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Table 1 Study characteristics for non-randomised studies reporting safety outcomes

Study	Study Sponsor	Study Design	Study Duration (weeks)	Duration of Drug Treatment (weeks)	Location	Willing to Quit?	Smokeless Tobacco?	Total N	Females N (%)	White %	Study Arms
Barrueco 2005¹		Case-Control	12.86	12.86	Salamanca, Spain	Yes	No	904	428 (47)		1. NRT Choice + Counselling 2. Bupropion + Counselling 3. Bupropion + NRT Choice + Counselling
Bars 2006²	This research was supported by the Chest Foundation, Pfizer Pharmaceuticals, the New York City Fire Commissioner's Fire Safety Education Fund, The Fire Department of the City of New York, the Uniformed Fire Officers Association, the Uniformed Firefighters Association, Emergency Medical Services unions (DC37 locals 2507 and 3621), and the International Association of Firefighters 9/11 Fund. Additional support was provided by a September 11 recovery grant from the American Red Cross Liberty Disaster Relief Fund	Case-Control	52	14	New York, US	Yes	No	220	64 (29)		1. No Drug Treatment + Individual + Group Counselling 2. NRT Choice + Individual + Group Counselling 3. NRT Combo + Individual + Group Counselling 4. NRT Combo + Individual + Group Counselling

Cartin-Ceba 2011³		Prospective Cohort	104		Minnesota, US	Yes	No	330	138 (42)	89	1. NRT Patch (24hrs) 2. No Drug Treatment
Cunningham 2016⁴	Funds from the FDA were used to support this study under an interagency agreement between the FDA and the Veterans Health Administration	Retrospective cohort	72		US	Yes	No	35322	2561 (7)	80	1. Varenicline 2. NRT Patch (24hrs)
Davies 2015⁵	The MRC Integrative Epidemiology Unit is supported by the Medical Research Council and the University of Bristol [MC_UU_12013/6, MC_UU_12013/9]. The research described in this paper was funded by the Medical Research Council (MR/N01006X/1), the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme (project number 14/49/94). A.E.T., M.R.M. and G.M.J.T.	Retrospective cohort	104		UK	Yes	No	126718	66505 (53)		1. NRT Choice 2. Varenicline

are members of the United Kingdom (UK) Centre for Tobacco and Alcohol Studies, a UKCRC Public Health Research: Centre of Excellence. Funding from the British Heart Foundation, Cancer Research UK, Medical Research Council, and the National Institute for Health Research, under the auspices of the UK Clinical Research Collaboration, is gratefully acknowledged . R.M.M. is supported by Cancer Research UK programme grant (C18281/A19169) (the Integrative Cancer Epidemiology Programme). T.J. is supported by the National Institute for Health Research (NIHR) Collaboration for Leadership in Applied

Health Research and Care West (CLAHRC West) at University Hospitals Bristol NHS Foundation Trust											
Demir 2004⁶		Retrospective cohort	52		Istanbul, Turkey	Yes	No	634	316 (50)		1. NRT Patch (24hrs) 2. No Drug Treatment
Deniz 2016⁷	None	Retrospective cohort	104	10.8	İzmir, Turkey	Yes	No	152	81 (53)		1. Varenicline + Individual + Group Long Counselling 2. Bupropion + Individual + Group Long Counselling
Dhelaria 2012⁸	None	Retrospective cohort	52		Massachusetts, US	Yes	No	371	214 (58)	44	1. Varenicline 2. NRT
Dollerup 2017⁹	The study data were provided by the CPRD without charge (via a Medical Research Council study grant). The analysis was conducted by the Observational and Pragmatic Research Institute Pte Ltd, in collaboration with the Respiratory Effectiveness Group (REG), and funded by the Observational and Pragmatic Research Institute Pte Ltd. Manuscript costs were covered by the REG	Historical, matched cohort database	52		UK	Yes	No	50214	25710 (51)		1. No Drug Treatment 2. NRT Choice
Ebbert 2009¹⁰	Mayo Clinic College of Medicine	Retrospective cohort	28	52	Minnesota, US	Yes	No	239	122 (51)		1. Varenicline Standard + NRT Combo + Individual + Group Long Counselling 2. NRT Combo + Individual + Group Long Counselling

