50mg/day for 12 wks	Individual counselling, 15-20 mins at 8 study visits	6m (biochem, car)	High
EAGLES 2016 ⁽⁹⁸⁾	International	Community volunteers	4028	46	66%	Patch, 21mg x 7 weeks, 14mg x 2 wks, 7mg x 2 weeks (11 weeks)	Placebo	All participants received counselling (up to 10 mins) at all contacts. Participants monitored at weeks 1-6, 8, 12, 13, 16, 20, 24; contacts were up to 15 face-to-face visits and 11 telephone visits	Abstinence at 6 months (biochem, car)	Low

Table 8.3 Included studies from systematic review: NRT inhaler versus placebo

Study	Country	Setting	Participants	Mean age	Female	Intervention	Control	Support	Outcome	Risk of bias
Hjalmarsen 1997 ⁽⁹⁹⁾	Sweden	Smoking cessation clinic	247	48	64%	Nicotine inhaler (recommended minimum 4/day, tapering after 3m, use permitted to 6m)	Placebo inhaler	8 group meetings over 6 wks	12m (biochem, car)	Low

Leischow 1996 ⁽¹⁰⁰⁾	USA	Community volunteers	222	44	55%	Nicotine inhaler (10mg). Advised to use 4-20 cartridges/day for 3m. After this tapering was encouraged until 6m	Placebo inhaler	Brief individual smoking cessation support at each study visit, 10 in all	12m (biochem, car)	Unclear
Schneider 1996 ⁽¹⁰¹⁾	USA	Community volunteers	223	44	37%	Nicotine inhaler (4-20 inhalers per day) for up to 6m, with weaning from 3m	Placebo inhaler	Repeated clinic visits for assessment	12m (biochem, car)	Low
Tonnesen 1993 ⁽¹⁰²⁾	Denmark	Community volunteers	286	39	60%	Nicotine inhaler (2-10/day) up to 6m	Placebo inhaler	Brief advice at 8 clinic visits, 0, 1, 2, 3, 6, 12, 24, 52 wks	12m (biochem, car)	Low

Table 8.4 Included studies from systematic review: NRT intranasal spray versus placebo

Study	Country	Setting	Participants	Mean age	Female	Intervention	Control	Support	Outcome	Risk of bias
Blondal 1997 ⁽¹⁰³⁾	Iceland	Community volunteers	159	42	44%	Nicotine nasal spray (NNS) ad lib use. Each dose (2 squirts) delivered 1mg nicotine. Maximum dose 5mg/hr and 40mg/day. Recommended duration of use 3m	Placebo nasal spray containing piperine to mimic sensory effect of nicotine	Group therapy 6x1hr sessions	12m (biochem, car)	Unclear
Hjalmarson 1994 ⁽¹⁰⁴⁾	Sweden	Smoking cessation clinic	248	45	57%	Nicotine nasal spray (0.5mg/spray) used as required up to 40mg/day for up to	Placebo spray	8x45-60min group sessions over 6 wks with	12m (biochem, car)	Unclear

						1yr		clinical psychologist		
Schneider 1995 ⁽¹⁰⁵⁾	USA	Community volunteers	255	NS	NS	Nicotine nasal spray (0.5mg of nicotine per spray)	Placebo spray	Repeated clinic visits for assessment	12m (biochem, car)	Unclear
Sutherland 1992 ⁽¹⁰⁶⁾	UK	Smoking cessation clinic	227	NS	NS	Nicotine nasal spray, maximum 40mg/day	Placebo spray	4 wks group support	12m (biochem, car)	Unclear

Table 8.5 Included studies from systematic review: NRT lozenge or tablet versus placebo

Study	Country	Setting	Participants	Mean age	Female	Intervention	Control	Support	Outcome	Risk of bias
Dautzenberg 2001 ⁽¹⁰⁷⁾	France	Community volunteers	433	39	52%	Nicotine lozenge (1mg, 8-24/day, 6 wks + 6 wks weaning for quitters)	Placebo lozenge	Not stated	6m (biochem, pp)	Unclear
Piper 2009 ⁽⁸⁵⁾	USA	Community volunteers	1504	45	58%	Nicotine lozenge 2 or 4mg for 12 wks (based on dose-for-dependence level as per instructions)	Placebo; 5 groups matched to above 5 interventions	7 one-to-one 10-20min counselling sessions	6m (biochem, pp)	Unclear
Shiffman 2002 (2mg) ⁽¹⁰⁸⁾	USA & UK	Community volunteers	917	41	58%	Nicotine lozenge, 2mg. Recommended dose 1 every 1-2hrs, min 9, max 20/day for 6 wks, decreasing 7-12 wks, available as needed 13-24 wks	Placebo lozenge, same schedule	Brief advice at 4 visits in 4 wks from enrolment	12m (biochem, car)	Unclear
Shiffman 2002 (4mg) ⁽¹⁰⁸⁾	USA & UK	Community volunteers	901	44	55%	Nicotine lozenge, 4mg. Recommended dose 1 every 1-2hrs, min 9, max 20/day for 6 wks,	Placebo lozenge, same schedule	Brief advice at 4 visits in 4 wks from enrolment	12m (biochem, car)	Unclear

						decreasing 7-12 wks, available as needed 13-24 wks				
Glover 2002 ⁽¹⁰⁹⁾	USA	Community volunteers	241	42	54%	Nicotine sublingual tablet (2mg). Recommended dosage 1 tab/hr for smokers with FTND<7, 2 tabs/hr for scores 7. After 3m treatment, tapering period of 3m if necessary	Placebo tablet	Brief counselling at all visits 1, 2, 3, 6 wks, 3, 6, 12m	12m (biochem, car)	Low
Wallstrom 2000 ⁽¹¹⁰⁾	Sweden	Community volunteers	247	45	59%	Nicotine sublingual tablet. Recommended dosage 1 tab/hr for smokers with FTND<7, 2 tabs/hr for scores 7. After 3m treatment, tapering period of 3m if necessary	Placebo tablet	Brief 5 mins counselling at study visits (0, 1, 2, 3, 6 wks, 3, 6m)	12m (biochem, car)	Unclear

Table 8.6 Included studies from systematic review: NRT intranasal spray versus placebo

Study	Country	Setting	Partici pants	Mean age	Female	Intervention	Control	Support	Outcome	Risk of bias
Tonnesen 2012 ⁽¹¹¹⁾	Germany/ Denmark	Community volunteers	479	47	56%	1mg/spray oral nicotine spray (in development, name not provided) Active: wks 1-6: 1-2 sprays when participants would normally have smoked a cigarette or experienced a craving, up to 4 sprays/hr and 64	Placebo on same schedule	General written and oral advice (less than 10min) at study start and less than 3mins at subsequent	12m (biochem, car)	Low

						sprays/day. Tapered down wks 7-12 (end of wk 9 instructed to be using half as much as in wks 1-6, reducing to max 4 sprays/ day by wk 12). Occasional use (max 4 sprays/day) permitted wks 13-24		visits up to and including wk 24 (9 visits total)		
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Table 8.7 Included studies from systematic review: choice of NRT versus placebo

Study	Country	Setting	Participants	Mean age	Female	Intervention	Control	Support	Outcome	Risk of bias
Kralikova 2002 ^(112, 113)	Czech Republic	Community volunteers	314	46	58%	Choice of 4mg nicotine gum (up to 24/day) or 10mg inhaler (6-12 daily) for up to 6m with further 3m tapering	Placebo gum or inhaler	Brief behavioural support at clinic visits (9 scheduled)	12m (biochem, car)	Unclear
Wittchen 2011 ⁽¹¹⁴⁾	Germany	Primary care	467	43	52%	CBT + NRT for 9-12 wks, patient's choice of patch (7mg-52.5mg), gum (2 or 4mg) or spray (10mg/ml)	No NRT	CBT, 4-5 one on one counselling sessions for 20-30min	12m (self, NR)	High

Table 8.8 Included studies from systematic review: Combination NRT versus placebo

Study	Country	Setting	Participants	Mean age	Female	Intervention	Control	Support	Outcome	Risk of bias
Piper 2009 ⁽⁸⁵⁾	USA	Community volunteers	1504	45	58%	Lozenge + patch (duration and dosage as above)	Placebo; 5 groups matched to above 5	7 one-to-one 10-20min counselling sessions	6m (biochem, pp)	Unclear

							interventions			
Tonnesen 2000 ⁽²⁾	Denmark	Lung clinic referrals	446	49	52%	15mg (16hr) nicotine patch for 12 wks (up to 9m on request) plus nicotine inhaler	5mg nicotine patch (placebo)	Physician advice at baseline, brief (15min) nurse counselling at 2, 6 wks, 3, 6, 9, 12m	12m (sustained, biochem)	Unclear
Kornitzer 1995 ⁽⁸¹⁾	Belgium	Worksite volunteers	374	40	39%	Nicotine patch (12 wks 15mg/16hr, 6 wks 10mg, 6 wks 5mg) and placebo gum	Placebo patch and placebo gum	Nurse counselling	12m (sustained, biochem)	Low

Table 8.9 Included studies from systematic review: NRT plus bupropion versus placebo

Study	Country	Setting	Participants	Mean age	Female	Intervention	Control	Support	Outcome	Risk of bias
Jorenby 1999 ⁽⁷⁹⁾	USA	Community volunteers	893	43	52%	Nicotine patch (21mg/24hr for 6 wks, tapered for 2 wks) and sustained release bupropion 300mg for 9 wks from 1 wk before quit day	Placebo patch and placebo tablets	<15min individual counselling session at each weekly assessment. One phone call 3 days after quit day	12m (biochem, car)	Unclear
Piper 2009 ⁽⁸⁵⁾	USA	Community volunteers	1504	45	58%	Bupropion + lozenge (duration and dosage as above)	Placebo; 5 groups matched to above 5 interventions	7 one-to-one 10-20min counselling sessions	6m (biochem, pp)	Unclear
Piper 2007 ⁽¹¹⁵⁾	US	Community volunteers	608	42	58%	Nicotine gum (4mg, 8 wks) and bupropion (300mg, 9 wks)	Placebo gum and bupropion		12m (biochem, pp)	Unclear

Table 8.10 Included studies from systematic review: NRT versus bupropion

Study	Country	Setting	Participants	Mean age	Female	Intervention	Control	Support	Outcome	Risk of bias
Patch										
Gariti 2009 ⁽¹¹⁶⁾	USA	Community volunteers	260	54	57%	Patch (for participants >10 cpd: 21mg/day for wks 1-4, 14mg/day wks 5-6, 7mg/day wks 7-8; participants 10cpd: 14mg/day for 6 wks, 7mg/day for wks 7-8) + 9 wks placebo bupropion + 10 wks individualised counselling sessions; Patch (dose as above) for 8 wks + 9 wks placebo bupropion + four 5-10min counselling sessions	Placebo patch for 8 wks + 9 wks bupropion SR + 10 wks individualised counselling sessions; Placebo patch for 8 wks + 9 wks bupropion SR + 4x5-10min counselling sessions	High level of support via individual counselling sessions	12m (biochem, pp)	Low
Jorenby 1999 ⁽⁷⁹⁾	USA	Community volunteers	893	43	52%	Nicotine patch and placebo tablets	Bupropion 300mg and placebo patch	<15min individual counselling session at each weekly assessment. One phone call 3 days after quit day	12m (biochem, car)	Unclear
Piper 2009 ⁽⁸⁵⁾	USA	Community volunteers	1504	45	58%	Nicotine patch (24hr, 21, 14, and 7mg titrated down over 8 wk period post quit)	Bupropion SR (150mg bid, 1 wk pre-quit, 8	7 one-to-one 10-20min	6m (biochem, pp)	Unclear

							wks post quit)	counsellin g sessions		
Smith 2009 ⁽¹¹⁷⁾	USA	Primary care	1346	44	56%	Nicotine patch only (21mg post quit wk 1-4; 14mg wk 5-6; 7mg wk 7-8)	Bupropion only (up-titrated during wk pre- quitting, 150mg bid for 8 wks post quit)	Behaviour al support optional	6m (self, pp)	High
EAGLES 2016 ⁽⁹⁸⁾	Internatio nal	Community volunteers	4028	46	66%	Nicotine patch, 21mg x 7 weeks, 14mg x 2 wks, 7mg x 2 weeks (11 weeks)	Bupropion SR, 150mg x 2/day (titrated for 3 days, then full dose for 11 weeks)	All participan ts received counsellin g (up to 10 mins) at all contacts. Participan ts were monitored at weeks 1 - 6, 8, 12, 13, 16, 20, 24; contacts were up to 15 face-to- face visits and 11 telephone visits	6m (biochem, car)	Low

Lozenge										
Piper 2009 ⁽⁸⁵⁾	USA	Community volunteers	1504	45	58%	Nicotine lozenge 2 or 4mg for 12 wks (based on dose-for-dependence level as per instructions)	Bupropion SR (150mg bid, 1 wk pre-quit, 8 wks post quit)	7 one-to-one 10-20min counselling sessions	6m (biochem, pp)	Unclear
Smith 2009 ⁽¹¹⁷⁾	USA	Primary care	1346	44	56%	Nicotine lozenge only (4mg lozenge if first cig of day smoked >30 min after waking, 2mg otherwise. 1 lozenge every 1-2hrs post-quit wk 1-6; 1 lozenge every 2-4hrs wk 7-9; 1 lozenge every 4-8hrs wk 10-12)	Bupropion only (up-titrated during wk pre-quit, 150mg bid for 8 wks post quit)	Behavioral support optional	6m (self, pp)	High
Choice of NRT										
Wittchen 2011 ⁽¹¹⁴⁾	Germany	Primary care	467	43	52%	CBT + NRT for 9-12 wks, patient's choice of patch (7mg-52.5mg), gum (2 or 4mg) or spray (10mg/ml)	CBT + bupropion SR (9-12 wks, 150mg; 1/d for first 6d; 2/d thereafter)	4-5 one-on-one counselling sessions for 20-30min	12m (self, NR)	High

Table 8.11 Included studies from systematic review: NRT versus NRT

Study	Country	Setting	Participants	Mean age	Female	Intervention	Control	Support	Outcome	Risk of bias
Komitzer 1995 ⁽⁸¹⁾	Belgium	Worksite volunteers	374	40	39%	Nicotine patch + gum	Patch	Nurse counselling	12m (biochem, car)	Low
Puska 1995 ⁽¹¹⁸⁾	Finland	Community volunteers	300	20-65	NS	Nicotine patch + gum	Gum	Advice from nurses	12m (biochem, car)	Unclear

Blondal 1999 ⁽¹¹⁹⁾	Iceland	Community volunteers	237	42	67%	Nasal spray + patch	Patch	4 support group meetings	12m (biochem, car)	Low
Caldwell, 2014 ⁽¹²⁰⁾	New Zealand		1423	45	54%	Nicotine patch + spray	Nicotine Patch + Placebo Spray	Physician advice and telephone calls to all participants	12 month (7-day PP, Biochem)	Low
Cooney 2009 ⁽¹¹⁾	US	Community volunteers + substance abuse clinic referrals	96	45	25%	Nicotine patch (titrated, 21mg/d for 8 wks, 14mg/d for 2 wks) + nicotine gum (2mg for 24 wks, ad lib but advised 6-20/day)	Nicotine patch + placebo gum (doses as above)	16 individual 1hr weekly outpatient sessions of behavioural alcohol and smoking treatment over 6m	12 month (continuous, Biochem)	Low
Croghan 2003 ⁽¹²¹⁾	USA	Community volunteers	1384	42	58%	Nasal spray + nicotine patch	Spray or patch	Advice at each visit, 30-45 mins total	6m (biochem, pp)	High
Bohadana 2000 ⁽¹²²⁾	France	Community volunteers	400	NS	51%	Nicotine patch + inhaler	Inhaler	Brief counselling and support from investigator at each visit	12m (biochem, car)	Unclear
Piper 2009 ⁽⁸⁵⁾	USA	Community volunteers	1504	45	58%	Nicotine patch + lozenge	Patch or lozenge	7 one-to-one 10-20min counselling sessions	6m (biochem, pp)	Unclear
Smith 2009 ⁽¹¹⁷⁾	USA	Primary care	1346	44	56%	Nicotine patch + lozenge	Patch or lozenge	Behavioural support optional	6m (self, pp)	High
Croghan 2003 ⁽¹²¹⁾	USA	Community volunteers	1384	42	58%	Nasal spray	Patch	Advice at each visit, 30-45 mins total	6m (biochem, pp)	High
Lerman 2004 ⁽¹²³⁾	USA	Community volunteers	350	46	54%	Nasal spray	Patch	7x90 min behavioural group	6m (biochem, pp)	Low

								counselling sessions. TQD in wk 3		
Piper 2009 ⁽⁸⁵⁾	USA	Community volunteers	1504	45	58%	Lozenge	Patch	7 one-to-one 10-20min counselling sessions	6m (biochem, pp)	Unclear
Schnoll 2010b ⁽¹²⁴⁾	USA	Community volunteers	642	45	57%	Lozenge	Patch	5 individual counselling sessions	6m (biochem, car)	High
Smith 2009 ⁽¹¹⁷⁾	USA	Primary care	1346	44	56%	Lozenge	Ppatch	Behavioural support optional	6m (self, pp)	High

Table 8.12 Included studies from systematic review: e-cigarette versus placebo

Study	Setting	Mean age	Ethnicity	Female	Participants	Intervention	Control	Behavioural support	Outcome	Risk of bias
Bullen 2013 ⁽¹²⁵⁾	New Zealand	42	33% Maori	62%	657	E-cig 16mg for 13 weeks	Placebo	Referred to quitline and received an invitation to access phone or text-based support.	Abstinence at 6m (biochem, car)	Low
Caponnetto 2013 ⁽¹²⁶⁾	Italy	44	NS	36%	300	E-cig 7.2mg for 12 wks or 7.2 for 6 wks + 5.4mg for 6 wks	Placebo	Baseline visit and up to 7 follow-up visits to receive more cartridges, hand in diaries, measure CO and vital signs	Abstinence at 12m (self, car)	Low

Table 8.13 Included studies from systematic review: e-cigarette versus nicotine patch

Study	Setting	Mean age	Ethnicity	Female	Participants	Intervention	Control	Behavioural support	Outcome	Risk of bias
Bullen 2013 ⁽¹²⁵⁾	New Zealand	42	33% Maori	62%	657	E-cig 16mg for 13 weeks	Patch 21mg/24-hour, for 13 weeks	Referred to quitline and received an invitation to access phone- or text-based support.	Abstinence at 6m (biochem, car)	Low

Table 8.14 Included studies from systematic review: bupropion versus placebo

Study	Setting	Mean age	Ethnicity	Female	Participants	Intervention	Control	Behavioural support	Outcome	Risk of bias
Ahluwalia 2002 ⁽¹²⁷⁾	USA	44	African American	70%	600	Bupropion 300mg for 7 weeks	Placebo	8 sessions of in-person or telephone counselling and self-help guide	Abstinence at 6m (biochem, car)	Low
Aubin 2004 ⁽¹²⁸⁾	France	41	NS	56%	504	Bupropion 300mg for 7 weeks	Placebo	Motivational support at clinic visits at baseline, w3, w7, w12 & 3 phone calls TQD, 2-3 days later, w5, w18	Abstinence at 6m (biochem, car)	Low
Brown 2007 ⁽¹²⁹⁾	USA	44	NS	48%	524	Bupropion 300mg/day for 12 weeks	Placebo	12 x 90 min groups twice weekly/ weekly/ monthly for 12w	Abstinence at 12m (biochem, car)	Unclear
Cinciripini 2013 ⁽¹³⁰⁾	USA	44	NS	39%	294	Bupropion 150mg/d days 1-3, 300mg/d thereafter for 12 weeks	Placebo	10 individual counselling sessions (6 in person, 4 via phone, 240mins total)	Abstinence at 6m (biochem, car)	Unclear
Collins 2004 ⁽¹³¹⁾	USA	46	NS	57%	555	Bupropion 300mg/day for 10 weeks	Placebo	7 sessions of group behavioural therapy	Abstinence at 6m (biochem, car)	Low

						begun 2 weeks before TQD			car)	
Cox 2012 ⁽¹³²⁾	USA	47	African American	66%	540	Bupropion 300mg for 7 weeks	Placebo	Up to 6 one-to-one 15-20 minute individual counselling sessions, self-help guide at start	Abstinence at 6m (biochem, pp)	Unclear
Dalsgard 2004 ⁽¹³³⁾	Denmark	43	NS	75%	335	Bupropion 300mg for 7 weeks	Placebo	Motivational support around TQD, at w3 & 7, and at 12w follow up	Abstinence at 6m (biochem, car)	Low
Fossati 2007 ⁽¹³⁴⁾	Italy	49	NS	40%	593	Bupropion 300mg for 7 weeks	Placebo	GP visits at enrolment & 4, 7, 26 & 52w, phone calls 1 day pre TQD, 3 days post TQD, 10w post enrolment. Classified as low intensity	Abstinence at 12m (biochem, car)	Unclear
Gonzales 2001 ⁽¹³⁵⁾	USA	45	NS	52%	450	Bupropion 300mg for 12 weeks, begun 7 days pre-TQD	Placebo	Brief individual counselling at visits w1-7, 9, 12, + telephone counselling at 4 and 5m	Abstinence at 12m (biochem, car)	Unclear
Gonzales 2006 ⁽¹³⁶⁾	USA	42	NS	46%	1025	Bupropion 300mg for 12 weeks, begun 7 days pre-TQD	Placebo	Brief (<10 min) standardised individual counselling at 12 weekly visits during drug phase and 11 clinic/phone visits during follow up, problem solving and relapse prevention	Abstinence at 12m (biochem, car)	Low
Haggstrom 2006 ⁽¹³⁷⁾	Brazil	44	NS	59%	156	Bupropion 300mg for 60 days, TQD during week 2	Placebo	6x 15-min individual CBT, weekly then bi-weekly	Abstinence at 6m (biochem, car)	Unclear
Hall 2002 ⁽¹³⁸⁾	USA	40	NS	44%	220	Bupropion 300mg/day for 12 weeks	Placebo	Medical management or psychological intervention	Abstinence at 12m (biochem, car)	High

