

Appendix 3: Trials investigating transdermal nicotine (page 1 of 3)

Study	Sample size	Design	Country	Mean CPD	Smoking abstinence (%)							
					6 Months				12 Months			
					Point prevalence		Continuous		Point prevalence		Continuous	
					Active	Control	Active	Control	Active	Control	Active	Control
ICRF GPRG 1994 ^{1,2}	1,686	R, DB, PC, MC	England	24	NR	NR	NR	NR	NR	NR	9	6
Tonnesen 1999 iv*† ³	1,430	R, DB, PC, MC	17 countries	27	NR	NR	15	12	NR	13	12	10
Tonnesen 1999 i*† ³	1,429	R, DB, PC, MC	17 countries	28	NR	NR	20	12	NR	13	15	10
Tonnesen 1999 ii*† ³	1,429	R, DB, PC, MC	17 countries	27	NR	NR	21	12	NR	13	16	10
Tonnesen 1999 iii*† ³	1,429	R, DB, PC, MC	17 countries	27	NR	NR	18	12	NR	13	14	10
Stapleton 1995‡ ⁴	1,200	R, DB, PC, MC	England	24	NR	NR	13	6	NR	NR	10	5
Hays* 1999 ⁵	643	R, DB, PC, MC	USA	NR	8	4	6	3	NR	NR	NR	NR
Gourlay 1995‡§ ⁶	629	R, DB, PC	Australia	27	6	3	2	1	NR	NR	NR	NR
TNSG 1991 i¶ ⁷	507	R, DB, PC, MC	USA	31	NR	NR	18	12	NR	NR	NR	NR
TNSG 1991 ii¶ ⁷	502	R, DB, PC, MC	USA	31	NR	NR	26	12	NR	NR	NR	NR
Jorenby 1999* ⁸	404	R, DB, PC, MC	USA	27	21	19	NR	NR	16	16	10	6
Daughton 1998 ⁹	369	R, DB, PC, MC	USA	28	NR	NR	18	10	NR	NR	15	9
Hughes 1999 i*,** ¹⁰	440	R, DB, PC, MC	Australia & USA	38	17	11	11	5	13	8	8	4
Hughes 1999 ii*,** ¹⁰	440	R, DB, PC, MC	Australia & USA	38	16	11	6	5	10	8	3	4
Richmond 1994 ¹¹	305	R, DB, PC	Australia	29	32	14	25	12	27	12	19	9
Kornitzer 1995* ¹²	225	R, DB, PC, MC	Sweden	26	NR	NR	34	12	NR	NR	25	9
Tonnesen 1991 ¹³	289	R, DB, PC	Denmark	21	24	5	NR	NR	17	4	11	2
Hurt 1994 ¹⁴	240	R, DB, PC, MC	USA	30	29	16	NR	NR	28	14	NR	NR
Hughes 1999 iii*,** ¹⁰	439	R, DB, PC, MC	Australia & USA	38	23	11	11	5	18	8	13	4
Sachs 1993 ¹⁵	220	R, DB, PC	England	28	NR	NR	15	15	NR	NR	13	13
Killen 1997 ii*†† ¹⁶	217	R, DB, PC	USA	24	16	12	NR	NR	14	10	NR	NR
Killen 1997 i*†† ¹⁶	207	R, DB, PC	USA	23	25	19	NR	NR	21	14	NR	NR
Abelin 1989‡ ^{17,18}	199	R, DB, PC, MC	Switzerland	28	22	12	NR	NR	NR	NR	NR	NR

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Study	Sample size	Design	Country	Mean CPD	Smoking abstinence (%)							
					6 Months				12 Months			
					Point prevalence		Continuous		Point prevalence		Continuous	
					Active	Control	Active	Control	Active	Control	Active	Control
Westman 1993 ¹⁹	159	R, DB, PC	USA	30	NR	NR	20	3	NR	NR	NR	NR
Paoletti 1996 ²⁰	120	R, DB, PC	Italy	24	NR	NR	NR	NR	NR	NR	28	8
Glavas 2003 ²¹	112	R, DB, PC	Croatia	23	NR	NR	NR	NR	23	16	NR	NR
Fiore 1994 ii* ^{‡‡} ²²	112	R, DB, PC, MC	USA	30	18	7	NR	NR	NR	NR	NR	NR
Fiore 1994 i* ^{‡‡} ²²	87	R, DB, PC, MC	USA	29	35	21	NR	NR	NR	NR	NR	NR
Daughton 1991 i* ^{§§} ²³	52	R, DB, PC	USA	33	NR	NR	30	12	NR	NR	NR	NR
Daughton 1991 ii* ^{§§} ²³	50	R, DB, PC	USA	33	NR	NR	24	12	NR	NR	NR	NR

CPD = cigarettes per day, R = randomized, DB = double-blind, PC = placebo controlled, MC = multi-center, NR = not reported, ICRF GPRG = Imperial Cancer Research Fund General Practice Research Group, TNSG = Transdermal Nicotine Study Group.

References appear on the next page.

*Number of subjects included in the analysis: participants who were from centres that did not biochemically validate abstinence claims, not randomized to either transdermal nicotine or placebo, received more than one pharmacotherapy or medications other than those included in our study, or participated in an open label arm of the study were excluded from our analyses.

†Patients randomized to 25 mg/day for 26 weeks (i), 25 mg/day for 12 weeks (ii), 15 mg/day for 26 weeks (iii), 15 mg/day for 12 weeks, or placebo.

‡The RCTs conducted by Stapleton (treatment length), Gourlay (dosage), and Abelin (dosage) did not report covariates that were included in our hierarchical model and thus were excluded from our analyses and forest plot.

§Study exclusively recruited smokers previously treated with transdermal nicotine and brief behavioural counselling.

¶Outcomes reported for only one member of each of the eight couples participating in the trial. Patients were randomized to 14 mg/day (i), 21 mg/day (ii), or placebo.

**Patients were randomized to 21 mg/day for 10 weeks (i), 35 mg/day for 14 weeks (ii), 42 mg/day for 16 weeks (iii), or placebo. Results obtained in part through correspondence.

‡‡The RCT by Killen et al used a factorial design. We compared patients randomized to transdermal nicotine, self-help manual, and self-help video to those randomized to placebo, self-help manual, and self-help video (i) and patients randomized to transdermal nicotine and self-help manual to those randomized to placebo and self-help manual (ii).

§§Fiore conducted two RCTs that were published together. Patients were randomized to 8 weeks of abrupt transdermal nicotine (i), 6 weeks of tapered transdermal nicotine (ii) or corresponding placebos.

¶¶The RCT by Daughton et al. randomized patients to transdermal nicotine patch for 16 hours/day (i), transdermal nicotine patch for 24 hours/day (ii), or placebo.

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