Ferketich 2013¹¹	This work was supported by the National Institutes of Health (R01HL090313-01, Smoking Cessation and the Natural History of HIV-Associated Emphysema)	Case-Control	12	12	Ohio, US	Yes	No	228	34 (15)	56	1. NRT Combo High + Individual + Telephone Counselling 2. Varenicline Standard + Individual + Telephone Counselling
Garcia-Portilla 2016¹²	This work was partly supported by the Spanish Ministry of Science and Innovation, Instituto de Salud Carlos III (FIS PI10/01758) and Fondos Europeos de Desarrollo Regional (FEDER)	Observational	36	12	Oviedo, Jaén and Vitoria, Spain	Yes	No	78	28 (36)		1. NRT Patch (24hrs) + Individual + Group Long Counselling 2. Varenicline Standard + Individual + Group Long Counselling
Gomez-Bastero 2012¹³		Prospective Cohort	24	8	Seville, Spain	Yes	No	312			1. Varenicline Low 2. Bupropion Low
Graham 2014¹⁴	This study was funded through an intraagency agreement between the Centers for Medicare & Medicaid Services and the FDA	Retrospective cohort	52		USA	Yes	No	88957	46103 (52)	90	1. Varenicline 2. Bupropion Standard
Gunnell 2009¹⁵	Small grant from the Medicines and Healthcare Products Regulatory Agency (MHRA)	Retrospective cohort		24	UK	Yes	No	80660	44662 (55)		1. NRT Choice 2. Bupropion 3. Varenicline
Hodgkin 2013¹⁶	St. Helena Hospital, using funds	Retrospective cohort	52		California, US	Yes	No	291	161 (56)		1. NRT Choice + Individual + Group Long Counselling 2. Bupropion + NRT Choice + Individual + Group Long Counselling

	generously donated by Tim Mondavi										3. Varenicline + NRT Choice + Individual + Group Long Counselling
Hsueh 2014¹⁷	Kaohsiung Veteran General Hospital (Grant numbers VGHKS98-CT3-07, VGHKS99-CT3-02). Robert West and Andy McEwen are funded by Cancer Research UK. Robert West is a member of the UK Centre for Tobacco and Alcohol Studies	Retrospective cohort	156	8	Kaohsiung City, Taiwan	Yes	No	587	83 (14)		1. Varenicline + Individual Short Counselling 2. NRT Patch (24hrs) + Individual Short Counselling
Hsueh 2015¹⁸	Kaohsiung Veteran General Hospital (Grant number VGHKS98-CT3-08)	Retrospective cohort	24	8	Kaohsiung City, Taiwan	Yes	No	469	66 (14)		1. Varenicline + Individual Short Counselling 2. NRT Patch (24hrs) + Individual Short Counselling
JimenezRuiz 2000¹⁹		Observational	52	10	Madrid, Spain	Yes	No	231	96 (42)		1. NRT Gum Standard + Individual Short Counselling 2. NRT Gum High + Individual Short Counselling
JimenezRuiz 2012²⁰	Government of the Community of Madrid, Spain	Retrospective cohort	24	24	Madrid, Spain	Yes	No	472	162 (34)		1. NRT Choice + Individual Long Counselling 2. Bupropion Standard + NRT Choice + Individual Long Counselling 3. Varenicline Standard + NRT Choice + Individual Long Counselling
Jimenez-Ruiz 2018²¹		Retrospective cohort	24	12	Madrid, Spain	Yes	No	349	215 (62)		1. NRT Combo High + Individual Counselling 2. Varenicline Standard + Individual Counselling
Kaduri 2015²²	Centre for Addiction and Mental Health to cover medication costs and salary support. Pamela Kaduri was supported by	Retrospective cohort			Ontario, Canada	Yes	No	196	72 (37)		1. Varenicline 2. NRT Choice

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Kerr 2016 ²³		Retrospective cohort			Canberra, Australia	Yes	No	252	100 (40)	1. NRT Patch (24hrs) 2. No Drug Treatment
Kocak 2015 ²⁴		Case-Control	52		Istanbul, Turkey	Yes	No	550	261 (48)	1. Varenicline + Counselling 2. Bupropion + Counselling 3. NRT Patch (24hrs) + Counselling 4. NRT Gum + Counselling
Korzeniowska 2013 ²⁵		Retrospective cohort			Poznań, Poland	Yes	No	32	13 (41)	1. Bupropion 2. Varenicline
Kotz 2015 ²⁶	The study was funded by Egton Medical Information Systems, the University of Nottingham, the Ministry of Innovation, Science and Research of the German Federal State of North Rhine-Westphalia, Cancer Research UK, the Medical Research Council, and the Commonwealth Fund. We acknowledge Egton Medical Information Systems practices, who contribute to QResearch,	Retrospective cohort	24	12	England	Yes	No	164776	83203 (51)	1. NRT 2. Bupropion 3. Varenicline

the University of Nottingham, and Egton Medical Information Systems for establishing, developing, and supporting the QResearch database, and supplying the data for this research project