Holt 2005 ⁽¹³⁹⁾	New Zealand	40	Maori	72%	134	Bupropion 300mg for 7 weeks	Placebo	Counselling at 3 clinic visits during medication and 3 monthly follow ups, motivational phone call 1 day before & 2 days after TQD	Abstinence at 12m (biochem, car)	High
Hurt 1997 ⁽¹⁴⁰⁾	USA	44	NS	55%	615	Bupropion 300mg for 7 weeks	Placebo	Physician advice, self-help materials, and brief individual counselling by study assistant at each visit	Abstinence at 12m (biochem, car)	Unclear
Jorenby 1999 ⁽⁷⁹⁾	USA	43	NS	52%	893	Bupropion 300mg for 9w from 1w before quit day	Placebo	Brief (< 15 min) individual counselling session at each weekly assessment. One telephone call 3 days after quit day	Abstinence at 12m (biochem, car)	Unclear
Jorenby 2006 ⁽¹⁴¹⁾	USA	42	NS	41%	1027	Bupropion 300mg for 12 weeks	Placebo	Brief (< 10 min) individual counselling at each weekly assessment for 12w & 5 follow-up visits. One telephone call 3 days after quit day	Abstinence at 12m (biochem, car)	Low
Levine 2010 ⁽¹⁴²⁾	USA	42	NS	100%	349	Bupropion SR for 26 weeks. 150mg/d for first 2 days and 300mg/d for remainder of treatment.	Placebo	12, 90 minute group counselling sessions delivered over 3 months	Abstinence at 12m (biochem, car)	High
McCarthy 2008 ⁽¹⁴³⁾	USA	39	NS	50%	463	Bupropion SR 300mg for 8 weeks	Placebo	Counselling; 8 x10min session, 2 pre-quit, TQD, 5 over 4 wks or psycho-education about medication, support and encouragement. Same no. of sessions, 80mins less contact time	Abstinence at 12m (biochem, pp)	Low
Nides 2006 ⁽¹⁴⁴⁾	USA	41	NS	51%	638	Bupropion 300mg for 7	Placebo	Up to 10 mins counselling at 7 weekly clinic visits, 12 &	Abstinence at 12m	Low

						weeks		24w	(biochem, car)	
Piper 2007 ⁽¹¹⁵⁾	USA	42	NS	58%	608	Bupropion 300mg for 9 weeks, starting 1wk before TQD	Placebo	3x 10 min counselling over 3 weeks	Abstinence at 12m (biochem, pp)	Unclear
Piper 2009 ⁽⁸⁵⁾	USA	45	NS	58%	1504	Bupropion SR (150mg bid, 1 wk pre-quit, 8 wks postquit)	Placebo	7 one-to-one 10-20min counselling sessions	Abstinence at 6m (biochem, pp)	Unclear
Rovina 2009 ⁽¹⁴⁵⁾	Greece	45	NS	40%	205	Bupropion 300mg for 19 weeks	No treatment	Cognitive behavioral group therapy (CBGT), 1 hour weekly for 1 m, then every 3 wks until 19 wks	Abstinence at 12m (biochem, car)	High
Schmitz 2007 ⁽¹⁴⁶⁾	USA	48	NS	100%	154	Bupropion 300mg for 7 weeks	Placebo	Either CBT based on relapse prevention model, or group support therapy, both 7 weekly 60 min meetings, TQD morning of first session, 10 days after start of medications	Abstinence at 12m (biochem, pp)	Low
Selby 2003 ⁽¹⁴⁷⁾	Canada	NR	NS	NS	284	Bupropion 300mg for 12 weeks	Placebo	Not described	Abstinence at 12m (biochem, pp)	Unclear
SMK20001 ⁽¹⁴⁸⁾	USA	42	NS	48%	286	Bupropion 300mg for 7 weeks	Placebo	Not described	Abstinence at 12m (biochem, car)	Unclear
Tonnesen 2003 ⁽¹⁴⁹⁾	Europe, Australia, New Zealand	42	NS	51%	710	Bupropion SR 300mg for 7 weeks	Placebo	Brief motivational support at weekly clinic visits and telephone support during follow up. 11 clinic visits and 10 phone calls scheduled.	Abstinence at 12m (biochem, car)	Low

Uyar 2007 ⁽¹⁵⁰⁾	Turkey	36	NS	19%	131	Bupropion 300mg for 7 weeks	No treatment	Brief counselling on consequences of smoking with follow up for 24 weeks - more than low intensity	Abstinence at 6m (biochem, pp)	High
Zellweger 2005 ⁽¹⁵¹⁾	Europe	40	NS	64%	667	Bupropion SR 300mg for 7 weeks	Placebo	Brief (10-15 min) motivational support at weekly clinic visits and telephone support one day before TQD, 3 days after TQD, monthly during follow up	Abstinence at 12m (biochem, car)	Unclear
Wittchen 2011 ⁽¹¹⁴⁾	Germany	43	NS	48%	467	Bupropion 300mg for 12 weeks	No treatment	CBT of 4-5 one-on-one counselling sessions for 20-30mins	Abstinence at 12m (self, car)	High
EAGLES 2016 ⁽⁹⁸⁾	International	46	NS	66%	4028	Bupropion SR, 150mg x 2/day (titrated for 3 days, then full dose for 11 weeks)	Varenicline 2mg/day for 12 weeks	All participants received counselling (up to 10 mins) at all contacts. Participants were monitored at weeks 1 - 6, 8, 12, 13, 16, 20, 24; contacts were up to 15 face-to-face visits and 11 telephone visits	Abstinence at 6m (biochem, car)	Low

Table 8.15 Included studies from systematic review: bupropion versus varenicline

Study	Setting	Mean age	Ethnicity	Female	Participants	Bupropion	Varenicline	Behavioural support	Outcome	Risk of bias
Cincirpini 2013 ⁽¹³⁰⁾	USA	44	NS	39%	294	Bupropion 150mg/d days 1-3, 300mg/d thereafter for 12 weeks	Varenicline 0.5mg days 1-3, 1mg days 4-7, 2mg thereafter for	10 individual counselling sessions (6 in person, 4 via phone, 240 mins total)	Abstinence at 6m (biochem, car)	Unclear

							12wks			
Gonzales 2006 ⁽¹³⁶⁾	USA	42	NS	46%	1025	Bupropion 300mg for 12 weeks, begun 7 days pre-TOD	Varenicline 2mg/day	Brief (< 10 min) standardised individual counselling at 12 weekly visits during drug phase and 11 clinic/phone visits during follow up, problem solving and relapse prevention	Abstinence at 12m (biochem, car)	Low
Jorenby 2006 ⁽¹⁴¹⁾	USA	42	NS	41%	1027	Bupropion 300mg for 12 weeks	Varenicline 2mg for 12 weeks	Brief (< 10 min) individual counselling at each weekly assessment for 12w & 5 follow-up visits. One telephone call 3 days after quit day	Abstinence at 12m (biochem, car)	Low
Nides 2006 ⁽¹⁴⁴⁾	USA	41	NS	51%	638	Bupropion 300mg for 7 weeks	Varenicline 2mg for 7 weeks	Up to 10 mins counselling at 7 weekly clinic visits, 12 & 24w	Abstinence at 12m (biochem, car)	Low
EAGLES 2016 ⁽⁹⁸⁾	International	46	NS	66%	4028	Bupropion SR, 150mg x 2/day (titrated for 3 days, then full dose for 11 weeks)	Varenicline 2mg/day for 12 weeks	All participants received counselling (up to 10 mins) at all contacts. Participants were monitored at weeks 1 - 6, 8, 12, 13, 16, 20, 24; contacts were up to 15 face-to-face visits and 11 telephone visits	Abstinence at 6m (biochem, car)	Low

Table 8.16 Included studies from systematic review: bupropion versus nicotine replacement therapy (NRT)

Study	Setting	Mean age	Ethnicity	Female	Participants	Bupropion	NRT	Behavioural support	Outcome	Risk of bias
NRT patches										
Gariti 2009 ⁽¹¹⁶⁾	USA	54	NS	57%	260	Bupropion SR for 9 weeks	Nicotine patch for 8 weeks	10 weeks of individual counselling sessions or four 5-10 minute counselling sessions	Abstinence at 12m (biochem, pp)	Low
Jorenby 1999 ⁽⁷⁹⁾	USA	43	NS	52%	893	Bupropion 300mg for 9w from 1w before quit day	Patch 24 hr, 21mg for 6 weeks, tapered for 2 weeks	Brief (< 15 min) individual counselling session at each weekly assessment. One telephone call 3 days after quit day	Abstinence at 12m (biochem, car)	Unclear
Piper 2009 ⁽⁸⁵⁾	USA	45	NS	58%	1504	Bupropion SR (150mg bid, 1 wk pre-quit, 8 wks postquit)	Patch 24 hr, 21, 14 and 7mg titrated down over 8 weeks	7 one-to-one 10-20min counselling sessions	Abstinence at 6m (biochem, pp)	Unclear
Smith 2009 ⁽¹¹⁷⁾	USA	44	NS	56%	1346	Bupropion SR (150mg bid, 1 wk pre-quit, 8 wks postquit)	Patch, 21, 14 and 7mg titrated down over 8 weeks	Quitline counselling - up to 4 calls + additional support if required	Abstinence at 6m (self, pp)	High
Uyar 2007 ⁽¹⁵⁰⁾	Turkey	36	NS	19%	131	Bupropion 300mg for 7 weeks	Patch 21mg for 6 weeks	Brief counselling on consequences of smoking with follow up for 24 weeks- more than low intensity	Abstinence at 6m (biochem, pp)	High
EAGLES 2016 ⁽⁹⁸⁾	International	46	NS	66%	4028	Bupropion SR, 150mg x 2/day (titrated for	Nicotine patch, 21mg x 7 weeks, 14mg x 2	All participants received counselling (up to 10 mins) at all contacts. Participants were monitored at weeks 1	Abstinence at 6m (biochem, car)	Low

						3 days, then full dose for 11 weeks)	wks, 7mg x 2 weeks (11 weeks)	- 6, 8, 12, 13, 16, 20, 24; contacts were up to 15 face-to-face visits and 11 telephone visits		
NRT lozenges										
Study	Setting	Mean age	Ethnicity	Female	Participants	Bupropion dose	NRT dose	Behavioural support	Outcome	Risk of bias
Piper 2009 ⁽⁸⁵⁾	USA	45	NS	58%	1504	Bupropion SR (150mg bid, 1 wk pre-quit, 8 wks postquit)	Lozenge 2 or 4mg for 12 weeks	7 one-to-one 10-20min counselling sessions	Abstinence at 6m (biochem, pp)	Unclear
Smith 2009 ⁽¹¹⁷⁾	USA	44	NS	56%	1346	Bupropion SR (150mg bid, 1 wk pre-quit, 8 wks postquit)	Lozenge 2 or 4mg for 12 weeks	Quitline counselling - up to 4 calls + additional support if required	Abstinence at 6m (self, pp)	High
NRT patch plus lozenge										
Study	Setting	Mean age	Ethnicity	Female	Participants	Bupropion dose	NRT dose	Behavioural support	Outcome	Risk of bias
Piper 2009 ⁽⁸⁵⁾	USA	45	NS	58%	1504	Bupropion SR (150mg bid, 1 wk pre-quit, 8 wks postquit)	Lozenge 2 or 4mg for 12 weeks + 24 hr Patch, 21, 14 and 7mg titrated down over 8 weeks	7 one-to-one 10-20min counselling sessions	Abstinence at 6m (biochem, pp)	Unclear
Smith 2009 ⁽¹¹⁷⁾	USA	44	NS	56%	1346	Bupropion SR (150mg bid, 1 wk pre-quit, 8 wks postquit)	Lozenge 2 or 4mg for 12 weeks + Patch, 21, 14 and 7mg titrated	Quitline counselling - up to 4 calls + additional support if required	Abstinence at 6m (self, pp)	High

							down over 8 weeks			
Any NRT										
Study	Setting	Mean age	Ethnicity	Female	Participants	Bupropion dose	NRT dose	Behavioural support	Outcome	Risk of bias
Stapleton 2013 ⁽¹⁵²⁾	UK	41	NS	53%	1071	Bupropion 300mg for 8 weeks	Choice of patches, gums, lozenges, inhalator, nasal spray or microtab, for 12 weeks	7 weekly behavioural support session, mainly in groups, lasting 60-90 mins each	Abstinence at 6m (biochem, car)	High
Wittchen 2011 ⁽¹¹⁴⁾	Germany	43	NS	48%	467	Bupropion 300mg for 12 weeks	Choice of patch (7-52.5mg), gum (2-4mg) or spray (10mg/ml)	CBT of 4-5 1on1 counselling sessions for 20-30mins	Abstinence at 12m (self, car)	High

Table 8.17 Included studies from systematic review: bupropion versus bupropion plus nicotine replacement therapy (NRT)

Gum										
Study	Setting	Mean age	Ethnicity	Female	Participants	Bupropion	Bupropion+ NRT	Behavioural support	Outcome	Risk of bias
Piper 2007 ⁽¹¹⁵⁾	USA	42	NS	58%	608	Bupropion 300mg for 9 weeks, starting 1wk	4mg nicotine gum, 300mg bupropion	3x 10 min counselling over 3 weeks	Abstinence at 12m (biochem, pp)	Unclear

						before TQD				
Lozenge										
Study	Setting	Mean age	Ethnicity	Female	Participants	Bupropion	Bupropion+ NRT	Behavioural support	Outcome	Risk of bias
Piper 2009 ⁽⁸⁵⁾	USA	45	NS	58%	1504	Bupropion SR (150mg bid, 1 wk pre-quit, 8 wks postquit)	Bupropion SR (150mg bid, 1 wk pre-quit, 8 wks postquit)+Lozenge 2 or 4mg for 12 weeks	7 one-to-one 10-20min counselling sessions	Abstinence at 6m (biochem, pp)	Unclear
Smith 2009 ⁽¹¹⁷⁾	USA	44	NS	56%	1346	Bupropion SR (150mg bid, 1 wk pre-quit, 8 wks postquit)	Bupropion SR (150mg bid, 1 wk pre-quit, 8 wks postquit)+Lozenge 2 or 4mg for 12 weeks	Quitline counselling - up to 4 calls + additional support if required	Abstinence at 6m (self, pp)	High
Any NRT										
Study	Setting	Mean age	Ethnicity	Female	Participants	Bupropion	Bupropion+ NRT	Behavioural support	Outcome	Risk of bias
Stapleton 2013 ⁽¹⁵²⁾	UK	41	NS	53%	1071	Bupropion 300mg for 8 weeks	Bupropion 300mg for 8 weeks + choice of patches, gums, lozenges, inhalator, nasal spray or microtab, for 12 weeks	7 weekly behavioural support session, mainly in groups, lasting 60-90 mins each	Abstinence at 6m (biochem, car)	High
Patch										
Study	Setting	Mean age	Ethnicity	Female	Participants	Bupropion	Bupropion+ NRT	Behavioural support	Outcome	Risk of bias
Jorenby	USA	43	NS	52%	893	Bupropion	Bupropion	Brief (< 15 min)	Abstinence at	Unclear

1999 ⁽⁷⁹⁾						300mg for 9wk from 1wk before quit day	300mg for 9w from 1w before quit day + Patch 24hr, 21mg for 6 weeks, tapered for 2 weeks	individual counselling session at each weekly assessment. One telephone call 3 days after quit day	12m (biochem, car)	
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Table 8.19 Included studies from systematic review: bupropion 300mg versus bupropion 150mg

Study	Setting	Mean age	Ethnicity	Female	Participants	Bupropion dose	Bupropion dose	Behavioural support	Outcome	Risk of bias
Swan 2003 ⁽¹⁵³⁾	USA	45	NS	57%	1524	Bupropion 300mg	Bupropion 150mg	4 telephone calls + quitline + self-help material or self-help + support line + 1 telephone call	Abstinence at 12m (biochem, pp)	High
Hurt 1997 ⁽¹⁴⁰⁾	USA	44	NS	55%	615	Bupropion 300mg for 7 weeks	Bupropion 150mg for 7 weeks	Physician advice, self-help materials, and brief individual counselling by study assistant at each visit	Abstinence at 12m (biochem, car)	Unclear

Table 8.20 Included studies from systematic review: varenicline versus placebo

Study	Setting	Mean age	Ethnicity	Female	Participants	Varenicline	Control	Behavioural support	Outcome	Risk of bias
Cinciripini 2013 ⁽¹³⁰⁾	USA	44	66% White	39%	294	12 weeks varenicline 0.5mg/day days 1-3, 1.0mg/day days 4-7, 2.0mg/day	Placebo	10 individual counselling sessions (6 in person, 4 via phone, 240mins total)	Abstinence at 6m (biochem, car)	Unclear

						thereafter				
Gonzales 2006 ⁽¹³⁶⁾	USA	42	79% White	46%	1025	Varenicline 2mg/day for 12 weeks	Placebo	Brief (<10 min) standardised individual counselling at 12 weekly visits during drug phase and 11 clinic/phone visits during follow up, problem solving and relapse prevention	Abstinence at 12m (biochem, car)	Low
Jorenby 2006 ⁽¹⁴¹⁾	USA	43	84% White	42%	1027	Varenicline 2mg/day for 12 weeks	Placebo	Brief (< 10 min) individual counselling at each weekly assessment for 12w and 5 follow-up visits. One telephone call 3 days after quit day	Abstinence at 12m (biochem, car)	Low
Nides 2006 ⁽¹⁴⁴⁾	USA	42	87% White	52%	638	Varenicline 2mg for 7 weeks	Placebo	Up to 10 mins counselling at 7 weekly clinic visits, 12 and 24w	Abstinence at 12m (biochem, car)	Low
Bolliger 2011 ⁽¹⁵⁴⁾	Internatio nal	44	NS	34%	593	Varenicline 2mg/day for 12 weeks	Placebo	All participants received 'You can quit smoking' self-help booklet at baseline, and brief counselling (≤10 mins) at each clinic or telephone contact, plus a phone call 3 days post-TQD	Abstinence at 6m (biochem, car)	Low
Nakamura 2007 ⁽¹⁵⁵⁾	Japan	40	NS	25%	619	Varenicline 2mg/day for 12 weeks	Placebo	All participants received a smoking cessation booklet 'Clearing the Air' at baseline, + brief counselling (≤10 mins) at each clinic visit. Weekly visits throughout treatment phase, plus a 5 min phone call at TQD	Abstinence at 12m (biochem, car)	Low

								and +3 days post-TQD		
Niaura 2008 ⁽¹⁵⁶⁾	USA	42	91% White	48%	320	Varenicline 0.5 to 2mg/day for 12 weeks	Placebo	All participants received a smoking cessation booklet 'Clearing the Air' at baseline, + brief counselling (≤10 mins) at each clinic visit. Weekly visits throughout treatment phase	Abstinence at 12m (biochem, car)	Low
Oncken 2006 ⁽¹⁵⁷⁾	USA	43	80% White	50%	647	Varenicline 2mg/day for 12 weeks	Placebo	All groups received self- help booklet at baseline, + brief (≤10mins) counselling at weekly clinic visits throughout treatment phase, and phone call 3d post-TQD. At each visit smoking status reported and CO- verified; vital signs, weight and adverse events. Urine, blood tests and ECGs at screening, baseline, wks 1, 2, 4, 7 and 12	Abstinence at 12m (biochem, car)	Low
Rennard 2012 ⁽¹⁵⁸⁾	Internatio nal	43	68% White	40%	659	Varenicline 2mg/day for 12 weeks	Placebo	All participants received 'Clearing the Air: Quit smoking today' booklet at baseline, + brief counselling (≤10 mins) at each clinic visit. Weekly visits throughout treatment phase and in follow-up phase clinic visits at wks 13, 16, 20 and 24. Phone calls at wks 14, 18 and 22	Abstinence at 6m (biochem, car)	Low

Tsai 2007 ⁽¹⁵⁹⁾	Taiwan and Korean	40	NS	11%	250	Varenicline 2mg/day for 12 weeks	Placebo	All participants received a smoking cessation booklet 'Clearing the Air' at baseline, + brief counselling (≤10 mins) at each clinic visit. Clinic visits at baseline and at wks 1, 2, 3, 4, 6, 8, 10, 12, plus a 5 min phone call at +3 days post-TQD, and at wks 5, 7, 9, 11	Abstinence at 6m (biochem, car)	Low
Wang 2009 ⁽¹⁶⁰⁾	China, Singapore Thailand	39	NS	3%	333	Varenicline 2mg/day for 12 weeks	Placebo	All participants received a smoking cessation booklet at baseline, + brief counselling (≤10 mins) at each clinic visit, except for wks 5 and 7, when counselling was conducted by phone	Abstinence at 6m (biochem, car)	Unclear
DeDios 2012 ⁽¹⁶¹⁾	USA	42	Latino	53%	32	Varenicline for 12 weeks	Placebo	30-minute face-to-face 'culturally informed' smoking cessation behavioural intervention, + a non-tailored self-help brochure, all available in both English and Spanish	Abstinence at 6m (biochem, pp)	Unclear
EAGLES 2016 ⁽⁹⁸⁾	Internatio nal	46	NS	66%	4028	Varenicline 2mg/day for 12 weeks	Placebo	All participants received counselling (up to 10 mins) at all contacts. Participants were monitored at weeks 1-6, 8, 12, 13, 16, 20, 24; contacts were up to 15 face-to-face visits and 11 telephone visits	Abstinence at 6m (biochem, car)	Low

Gonzales 2014 ⁽¹⁶²⁾	International	48	93% White	50%	498	Varenicline 12 wks, titrated in 1st wk, 1mg x 2/day	Placebo	Brief (< 10 mins) counselling at each contact. TOD set for wk 1 visit. Clinic visits at wks 1-4, 6, 8-13, 16, 24, 32, 40, 48, 52. Brief phone calls at wks 5, 7, 14, 20, 36, 44	Abstinence at 12m (biochem, car)	Low
Heydari 2012 ⁽¹⁶³⁾	Iran	43	NS	41%	272	Varenicline 2mg/day for 8 weeks	No treatment	All received brief (5 mins) education and counselling at 4 x weekly sessions	Abstinence at 12m (biochem, pp)	High
Long-term use										
Study	Setting	Mean age	Ethnicity	Female	Participants	Varenicline	Control	Behavioural support	Outcome	Risk of bias
Williams 2007 ⁽¹⁶⁴⁾	USA, Australia	47	89% White	50%	377	Varenicline 2mg/day for 52 weeks	Placebo	Weekly visits throughout wks 1-8, then every 4 wks to wk 52, + wk 53 assessment	Abstinence at 12m (biochem, pp)	Unclear
Ebbert 2015 ⁽¹⁶⁵⁾	International	44	NS	44%	1510	Varenicline for 24 weeks	Placebo	All participants asked to reduce their smoking rate by 50% by wk 4, by 75%+ by wk 8, and 100% by wk 12. Individual 10-minute counselling at each visit (18 face-to-face and 10 phone calls), + a self-help book	Abstinence at 12m (biochem, car)	Low
NCT00828113 ⁽¹⁶⁶⁾	USA	43	NS	43%	101	52-week varenicline therapy (2mg/day)	13 weeks of varenicline therapy (2mg/day)	Individual smoking cessation counselling. Brief (<10 minutes) smoking cessation counselling delivered at clinic visits	Abstinence at 12m (biochem, pp)	High