Kotz 2017²⁷	QInnovation Award (provided by the software provider EMIS and the University of Nottingham) with additional support from the Ministry for Innovation, Science and Research of the German Federal State of North Rhine-Westphalia (“NRW-Rückkehrprogramm”), Cancer Research UK, the Medical Research Council and The Commonwealth Fund. The funder provided access to the QResearch	Retrospective cohort	24	12	UK	Yes	No	14350	7377 (51)			1. NRT 2. Bupropion 3. Varenicline
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	database, which included collection and management of data											
Lee 2007²⁸	Supported, in part, by the Office of Faculty Development, Department of Medicine, and the Center for Patient Oriented Research, Mayo Clinic College of Medicine, Rochester, MN	Retrospective, case-control	4		US	Yes	No	180	89 (49)	93		1. NRT 2. No Drug Treatment
Mainar 2011²⁹	Pfizer S.A. Laboratories	Retrospective cohort	52	12	Girona, Asturias, Catalonia, Barcelona, Spain	Yes	No	957	396 (41)			1. Varenicline Standard + Individual + Group Long Counselling 2. Bupropion Low + Individual + Group Long Counselling 3. NRT Choice + Individual + Group Long Counselling
Manzoli 2015³⁰	The first 2 years of the study were unfunded. The next 3 years of follow-up were to be funded through crowdfunding (Kickstarter project titled 'E-cigarette long-term efficacy & safety: a study to complete'). Besides seven authors (MEF, RS, MRG, GL, MFi, PV, CM) and seven anonymous contributors, who donated	Prospective Cohort	208	208	Abruzzo, Italy	Yes	No	1355	598 (44)			1. Electronic Cigarette Standard 2. No Drug Treatment 3. Dual Use Standard

a total of
€515 and €80,
respectively,
all other
contributors
are private
citizens. The
authors are
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	and Alexander van der Wal										
Meine 2005³¹		Retrospective cohort	52		North Carolina, US	Yes	No	374	110 (29)	75	1. No Drug Treatment 2. NRT Patch (24hrs)
Meyer 2013³²	Funds from the FDA were used to support this study under an inter-agency agreement between the FDA and MEDCOM	Retrospective cohort	8.57		US	Yes	No	35800	13864 (39)	54	1. Varenicline 2. NRT Patch (24hrs)
Molero 2015³³	Wellcome Trust (095806); Karolinska Institutet; the Swedish Research Council for Health, Working Life and Welfare; and the Swedish Research Council	Population cohort		12	Sweden	Yes	No	7917436	4008124 (51)		1. Varenicline 2. No Drug Treatment
Orsel 2005³⁴		Retrospective cohort	52		Ankara, Turkey	Yes	No	561	263 (47)		1. NRT 2. No Drug Treatment
Ossip 2009³⁵	New York State Department of Health (Contract no CO20137)	Prospective cohort	12	4	US	Yes	No	21029			1. NRT Patch (24hrs) + Telephone Short Counselling 2. NRT Gum + Telephone Short Counselling 3. NRT Lozenge + Telephone Short Counselling
Panos 2010³⁶		Retrospective cohort		1.26	Illinois, US	Yes	No	340	194 (57)	58	1. NRT Patch (24hrs) 2. No Drug Treatment
Pasternak 2013³⁷	Danish Medical Research Council	Population cohort	4.29		Denmark	Yes	No	77726	39172 (50)		1. Varenicline 2. Bupropion
Pena 2013³⁸	None	Retrospective cohort	52	12	Providencia, Chile	Yes	No	198	87 (44)		1. Varenicline + Individual Long Counselling 2. Bupropion + Individual Long Counselling
Politis 2018³⁹	Department of Respiratory Medicine of the University of Thessaly and by a scholarship awarded to	Prospective cohort	52	12	Kavala, Greece	Not necessarily motivated to quit	No	101	32 (32)		1. Varenicline Standard + Individual Long Counselling 2. No Drug Treatment + Individual Long Counselling

	this research from the Hellenic Thoracic Society										
Postolache 2013⁴⁰		Retrospective cohort		12	Iasi, Romania	Yes	No	343	132 (39)		1. Varenicline Standard 2. Bupropion Standard
Roth 2005⁴¹		Prospective Cohort	24	9.5	North Carolina, US	Yes	No	198	5 (3)	62	1. NRT Patch (24hrs) + Individual Counselling 2. Bupropion + Individual Counselling 3. NRT Combo + Individual Counselling 4. NRT Inhalator + Individual Counselling
Sachs 2012⁴²	Funded by a program grant to B.A.F. and T.C.W. from the Alberta Alcohol and Drug Abuse Commission	Prospective Cohort	24		Alberta, Canada	Yes	No	288	133 (46)		1. No Drug Treatment 2. NRT Patch (24hrs) + Individual + Telephone Counselling
Saxon 2003⁴³	This work was supported by and conducted at the Center of Excellence in Substance Abuse Treatment and Education, VA Puget Sound Health Care System, Seattle, Washington	Prospective Cohort	8	8	Washington, US	Yes	No	115	7 (6)	74	1. No Drug Treatment + Group Counselling 2. NRT Patch (24hrs) + Group Counselling 3. Bupropion Standard + Group Counselling 4. Bupropion Standard + NRT Patch (24hrs) + Group Counselling
Shiltz 2011⁴⁴		Retrospective cohort		12	Wisconsin, US	Yes	No	489			1. Bupropion Standard + NRT Patch (24hrs) Standard + Long Counselling 2. Varenicline Standard + Bupropion Standard + Long Counselling 3. Varenicline Standard + Long Counselling
Stapleton 2008⁴⁵		Retrospective cohort	7	12	London, UK	Yes	No	412	242 (59)	74	1. NRT Choice + Group Long Counselling 2. Varenicline + Group Long Counselling
Steinberg 2011⁴⁶	None. The UMDNJ-Tobacco Dependence Clinic is funded through a grant from the New Jersey Department	Retrospective cohort	24		New Jersey, US	Yes	No	723	381 (53)	59	1. No Drug Treatment + Counselling 2. Bupropion Standard + Counselling 3. NRT Choice + Counselling 4. Varenicline Standard + Counselling 5. Bupropion Standard + NRT Choice + Counselling

of Health and Senior Services – Comprehensive Tobacco Control Program

Svanstrom 2012⁴⁷	None	Population cohort	104	Denmark	Yes	No	35852	18539 (52)	1. Varenicline 2. Bupropion
Thomas 2013⁴⁸	The study was supported by a grant from the MHRA (grant no SDS 33437); the agency approved the study design during the funding process but aside from this the authors carried out the study and publication independently without further involvement of the funder. DG is a senior investigator at the National Institute for Health Research. NMD was the recipient of a four year studentship with the Medical Research Council Centre for causal analysis in translational epidemiology (G0600705) and is currently	Prospective Cohort	36	England, UK	Yes	No	119546	63457 (53)	1. NRT 2. Bupropion 3. Varenicline

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Williams 2012⁴⁹	Financial support (in the form of NRT) was provided by Pharmacia Aust Pty Ltd.	Prospective Cohort	52		South Australia, Australia	Yes	No	123	58 (47)		1. NRT Inhalator Low + Individual Short Counselling 2. NRT Patch (16hrs) Standard + Individual Short Counselling 3. No Drug Treatment + Individual Short Counselling
Wolfenden 2008⁵⁰	National Heart Foundation, the Cancer Council NSW, and NSW Health through the Hunter Medical Research Institute	Quasi-randomised	24		New South Wales, Australia	Yes	No	146			1. Usual Care 2. NRT + Telephone Short Counselling
Woolf 2012⁵¹	John C. Sable Heart Fund, Rochester, New York	Retrospective cohort	52		New York, US	Yes	No	663	213 (32)	85	1. NRT Choice 2. No Drug Treatment
Xiao 2014⁵²	Shanghai Johnson & Johnson Pharmaceuticals Ltd.	Observational	24	12	Beijing, Shanghai and Guangzhou, China	Yes	No	300	3 (1)		1. NRT Gum Standard + Individual + Telephone Short Counselling 2. NRT Gum High + Individual + Telephone Short Counselling 3. NRT Patch (16hrs) Standard + Individual + Telephone Short Counselling