Table 8.21 Included studies from systematic review: varenicline versus NRT

Study	Setting	Mean age	Ethnicity	Female	Participants	Varenicline dose	Patch dose	Behavioural support	Outcome	Risk of bias
Aubin 2008 ⁽¹⁶⁷⁾	Europe & USA	43	93% White	51%	757	Varenicline 2mg for 12 weeks	Patch 21mg week 2-6, 14mg weeks 7-9, 7mg weeks 10-11	Self-help booklet at baseline, and brief counselling (≤ 10 mins) at each clinic visit or by phone . TQD was at wk 1 visit. Weekly visits throughout treatment phase, plus a phone call 3 days post-TQD	Abstinence at 6 months (biochem, car)	High
Baker 2016 ⁽¹⁶⁸⁾	USA	48	67% White	52%	1086	Varenicline 2mg for 12 weeks	Patch 21mg wks 1-8, 14mg weeks 9-10, 7mg weeks 11-12 (11+ CPD): Patch 14mg wk 1-10, 7mg wks 11-12 (5-10 CPD)	All participants received counselling (20 mins at visits 1, 2 and 3, and 10 mins by phone and at visits 4, 5) at 1 week pre-TQD and at TQD, wks 1, 4, 12 post-TQD, plus phone call at wk 8. In follow-up phase, participants were contacted at wks 26 and 52 by phone	Abstinence at 6 months (biochem, car)	High
DeDios 2012 ⁽¹⁶¹⁾	USA	42	Latino	53%	32	Varenicline for 12 weeks	Patch 12 wks: 4 wks @ 14mg, 8 wks @ 7mg	30-minute face-to-face 'culturally informed' smoking cessation behavioural intervention, + a non-tailored self-help brochure, all available in both English and Spanish	Abstinence at 6m (biochem, pp)	Unclear
EAGLES 2016 ⁽⁹⁸⁾	International	46	NS	66%	4028	Varenicline 2mg/day for 12 weeks	Patch, 21mg x 7 weeks, 14mg x 2 wks, 7mg x 2	All participants received counselling (up to 10 mins) at all contacts. Participants were	Abstinence at 6m (biochem, car)	Low

							weeks (11 weeks)	monitored at weeks 1-6, 8, 12, 13, 16, 20, 24; contacts were up to 15 face-to-face visits and 11 telephone visits		
Heydari 2012 ⁽¹⁶³⁾	Iran	43	NS	41%	272	Varenicline 2mg/day for 8 weeks	Patch: 8 wks of 15mg	All received brief (5 mins) education and counselling at 4 x weekly sessions	Abstinence at 6m (biochem, pp)	High
Tsukahara 2010 ⁽¹⁶⁹⁾	Japan	46	NS	25%	32	Varenicline 1.0mg x 2/day for 12 wks, following 1 wk titration	Patch for 8 wks (52.5mg/day for 4 wks, 35mg/day for 2 wks, 17.5mg/day for 2 wks)	Varenicline group received 8 clinic visits and nicotine group 5 visits over 12 wks, with 5 brief counselling sessions (≤ 10 mins)	Abstinence at 6m (self car)	High
NRT patch and lozenge										
Study	Setting	Mean age	Ethnicity	Female	Participants	Varenicline	Patch + lozenge	Behavioural support	Outcome	Risk of bias
Baker 2016 ⁽¹⁶⁸⁾	USA	48	67% White	52%	1086	Varenicline 2mg for 12 weeks	Patch (21mg week 1-8, 14mg weeks 9-10, 7mg weeks 11-12 (11+ CPD) : Patch 14mg week 1-10, 7mg weeks 11-12 (5-10 CPD)) + Lozenge (2mg or 4mg 5 id for 12 weeks)	All participants received counselling (20 mins at visits 1, 2 and 3, and 10 mins by phone and at visits 4, 5) at 1 week pre-TOD and at TOD, wks 1, 4, 12 post-TOD, plus phone call at wk 8. In follow-up phase, participants were contacted at wks 26 and 52 by phone	Abstinence at 6 months (biochem, car)	High

Table 8.22 Included studies from systematic review: varenicline versus bupropion

Study	Setting	Mean age	Ethnicity	Female	Participants	Varenicline	Bupropion	Behavioural support	Outcome	Risk of bias
EAGLES 2016 ⁽⁹⁸⁾	International	46	NS	66%	4028	Varenicline 2mg/day for 12 weeks	Bupropion SR, 150mg x 2/day (titrated for 3 days, then full dose for 11 weeks)	All participants received counselling (up to 10 mins) at all contacts. Participants were monitored at weeks 1-6, 8, 12, 13, 16, 20, 24; contacts were up to 15 face-to-face visits and 11 telephone visits	Abstinence at 6m (biochem, car)	Low
Gonzales 2006 ⁽¹³⁶⁾	USA	42	79% White	46%	1025	Varenicline 2mg/day for 12 weeks	Bupropion 150mg x 2/day for 12 weeks	Brief (<10 min) standardised individual counselling at 12 weekly visits during drug phase and 11 clinic/phone visits during follow up, problem solving and relapse prevention	Abstinence at 12m (biochem, car)	Low
Jorenby 2006 ⁽¹⁴¹⁾	USA	42	NS	41%	1027	Varenicline 2mg for 12 weeks	Bupropion 300mg for 12 weeks	Brief (< 10 min) individual counselling at each weekly assessment for 12w & 5 follow-up visits. One telephone call 3 days after quit day	Abstinence at 12m (biochem, car)	Low
Nides 2006 ⁽¹⁴⁴⁾	USA	41	NS	51%	638	Varenicline 2mg for 7 weeks	Bupropion 300mg for 7 weeks	Up to 10 mins counselling at 7 weekly clinic visits, 12 & 24w	Abstinence at 12m (biochem, car)	Unclear
Cinciripini 2013 ⁽¹³⁰⁾	USA	44	66% White	39%	294	Varenicline 0.5mg days 1-3, 1mg days 4-7, 2mg thereafter for	Bupropion 150mg/d days 1-3, 300mg/d thereafter for	10 individual counselling sessions (6 in person, 4 via phone, 240 mins total)	Abstinence at 6m (biochem, car)	Unclear

						thereafter for 12 weeks	12 weeks			
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Table 8.23 Included studies from systematic review: cytisine versus placebo

Study	Setting	Mean age	Ethnicity	Female	Participants	Cytisine	Control	Behavioural support	Outcome	Risk of bias
Scharfenberg 1971 ⁽¹⁷⁰⁾	East Germany	NS	NS	12%	1214	20-day course. 1.5mg tabs: Days 1-3 6/day; days 4-12 5/day; days 13-16 4/day; days 17-20 3/day	Placebo	None	Abstinence at 24m (self reported pp)	Unclear
Vinnikov 2008 ⁽¹⁷¹⁾	Kyrgyzstan	39	NS	3%	197	25-day course. 1.5mg tabs: First 3 days: 6 tabs per day; reduce smoking by half. Days 4-12: 5 tabs per day; stop smoking completely. Days 13-16: 4 tabs per day. Days 17-20: 3 tabs per day. Days 21-22: 2 tabs per day. Days 23-25: 1 tab per day	Placebo	Behaviour counselling	Abstinence at 6m (biochem car)	Low
West 2011 ⁽¹⁷²⁾	Poland	48	NS	53%	740	25-day course. 1.5mg tabs: First 3 days: 6 tabs per day. Days 4-12: 5 tabs per day. Days 13-16: 4 tabs per day. Days 17-20: 3	Placebo	Quitting advice, randomisation and drugs dispensed at baseline visit; phone calls at TQD + 1 wk	Abstinence at 12m (biochem car)	Low

						tabs per day. Days 21-22: 2 tabs per day. Days 23-25: 1 tab per day		later (+ optional clinic visit). Clinic visit 4wks post-TQD, then phone calls at 6m and 12m, with visit to confirm abstinence if claimed. Behavioural support was minimal		
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Table 8.24 Included studies from systematic review: cytisine versus NRT

Study	Setting	Mean age	Ethnicity	Female	Participants	Cytisine	NRT	Behavioural support	Outcome	Risk of bias
Walker 2014 ⁽¹⁷³⁾	New Zealand	38	Maori	57%	1310	Cytisine for 25 days + NRT vouchers if they needed them after 25 days	Choice of NRT (patch/gum/lozenge) for 8 weeks	Quitline support (3 10-15 minute calls over 8 weeks)	Abstinence at 6m (self reported, car)	High

Table 8.25 Included studies from systematic review: acupuncture versus sham acupuncture or no treatment

Study	Setting	Participants	Mean age	Ethnicity	Female	Intervention dose	Control dose	Other support	Outcome	Risk of bias
Clavel 1992 ⁽¹⁷⁾	France	515	>18	NS	NS	Facial acupuncture to two points (GB8 and Bitong)	Sham acupuncture (wrong)	Both groups received placebo nicotine gum	Abstinence at 13m (self, car)	Unclear

							points 2cm from the active sites)			
Clavel 1992 +NG ⁽¹⁷⁾	France	481	>18	NS	NS	Facial acupuncture to two points (GB8 and Bitong)	Sham acupuncture (wrong points 2cm from the active sites)	Both groups received active nicotine gum (2mg dose, up to 30 pieces/day, during first 6 months)	Abstinence at 13m (self, car)	Unclear
Cottraux 1983 ⁽¹⁷⁴⁾	France	558	18-50	NS	NS	Facial acupuncture, 3 weekly sessions	Waiting list control (assessed at 12 months only)	NR	Abstinence at 12m (self, car)	High
Gillams 1984 ⁽¹⁷⁵⁾	UK	81	NS	NS	NS	Indwelling needle in active auricular point ('Lung') for 4 weeks	Indwelling needle in inactive auricular point (as far from 'Lung' as possible) for 4 weeks	NR	Abstinence at 6m (self, car)	Low
He 1997 ⁽¹⁷⁶⁾	Norway	46	NS	NS	NS	Combined body & auricular acupuncture. Genuine points described for smoking cessation: Body: LU6, LU7; Ear: Shenmen, mouth, lung; Ear sustained acupressure: Shenmen, mouth,	Sham points described for treating musculoskeletal conditions: Body: LI10, TE8; Ear: knees, lumbar	Both groups received combination of body electroacupuncture, ear acupuncture and ear acupressure. 6 treatments over 3 weeks	Abstinence at 8m (biochem, pp)	Low

						lung, trachea, hunger, endocrine	vertebra, neck; Ear sustained acupressure: knees, lumbar vertebra, neck, shoulder, shoulder joint, buttock			
Lamontagne 1980 ⁽¹⁷⁷⁾	Canada	75	20-50	NS	NS	Acupuncture to auricular points ('Zero' and 'Lung')	Self-monitor and report back	All subjects given 2 appointments 1 week apart. All smokers also given written advice on smoking cessation	Abstinence at 6m (self, pp)	Unclear
Leung 1991 ⁽¹⁷⁸⁾	Hong Kong	95	NS	NS, Asian	NS	Indwelling needles in auricular points ('Shenmen' and 'Lung') checked every 7 days; Introductory information sessions followed by 8 attendances in total, for supervision of needles	Waiting list control	NR	Abstinence at 6m (self, pp)	High
Martin 1981a ⁽¹⁷⁹⁾	New Zealand	126	NS	NS	NS	Indwelling needles to 'effective' auricular points (lung and hunger) for 3 weeks	Indwelling needles to 'ineffective' auricular points (elbow and	NR	Abstinence at 6m (self, pp)	Unclear

							eye)			
Martin 1981b ⁽¹⁷⁹⁾	New Zealand	126	NS	NS	NS	Combined body & auricular acupuncture indwelling needles to 'effective' auricular points (lung and hunger) for 3 weeks plus electroacupuncture for 20 minutes to LI4 in the hand and tongue point in the ear at the second attendance	Indwelling needles to 'ineffective' auricular points (elbow and eye) plus electroacup uncture for 20 minutes to LI4 in the hand and tongue point in the ear at the second attendance	NR	Abstinence at 6m (self, pp)	Unclear
Vandevenne 1985 ⁽¹⁸⁰⁾	France	200	NR	NS	NS	Combined body & auricular acupuncture to 3 auricular and 2 body points	Sham acupunctur e to nearby areas	Both interventions given on days 1, 4, 10 and 20	Abstinence at 12m (self, pp)	Low
Waite 1998 ⁽¹⁸¹⁾	UK	78	>18	NS	NS	Active group, lung point in ear	Control group, medial aspect of the patella, not on recognised acupunctur e point	All smokers received structured counselling and written information before randomisation	Abstinence at 6m (biochem, pp)	Low
Wu 2007 ⁽¹⁸²⁾	Taiwan	131	≥18	NS, Asian	NS	'Real' points Shenmen, Lung,	'Irrelevant' points eye,	NR	Abstinence at 6m (self, pp)	Low

						Mouth, Sympathetic (auricular and active states on pg 9)	elbow, shoulder, knee			
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Table 8.26 Included studies from systematic review: Acupuncture versus NRT

Study	Setting	Participants	Mean age	Ethnicity	Female	Intervention dose	NRT dose	Other support	Outcome	Risk of bias
Clavel 1992 ⁽¹⁷⁾	France	515	>18	NS	NS	Facial acupuncture to two points (GB8 and Bitong)	2mg nicotine gum	NR	Abstinence at 13m (self, car)	Unclear
Clavel 1985 ⁽¹⁶⁾	France	651	NS	NS	NS	Facial acupuncture using 2 points bilaterally, single session	2mg nicotine gum	All groups also received 3 one-hour sessions of group therapy in first month	Abstinence at 13m (self, car)	Unclear

Table 8.27 Included studies from systematic review: Acupuncture versus counselling/psychological intervention

Study	Setting	Participants	Mean age	Ethnicity	Female	Intervention	Control	Other support	Outcome	Risk of bias
Cottraux 1983 ⁽¹⁷⁴⁾	France	558	18-50	NS	NS	Facial acupuncture, 3 weekly sessions	Behavioural therapy, 3 weekly sessions	NS	Abstinence at 12m (self, car)	High
Gillams 1984 ⁽¹⁷⁵⁾	UK	81	NS	NS	NS	Indwelling needle in active auricular point ('Lung') for 4 weeks	Group therapy sessions, 1 hr/wk for 4 weeks	NS	Abstinence at 6m (self, car)	Low
Leung 1991 ⁽¹⁷⁸⁾	Hong Kong	95	NS	Asian	NS	Indwelling needles in auricular points ('Shenmen' and 'Lung')	10 daily sessions of behavioural therapy lasting 1.5 hours	NS	Abstinence at 6m (self, pp)	High

Table 8.28 Included studies from systematic review: group behavioural therapy (n=34)

Study	Setting	Participants	Mean age	Ethnicity	Female	Intervention dose	Control dose	Other support	Outcome	Risk of bias
Bakkevig 2000 ⁽¹⁸³⁾	Norway	139	44	NS	67%	Group therapy; participants asked to attend 'Smokenders' . 7 weekly sessions + 1 follow up 4w later. Quit day after 5w. Multifaceted including cognitive therapies	Physician (GP) advice; participants instructed to visit their GP for support. GP told to offer NRT as appropriate and provide 1 follow-up visit		Abstinence 1 yr post-quit date Biochem	Unclear
Batra 1994 ⁽¹⁸⁴⁾	Germany	232	41	NS	53%	Group therapy, 9 weekly 90 min sessions	Self-help materials	Both conditions received nicotine patch	Continuous abstinence at 12m SR	Unclear
Camarells 2002 ⁽¹⁸⁵⁾	Spain	106	47	NS	54%	Group therapy, 7 x2hrs over 3w, TOD after w3	Individual counselling, not matched for intensity, 2 sessions over 2w, with self-help materials	72 participants eligible for nicotine patch, 53 used.	Sustained abstinence at 6m SR	Unclear
Cottraux 1983 ⁽¹⁷⁴⁾	France	558 (418 in arms of interest)	NS	NS	24%	Behaviour therapy. Includes discussion, training in relaxation. 3 x 3 hr sessions over 2 weeks. Relaxation and stress-desensitisation audiotape for daily use	Placebo - lactose capsules for 2w. Met 2 x10min with a doctor		Abstinence at 12m SR	Unclear

Cottraux 1983 ⁽¹⁷⁴⁾	France	558 (418 in arms of interest)	NS	NS	24%	Behaviour therapy. Includes discussion, training in relaxation. 3 x 3 hr sessions over 2 weeks. Relaxation and stress-desensitisation audiotape for daily use	1 year waiting list control		Abstinence at 12m SR	Unclear
Curry 1988 ⁽¹⁸⁶⁾	USA	139	41	NS	51%	Relapse prevention group. Focused on smoking as learned behaviour. Quit day at 3rd session. Additional elements included identifying high-risk situations, cognitive restructuring and role playing. AND ' Absolute Abstinence ' (AA) group. Focused on addictive component of smoking. Quit day at 5th session. Additional elements included focused smoking, health education and contingency contract	Relapse prevention self help, workbook units absolute abstinence self help		Abstinence from months 9 to 12 of follow up. Biochem	Unclear

DePaul 1987 ⁽¹⁸⁷⁾	USA	233	43	NS	72%	Twice weekly 45 min group meetings for 3w	Self help alone		Abstinence at 12m (multiple PP) SR	Unclear
DePaul 1989 ⁽¹⁸⁸⁾	USA	419	38	NS	63% in groups, 54% in S-H.	6 x twice-weekly group meetings to coincide with the 3w television series, then monthly meetings for 1 yr. Abstinent smokers and 5 of their family and 5 co-workers entered for a lottery at the final group meeting and 12m follow up	Self-help manuals only		Abstinence from end of programme to 12m Biochem	Unclear
DePaul 1994 ⁽¹⁸⁹⁾	USA	564	38	NS	58%	6 group meetings over 3w followed by 14 booster meetings over 6m. Incentive payments. Handouts from same self-help manual. Maintenance manual (ALA A Lifetime of Freedom from Smoking)	Self-help manual and incentive payment of US\$1 for each day abstinent up to US\$175	Worksite interventions were timed to coincide with a mass media intervention consisting of a week-long smoking cessation series on TV, and a complementary	Sustained abstinence at 12m Biochem	Unclear

								newspaper supplement		
Garcia 1989 ⁽²³⁾	Spain	68	34	NS	41%	Group therapy, 7 sessions over 3m	Individual counselling in clinic, same schedule as groups	Both received NG 2mg	Sustained abstinence (quit at previous follow ups) at 6m Biochem	Unclear
Garcia 2000 ⁽¹⁹⁰⁾	Spain	162	32	NS	52%	1. Multi-component programme, 10x 1hr sessions over 5w AND 2. Multi-component, 5x 1hr over 5w AND 3. As 2 plus self-help manual	4. Self-help manual, 1 orientation session		PP (7 day) abstinence at 12m Biochem	Unclear
Ginsberg 1992 ⁽¹⁹¹⁾	USA	99	38	NS	54%	Nicotine gum and behavioural programme including skill training, 5 sessions over 4w AND Nicotine gum and behavioural programme and partner support programme, 8 sessions over 5w	Nicotine gum and educational materials, 2 sessions over 2 weeks		Abstinence at 52w (not clear if abstinence required at prior assessment at weeks 4, 12, 26) 2&3v1 Biochem	Unclear

Glasgow 1981 ⁽¹⁹²⁾	USA	88 (85 included in analysis)	NS	NS	NS	Therapist-administered programme based on either Danaher & Lichtenstein manual, Pomerleau & Pomerleau manual or I Quit Kit . 8 sessions over 8w	Self- administered using same 3 manuals		Abstinence at 6m Biochem	Unclear
Gruder 1993 ⁽¹⁹³⁾	USA	1440	NS	NS	NS	1. Social Support. 3 x90 min group meetings and copy of 'Quitters Guide' for smokers, and 1 group meeting + Buddy Guide for buddies. Participants were instructed on how to get help from their buddies and others. Telephone calls to subjects and buddies at 1 and 2m AND 2. Discussion. Same schedule of meetings and phone calls as 1, but general information and review of self-help manual	3. No-contact control	All participants sent 'ALA Freedom from Smoking in 20 days' manual and instructed to watch TV programme	Multiple point prevalence abstinence (post- intervention , 6m and 12m). 24m rates also given but substantial loss to follow up by this time so 12m rates used here.	Unclear

Hill 1993 ⁽¹⁹⁴⁾	USA	82	50+	NS	NS	1. Behavioural training adapted from Lung Health Study programme. Included quit date setting, training with role play of coping responses. 12 x 90 min session over 3m	2. Exercise and self-help pamphlet. This was a placebo control matched for contact time to 3. Therapist, who was blind to study hypothesis, encouraged smokers to quit at the exercise meetings		5 day abstinence at 12m. (Abstinence at previous follow ups not required) Biochem	Unclear
Hilleman 1993 ⁽¹⁹⁵⁾	USA	150	50	NS	67%	1. Behaviour modification training, 12 x 1hr classes over 3m + transdermal clonidine 2. Same behaviour modification as 1, plus placebo patches	3. Self-help printed material (I Quit Kit), transdermal clonidine AND 4. S-H printed material, placebo patches		Cessation at 1 yr SR	Unclear
Hollis 1993 ⁽¹⁹⁶⁾	USA	2707	NS	NS	NS	3. Group referral. Cessation advice, CO assessment. Video encouraged use of intensive (9 meetings over 2m) group programme, and waiver of fee. Effort made to schedule attendance	2. Self quit - cessation advice, CO assessment, 10 min video, stop smoking kit, and choice of self-help manuals. Encouraged to set quit date. 1 follow-up telephone call and mailings	Smokers who received provider (physician, physician assistant or nurse practitioner) advice to quit	1 yr 2-PP abstinence (7 days at 3 and 12m) Biochem	High

Hollis 1993 ⁽¹⁹⁶⁾	USA	2707	NS	NS	NS	3. Group referral. Cessation advice, CO assessment. Video encouraged use of intensive (9 meetings over 2m) group programme, and waiver of fee. Effort made to schedule attendance	1. Advice - In addition to provider advice, given brief pamphlet by health counsellor	Smokers who received provider (physician, physician assistant or nurse practitioner) advice to quit		
Jorenby 1995 ⁽¹⁹⁷⁾	USA	504	44	NS	53%	Group: Given self-help pamphlet at screening visit along with motivational message. Received 8x 1hr weekly group sessions. Skills training, problem-solving skills	Individual: Given self-help pamphlet at screening visit along with motivational message. Also met nurse counsellor x3 following quit date. Nurse helped generate problem-solving strategies and provided praise and encouragement	Compared 22mg vs 44mg nicotine patch and 3 types of adjuvant treatment. Patch groups collapsed. All participants had 8 weekly assessments by research staff	7 day PP abstinence at 26w Biochem	Unclear

Leung 1991 ⁽¹⁷⁸⁾	Hong Kong	95 (65 in relevant arms)	37	NS, Asian	26%	Behavioural programme including self monitoring, management techniques, coping skills. 10 x 1½ hr sessions over 2w	Waiting list control		Abstinence (not defined) at 6m SR	Unclear
McDowell 1985 ⁽¹⁹⁸⁾	Canada	366	36	NS	60%	Operation Kick-It programme. 9 sessions. Therapists: public health nurse or health educator and 3. Cognitive Behavior Modification programme. 9 sessions. Therapists: 1 of 2 M. Educational psychologists	Physician advice by one of 12 family physicians. 15 min counselling session with U.S. 'NCI Helping Smokers Quit Kit' and one postal follow up		Abstinence (over 1w diary period) at 12m SR	Unclear
McDowell 1985 ⁽¹⁹⁸⁾	Canada	366	36	NS	60%	Operation Kick-It programme. 9 sessions. Therapists: public health nurse or health educator and 3. Cognitive Behavior Modification programme. 9 sessions. Therapists: 1 of 2 M. Educational psychologists	Self-monitoring control followed up at 2, 6 and 12m			

Minthorn-Biggs 2000 ⁽¹⁹⁹⁾	Canada	75	41	NS	68%	1. Canadian Lung Association Countdown programme. 7 weekly sessions and 2. Social interaction programme. 12 sessions over 6w + 4 weekly. Skills training	3. No-treatment control		Abstinence at 6m (12m rates only available for groups 1 and 2) SR	Unclear
Nevad 1997 ⁽²⁰⁰⁾	USA	93	44	Hispanic	48%	Group therapy. 8 x 2 hrs. Included videos using culturally specific components. Motivation, nicotine fading, quitting techniques, RP, 'buddy' support. TQD 5th week	Self help with one group session for motivation and instructions and telephone contact. ALA Freedom from Smoking in 20 days in English and Spanish, also Guia para Dejar de Fumar	Both conditions received same maintenance programme ; ALA self-help manual 'A Lifetime of Freedom from Smoking' and 2 telephone calls a month for 6m	Abstinence at 12m (sustained from post-treatment). PP rates also reported. (excludes 56 people, 35 Gr, 21 S-H who were randomised but did not attend any session and were not included in further analysis); Biochem valid	Unclear

Omenn 1988 ⁽²⁰¹⁾	USA	159	43	NS	44%	1. Multiple component programme. 3 sessions over 3w. Didactic format and 2. relapse prevention programme. 8 sessions over 8w. Interactive format, choice of immediate or phased quit	3. Minimal treatment programme. self-help materials only. ACS 22-page Quitter's Guide 7-day plan		Abstinence at 12m (single PP) Biochem	Unclear
Otero 2006 ⁽⁹⁴⁾	Brazil	1199 (includes 254 non-attenders)	42	NS	63%	2. Cognitive behavioural, 1 or 2 weekly x1 hr sessions AND 3. As 2, with 3 or 4 weekly sessions	1. Single 20 min session - classified as brief intervention control in meta-analysis	No patch in comparison 5 levels of behavioural support collapsed into 3 for analysis. Maintenance or recycling sessions provided to all groups at 3, 6, 12m	Abstinence at 12m (7 day PP) SR	Low

Otero 2006 ⁽⁹⁴⁾	Brazil	1199 (includes 254 non-attenders)	42	NS	63%	2. Cognitive behavioural, 1 or 2 weekly x1 hr sessions AND 3. As 2, with 3 or 4 weekly sessions	1. Single 20 min session-classified as brief intervention control in meta-analysis	Patch in comparison Factorial design with NRT 21mg or 14mg patch for 8w incl tapering and 5 levels of behavioural support collapsed into 3 for analysis. Maintenance or recycling sessions provided to all groups at 3, 6, 12m	Abstinence at 12m (7 day PP) SR	Low
Pederson 1981 ⁽²⁰²⁾	USA	40	39	NS	60%	1. Pomerleau & Pomerleau manual, an introductory session, followed by 1 hr group meetings at 2 and 6w AND 2. Danaher & Lichtenstein manual and same schedule of meetings as 1	3. Waiting list control		Abstinence at 6m for at least 3m SR	Unclear

Pisinger 2005 ⁽²⁰³⁾	Denmark	2408	46	NS	40%	1. 'Low intensity': single 15-45 min session of individual lifestyle counselling using motivational interviewing	2. 'High intensity': as 1 plus offer of participation in 6 session group course over 5m. Option to consider and be invited again in 3m		PP abstinence at 5 yrs (follow up at 1 and 3 yrs also) Biochem	Unclear
Rabkin 1984 ⁽²⁰⁴⁾	Canada	168 (67 in relevant arms)	40	NS	NS	Behaviour modification. Multi-component, 5 x 45-90 min meetings over 3w	Health Education. Single group meeting with didactic lectures by a health professional, film, discussion. Individual session with a therapist 1w later including a counselling element		Self-reported abstinence via questionnaire at 6m follow up SR	
Romand 2005 ⁽²⁰⁵⁾	France	228	42	NS	54%	Five Day Plan; 5 sessions on consecutive nights, and supplementary sessions 1-2w later	Control; 1hr of general information on tobacco-related health problems		Abstinence at 12m, lapse-free (PP also reported) Biochem	Unclear

Slovinec 2005 ⁽²⁰⁶⁾	Canada	332	40	NS	100%	As control, plus Stress Management Training. 8 x 2 hr, 2 & 1w before TQD, 1,2,3,4,5,7w after. CBT targeted smoking-specific and life stressors	'Usual care' 3 x15 min physician visits, 2w before & 4 & 8w after TQD. Nicotine patch, S-H materials		Abstinence at 12m (7 day PP) Biochem	Low
Zheng 2007 ⁽²⁰⁷⁾	China	232	56 (int), 53 (control)	NS, Asian	6%	Social cognitive group intervention, 5 x 2 hr twice weekly sessions	Waiting list control		Sustained abstinence at 6m Biochem	High

Table 8.29 Included studies from systematic review: individual behavioural counselling

Study	Setting	Participants	Mean age	Ethnicity	Female	Intervention	Control	Other support	Outcome	Risk of bias
Ahluwalia 2006 ⁽¹¹⁾	USA	755	45	African American	67%	Counselling using motivational interviewing approach. 3 in-person visits at randomisation, wk1, wk8, and phone contact at wk3, wk6, wk16, self-help materials	Counselling using health education approach. Same schedule & materials as intervention		PP abstinence at 6m (7 day PP) Biochem	Low
Aleixandre 1998 ⁽²⁰⁸⁾	Spain	48	36	NS	65%	'Advanced', 4 x30 min over 4 wks, video, cognitive therapy, social influences, relapse prevention	'Minimal' 3 min advice immediately after randomisation		Abstinence at 12m, SR	Unclear

Aveyard 2007 ⁽²⁰⁹⁾	UK	925	43	NS	51%	Weekly support; as control, plus additional call at 10 days and visits at 14 and 21 days	Basic support; 1 visit (20-40 mins) before quit attempt, phone call on TQD, visits/ phone calls at 7-14 days & at 21-28 days (10-20 mins)	Both include 8 wks 16mg nicotine patch	Abstinence at 12m (sustained at 1, 4, 12, 26 wks) Biochem	Low
Bronson 1989 ⁽²¹⁰⁾	USA	155	42	NS	62%	Two 20 min counselling sessions during a periodic health examination (benefits of quitting, assessment of motivation, quit plan, high risk or problem solving)	Control (completed smoking behaviour questionnaire)		Abstinence at 18m (sustained from 6-18m) Biochem	Unclear
Glasgow 2000 ⁽²¹¹⁾	USA	1154	24	NS	100%	Video (9 min) targeted at young women. 12-15 min counselling session, personalised strategies, stage-targeted self-help materials. Offered telephone support call	Generic self-help materials	Both groups received 20sec provider advice	Abstinence at 6m (for 30 days) Biochem	Unclear

Jorenby 1995 ⁽¹⁹⁷⁾	USA	504	44	NS	NS	Individual – self-help at screening visit + motivational message. Met nurse counsellor x3 after TQD. Counsellor helped generate problem-solving strategies and provided praise and encouragement	Minimal - self-help materials from physician at screening visit for trial entry, instructed not to smoke while wearing patch. No further contact with counsellors		7 day PP abstinence at 26 wks Biochem	Unclear
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Table 8.30 Included studies from systematic review: brief advice

Study	Setting	Participants	Age	Ethnicity	Female	Intervention	Control	Outcome	Biochem	Risk of bias
Betson 1997 ⁽²¹²⁾	Hong Kong	865	>65	NS	8%	Arm 3. Physician advice (1min, based on 4As) AND Arm 4. Physician advice and booklet	Arm 1. No intervention and Arm 2. Written materials (Chinese translation of American Cancer Society booklet)	Abstinence at 1 yr (sustained from 3m)	N	Unclear
Butler 1999 ⁽²¹³⁾	UK	536	NS	NS	70%	Standardised brief advice (estimated time 2 minutes)	Structured motivational counselling (mean length 10mins) (based on stage of readiness to change)	PP at 6m (self-reported abstinence in the previous month)	N	Unclear

Demers 1990 ⁽²¹⁴⁾	USA	519	NS	NS	NS	3 - 5 min smoking cessation counselling (and written materials) plus routine care	Routine care	Sustained at 12m (& 6m)	N	
Fagerström 1984 ⁽²⁰⁾	Sweden	145 (49 in relevant arms)	NS	NS	NS	Advice plus 2 appointments, phone call + letter (long follow up)	Advice plus 1 appointment (short follow up)	Sustained abstinence at 1, 6 and 12m	Y on random subset only	High
Haug 1994 ⁽²¹⁵⁾	Norway	274	18-34	NS	100%	Advice + leaflet + invitation to attend 4 follow-up visits	Normal care controls	Abstinence at 18m	Y at 12m only not at 18m	High
Higashi 1995 ⁽²¹⁶⁾	Japan	957	NS	NS	NS	Brief advice plus leaflet, encouragement card at 1m and telephone card (incentivised) at 6m	No intervention	PP abstinence at 12m	N	Unclear
Jamrozik 1984 ⁽³⁶⁾	UK	2110	NS	NS	NS	Brief advice to quit plus smoking cessation pamphlet	Normal care control group	PP abstinence at 12m	Y, random sample	High
Janz 1987 ⁽²¹⁷⁾	USA	250	NS	NS	NS	Brief advice from physician and brief consultation from nurse	Normal care	PP abstinence at 6m	N	High

Lang 2000 ⁽²¹⁸⁾	France	1095	NS	NS	17%	Intensive intervention; contract with quit date, phone call 7 days post-quit date, follow-up visit	Minimal advice; 5-10 min from occupational physician	Sustained abstinence (≥ 6m) at 12m, assessed at annual check up	Y for subsample	Low
Marshall 1985 ⁽²¹⁹⁾	UK	200	NS	NS	NS	As control, plus offer of 4 follow-up visits over 3m	Advice plus nicotine gum	Sustained at 12m (from 6m)	Y	Low
McDowell 1985 ⁽¹⁹⁸⁾	Canada	366 (153 relevant to review)	NS	NS	NS	Brief physician advice	Control: self-monitoring of smoking	PP abstinence at 12m	N (but threatened to test them)	High
Meyer 2008 ⁽²²⁰⁾	Germany	1499 (1011 in relevant conditions?)	18-70	NS	48%	Brief advice from trained physician and selected self-help manuals	Control group (assessment only - 22-sided questionnaire administered in waiting room)	Abstinence at 24m (sustained for 6m)	N	High

Morgan 1996 ⁽²²¹⁾	USA	659	50-74	NS	NS	Physician advice, stage-based, tailored self-help guide. Follow-up letter from physician and call from project staff. Smokers in contemplation given prescription and free 1 wk supply of gum	Usual care (delayed intervention)	Abstinence at 6m (assume PP)	N	Unclear
Nebot 1989 ⁽²²²⁾	Spain	424	NS	NS	NS	Brief physician advice, 3-5 min, and self-help leaflet	Usual care	Abstinence at 12m (states definition unclear)	N incomplete	High
Ockene 1991 ⁽⁴⁹⁾	USA	1286	NS	NS	NS	Patient-centred counselling, written materials, asked to schedule follow-up visit, follow-up letter	Advice only	PP abstinence at 6m (self-reported)	N	Unclear
Page 1986 ⁽⁵⁰⁾	Canada	289	NS	NS	NS	Advice to quit	No advice	PP abstinence at 6m	N	High
Pieterse 2001 ⁽²²³⁾	Netherlands	530	NS	NS	NS	Advice or counselling tailored to stage of change, self-help manual, follow-up visit if quit date set. Approx 10 mins	Usual care	Sustained at 12m (from 6m)	N	Unclear

Porter 1972 ⁽²²⁴⁾	UK	191	NS	NS	NS	5 mins of advice delivered 'with conviction and vigour' plus anti- smoking leaflet	No advice	PP abstinence at 6m	N, validation: by family report/nei ghbour report	High
Richmond 1986 ⁽²²⁵⁾	Australia	200	NS	NS	NS	Six visits to the GP over 6m, including advice, spirometry demonstration and serum cotinine and written materials	Control group completed questionnaire and gave blood sample at single visit	Sustained abstinence 3 yrs (assessed at 6m & 3 yrs)	Y but not on all, some confir- mati on by relatives and or friends	High
Russell 1979 ⁽²²⁶⁾	UK	2138	NS	NS	NS	Advice to stop smoking. and 4. Advice to stop smoking plus leaflet plus a warning that the patient would be followed up	1. No intervention and 2. Questionnaire only	Sustained abstinence at 12m (& 1m)	Y, sample only(n=23)	High
Russell 1983 ⁽⁵⁵⁾	UK	2106 (1377 in relevant arm)	NS	NS	NS	Advised to stop smoking plus provided with a 'give up smoking' booklet	No intervention	Sustained abstinence 12m (& 4m)	Y, 66% of quitters biochem val	High
Segnan 1991 ⁽⁵⁷⁾	Italy	923	20- 60	NS	NS	Repeated counselling (follow-up at 1,3,6,9m) or repeated counselling plus spirometry (conducted by specialist centre)	Advice and leaflet	Sustained abstinence at 12m (sustained for 3m by self report)	Y	Low

Severson 1997 ⁽²²⁷⁾	USA	1478	New moth ers	NS	100%	As control, and extended support (counselling plus follow-up at 2, 4, and 5m visits) and materials (incl video tape, written materials)	Information pack including a letter from paediatrician on risks of passive smoking, provided by birth hospital	PP abstinence at 12m	N	Low
Slama 1990 ⁽²²⁸⁾	Australia	311	18- 64 , mean age NR	NS	NS	Advice plus leaflets (minimal intervention)	Control	Sustained abstinence at 12m (& 1m & 6m)	Y	Unclear
Thompson 1988 ⁽²²⁹⁾	USA	1039	NR	NS	NS	A. Structured physician advice (3 - 5 min talk); C. Referral to group therapy	A. Structured physician advice (3 - 5 min talk)	PP abstinence at 9m	N	Unclear
Unrod 2007 ⁽²³⁰⁾	USA	518	NR	NS	NS	Physician & patient given 1-page tailored report based on computer-based assessment in waiting room. Physician trained to provide 5As-based brief counselling. Follow-up appointment could be arranged	No intervention (usual care)	PP abstinence at 6m	Y	High

Wilson 1982 ⁽²³¹⁾	Canada	211	NR	NS	NS	Brief advice plus follow-up appointments at 1, 3 and 6m	Brief advice (5 min counselling)	PP abstinence at 6m	N	Unclear
Wilson 1990 ⁽²³²⁾	Australia	1238	NR	NS	NS	Personalised advice plus leaflets and visual aids at single visit	Normal care control group (advice given if clinically indicated)	Sustained abstinence at 12m (and 6m)	N	Low

Table 8.31 Included studies from systematic review: nursing interventions

Study	Setting	Participants	Mean age	Ethnicity	Female	Intervention	Control	Adjunct	Outcome	Biochem valid	Risk of bias
Aveyard 2003 ⁽²³³⁾	UK	831	NR	NS	NS	In addition to tailored self help, asked to make appointment to see practice nurse. Single postal reminder if no response. Up to 3 visits, at time of letters. Reinforced use of manual	Self-help manual based on Transtheoretical model, maximum of 3 letters generated by expert system. No face-to-face contact		Abstinence at 12m, self-reported sustained for 6m	Y	Low

Aveyard 2007 ⁽²⁰⁹⁾	UK	925	43	NS	NS	Basic support; 1 visit (20 - 40 mins) before quit attempt, phone call on TQD, visits/phone calls at 7 - 14 days and at 21 - 28 days (10 - 20 mins)	Weekly support; as 1. plus additional call at 10 days and visits at 14 and 21 days	Both interventions included 8 wks 16mg nicotine patch. Intensity high for both groups	Abstinence at 12m (sustained at 1, 4, 12, 26 wks)	Y	Low
Borrelli 2005 ⁽²³⁴⁾	USA	278	57	NS	54%	Motivational enhancement. 3 x 20-30min sessions during nursing visits. 5min follow-up call	Standard care control based on 5As model, single 5-15min session with brief support at subsequent nursing visits, consistent with guidelines		Abstinence at 12m (no smoking since 6m assessment)	Y but obtained for 60% only	Unclear
Janz 1987 ⁽²¹⁷⁾	USA	NR?	NS	NS	NS	Physician discussed personal susceptibility, self efficacy and concern, trained nurse counselled on problems and strategies. 2. As 1, and self-help manual 'Step-by-Step Quit Kit' + 1 telephone call	Usual Care control (from physicians not involved in study)		Abstinence at 6m (self report by telephone)	N	High

Lancaster 1999 ⁽²³⁵⁾	UK	497	NS	NS	NS	As control, plus invitation to contact a trained practice nurse for more intensive tailored counselling. Up to 5 follow-up visits offered	Physician advice (face-to-face or in a letter) and a leaflet	Physician advice (face-to-face or in a letter) and a leaflet to both groups	Abstinence at 12m (sustained at 3m and 12m)	Y	Low
Sanz-Pozo 2006 ⁽²³⁶⁾	Spain	125	40	NS	52% (intervention) 62% (control)	1. Brief advice from doctor at recruitment, appointment with clinic nurse 7 days before TQD, on TQD, 1wk, 1m, 2m, 3m	2. Brief advice only		Sustained abstinence at 24m (from 12m)	Y	Unclear

Table 8.32 Included studies from systematic review: Internet interventions

Study	Setting	Mean age	Ethnicity	Female	Participants	Intervention	Control	Adjunct	Outcome	Risk of bias
An 2008 ⁽²³⁷⁾	USA	20	NS	75%	517	Interactive, tailored	Non-active		30w Abstinence (biochem, pp)	Low
Brendryen 2008a ⁽²³⁸⁾	Norway	29.5	NS	50%	290	Interactive, tailored, phone contact	Self-help book		Abstinence at 6m (SR, PP), 12m (SR, car)	Low
Brendryen 2008b ⁽²³⁹⁾	Norway	36	NS	50%	396	Interactive, tailored, phone contact	Self-help book	NRT (both groups)	Abstinence at 6m (SR, PP), 12m (SR, car)	Low
Elfeddali 2012 ^(240, 241)	Netherlands	42	NS	62%	2031	Interactive, tailored (2	Usual care		Abstinence at 12m (SR, car)	High

						different types, combined for analysis)				
McDonnell 2011 ⁽²⁴²⁾	USA	35	Korean-American	12%	1409	Interactive, not tailored	Booklet of same content		Abstinence at 6m (SR, car)	Low
Smit 2012 ⁽²⁴³⁾	Netherlands	49.5	NS	52%	1123	Interactive, tailored	No Intervention		Abstinence at 6m (SR, car)	High

Table 8.33 Included studies from systematic review: motivational interviewing(MI) versus routine care

Study	Setting	Mean age	Ethnicity	Female	Participants	Intervention	Control	Adjunct	Outcome	Risk of bias
Bastian 2013 ⁽²⁴⁴⁾	USA	47	NS	58%	496	6 weekly MI telephone calls & control group Interventions	Self-directed materials	NRT (patches) to both groups	Abstinence at 6m (SR. PPA)	Unclear
Bock 2008 ⁽²⁴⁵⁾	USA	47.7	NS	47%	543	30 min MI counselling session, follow-up telephone calls	Usual care - referral sheet to smoking cessation resources	NRT (patches) to both groups	Abstinence at 6m (biochem. car)	Unclear
Bock 2014 ⁽²⁴⁶⁾	USA	39.6	NS	69%	846	45 min MI counselling, follow-up telephone call	Usual care - self-help guides	NRT (patches) to both groups	Abstinence at 6m, 12m (biochem (eCO2. PP)	Unclear
Borrelli 2005 ⁽²³⁴⁾	USA	57.2	NS	54%	278	3 x 20-30min MI counselling by nurse	5-15min brief counselling (1 visit - nurse)	All received manual (clear horizons)	Abstinence at 6m, 12m (biochem (eCO2), car)	Unclear
Butler 1999 ⁽²¹³⁾	UK	41	NS	71%	536	MI counselling (mean 10 mins) by GP	Brief advice (2 mins) by GP		Abstinence at 6m (SR. PPA)	Low

Davis 2011 ⁽²⁴⁷⁾	USA	37.6	NS	45%	218	MI counselling (nurse, mean 15min)	Prescriptive 15 min interview, nurse	No pharmacotherapy	Abstinence at 6m (SR. PPA)	Unclear
De Azevedo 2010 ⁽²⁴⁸⁾	Brazil	47	NS	36%	273	MI counselling (counsellor) 30min Follow-up telephone call (x&, 10mins)	Low-intensity counselling (15min) by counsellor	No pharmacotherapy	Abstinence at 6m (SR. PPA)	High
Dornelas 2000 ⁽²⁴⁹⁾	USA	54	NS	22%	100	MI counselling (psychologist, 20 mins, follow up phone calls)	Brief advice (10mins, psychologist)		Abstinence at 6m (SR. car)	High
Ellerbeck 2009 ⁽²⁴⁰⁾	USA	47.2	NS	59%	726	MI counselling calls (both medium and high-intensity groups), counsellors	Smoking cessation materials mailed	Both groups offered NRT +/- bupropion	Abstinence at 12m (biochem. PP)	Low
Glasgow 2000 ⁽²¹¹⁾	USA	24	NS	100%	1154	MI counselling (12-15min, counsellor)	Brief advice + brochure		Abstinence at 12m (biochem. PP)	Low
Hennrikus 2005 ⁽²⁵⁰⁾	USA	47	NS	53%	2095	MI counselling (nurse, 20mins) and usual care. Follow-up telephone calls	Usual care	NRT / Bupropion encouraged but not provided	Abstinence at 12m (biochem. PP)	Unclear
Hollis 2007 ⁽²⁵¹⁾	USA	41	NS	60%	4614	MI counselling (40 mins MI counselling, follow-up call)	Usual care (brief counselling, 15 min call)	NRT in groups	Abstinence at 6m, 12m (SR. PPA)	Low
Lindqvist 2013 ⁽²⁵²⁾	Sweden	48.6	NS	81%	772	MI counselling	Standard Swedish usual care	Pharmacotherapy received both groups	Abstinence at 12m (SR. PP)	High
McClure 2005 ⁽²⁵³⁾	USA	33	NS	100%	275	MI counselling (15 min telephone calls, up to 4). Counsellor	Usual care	Pharmacotherapy to both	Abstinence at 12m (biochem. PP)	Unclear

								groups	car)	
Rigotti 1997 ⁽²⁵⁴⁾	USA	48	NS	46%	650	MI counselling (15 mins) + brief advice	Usual care		Abstinence at 6m (biochem. PP)	High
Soria 2006 ⁽²⁵⁵⁾	Spain	38	NS	53%	200	MI counselling (3x20 mins, GP)	Brief advice (GP)	Bupropion offered to highly dependent - both groups	Abstinence at 6m, 12m (biochem. PPA)	Low
Tevyaw 2009 ⁽²⁵⁶⁾	USA	19.8	NS	NR	110	MET (with MI principles) x3 sessions (60min, 30min, 30min)	Muscle relaxation (progressive muscle relaxation) to match intervention contact time	No pharmacotherapy	Abstinence at 6m (biochem. PP)	Unclear