Xu 2018⁵³	Retrospective cohort	24	Connecticut, USA	Not necessarily motivated to quit	No	254	254 (100)	1. NRT 2. No Drug Treatment
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Table 2 Additional study characteristics for non-randomised studies reporting safety outcomes

Study	Trial Registration	Population Studied	Smoking History M(SD)
Barrueco 2005 ¹		Smokers with a history of unsuccessful attempts to quit because of withdrawal symptoms	
Bars 2006 ²		New York City Fire Department (FDNY) tobacco users and their household family members who smoked	22 (8)
Cartin-Ceba 2011 ³		Critically ill smokers	
Cunningham 2016 ⁴		Smokers who were Veteran Affairs patients with or without psychiatric comorbidities	
Davies 2015 ⁵	NCT02681848		
Demir 2004 ⁶			
Deniz 2016 ⁷			28.2 (11.6)
Dhelaria 2012 ⁸			22
Dollerup 2017 ⁹	ENCePP/SDPP/4238		
Ebbert 2009 ¹⁰			
Ferketich 2013 ¹¹		Smokers with HIV	
Garcia-Portilla 2016 ¹²		Smokers with DSM-IV diagnosis of schizophrenia, or schizoaffective or bipolar disorder	
Gomez-Bastero 2012 ¹³			
Graham 2014 ¹⁴		Smokers aged 65 years who were Medicare patients	
Gunnell 2009 ¹⁵			
Hodgkin 2013 ¹⁶			
Hsueh 2014 ¹⁷			
Hsueh 2015 ¹⁸			24.3 (12.4)
JimenezRuiz 2000 ¹⁹			
JimenezRuiz 2012 ²⁰		Smokers with severe or very severe chronic obstructive pulmonary disease (COPD)	40.6 (9.9)
Jimenez-Ruiz 2018 ²¹		Smokers with with psychiatric disorders	32.2 (11)
Kaduri 2015 ²²		Smokers with and without psychiatric disorders	
Kerr 2016 ²³		Critically ill smokers	
Kocak 2015 ²⁴			
Korzeniowska 2013 ²⁵			
Kotz 2015 ²⁶			
Kotz 2017 ²⁷		Smokers with chronic obstructive pulmonary disease (COPD)	
Lee 2007 ²⁸		Smokers who were critically ill admitted to medical intensive care units	
Mainar 2011 ²⁹		Smokers who were primary care patients	19.5 (6.7)
Manzoli 2015 ³⁰	NCT01785537		22.9 (12.1)
Meine 2005 ³¹		Smokers admitted with acute coronary syndromes	
Meyer 2013 ³²			
Molero 2015 ³³			
Orsel 2005 ³⁴			
Ossip 2009 ³⁵			
Panos 2010 ³⁶		Smokers admitted to the neurosurgery ICU for neurologic insults	
Pasternak 2013 ³⁷			
Pena 2013 ³⁸			
Politis 2018 ³⁹		Smokers who were inpatients with acute exacerbation of chronic obstructive pulmonary disease (COPD), bronchial asthma, or community-acquired pneumonia	
Postolache 2013 ⁴⁰			
Roth 2005 ⁴¹			34.7 (12.6)

Study	Trial Registration	Population Studied	Smoking History M(SD)
Sachs 2012 ⁴²		Smokers who were hospital patients	
Saxon 2003 ⁴³		Smokers who were veterans in treatment for alcohol or drug dependence	
Shiltz 2011 ⁴⁴			34.1
Stapleton 2008 ⁴⁵			
Steinberg 2011 ⁴⁶		Smokers most with significant medical and psychiatric comorbidity	
Svanstrom 2012 ⁴⁷			
Thomas 2013 ⁴⁸			
Williams 2012 ⁴⁹		Smokers who were hospital patients	38.5 (16)
Wolfenden 2008 ⁵⁰		Smokers scheduled for surgery	
Woolf 2012 ⁵¹		Smokers with an acute coronary syndrome who underwent cardiac catheterization	
Xiao 2014 ⁵²			
Xu 2018 ⁵³		Female smokers undergoing breast surgery	

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