Table 8.34 Included studies from systematic review: Motivational interviewing (MI) versus nothing

Study	Setting	Mean age	Ethnicity	Female	Participants	Intervention	Control	Adjunct	Outcome	Risk of bias
Harris 2010 ⁽²⁵⁷⁾	USA	19.5	NS	46%	452	MI counselling (smoking cessation) (20-30mins, 4 sessions)	MI counselling (healthy eating) (20-30mins, 4 sessions)	Pharmacotherapy to both (heavy smokers)	Abstinence at 6m (biochem. PP)	Unclear

Table 8.35 Included studies from systematic review: Mobile phone interventions

Study	Setting	Mean age	Ethnicity	Female	Participants	Intervention	Control	Adjunct	Outcome	Risk of bias
Borland 2013 ⁽²⁵⁸⁾	Australia	42.1	NS	60%	3530	Internet intervention: personalised tailored Internet-delivered	Minimal advice	No pharmacological	7 months (6-month CAR), SR	Low

						(QuitCoach)		adjunct		
Borland 2013 ⁽²⁵⁸⁾	Australia	42.1	NS	60%	3530	SMS intervention: interactive automated SMS programme (onQ)	Minimal advice	No Pharmacological adjunct	7 months (6-month CAR), SR	Low
Borland 2013	Australia	42.1	NS	60%	3530	Combined Internet and SMS intervention	Minimal advice	No pharmacological adjunct	7 months (6-month CAR), SR	Low
Ferguson 2015 ⁽²⁵⁹⁾	Australia	42.1	NS	51%	284	SMS and self-help booklet	Self-help booklet		Abstinence PP	Unclear
Haug 2013 ⁽²⁶⁰⁾	Switzerland	18.2	NS	52%	755	SMS (3months)	Online health screen		Abstinence at 6m (sr, pp)	Low
Naughton 2014 ⁽²⁶¹⁾	UK	41	NS	53%	602	SMS (90 days), counselling, pharmacotherapy	Counselling, pharmacotherapy - fairly intensive		Abstinence at 6m (sr, car)	Low
Whittaker 2011 ⁽²⁶²⁾	New Zealand	27	24% Maori	47%	226	SMS and video message (6 months)	General health video message		Abstinence at 6m (SR, car)	Low

Table 8.35 Included studies from systematic review: telephone interventions

Study	Setting	Mean age	Ethnicity	Female	Participants	Intervention	Control	Outcome	Risk of bias
Abdullah 2005 ⁽²⁶³⁾	Hong Kong	NS; > 50% aged 36 - 45	NS	16%	903	Telephone intervention; smoker did not initiate contact	Self-help or minimal intervention	Abstinence at 6m (biochem, pp)	Unclear
An 2006 ⁽²⁶⁴⁾	USA	57	NS	9%	821	Telephone intervention; smoker did not initiate contact	Self-help or minimal intervention	Abstinence at 12m (SR, CAR)	High
Aveyard 2003 ⁽²³³⁾	UK	41	NS	54%	2471	Telephone intervention; smoker	Self-help or minimal intervention	Abstinence at 12m	Low

						did not initiate contact		(biochem, car)	
Borland 2001 ⁽²⁶⁵⁾	Australia	NS; 37% aged 15 - 29, 26% aged 30 - 39	NS	52%	998	Additional proactive call(s)	Mailed material	Abstinence at 12m (SR, car)	High
Borland 2003 ⁽²⁶⁶⁾	Australia	NS; modal age 30 - 49	NS	54%	1578	Additional proactive call(s)		Abstinence at 12m (SR, car)	High
Borland 2008 ⁽²⁶⁷⁾	Australia	41	NS	55%	1039	Adjunct telephone intervention; smoker did not initiate contact	Brief intervention or counselling Adjunct: pharmacotherapy to both groups	Abstinence at 12m (SR, car)	High
Boyle 2007 ⁽²⁶⁸⁾	USA	47	NS	58%	1329	Adjunct telephone intervention to pharmacotherapy; smoker did not initiate contact	Pharmacotherapy	Abstinence at 12m (SR, PP)	High
Brown 1992 ⁽²⁶⁹⁾	Australia	40	NS	62%	45	Adjunct telephone intervention; smoker did not initiate contact	Brief intervention or counselling	Abstinence at 12m (SR, PP)	Unclear
Curry 1995 ⁽²⁷⁰⁾	USA	41	NS	52%	1137	Telephone intervention; smoker did NOT initiate contact	Self-help or minimal intervention	Abstinence at 12m (biochem, car)	Unclear
Ebbert 2007 ⁽²⁷¹⁾	USA	NS	NS	NS	82	Adjunct telephone intervention; smoker did not initiate contact	Brief intervention or counselling	Abstinence at 6m (SR, pp)	High
Ellerbeck 2009 ⁽²⁴⁰⁾	USA	47	NS	59%	750	Adjunct telephone intervention to	Pharmacotherapy	Abstinence at 24m	Low

						pharmacotherapy; smoker did not initiate contact		(biochem, pp)	
Emmons 2005 ⁽²⁷²⁾	USA	31	NS	47%	794	Telephone intervention; smoker did not initiate contact	Self-help or minimal intervention	Abstinence at 12m (SR, PP)	Unclear
Ferguson 2012 ⁽²⁷³⁾	UK: English QUITline	38	NS	55%	2591	Additional proactive call(s)	Standard phonecall Adjunct: NRT provided to both group	Abstinence at 6m (biochem, car)	Low
Fiore 2004 ⁽²⁷⁴⁾	USA	40	NS	58%	961	Adjunct telephone intervention to pharmacotherapy; smoker did NOT initiate contact	Pharmacotherapy	Abstinence at 12m (biochem, car)	Unclear
Flöter 2009 ⁽²⁷⁵⁾	Germany	35.9	NS	NS	527	Adjunct telephone intervention; smoker did NOT initiate contact	Brief intervention or counselling	Abstinence at 6m (SR, pp)	High
Gilbert 2006 ⁽²⁷⁶⁾	UK: English QUITline	39	NS	66%	1457	Additional proactive call(s)		Abstinence at 12m (SR, car)	High
Girgis 2011 ⁽²⁷⁷⁾	Australia	29	NS	52%	407	GP-referral to telephone counselling	Usual care	Abstinence at 12m (SR, PP)	High
Graham 2011 ⁽²⁷⁸⁾	USA	35.9	NS	51%	2005	Telephone intervention; smoker did not initiate contact	Self-help or minimal intervention	Abstinence at 18m (SR, PP)	High
Halpin 2006 ⁽²⁷⁹⁾	USA	67% age 40+	NS	66%	388	Coverage by health insurance for telephone counselling and pharmacotherapy	Coverage by health insurance for pharmacotherapy alone	Abstinence at 6m (SR, pp)	High
Hennrikus 2002 ⁽²⁸⁰⁾	USA	36	NS	50-64%	2402	Telephone counselling	Group therapy	Abstinence at 24m (biochem,	Unclear

								car)	
Hollis 2007 ⁽²⁵¹⁾	USA Oregon QUITline	41	NS	60%	4500	Additional proactive call(s)	Brief counselling	Abstinence at 12m (SR, car)	High
Joyce 2008 ⁽²⁸¹⁾	USA	65+	NS	60%	7354	Offer of quitline: Reactive or proactive counselling vs provider counselling		Abstinence at 12m (SR, pp)	High
Katz 2004 ⁽²⁸²⁾	USA	43/40	NS	56%	1141	Interactive TC	Information on guidelines, no specific advice	Abstinence at 6m (biochem, car)	High
Lando 1992 ⁽²⁸³⁾	USA	47	NS	50%	1827	Telephone intervention; smoker did not initiate contact	Self-help or minimal intervention	Abstinence at 18m (biochem, car)	High
Lando 1997 ⁽²⁸⁴⁾	USA	42	NS	56%	509	Adjunct telephone intervention to pharmacotherapy; smoker did not initiate contact	Pharmacotherapy	Abstinence at 12m (biochem, pp)	Unclear
Lichtenstein 2000 ⁽²⁸⁵⁾	USA	NS	NS	NS	1006	Telephone intervention; smoker did not initiate contact	Self-help or minimal intervention	Abstinence at 12m (SR, car)	High
Lichtenstein 2008 ⁽²⁸⁶⁾	USA	NS	NS	NS	1821	Telephone intervention; smoker did not initiate contact	Self-help or minimal intervention	Abstinence at 12m (SR, car)	High
Lipkus 1999 ⁽²⁸⁷⁾	USA	49% aged > 50	African American	52%	266	Telephone intervention; smoker did not initiate contact	Self-help or minimal intervention	Abstinence at 16m (SR, pp)	High
MacLeod 2003 ⁽²⁸⁸⁾	Australia	42	NS	51%	854	Adjunct telephone intervention to pharmacotherapy; smoker did not initiate contact	Pharmacotherapy	Abstinence at 6m (SR, CAR)	High
McBride	USA	36	NS	100%	580	Telephone	Self-help or minimal	Abstinence	Unclear

1999 ⁽²⁸⁹⁾						intervention; smoker did not initiate contact	intervention	at 15m (biochem, pp)	
McClure 2005 ⁽²⁵³⁾	USA	33	NS	100%	275	Telephone intervention; smoker did not initiate contact	Self-help or minimal intervention	Abstinence at 12m (biochem, pp)	Unclear
McClure 2011 ⁽²⁹⁰⁾	USA	44.5	NS	67%	52	Telephone intervention; smoker did not initiate contact	Self-help or minimal intervention	Abstinence at 6m (SR, pp)	High
McFall 1993 ⁽²⁹¹⁾	USA	NS; 23% age 18 - 30, 40% age 31 - 45, 30% 45 - 64	NS	70%	1745	Offer of quitline: quitline + self help	Nothing	Abstinence at 24m (SR, pp)	High
Metz 2007 ⁽²⁹²⁾	Germany	47	NS	41%	290	Adjunct telephone intervention; smoker did not initiate contact	Brief intervention or counselling	Abstinence at 12m (SR, pp)	High
Miguez 2002 ⁽²⁹³⁾	Spain	35	NS	38%	200	Telephone intervention; smoker did not initiate contact	Self-help or minimal intervention	Abstinence at 12m (biochem, car)	Unclear
Miguez 2008 ⁽²⁹⁴⁾	Spain	37	NS	46%	228	Telephone intervention; smoker did not initiate contact	Self-help or minimal intervention	Abstinence at 12m (sr, car)	Unclear
Miller 1997 ⁽²⁹⁵⁾	USA	51	NS	49%	1942	Intensive intervention (TC and FTF)	Minimal intervention (TC + FTF)	Abstinence at 12m (biochem, car)	Low
Ockene 1991 ⁽⁴⁹⁾	USA	35	NS	57%	1223	Adjunct telephone intervention; smoker did not initiate contact	Brief intervention or counselling	Abstinence at 6m (SR, pp)	High
Orleans 1991 ⁽²⁹⁶⁾	USA	44	NS	63%	2021	Telephone intervention; smoker	Self-help or minimal intervention	Abstinence at 16m	Unclear

						did not initiate contact		(biochem, car)	
Orleans 1998 ⁽²⁹⁷⁾	USA	NS; 62% in 20 - 39 age group	African American	64%	1422	Two different interventions during single call (tailored vs standard counselling)		Abstinence at 6m (SR, pp)	High
Osinubi 2003 ⁽²⁹⁸⁾	USA	52	NS	7%	58	Adjunct telephone intervention; smoker did not initiate contact	Brief intervention or counselling	Abstinence at 6m (SR, pp)	High
Ossip-Klein 1991 ⁽²⁹⁹⁾	USA	43	NS	NS	1813	Offer of quitline: quitline + self help	Self help	Abstinence at 18m (biochem, car)	Unclear
Ossip-Klein 1997 ⁽³⁰⁰⁾	USA	NS	NS	61%	177	Telephone intervention; smoker did not initiate contact	Self-help or minimal intervention	Abstinence at 6m (SR, pp)	Unclear
Prochaska 1993 ⁽³⁰¹⁾	USA	43	NS	62%	756	Telephone intervention; smoker did not initiate contact	Self-help or minimal intervention	Abstinence at 18m (sr, pp)	Unclear
Prochaska 2001 ⁽³⁰²⁾	USA	38	NS	56%	1447	Telephone intervention; smoker did not initiate contact	Self-help or minimal intervention	Abstinence at 18m (sr, car)	High
Rabius 2004 ⁽³⁰³⁾	USA	NS; (\leq 25/ > 25): 61%/67 % F, av.age 22/44,	NS	NS	3522	Additional proactive call(s)		Abstinence at 6m (SR, car)	Unclear
Rabius 2007 ⁽³⁰³⁾	USA	43	NS	70%	6322	Additional proactive call(s)		Abstinence at 7m (SR, pp)	Unclear
Reid 1999 ⁽³⁰⁴⁾	Canada	38	NS	48%	396	Adjunct telephone intervention to pharmacotherapy;	Pharmacotherapy	Abstinence at 12m (SR, pp)	Unclear

						smoker did not initiate contact			
Rimer 1994 ⁽³⁰⁵⁾	USA	61	NS	63%	1867	Telephone intervention; smoker did not initiate contact	Self-help or minimal intervention	Abstinence at 12m (SR, pp)	High
Sims 2013 ⁽³⁰⁶⁾	USA	21.3	NS	58%	410	Additional proactive call(s)		Abstinence at 6m (SR, pp)	Unclear
Smith 2004 ⁽³⁰⁷⁾	USA	42	NS	61%	632	Additional proactive call(s)		Abstinence at 12m (sr, car)	High
Solomon 2000 ⁽³⁰⁸⁾	USA	33	NS	100%	214	Adjunct telephone intervention to Pharmacotherapy; smoker did not initiate contact	Pharmacotherapy	Abstinence at 6m (biochem, pp)	High
Solomon 2005 ⁽³⁰⁹⁾	USA	34	NS	100%	330	Adjunct telephone intervention to pharmacotherapy; smoker did not initiate contact	Pharmacotherapy	Abstinence at 6m (sr, pp)	High
Sood 2009 ⁽³¹⁰⁾	USA	43	NS	62%	990	Two different interventions during single call (reactive counselling vs self-help materials)		Abstinence at 12m (SR, pp)	Low
Sorensen 2007a ⁽³¹¹⁾	USA	40	NS	6%	231	Telephone intervention; smoker did not initiate contact	Self-help or minimal intervention	Abstinence at 6m (SR, pp)	High
Swan 2003 ⁽¹⁵³⁾	USA	45	NS	57%	1524	Free and clear proactive TC (4 brief calls), access to quitline & self-help materials	Zyban Advantage Program (ZAP) tailored self-help materials, single telephone call, Zuban support line	Abstinence at 12m (SR, pp)	High
Swan 2010 ⁽³¹²⁾	USA	47.3	NS	67%	1202	Adjunct telephone intervention to pharmacotherapy; smoker did not initiate	Pharmacotherapy	Abstinence at 6m (SR, pp)	High

						contact			
Thompson 1993 ⁽³¹³⁾	USA	41	NS	59%	382	Two different interventions during single call (stage-based counselling vs general information)		Abstinence at 6m (SR, pp)	Unclear
Tzelepis 2011 ⁽³¹⁴⁾	Australia	45	NS	50%	1562	Telephone intervention; smoker did not initiate contact	Self-help or minimal intervention	Abstinence at 13m (SR, car)	High
Velicer 2006 ⁽³¹⁵⁾	USA	51	NS	23%	2054	Adjunct telephone intervention to pharmacotherapy; smoker did not initiate contact	Pharmacotherapy	Abstinence at 30m (SR, car)	High
Young 2008 ⁽³¹⁶⁾	Australia	37	NS	53%	318	Telephone intervention; smoker did not initiate contact	Self-help or minimal intervention	Abstinence at 12m (SR, pp)	High
Zhu 1996 ⁽³¹⁷⁾	USA (Quitline)	36	NS	57%	3030	Telephone contact and self help	Self help	Abstinence at 13m (biochem, car)	High
Zhu 2002 ⁽³¹⁸⁾	USA (Quitline)	38	NS	56%	3282	Additional proactive call(s)		Abstinence at 13m (SR, car)	High
Zhu 2012 ⁽³¹⁹⁾	USA (Quitline)	approx. 45% 25 - 44 and 45% 45 - 64	Chinese Vietnamese Korean	10%	2278	Additional proactive call(s)		Abstinence at 7m (SR, car)	Low

Table 8.36 Updated review. Included studies: NRT versus placebo

Study	Setting	Mean age	Female	Participants	Intervention dose	Control dose	Support	Outcome	Risk of bias
Tuisku 2016a ⁽³²⁰⁾	Finland	21	52%	291	NRT: Nicotine patch (10mg/16h) X 8/52	Placebo Patch X8/52	All received 20min counselling based on motivational interviewing x 22	6 month (PP, SR)	High
Ward 2013 ⁽³²¹⁾	Aleppo, Syria	40	22%	269	NRT: Nicotine patch (dose related to nicotine dependence) - 6 weeks	Placebo Patch	Individual behavioural counselling to both groups. 3x30 min individual counselling and 5x10min phone call	12 month (prolonged, Biochem)	Low

Table 8.37 Updated review. Included studies: Bupropion plus Varenicline versus Varenicline

Study	Setting	Mean age	Female	Participants	Intervention	Control	Adjunct	Outcome	Risk of bias
Ebbert 2014 ⁽³²²⁾	USA	42.2 (Intervention) 41.9 (Control)	45% (Intervention) 49% (Control)	506	Bupropion SR + Varenicline (12 weeks)	Placebo + Varenicline (12 weeks)	Brief advice to both groups	12 month (prolonged, Biochem)	Low

Table 8.38 Updated review. Included studies: Varenicline plus NRT versus Varenicline

Study	Setting	Mean age	Female	Participants	Intervention 1	Intervention 2	Adjunct	Outcome	Risk of bias
Ramon 2014 ⁽³²³⁾	Spain	45.1	42%	341	NRT (Nicotine Patch 21mg for 11weeks) + Varenicline (12 weeks)	Placebo Nicotine Patch + Varenicline (12 weeks)	Both groups received behavioural support 10-	6 month (CAR, Biochem)	Low

					weeks)		15min x 5		
Koegelenberg 2014 ⁽³²⁴⁾	South Africa	46.3	15%	446	NRT (Nicotine Patch 15mg for 14 weeks) + Varenicline	Placebo Nicotine Patch + Varenicline		6 month (CAR, Biochem)	Low

Table 8.39 Updated review. Included studies: Varenicline versus NRT versus Bupropion

Study	Setting	Mean age	Ethnicity	Female	Participants	Intervention 1	Intervention 2	Intervention 3	Outcome	Risk of bias
Zincir 2013 ⁽³²⁵⁾	Turkey	NS	NS	NS	251	NRT with patch or gum, or combination NRT (patch and gum) - 12 weeks	Varenicline (12 weeks)	Bupropion (12 weeks)	6 month (PP, Biochem)	High

Table 8.40 Updated review. Included studies: Varenicline versus NRT

Study	Setting	Mean age	Ethnicity	Female	Participants	Intervention 1	Intervention 2	Intervention 3	Outcome	Risk of bias
Tulloch 2016 ⁽³²⁶⁾	Canada	48.61	NS	47%	737	NRT - 10 weeks (21mg daily)	NRT (35mg daily) + Nicotine gum or inhaler - 22 weeks	Varenicline (1mg BID) - 24 weeks	12 month (CAR, Biochem)	High (open-label)
Study	Setting	Mean age	Ethnicity	Female	Participants	Intervention 1	Intervention 2		Outcome	Risk of bias
Tuisku 2016b ⁽³²⁰⁾	Finland	22 (NRT), 21 (Varenicline)	NS	45% (NRT) 50% (Varenicline)	291	NRT: Nicotine patch (15mg/16h)	Varenicline		6 month (PP, SR)	High

Table 8.41 Updated review. Included studies: telephone interventions

Study	Setting	Mean age	Ethnicity	Female	Participants	Intervention	Control	Adjunct	Outcome	Risk of bias
Killen 2008 ⁽³²⁷⁾	USA	Telephone support: M 46.56, F 44.59; CBT: M 45.9, F 46.23	82% White	40%	301	CBT - on site - 30 mins x 4 sessions	Support telephone calls - 5 mins x 4 sessions	9 weeks of Bupropion and 8 weeks of NRT to all participants in open-label 8 week period	12 months, CAR, Biochem	Low
Zwar 2014 ⁽³²⁸⁾	Australia	42.6 (Practice Nurse), 43.5 (QUITline), 42.1 (Control)	NS	55% (PN), 55% (QUITline), 53% (Control)	2390	Practice nurse intervention (face-to-face or by telephone)	Usual care (GP care: brief advice)	Pharmacotherapy offered to all participants (NRT, bupropion or varenicline)	12 months (CAR 10 Months, SR)	Low
Zwar 2014	Australia	42.6 (Nurse), 43.5 (QUITline), 42.1 (Control)	NS	55% (PN), 55% (QUITline), 53% (Control)	2390	QUITline referral by GP (proactive call)	Usual care (GP care: brief advice)	Pharmacotherapy offered to all participants (NRT, bupropion or varenicline)	12 months (CAR 10 Months, SR)	Low

Table 8.42 Updated review. Included studies: Internet interventions

Study	Setting	Mean age	Female	Participants	Intervention	Control	Adjunct	Outcome	Risk of bias
Borland 2013 ⁽²⁵⁸⁾	Australia	42.1	60%	3530	Internet intervention: personalised tailored Internet-delivered (QuitCoach)	Minimal advice	No pharmacological adjunct	7 months (6-month CAR), SR	Low
	Australia	42.1	60%	3530	SMS intervention: interactive automated	Minimal advice	No pharmacological	7 months (6-month CAR),	Low

					SMS programme (onQ)		adjunct	SR	
	Australia	42.1	60%	3530	Combined Internet and SMS intervention	Minimal advice	No pharmacological adjunct	7 months (6-month CAR), SR	Low
Stanczyk 2016 ⁽³²⁹⁾	Holland	45.7	61%	2099	Enhanced Internet (video messages)	Brief generic text advice	No pharmacological adjunct	12 months (CAR, Biochem)	Unclear

Table 8.43 Updated review. Included studies: Mobile phone interventions

Study	Setting	Mean age	Female	Participants	Intervention	Control	Adjunct	Outcome	Risk of bias
Borland 2013 ⁽²⁵⁸⁾	Australia	42.1	60%	3530	Internet intervention: personalised tailored Internet-delivered (QuitCoach)	Minimal advice	No pharmacological adjunct	7 months (6-month CAR), SR	Low
Borland 2013	Australia	42.1 (Females)	60%	3530	SMS intervention: interactive automated SMS programme (onQ)	Minimal advice	No pharmacological adjunct	7 months (6-month CAR), SR	Low
Borland 2013	Australia	42.1 (Females)	60%	3530	Combined Internet and SMS intervention	Minimal advice	No pharmacological adjunct	7 months (6-month CAR), SR	Low

Table 8.44 Updated review. Included studies: motivational interviewing

Study	Setting	Mean age	Ethnicity	Female	Participants	Intervention	Control	Adjunct	Outcome	Risk of bias
Bock 2014 ⁽²⁴⁶⁾	USA	39.6	53% White	69%	846	Motivational interviewing (45min trained professional and follow-up telephone calls) + brief physician advice + NRT	Usual care: brief physician advice + NRT	All received 8 weeks NRT	12 months (PP 7-day, Biochem)	Low

Table 8.45 Updated review. Included studies: individual behavioural counselling

Study	Setting	Mean age	Ethnicity	Female	Participants	Intervention	Control	Adjunct	Outcome	Risk of bias
Killen 2008 ⁽³²⁷⁾	USA	Telephone support: M 46.56, F 44.59; CBT: M 45.9, F 46.23	82% White	40%	301	CBT - on site - 30 mins x 4 sessions & telephone counselling	Support Telephone calls - 5 mins x 4 sessions	9 weeks of Bupropion and 8 weeks of NRT to all participants in open-label 8 week period	12 months (CAR, Biochem)	Low

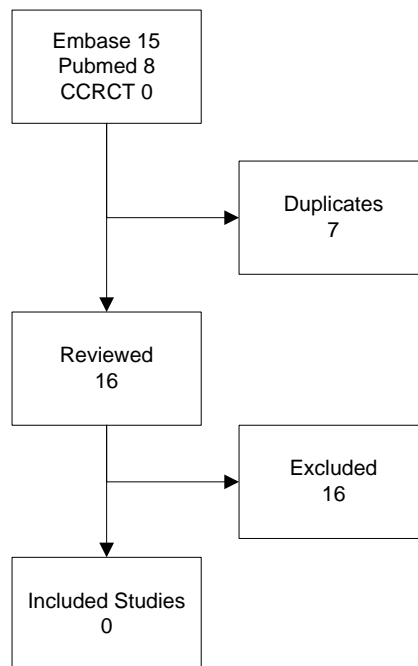
Table 8.46 Updated review. Included studies: nursing interventions

Study	Setting	Mean age	Female	Participants	Intervention	Control	Adjunct	Outcome	Risk of bias
Zwar 2014 ⁽³²⁸⁾	Australia	42.6 (Practice Nurse), 43.5 (QUITline), 42.1 (Control)	545% (PN), 57% (QUITline), 58% (Control)	2390	Practice Nurse Intervention (face-to-face or by telephone)	Usual care (GP care: brief advice)	Pharmacotherapy offered to all participants (NRT, bupropion or varenicline)	12 months (CAR 10 Months, SR)	Low
Zwar 2014	Australia	42.6 (Practice Nurse), 43.5 (QUITline), 42.1 (Control)	55% (PN), 57% (QUITline), 58% (Control)	2390	QUITline referral by GP (proactive call)	Usual care (GP care: brief advice)	Pharmacotherapy offered to all participants (NRT, bupropion or varenicline)	12 months (CAR 10 Months, SR)	Low

Table 8.47 Search strategy for studies involving the Allen Carr method

Database (Date of search)	Search string	Results
Pubmed (20/5/2016)	Allen AND Carr AND smoking	8
Embase (20/5/2016)	Allen AND Carr AND smoking	15
Cochrane Registry of Controlled Trials (20/5/2016)	Allen AND Carr AND smoking	0

Figure 8.1 Flowchart of included studies for the Allen Carr smoking cessation intervention



Appendix 9 Search details for review of smoking cessation interventions in pregnancy

Figure 9.1 Flow diagram of included studies from the updated search: Psychosocial and pharmacological interventions for smoking cessation in pregnancy

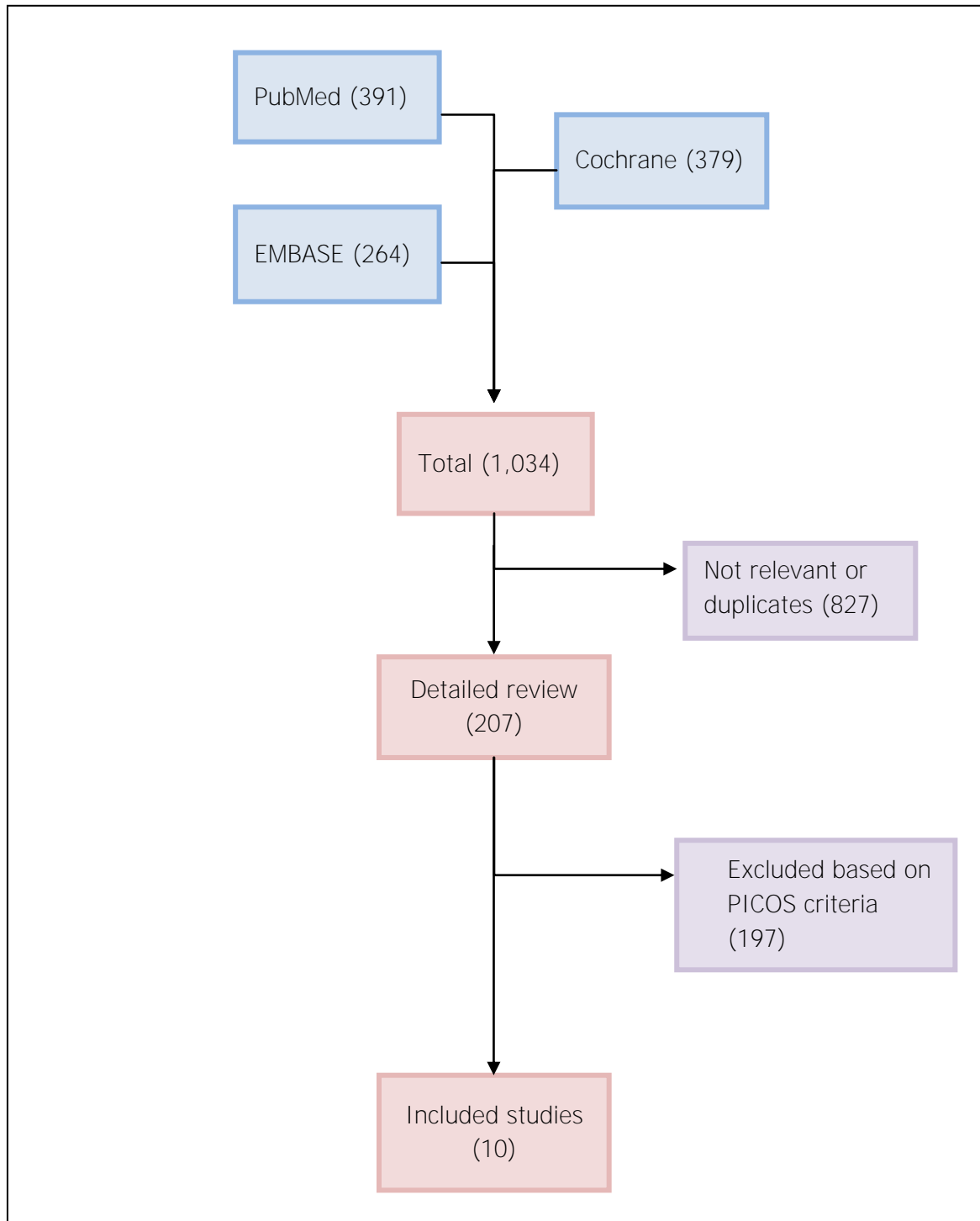


Table 9.1 Search string used in Medline (PubMed)

Pubmed (Date 18/10/2016)	Search strings	Results
#1	("Smoking Cessation"[Mesh]) OR ("Tobacco Use Cessation"[Mesh]) OR (Stop* smoking) OR (Quit* smoking))	31604
#2	("Pregnancy"[Mesh]) OR ("Pregnant Women"[Mesh]) OR ("Postpartum Period"[Mesh]) OR ("Postnatal Care"[Mesh]) OR (Pregnancy [tiab]) OR (Pregnant [tiab]) OR (Postpartum [tiab]) OR (Post-partum [tiab]) OR (Postnatal [tiab]) OR (Post-natal [tiab]) OR (Prenatal [tiab]) OR (Pre-natal [tiab]))	984290
#3	#1 AND #2	2264
#4	#3 AND Filters (Years: 2013-2016, Type: RCT, Systematic Review, Meta-analysis, Humans)	391

Appendix 10 Included studies smoking cessation interventions in pregnancy

Table 10.1 Included studies: NRT and BCS versus placebo and BCS, n=5

Study	Country	Ethnicity	Participants (n)	Gestational cut-off (weeks)	Intervention	Control	BCS	Outcome	Risk of bias
Berlin 2014 ⁽³³⁰⁾	France	European (96%)	402	≤ 20	Nicotine patch 10mg/16hr or 15mg/16hr for eight weeks. Dose adjusted to max of 30mg/hr	Placebo patch	Behavioural support at each visit from a midwife or doctor who had been specifically trained. At least 10mins of counseling or visit	Continuous abstinence until birth and birth weight	Low
Coleman 2012 ⁽³³¹⁾	England	White British (97%)	1050	≤ 24	Nicotine patch 15mg/16h	Placebo patch	Behavioural support provided by research midwives. First face-to-face and three by telephone. Face-to-face if collected a second month's supply	Continuous abstinence until birth	Low
Kapur 2001 ⁽³³²⁾	Canada	NS	30	≤ 24	Nicotine patch 15mg/18 hr for eight weeks followed by 10mg/18hr for two weeks followed by 5mg/18hr for two weeks	Placebo patch	Four counselling sessions. One of the investigators maintained weekly telephone contact	Point prevalence abstinence after eight weeks of treatment	Low
Oncken 2008 ⁽²³⁷⁾	US	Hispanic	194	≤ 26	Nicotine gum 2mgs for six weeks followed by a six week taper period	Placebo gum	Two 35min counselling sessions in English or Spanish delivered by a research assistant using a motivational interviewing approach	Seven day point prevalence abstinence after six weeks of gum use and at end of pregnancy	Low
Wisborg 2000 ⁽³³³⁾	Denmark	NS	250	< 22	Nicotine patch/16hr: 15mg/16hr for eight weeks followed by 10mg/16hr for three weeks	Placebo	Four sessions of smoking cessation counselling with midwife independent of routine antenatal care visits	Seven day point prevalence abstinence at 2 nd , 3 rd and 4 th prenatal visits	Low

BCS: behavioural cessation support

Table 10.2 Included studies: NRT patches and BCS versus BCS, n=3

Study	Country	Ethnicity	Participants (n)	Gestational cut-off (weeks)	Intervention	Control	BCS	Outcome	Risk of bias
El-Mohandes 2013 ⁽³³⁴⁾	US	African-American Hispanic	52	≤ 30	Nicotine patch 7mg or 14mg or 21mg/24 hr – two dosing schedules for 10 weeks based on baseline salivary cotinine levels	None	SCRIPT* programme – reinforcement and behavioural methods at four visits	Seven day point prevalence after six weeks and between 32 and 34 weeks' gestation	High
Hotham 2006 ⁽³³⁵⁾	Australia	NS	40	≤ 28	Nicotine patch 15mg/16h for 12 weeks	None	Counselled for approx 5mins at randomisation and for approx 2mins at subsequent visits by a researcher or midwives who has undergone training with QUIT	Self-reported abstinence at end of treatment and within 48 hours of birth	High
Pollak 2007 ⁽³³⁶⁾	US	White 69%, Black 24%	181	≤ 25	Nicotine patch or gum (2mg) or lozenge. Patch 7mgs/16hr if less than 10cigs/day, 14mg/16hr if 10-14 14 cigs/day and 21mg/day if ≥ 15 cigs/day	None	Six one-on-one counselling sessions. Five face-to-face at prenatal visits and one via telephone. Contacts designed to be relapse-sensitive and to coincide with prenatal visits	Seven day point prevalence after seven weeks of treatment and between 32-34 weeks' gestation	High

BCS: behavioural cessation support *The SCRIPT (Smoking Cessation and Reduction in Pregnancy Treatment Program)

Table 10.3 Included studies: Bupropion and BCS versus BCS, n=1

Study	Country	Ethnicity	Participants (n)	Gestational cut-off (weeks)	Intervention	Control	BCS	Outcome	Risk of bias
Stotts 2015 ⁽³³⁷⁾	US	African-American Hispanic	11	≤ 26	Bupropion 150mg/day for three days followed by 150mg twice daily for eight weeks	Placebo	Four, weekly, 15-minute smoking cessation counselling sessions delivered by a research nurse	Seven day point prevalence abstinence at end of treatment	Unclear

Table 10.4 Included studies: counselling, n=44

Study	Country	Ethnicity	Participants (n)	Gestational cut-off (weeks)	Intervention	Control	Comparison type	Outcome	Risk of bias
Baric 1976 ⁽³³⁸⁾	England	NS	110	< 20	One-to-one counselling from a senior medical student. Half were given a diary and a gift of a free smoking diary	Usual care	Counselling (single intervention) versus usual care	Self-reported abstinence 11 weeks after baseline visit	High
Cinciripini 2000 ⁽³³⁹⁾	USA	NS	82	≤ 30	Control and posted a video with six 25-30 minute vignettes	Quit calendar and tip guide	Counselling (single intervention) versus less intensive intervention	Biochemically validated point prevalence abstinence within 2-3 days of quit, 4-5 weeks after quit and 1 month (0-5) postpartum	High
Cook 1995 ⁽³⁴⁰⁾	USA	NS	150	< 24	Control and regular meetings with	Discussion of risks by a nutritionist	Counselling (multiple intervention) versus less	Biochemically validated at	High

					smoking cessation counsellor + physician reinforcement at each visit. Feedback from urine cotinine	and resident physician at initial visit	intensive intervention	term or birth, > 50% reduction in mean cotinine and mean birth weight	
Cummins 2016 ⁽³⁴¹⁾	USA	NS	1173	< 27	Telephone counselling provided by veteran staff members of quitline and self-help materials	Self-help materials only	Counselling (multiple intervention) versus less intensive intervention	Self-reported abstinence; 30-day abstinence in third trimester (about 29 weeks), 90 day abstinence at two months postpartum and 190 abstinence at six months postpartum	High
Dornelas 2006 ⁽³⁴²⁾	USA	66% Hispanic	107	< 30	One 90 min psychotherapy session by mental health therapist. Bimonthly phone calls	Usual care and booklet, chart prompt and audited chart	Counselling (single intervention) versus less intensive intervention	Biochemically validated seven day point prevalence abstinence and six months (6-11) postpartum	High
Dunkley 1997 ⁽³⁴³⁾	UK	NS	100	< 18	Brief contact (< 5mins) x eight visits with trained midwives	Usual care	Counselling (single intervention) versus usual care	Self-reported abstinence at 37 weeks and one month (0-5) postpartum	High
Eades 2012 ⁽³⁴⁴⁾	Australia	Aboriginal or Torres Strait Islander	263	≤ 20	Advised to quit 'cold turkey' at first visit. Bring a support person to second visit. Offered NRT at	Usual care	Counselling (tailored intervention) versus usual care	Biochemically validated point prevalence abstinence at 36 weeks	High

					third visit. Follow-up visits with health workers and midwives				
Ershoff 1989 ⁽³⁴⁵⁾	USA	64% white	242	< 18	Control and eight self-help booklets, taught behavioural strategies and asked to read first one, other mailed weekly	Two-page pamphlet, two minutes with a health educator and advised about free cessation programme	Counselling (single intervention) versus less intensive intervention	Biochemically validated abstinence at 34 weeks	High
Ershoff 1999 ⁽³⁴⁶⁾	USA	60% white	257	≤ 26	Control and 4-6 x 10-15 min phone counselling sessions by nurse educators trained in motivational interviewing	Received a 32-page self-help booklet	Counselling (single intervention) versus less intensive intervention	Biochemically validated cessation at 34 weeks and mean cigs/day	High
Gielen 1997 ⁽³⁴⁷⁾	USA	African American: 81%, 89%	391	≤ 28	Written information, a 15 minute one-to-one counselling session, educational materials, reinforcement and two letters of encouragement	Usual clinic + inpatient smoking cessation	Counselling (multiple intervention) versus usual care	Biochemically validated seven day point prevalence abstinence in hospital after delivery, six months (6-11) postpartum, > 50% reduction in cotinine from baseline to late pregnancy	High
Hajek 2001 ⁽³⁴⁸⁾	NS	NS	732	12	Midwives received two hours of training on CO monitor and stage of change advice and CO assessments.	Midwives received one hour of training to discuss the study and were asked to provide usual care	Counselling (tailored intervention) versus usual care	Biochemically validated point prevalence abstinence at birth and self-reported	High

					Participants received written advice, motivational materials and offer of buddying to another pregnant smoker for support	and any usual pamphlets		continuous abstinence at six months (6-11) postpartum	
Hartmann 1996 ⁽³⁴⁹⁾	USA	White: 78%, 74%	219	≤ 36	Counselling by residents at each visit, Windsor's guide, contacted by smoking cessation counsellor and quitters sent encouraging postcard each week	Usual care	Counselling (multiple intervention) versus usual care	Biochemically validated abstinence at last prenatal visit, > 50% reduction in self-reported smoking and mean cigs/day	High
Haug 1994 ⁽³⁵⁰⁾	Norway	NS	322	≤ 12	GP advice < 15 minutes at first visit, written information, invited to consult GP after 1, 6, 12 and 18 months	Usual care	Counselling (multiple intervention) versus usual care	Self-reported smoking abstinence 6 months after study entry, biochemically validated 12 months after start (0-5 months postpartum), self-reported abstinence at 15 (6-11) and 18 (12-17) months postpartum	High
Hegaard 2003 ^(351, 352)	Netherlands	NS	647	≤ 22	30-40 minute consultation, written information, invitation to join smoking cessation programme based on CBT, all offered NRT	Usual care (included advice in a 30 minute consultation)	Counselling (tailored intervention) versus usual care	Biochemically validated cessation at 37 weeks, mean birth weight, low birth weight	High

					(2mg gum or 15mg patch/16 hours) for 11 weeks + encouragement at subsequent clinic visits			and preterm births	
Kendrick 1995 ⁽³⁵²⁾	USA	NS	1,885	≤ 32	Based on stages of change but differed by state. 1-5 minutes counselling or brief clinic based counselling or six minutes with brochures and written materials	Usual care (not otherwise specified by usual clinic staff)	Counselling (multiple intervention) versus usual care	Biochemically validated point prevalence abstinence at eight months' gestation	High
Lawrence 2003 ⁽³⁵³⁾	UK	NS	613	≤ 19	Midwives trained on theory of transtheoretical model (TTM). Assessed by midwife and given TTM based self-help manual and interactive computer programme giving individualised advice	Usual care. Midwives asked to give a booklet to women	Counselling (multiple intervention) versus usual care	Biochemically validated point prevalence abstinence at 28-30 weeks, 10 days after birth and at 0-5 months postpartum	High
Lee 2015 ⁽³⁵⁴⁾	USA	56% Black 12% Hispanic	277	≤ 25	Cognitive behavioural therapy provided by a health educator- two prenatal and two postnatal	Best practice - brief advice based on the 5A's	Counselling (multiple intervention) versus usual care	Biochemically verified seven day point prevalence abstinence in late pregnancy and at one and five months postpartum	High
Lillington 1995 ⁽³⁵⁵⁾	USA	53% African American	34	NS	Assessment of motivation and intention. Bilingual health educators. 15	Usual care. Printed information and group quit	Counselling (multiple intervention) versus usual care	Self-reported smoking cessation at nine months'	High

					minute individual counselling, self-help guide, how to win prizes and booster postcard every month	message		gestation and six weeks (0-5 months) postpartum	
Loeb 1983 ⁽³⁵⁶⁾	USA	NS	963	NS	Letter of invitation, reminder letter, group information meeting, individual session with trained smoking counsellor, six 1.5 hour group sessions, once a week and subsequent optional groups, individual sessions + phone calls	Usual care	Counselling (tailored intervention) versus usual care	Self-reported smoking cessation in late pregnancy. Biochemically validated with cord blood thiocyanate	High
Mayer 1990 ⁽³⁵⁷⁾	USA	75% White	149	≤ 28	20min 1:1 counselling and behavioural change manual focusing on contracting and self-monitoring (CBT)	Usual care which included printed information	Counselling (multiple intervention) versus usual care	Self-reported smoking cessation at 9 months' gestation and approx. 4.7 weeks (0-5months) postpartum	High
McBride 1999 ⁽³⁵⁸⁾	USA	88% White	501	< 20	Receive a personalised letter, a relapse prevention kit, a booklet, three antenatal counselling phone calls, three additional counselling calls in first four months after birth and three newsletters	Self-help booklet and suggestions for quitting	Counselling (multiple intervention) versus less intensive intervention	Self-reported and biochemically validated 7 day point prevalence abstinence at 28 weeks. Abstinence at two (0-5), six (6-11) and 12 (12-17)	High

								months postpartum (combined baseline smokers and spontaneous quitters)	
McLeod 2004 ⁽³⁵⁹⁾	New Zealand	NS	272	NS	Four armed approach. Intervention 1: midwife training-smoking cessation and support. Intervention 2: midwife - breastfeeding support for smokers. Intervention 3: Interventions 1 and 2 combined. Intervention 4: Control and intervention 2 compared with interventions 1 and 3	Usual care and midwife training and support to implement education and support for breastfeeding for women who smoked	Counselling (single intervention) versus usual care	Biochemically validated cessation at 28 and 36 weeks and at six weeks and four months (0-5) postpartum. Breastfeeding outcomes also reported	High
Messimer 1989 ⁽³⁶⁰⁾	USA	98% White	59	< 28	Control and use of American Lung Association materials, encouragement to send off for materials and slide tape presentation at first visit	Three counselling sessions with physicians, removal of ashtrays and staff asked not to smoke in front of patients	Counselling (multiple intervention) versus less intensive intervention	Self-reported smoking abstinence at 32-36 weeks and at first postpartum visit (0-5 months)	High
Moore 2002 ⁽³⁶¹⁾	England	NS	1090	≤ 32	Midwives spent ≥ 5mins introducing a series of 5 self-help booklets based on	Usual care	Counselling (single intervention) versus usual care	Self-reported 7 day point prevalence abstinence at	High

					stages of change theory. Given copy of first booklet and remainder posted			26 weeks (94% biochemically validated). Self-reported mean cigs/day in late pregnancy	
Panjari 1999 ⁽³⁶²⁾	Australia	NS	1013	≤ 20	Control and four counselling sessions by a midwife specifically trained and employed to provide smoking cessation counselling using CBT. Video, interactive discussions and strong verbal messages. Followed by a 5-10min personalised counselling session	Usual care (advice and pamphlet distribution during a group info session)	Counselling (single intervention) versus less intensive intervention	Biochemically validated self-reported smoking cessation at 36 weeks, at six weeks (0-5 months) and at six months (6-11 months) postpartum. Mean birth weight, proportion < 2.5kg and preterm birth	High
Parker 2007 ⁽³⁶³⁾	USA	Majority White	736	≤ 26	Received quit kit, enrolled in quit and win monetary incentive lottery programme and up to three motivational interviewing (MI) phone calls	Received self-help materials (quit kit and video - SCRIPT)	Counselling (multiple intervention) versus less intensive intervention	Biochemically validated self-reported smoking cessation at 32 weeks, six weeks and six months postpartum (outcomes not reported)	High
Patten 2009 ⁽³⁶⁴⁾	USA	Alaskan natives	33	≤ 24	Self-help guide adapted from SCRIPT trials, 15-25 min face-to-face counselling based on	5A's component treatment, five minute face to face at first visit and culturally	Counselling (multiple intervention) versus less intensive intervention	Biochemically validated tobacco use 60 days post-randomisation	High

					5A's, a video, 4 x 10-15 minute proactive interactive phone sessions	specific brochures		(late pregnancy)	
Pbert 2004 ⁽³⁶⁵⁾	USA	NS	434	< 32	Dissemination intervention consisted of provider training based on national CPGs, office management system and establishment of programme boards. Based on MI and 4 A's from the SCRIPT trial.	Usual care, in which no training or intervention occurred	Counselling (single intervention) versus usual care	Biochemically validated smoking cessation at one month postpartum (late pregnancy), at three (0-5) and at six (6-11) months postpartum. Mean cigs/day	High
Price 1991 ⁽³⁶⁶⁾	USA	70% White	141	≤ 28	Tailored educational videotape for 6.5 minutes, pamphlet on quitting, a second four minute video one month later and questions answered by health educator	Usual care	Counselling (single intervention) versus usual care	Biochemically validated smoking cessation two or three weeks prior to delivery. Mean cigs/day	High
Rigotti 2006 ⁽³⁶⁷⁾	USA	NS	421	≤ 26	Control and a series of telephone calls accompanied by additional mailed written materials. Each participant had a trained counsellor who offered up to 90mins of counselling in pregnancy and up to 15mins postpartum	Usual care and mailed a validated smoking cessation booklet. Less than five minutes counselling at enrolment by a trained counsellor	Counselling (multiple intervention) versus less intensive intervention	Biochemically validated seven day point prevalence abstinence at 28 weeks to term, at three (0-5) months postpartum and > 50% reduction in cigs/day	High
Secker-Walker	USA	NS	513	< 25	Counselling from a trained health	Usual advice about smoking	Counselling (multiple intervention) versus usual	Self-reported smoking	High

1994 ⁽³⁶⁸⁾					educator. Follow up at second visit, 36 weeks and six weeks postpartum	provided by obstetrician or midwife	care	cessation at 36 weeks (75% biochemically validated). Self-reported cessation at 8-15 months (6-11), 16-24 months (18) and 25-54 months postpartum. Mean + low birth weight, PPROM, placenta praevia + placental abruption	
Secker-Walker 1997 ⁽³⁶⁹⁾	USA	98% White	49	NS	Control and a 29 minute video of four women going through process of quitting during pregnancy. Based on social learning theory	Advice from obstetrician or nurse-midwife and a booklet on quitting	Counselling (single intervention) versus less intensive intervention	Biochemically validated cessation at 36 weeks	High
Secker-Walker 1998 ⁽³⁷⁰⁾	USA	NS	291	NS	Structured smoking cessation protocol provided by physicians trained in its use. First, second, third and fifth visits	Received a baseline questionnaire, a booklet, physician advice, CO measured and a brief standardised health risk message from a research nurse	Counselling (multiple intervention) versus less intensive intervention	Biochemically validated seven day point prevalence abstinence at 36 weeks and one year postpartum. Mean birth weight, low birth weight, mean cigs/day	High

								at 36 weeks and one year postpartum. Preterm births	
Stotts 2002 ⁽³⁷¹⁾	USA	NS	269	28	Control and 20-30 mins of motivational interviewing (MI) telephone counselling, a personalised stages-of-change based feedback letter and a final MI call 4-5 days after the feedback letter was sent	Provided with MI counselling (3-5 minutes) and a series of eight motivational self-help books	Counselling (multiple intervention) versus less intensive intervention	Biochemically validated cessation at 34 weeks. Self-reported smoking cessation at six weeks and three and six months postpartum	High
Stotts 2004 ⁽³⁷²⁾	USA	NS	54	< 28	MI intervention over eight weeks consisting of one face-to-face MI session, three MI based telephone counselling calls and a personalised feedback letter providing assessment results	Usual care which included physicians or nurses acknowledging smoking and advising quitting	Counselling (multiple intervention) versus usual care	Biochemically validated cessation at post treatment assessment (late pregnancy)	High
Tappin 2000 ⁽³⁷³⁾	Scotland	NS	97	NS	Received 2 to 5 MI sessions (mean 2.6hrs) at home by a midwife with 3 weeks training in smoking cessation counselling	Usual care (received usual advice which should include information about smoking)	Counselling (single intervention) versus usual care	Biochemically validated cessation at greater than or equal to 27 weeks. Mean birth weight, preterm birth and stillbirths	High
Tappin 2005 ^(374, 375)	Scotland	NS	756	≤ 24	Control and offered 2-5 additional home visits of about 30mins from same study midwife	Midwives provided standard health promotion including information from a	Counselling (single intervention) versus usual care	Biochemically validated and self-reported quitting after the 36 week	High

						book given to all pregnant women in Scotland		visit , mean birth weight, low and very low birth weight, perinatal deaths, admission to NICU, preterm delivery, stillbirths and neonatal deaths	
Thornton 1997 ⁽³⁷⁶⁾	Ireland	NS	367	NS	Control and structured one-to-one counselling by a trained facilitator. Partners invited to be involved in the programme. Received an information pack which included a self-help booklet and invited to join a support group. A CO monitor was available for the intervention group.	Routine prenatal advice on a range of health issues from midwives and obstetricians	Counselling (tailored intervention) versus usual care	Biochemically validated abstinence and relapse prevention at delivery and at three months postpartum, mean birth weight, low birth weight, preterm birth, perinatal deaths and admission to NICU	High
Tsoh 2010 ⁽³⁷⁵⁾	USA	NS	42	< 26	Tailored advice from 'Video Doctor' designed to simulate an ideal discussion with a prenatal healthcare professional who provided non-judgemental counselling following	Usual care	Counselling (multiple intervention) versus usual care	Self-reported 30 day abstinence after one month and two months. Mean reduction in cigs smoked per day and	High

					principles of MI. At the end of each session two documents printed automatically (a cueing sheet for providers and education worksheet for participants)			days smoked	
Valbo 1996 ⁽³⁷⁷⁾	Norway	NS	130	18	Anaesthetist provided two 45min sessions at 2 week intervals of a protocol-based script (Handbook of the American Society of Clinical Hypnosis). Two different tapes played after hypnosis established	Usual care	Counselling (single intervention) versus usual care	Self-reported abstinence at birth, mean cigs per day at birth and self-reported reduction in smoking	High
Walsh 1997 ⁽³⁷⁸⁾	Australia	NS	252	< 26	CBT. 2-3 minute standardised information from doctor, 14 minute video, 10 minute standardised information, counselling from midwife after video, self-help manual, 4 packets of confectionary gum, lottery chance for biochemically validated abstinence at next visit, social support, letters, 34 weeks, 5 minute counselling from doctor and 1-2	Women advised to stop smoking by doctors and midwives. Midwife provided a package which included (sticker, pamphlet and a two page cessation guide, not specifically tailored to pregnancy)	Counselling (tailored intervention) versus less intensive intervention	Biochemically validated abstinence at 34 weeks and at 6-12 weeks postpartum and preterm births	High

					minute risk advice from doctor				
Windsor 1985 ⁽³⁷⁹⁾	USA	57% Black	206	< 32	Received a 10min standardised counselling session from a health educator, a self-help guide to quit smoking and a pamphlet	Smoking cessation advice routinely given at prenatal visits: 2-3 minutes within a group prenatal education session at the first visit	Counselling (multiple intervention) versus usual care	Biochemically validated point prevalence abstinence mid-pregnancy, during last month of pregnancy, or within 48hrs of birth. Self-reported reduction in late pregnancy	High
Windsor 1993 ⁽³⁸⁰⁾	USA	52% Black	814	< 32	15 minute standardised cessation skills and risk counselling session based on CBT from trained female health education counsellor, a 7 day self-directed cessation guide, clinic reinforcement, social support and monthly newsletter	Two minute talk in a 30 minute group session. Given two pamphlets, including details and contact of local quit programme	Counselling (multiple intervention) versus less intensive intervention	Biochemically validated point prevalence abstinence at four to eight weeks after first visit and at 32 weeks	High
Windsor 2011 ⁽³⁸¹⁾	USA	NS	993	< 32	Received Assist procedures 4 through 8: 14 min video, written guide with 10 day self-help guide, a ≤ 10 min MI counselling session	Received four elements of the '5A's' best practice guidelines	Counselling (multiple intervention) versus less intensive intervention	Biochemically validated point prevalence abstinence in late pregnancy (> 60 days after first visit and < 90 days postpartum)	High

Table 10.5 Included studies: health education studies, n=6

Study	Country	Ethnicity	Participants (n)	Gestational cut-off (weeks)	Intervention	Control	Outcome	Risk of bias
Burling 1991 ⁽³⁸²⁾	USA	52% White	139	any	Personal letter + pamphlet, CO test mentioned and simple guidelines for self-directed smoking cessation	Usual care	Biochemically validated point prevalence abstinence at 34 weeks	High
Herbec 2014 ⁽³⁸³⁾	UK	94% White	200	NS	Fully automated smoking cessation website targeted to pregnancy (tailored, personalised and structured) 'MumsQuit'	Information only website	Self-reported continuous abstinence (4 week abstinence) 8 weeks post-baseline	High
Hjalmarson 1991 ⁽³⁸⁴⁾	Sweden		653	< 12	Self-help manual on stopping smoking, based on Windsor 1985	Given information sheet by their doctor as included in the last pages of the self-help manual	Biochemically validated abstinence at 30-34 weeks and at eight weeks (0-5 months) postpartum. Mean birth weight, births < 36 weeks, low birth weight*, mean cigs/day at 30-34 weeks among baseline smokers	High
Lilley 1986 ⁽³⁸⁵⁾	England		145	< 28	Control + 10 min advice from junior doctor based on booklet, a leaflet and copies of booklet for family, letter to GP, letter to woman and pre-planned home visit	Usual care with possible exposure to a concurrent television series on stopping smoking in pregnancy	Self-reported abstinence 9-16 weeks after booking visit. Mean cigs per day	High
Naughton 2012 ⁽³⁸⁶⁾	England	100% White	198	< 21	Tailored self-help leaflet by post. Automated tailored text messages. 80 texts sent over eleven weeks. Participants could request instant response supportive text 24 hours a day	Non-tailored self-help leaflet and the same assessment texts as intervention	Biochemically validated 7 day point prevalence abstinence at three month follow-up. Self-reported four week point prevalence abstinence initiation	High

						arm but no intervention texts	and frequency of quit attempts and seven day point prevalence abstinence at three and seven weeks after enrolment	
Petersen 1992 ⁽³⁸⁷⁾	USA	Majority White	90	≤ 24	Brief counselling by a healthcare professional. Pregnancy specific self-help manual and an audiotape on safe exercise and relaxation posted to participants. Behavioural strategies for quitting and maintenance section for postpartum period	Brief repeated counselling by a healthcare professional and information about community resources posted to participants	Self-reported abstinence at six months gestation and at eight weeks (0-5) postpartum	High

Table 10.6 Included studies: financial incentives studies, n=3

Study	Country	Ethnicity	Participants (n)	Gestation (weeks)	Intervention	Control	Outcome	Risk of bias
Harris 2015 ⁽³⁸⁸⁾	USA	88% White	17	≤ 12	A web-based contingency management programme and financial incentives (\$100 cash)	A phone-delivered cessation counselling programme (Smoking Cessation for Healthy Births)	Biochemically validated continuous abstinence in late pregnancy. Abstinence was determined by self-reported smoking using a timeline follow-back calendar and urinary cotinine values	High
Undersma 2012 ⁽³⁸⁹⁾	USA	90% Black	114	≤ 27	Incentives. Maximum of five episodes of reinforcement (in the form of retail gift cards)	Usual care	Biochemically validated seven day point prevalence	High

					worth \$50)		abstinence at 10 week follow-up	
Tappin 2015 ⁽³⁹⁰⁾	UK	NS	612	< 24	Routine care and the offer of up to £400 of shopping vouchers. £50 for attending a face to face appointment and setting a quit date, another £50 if at four weeks' post-quit date exhaled carbon monoxide confirmed quitting; a further £100 was provided for continued validated abstinence of exhaled carbon monoxide after 12 weeks; a final £200 voucher was provided for validated abstinence of exhaled carbon monoxide at 34-38 weeks' gestation	Usual care (offer of a face to appointment), offer of free NRT x 10 weeks if set a quit date, 4 weekly support phone calls	Biochemically validated point prevalence abstinence at 34-38 weeks	High

Table 10.7 Included studies: social support studies, n=7

Study	Country	Ethnicity	Participants (n)	Gestation (weeks)	Intervention	Control	Outcome	Risk of bias
Albrecht 1998 ⁽³⁹¹⁾	USA	63% African-American	84	≤ 28	Teen Fresh Start (TFS) plus peer support compared with TFS and control	30 minute education session with project nurse and provision of brochures	Biochemically validated point prevalence abstinence 4-6 wks after baseline	High
Albrecht 2006 ⁽³⁹²⁾	USA	NS	95	≤ 28	TFS plus a peer buddy	Usual care. Given educational materials and explanation at a 45-60 minute meeting, attendance incentive (lipstick or nail polish)	Biochemically validated point prevalence abstinence after eight weeks and at one year after the intervention (6-11 months)	High
Bullock 2009 ⁽³⁹³⁾	USA	95% White	66	< 24	Received eight booklets and nurse delivered social support	Pamphlet from AHA, research team member to call each month to	Biochemically validated point prevalence abstinence	High

						arrange salivary sample, measure exposure, ask some questions for two more interviews	at 28-32 weeks and at six weeks (0-5 months) postpartum	
Hennrikus 2010 ⁽³⁹⁴⁾	USA	67% racial minority	82	≤ 28	Control and one in-person visit and monthly phone sessions with peer supporters. Given a pregnancy scrapbook with pages that related to smoking cessation tasks	One in-person counselling session to increase motivation to quit and to provide information about community cessation resources	Biochemically validated smoking status just prior to EDD and at three (0-5) months postpartum	High
Malchodi 2003 ⁽³⁹⁵⁾	USA	Majority Black	142	< 20	Control and peer counselling (trained) from lay community outreach workers (phone or home visits)	Usual care which included a programme of AAA, provision of self-help materials, smoking cessation counselling as per protocol at each visit	Biochemically validated abstinence at 36 weeks, mean birth weight and proportion low birth weight	High
McBride 2004 ⁽³⁹⁶⁾	USA	77% White	180	≤ 20	Control and booklet, gift items, six counselling calls based on motivational interviewing (three in antenatal period and three in postnatal period) and partner assistance	Usual care, provider advice, mailed American Cancer Society self-help guide designed for pregnant women	Self-reported ppa at 28 weeks (baseline smokers and baseline quitters reported separately) combined continued abstinence at two (0-5), 6 (6-11) and 12 (12-17) months postpartum	High
Solomon 2000 ⁽³⁹⁷⁾	USA	Majority White	151	NS	Control + if intended to quit offered phone peer support by a healthcare professional. Phone peer support from a trained female ex-smoker - weekly, average duration 10 minutes	Brief smoking cessation advice from trained healthcare professionals at each of three prenatal visits and provided with printed materials	Biochemically validated seven day point prevalence abstinence at 28-34 weeks	High

Included studies: Feedback studies, n=4

Study	Country	Ethnicity	Participants (n)	Gestation (weeks)	Intervention	Control	Outcome	Risk of bias
Bauman 1983 ⁽³⁹⁸⁾	USA	56% Black	79	≤ 32	Control and exhaled CO with feedback on result	A 135 word script which described the relationship between cigarette smoking and CO, and the harmful consequences of smoking during pregnancy was read	Biochemically validated abstinence six weeks after intervention	High
Cope 2003 ⁽³⁹⁹⁾	England	NS	270	NS	Urinary CO with feedback on result. Quit date set and given a leaflet. Information, feedback and encouragement protocol followed at every visit until 36 weeks	Urinary CO measured but without feedback	Biochemically validated point prevalence abstinence at 36 weeks, mean birth weight and preterm birth	High
Stotts 2009 ⁽⁴⁰⁰⁾	USA	NS	240	≤ 26	Three armed RCT. Best practice counselling, feedback on results of ultrasound and information about effect of cigarette smoke on the fetus and one 45-50min fac-to-face session of motivational interviewing-based counselling	5A's, 5R's, 10-15 minute counselling (best practice counselling)	Biochemically validated abstinence at eight months gestation	High
Valbo 1994 ⁽⁴⁰¹⁾	Norway	NS	111	18	Offered Windsor self-help manual, extra ultrasound at 32 weeks and two reminders	Information about harm at time of 18 week ultrasound. Given a pamphlet and encouraged to quit	Self-reported abstinence, self-reported reduction, mean cigs per day at delivery and stillbirths	High

Appendix 11 Studies smoking cessation interventions in pregnancy that were excluded from this review

	Exclude	Reason for Exclusion	Explanation
1	Belizan 1995	Intervention	Intervention included advice on nutrition, alcohol and drugs.
2	Bullock 1995	Intervention	Intervention included advice on nutrition, alcohol and drugs.
3	Byrd 1993	Outcome	Smoking status not reported by intervention group.
4	Campbell 2006	Comparison	Assessed the differential effectiveness of two methods of disseminating a smoking cessation programme.
5	Cinciripini 2010	Comparison	Counselling compared to an Alternative (traditional health education or MI).
6	Donatelle 2000	Comparison	Comparison - incentives was part of a multiple intervention, compared to a less intensive intervention.
7	Donovan 1977	Outcome	No data on smoking cessation (just mean cigs/day).
8	El-Mohandes 2011	Intervention	Smoking cessation part of multi-component intervention.
9	Graham 1992	Outcome	Unclear how many smokers were in each arm.
10	Haddow 1991	Outcome	No data on smoking cessation.
11	Haug 2004	Population	Opioid dependent only. In addition, actual figures not reported.
12	Heil 2008	Comparison	Intervention group (contingent voucher) versus control (non-contingent voucher) - equally intensive alternative.
13	Hiett 2000	Outcome	Outcomes not reported.
14	Hughes 2000	Outcome	Outcomes not reported.
15	LeFevre 1995	Outcome	No specific smoking intervention provided. No data on cessation outcomes.
16	Lowe 1997	Population	Spontaneous quitters within 3 months of first prenatal visit.
17	Lowe 2002	Intervention	Dissemination trial. Smoking cessation rates not included as an aim of this study.
18	Manfredi 1999	Population	Unable to separate pregnant women from women attending family planning and paediatric clinics.
19	Moore 1998	Outcome	Not clear what proportion of outcomes related to smokers. Low birthweight and preterm births were study outcomes.
20	Moore 2002	Outcome	Outcomes for smokers and recent quitters are combined in analysis.
21	Olds 1986	Intervention	Multicomponent intervention (nutrition, alcohol, drugs, enhancement of informal support systems; high intensity) .

22	Olds 2002	Outcome	Only mean reduction in cotinine reported.
23	Polanska 2004	Outcome	Outcomes in late pregnancy not reported - 'shortly after delivery at home' (0 to 5 months postpartum).
24	Reading 1982	Comparison	Three arms based upon visualisation of ultrasound; no specific smoking cessation component. Also, control outcomes not reported.
25	Strecher 2000	Population	Included women who had quit since becoming pregnant. In addition, no late pregnancy outcomes (only postpartum).
26	Tuten 2012	Population	Methadone users only.
27	Vilches 2009	Outcome	Abstinence not reported: mean cigs/day reported in late pregnancy.

Appendix 12 Estimating the opportunity cost of a GP visit for a patient with a GMS or GP Visit Card

For the purposes of the economic model it was necessary to estimate the opportunity cost of a GP attendance for those with a Medical or GP Visit Card. Primary healthcare services are free at the point of care through the General Medical Services (GMS) scheme. Eligibility is means-tested based on the total income in a household. There are two types of eligibility:

- full GMS or Medical Card, which entitles the holder to free access to:
 - GP services
 - Prescribed medicines or aids listed for reimbursement by the Primary Care Reimbursement Service (PCRS) subject to a prescription charge¹;
- a GP Visit Card which entitles the holder to free GP services only.

Medical Card coverage is near universal for those aged over 70 years although means testing is applied. Medical Card coverage is universal for those aged less than six years. In 2015, almost 2.2 million people or 47% of the population were covered by a Medical Card or a GP Visit Card. In the subsequent text we will refer to patients with a Medical Card or GP Visit Card as ‘public patients’, and all those who must pay at the point of care as ‘private patients’. The purpose of this analysis was to determine the opportunity cost of a GP visit for public patients; prescription costs were considered separately in the economic evaluation and are not considered here.

Methods

The opportunity cost of a GP visit is a function of the number of GP visits, total income of GP services, and other services that must be funded through that income.

GP visits

We reviewed datasets available through the Irish Social Science Data Archive, the Central Statistics Office (CSO), and other published sources that included evidence of GP visit rates. Rates were extracted at the highest level of detail with regard to age, sex and Medical Card status. Where there was no clear distinction between Medical Card and GP Visit Card, we assumed the same visit rate for Medical Cards applied to both groups. Where a visit rate was computed for an age range, we assumed that the same rate applied to each single year of age within that age band. Use of single year of age enabled calculation of total number of visits for different age ranges for comparison across datasets.

¹ For those aged less than 70 years, a **€2.50 prescription charge** applies per item dispensed (subject to a monthly ceiling of €25 per family). The prescription charge for persons aged 70 years & over, and their dependents, is **€2.00 per item and the monthly cap for prescription charges is €20.00** for this cohort.

Population data

The relevant population is the total population of Ireland classified by age, sex and Medical Card status. The Medical Card population was estimated for males and females using PCRS data for 2015.[1] Total population by single year of age for 2015 was extracted from the CSO website.[2]

Income for GP services

GPs are paid through a mix of capitation fee per Medical Card patient, fee-per-item, allowances and investment in general practice development. The capitation fee per patient is a function of the age and sex of the patient. In 2015, total fees and **allowances of €489.69m** were paid to GPs for provision of services through the PCRS, which covers services provided to public patients.[1] PCRS funding is used to pay towards practice premises, equipment, disposables, running costs, and staff.

Income is also generated by patients who pay out of pocket at the point of care. This is a combination of consultation fees to attend the GP and a practice nurse. Data on typical consultation fees were extracted from the www.WhatClinic.com website which includes data on 1,651 clinics (or 95% of practices).[3] A subset of 644 (39%) of the listed clinics include data on the cost of a GP consultation. The locations of the subset of practices were mapped to counties and the estimated mean cost was weighted by the expected number of private patient visits.

A 2010 survey of 123 (7%) GP practices by the National Consumer Agency found an **average cost of €51 for a GP consultation**. [4] **Inflation in doctors' fees as measured** in the consumer price index was unchanged from 2010 to 2015.[5]

Practice nurse data

Included in PCRS payments to GPs is funding for practice nurses who provide clinical consultations. Practice nurses provide a wide range of services within primary care such as carrying out immunisations, phlebotomy, weight management, wound management, and travel vaccinations. To account for this in estimates of opportunity cost, data on practice nurses was included.

The cost of a practice nurse consultation was provided by only three practices in the www.WhatClinic.com data, ranging from €20 to €45.[3] We assumed that the recouped cost of a private practice nurse visit was an average of **€25 with relatively wide confidence bounds to reflect uncertainty in the true mean (95% CI: €20.55 to €30.41)**. That is, it was assumed that a private consultation with a practice nurse **would generate an average €25 for the practice**. Salaries for practice nurses are not set according to a specified scale. The Irish Nurses & Midwives Organisation recommends that the minimum salary of the Practice Nurse should be the salary at the maximum point of the staff nurse scale, **which is €42,469 based on the January**

2016 Revised HSE Consolidated Payscale,[6] plus any other allowance that is applicable (such as dual qualification).[7] Approximately 13% of practice nurses are Clinical Nurse Specialist Grade[8] and the remainder are a mix of Staff Nurse Grade, Senior Staff Nurse Grade, Dual Qualified Practice Nurse and Senior Dual Qualified Practice Nurse. Based on this distribution of grades, we assumed an average salary **of €50,000, which approximately represents the mid-point** of the scale for a clinical nurse manager, clinical nurse specialist or public health nurse. In accordance with national guidelines, salaries were adjusted to take into account pay-related costs.[9] **After taking into account employers' PRSI, pension contributions and overheads, the average practice nurse salary was estimated to be €69,875 per annum. The total** number of full time equivalent practice nurses was derived from a national study.[10]

Data on the number of practice nurse consultations for people aged 15 years and over were extracted by age, sex and medical card status from the 2015 Healthy Ireland survey.[11]

Statistical methods

Given the uncertainty in a number of the parameters required for estimating the opportunity cost of a GP visit, a simple simulation model was used. Uncertainty in the number of GP visits, practice nurse visits, and cost of a private GP consultation was captured using bootstrapping of the survey data. Uncertainty in practice nurse numbers, salary and consultation fee was set by statistical distributions informed by the available data.

We used sensitivity analysis to explore some of the assumptions that were supported by limited evidence.

Findings

Data sources on GP visits

We identified eight sources of GP visit data (Table 13.1). Seven are nationally representative population surveys that include a question on GP utilisation. The question is predominantly phrased as utilisation in the 12 months prior to the survey. The Healthy Ireland survey is based on four-week recall. We identified one nationally representative survey of GPs, which provided supply-side data based on reported productivity per session, and number of sessions provided per week.

Table 13.1 Details of sources of GP visit data

Source	Sample size	Sample type	Recall period	Year	Age range
<i>Broad age range</i>					
Living in Ireland[12]	14,510	National	12 months	2004	16+
CSO QNHS 2010[13]	15,673	National	12 months	2010	18+
Irish Health Survey[14]	10,323	National	4 weeks	2015	15+
Healthy Ireland[11]	7,539	National	4 weeks	2015	15+
<i>Narrow age range</i>					
Growing Up in Ireland[15, 16]	19,600	National	12 months	2013	<10
TILDA[17]	8,175	National	12 months	2013	50+
<i>GMS only</i>					
EU-SILC[18]	13,793	National	4 weeks	2015	15+
<i>Supply-side</i>					
GP Survey[19]	464 practices	National	1 week	2015	All

An 2013 audit of six general practices by Behan *et al.* was also identified.[20] The study collected data on GP and practice nurse visits over the course of 12 months. As GP and practice nurse consultations could not be disaggregated in the reported study data, the study was not included in this analysis.

Volume of visits

The Living in Ireland, CSO Quarterly Household Survey, and Healthy Ireland survey all generate similar estimates for the number of visits by the total population aged 18 years and over (Table 13.2). The Irish Health Survey generates a much higher estimate of utilisation (55% higher than the next highest estimate).

In terms of only the Medical Card population, the Living in Ireland, CSO Quarterly Household Survey, and Healthy Ireland again all generate similar estimates. The study by Behan *et al.* generates a higher estimate (16% higher than Living in Ireland) while the EU-SILC data generates a much higher estimate (54% higher than Healthy Ireland survey), as does the Irish Health Survey (59% higher than Healthy Ireland).

The Irish Longitudinal Study on Ageing (TILDA) asks about GP utilisation in a cohort of people aged 50 years and older. It generates a lower estimate of utilisation than any of the other datasets including the equivalent age range. Growing Up In Ireland was the only dataset identified estimating visit rates for those aged less than 15 years.

The GP Survey did not provide figures by age, but enabled calculation of a total number of visits for all patients. Based on the GP Survey an estimated 17.1 million patients are seen each year.

With one exception, the data sources on visits are based on surveys of the general population and potentially subject to recall bias. The Healthy Ireland survey is the only source that used four-week recall, with all other identified general population surveys using 12-month recall. There is the potential for substantial recall bias over a longer time span, although it is not clear whether this would result in systematic under- or over-reporting. A shorter time span should limit the risk of recall bias, but may introduce other bias if the survey is carried out at a time of year when visit rates are higher (e.g., Winter) or lower (e.g. Summer). The Healthy Ireland surveys were carried out between Autumn 2014 and Summer 2015, capturing data over almost a 12-month period. This provides reassurance that the data are likely to limit seasonal bias. The Quarterly National Household survey results for 2010 have an unusual pattern for public patients in that the visit rate peaks for those aged 55-64 years.

Two of the surveys generated substantially higher estimates of total visits: the Irish Health Survey and the EU-SILC survey, both conducted by the CSO. The former survey was carried out for the first time in 2015, and there are limited details available on the survey results. The Irish Health Survey estimates that 74% of respondents consulted a GP in the previous month, which is very similar to the 72.3% estimated in the Healthy Ireland survey. As it is based on a cross-European survey, it does not ask questions such as Medical Card status, so it is not possible to interrogate whether the higher visit rates apply to both private and public patients, or just to a subset. The Irish Health Survey is unique in the datasets in the visit rate does not follow a curve of increasing attendance with age – visit rates decrease from age 16-24 years to a minimum at age 45-54 years before increasing thereafter. This raises questions about the methodology used and the applicability of the data.

The EU-SILC survey only gathers data with respect to **“free GP visits”** and therefore excludes private patients. The results obtained by the EU-SILC survey would appear to be an outlier, generating estimated visit rates well in excess of any of the other data sources for an equivalent population.

Figure 13.1 Number of visits per annum by age (for public and private patients)

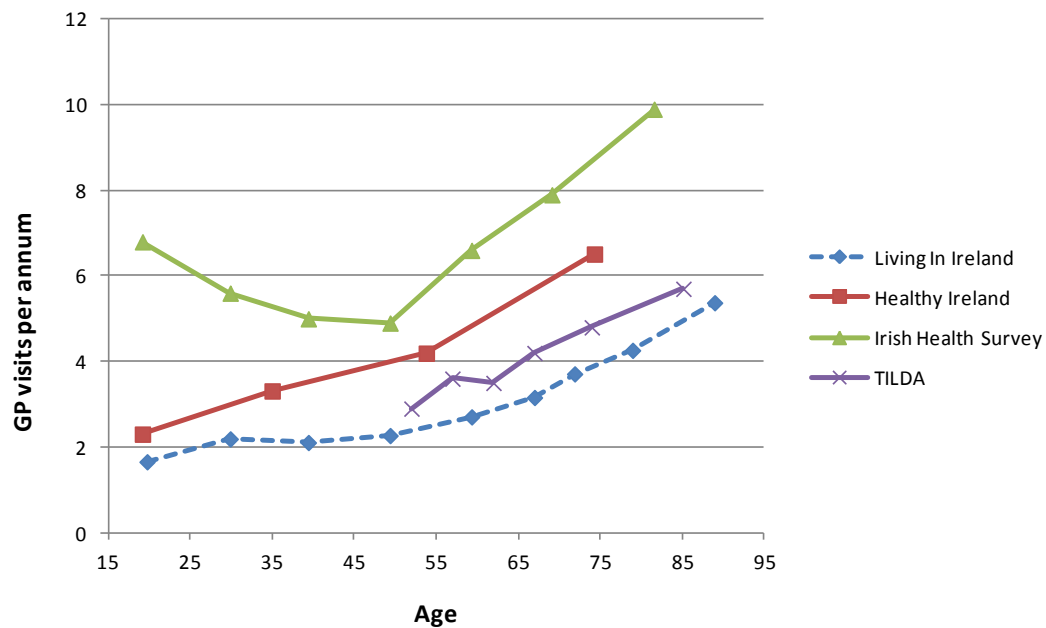


Figure 13.2 Number of visits per annum by age (public patients only)

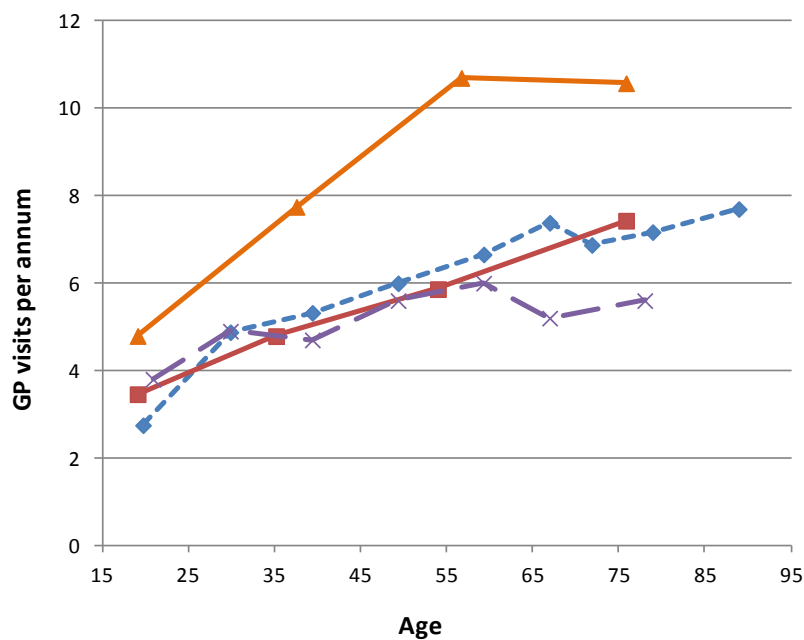


Table 13.2 Estimated numbers of GP visits per annum

Source	Estimated visits					All ages		
	18+ (all) ^a	18+ (public only) ^a	50+ (all) ^a	<15 (all) ^a	<15 (public only) ^a	Public ^b	Private ^b	Total ^b
<i>Broad age range</i>								
Living in Ireland	13,408,472	8,464,929	7,308,414			10,482,782	5,673,650	16,156,432
CSO QNHS 2010	12,284,036	7,784,524	6,210,329			9,296,519	5,274,371	14,570,890
Irish Health Survey	21,318,315		10,238,417					25,534,391
Healthy Ireland	13,796,808	7,976,554	7,410,240			9,481,691	6,594,875	16,076,566
<i>Narrow age range</i>								
Growing Up in Ireland ^c				1,877,700	1,275,581			
TILDA			5,660,838					
<i>GP side</i>								
GP Survey								17,092,628
<i>GMS only</i>								
EU-SILC (GMS only)		12,272,314				14,580,205		

Notes:

^a To facilitate comparison, data are presented for age ranges available across a number of datasets.

^b The estimated number of cases for all ages was calculated by including data from the Growing Up in Ireland and Healthy Ireland surveys for age ranges not included. For the Irish Health Survey and EU-SILC the data for the additional age ranges were adjusted to account for the higher estimate in the observed data. For example, the EU-SILC data produced a 54% higher estimate in the 18 years and over group, so data on under 18 year olds were multiplied by 1.54 before being included.

^c The Growing Up in Ireland data only provided data for infants, three year olds and nine year-olds. It was assumed that visit rates for 10-14 year olds would be the same as for 5-9 year olds.

The remaining data source investigated utilisation from the supply-side. The GP Survey was based on a 23% national sample and achieved a 72% response rate. GPs were asked to report the number of clinical sessions worked per week and the average number of patients seen in a session. Using the GP survey data generated a total estimate only 2% larger than that calculated using data from the Healthy Ireland survey combined with Growing Up in Ireland data for children aged less than 15 years.

Practice nurse visits

The Healthy Ireland survey data included a question on the number of practice nurse visits in the previous four weeks. From this, it was possible to estimate the rate of visits by age, sex and public/private status. Data were only available for respondents aged 15 years and over. For the population aged less than 15 years, the ratio of practice nurse visits to GP visits for the corresponding sex-GMS status group aged 15 to 24 years was applied to the available GP visit data for those aged less than 15 years.

The total estimated number of practice nurse visits was 5,883,598 per annum (3,724,532 for public patients; 2,159,066 for private patients).

Total visits to General Practice

The combined number of visits (including GP and practice nurse) was 21,960,164 visits per annum across public and private patients.

Opportunity cost of visits

Based on data from the 2015 GP Survey, only 6.9% of GPs work in purely private practice, and 9.0% work in purely GMS practice.[19] In other words, 84.1% of GPs have a mix of public and private patients. Income from both public and private practice is therefore combined to provide total income that is used to fund resources in terms of staff, equipment, and premises. We sought to estimate total income for general practice by combining income from public and private practice.

The opportunity cost of a GP visit was calculated as:

$$cost_{GP} = \frac{\left[income_{pcrs} + (cost_{privateGP} * visits_{privateGP}) \right. \\ \left. + (cost_{privatenurse} * visits_{privatenurse}) \right. \\ \left. - (N_{nurse} * salary_{nurse}) \right]}{(visits_{publicGP} + visits_{privateGP})}$$

Where:

- $income_{pcrs}$ = total income from PCRS (€489.7m in 2015)
- $cost_{privateGP}$ = mean GP consultation fee for private patient, €49.97
- $visits_{privateGP}$ = total number of GP visits by private patients
- $cost_{privatenurse}$ = mean practice nurse consultation fee for private patient, €25
- $visits_{privatenurse}$ = total number of practice nurse visits by private patients
- N_{nurse} = total number of practice nurses
- $salary_{nurse}$ = average salary for a practice nurse
- $visits_{publicGP}$ = total number of GP visits by public patients

The above figure represents the opportunity cost across both public and private patients. The opportunity cost of a public patient GP visit was calculated as:

$$cost_{publicGP} = \frac{cost_{GP} - cost_{privateGP} * p_{private}}{p_{public}}$$

Where:

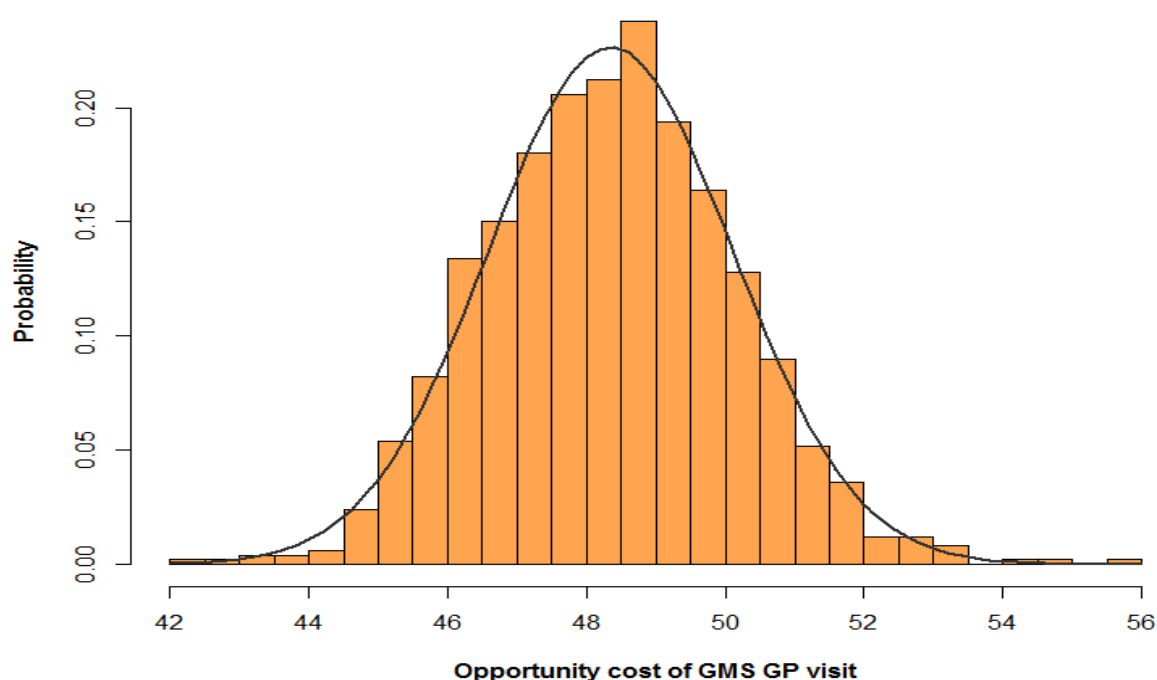
- $p_{private}$ = proportion all GP visits by private patients
- p_{public} = proportion all GP visits by public patients

The opportunity cost of seeing a GP across both public and private patients based on the WhatClinic data, $cost_{GP}$, was estimated to be €49.01 (95% CI: 47.07 to 51.04) in 2015.

The opportunity cost of seeing a GP for public patients only, $cost_{publicGP}$, was estimated to be €48.35 (95% CI: 45.18 to 51.83) in 2015. The modelled distribution of costs was approximately normal with a mean of €48.35 and standard deviation of 1.76 (Figure 13.3).

Using the higher National Consumer Agency estimate of private GP visit costs, the average opportunity cost of seeing a GP for public patients only, $cost_{publicGP}$, was estimated to be €48.42 (95% CI: 45.22 to 52.08).

Figure 13.3 Distribution of estimated opportunity cost of a public patient GP visit



Sensitivity analysis

The cost of a private practice nurse visit was supported by very limited data. If the cost recouped was €20, the opportunity cost of a public GP visit would be €47.21 (95% CI: €43.95 to €50.78). If the cost recouped was reduced to €15, then the opportunity cost of a public GP visit would be €46.07 (95% CI: €42.98 to €49.42).

Discussion

We identified a range of data sources reporting GP utilisation data. There is substantial variability in the estimated total number of GP visits per annum for both the total population and for the population of public patients. The Healthy Ireland survey was considered the most applicable dataset due to the short recall period (four weeks), nationally representative sample, limited potential for seasonal bias, and the fact that it was carried out relatively recently. In addition, the Healthy Ireland survey also gathered relevant data on practice nurse consultations. The cost associated with a public **patient GP visit was estimated to be €48.35 (95% CI: 45.18 to 51.83). This is very similar to the average cost of a private GP visit (€49.97).**

It should be remembered that the figures estimated here reflect an opportunity cost. That is, it is intended to reflect what a GP could have done in the time taken for a consultation. In the context of the smoking cessation HTA, a patient presenting to obtain a prescription or advice on smoking cessation displaces another patient. By including the total PCRS expenditure on general practice, we recognise that what is displaced is the average consultation. Clearly some patients generate more income

per visit than others, but we are interested in the average consultation. An alternative approach would be to micro-cost a consultation in terms of duration of a consultation, income of a typical GP, the cost of the practice premises, equipment and auxiliary staff, training, etc. However, in the absence of data on all of these individual contributors to cost, a pragmatic approach is to use the total annual spend on general practice by the PCRS divided by the activity that is covered by that spend. It is understood that investment in equipment and premises must be funded through the PCRS income or through revenue generated by private patients. Given the similarity in the estimated average value of a consultation, it is unlikely that private practice subsidises GMS practice other than potentially through economy of scale. Indeed, PCRS funding can provide grants for auxiliary staff and equipment that may in effect subsidise private practice when a practice is being developed.

The figures presented here represent an average across the system. Within individual practices the mix of patient demographics, ratio of PCRS to private income, and practice set-up will mean that opportunity costs will vary. For the purposes of the HTA, the average opportunity cost is the relevant figure.

The methodology used here is subject to some limitations. A large portion of GMS income is generated on the basis of fee-per-item. Private practice, on the other hand, has been represented solely through consultation fees. Many practice charge for certain services, for example 24-hour blood pressure monitoring, which may generate profits over and above what is required to cover the cost of the equipment or associated testing. There is little basis for determining how much income is generated in this manner, and hence we have not included it. We have also not taken into account that some practices charge a lower fee for repeat visits and repeat prescriptions. It is not possible to determine what proportion of practices charge a lower fee for repeat visits or what proportion of visits would classify as repeat visits. It must also be assumed that the reason why a repeat visit may incur a lower fee is because it is shorter than a standard consultation, and hence may incur a similar cost per minute as a full consultation. Failure to include additional income will have biased the average cost downwards, while not accounting for reduced repeat visit fees may have biased the estimated cost upwards. The data on private GP consultation costs come from a commercial website. Approximately 95% of practices are listed, of which 39% have provided data on GP consultation fees. As the advertising of consultation fees is optional, there may be a bias in the figures. Practices with higher fees, for example, may be less inclined to advertise fees if they perceive that it will discourage prospective patients on the basis of cost. However, the average cost is similar to that determined from a smaller survey by the National Consumer Agency and a sensitivity analysis showed that using the latter dataset had a minimal impact on the estimated mean opportunity cost of a public GP visit.

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Health Information and Quality Authority

Dublin Regional Office

George's Court

George's Lane

Smithfield

Dublin 7

Phone: +353 (0) 1 814 7400

URL: www.hiqa.ie

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