Supplemental Online Content

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This supplemental material has been provided by the authors to give readers additional information about their work.

eTable 1. Medication dosing in the experimental conditions

Active Condition[a]	Weeks 1-12		Weeks 13-24	
	Varenicline	**Patch**	**Varenicline**	**Patch**
12-week Varenicline-only	Active	Placebo	Placebo	Placebo
12-week Varenicline + Patch	Active	Active	Placebo	Placebo
24-week Varenicline-only	Active	Placebo	Active	Placebo
24-week Varenicline + Patch	Active	Active	Active	Active

[a] All participants were given 24 weeks of pills and 26 weeks of patches (active and/or placebo medications) to mask treatment assignment. Patch treatment began two weeks before the target quit day and extended to post-quit Week 24.

eTable 2A. Results for logistic regression analyses under four assumptions about missing outcomes, biochemically-confirmed 7-day point prevalence abstinence rates (CO cutoff=5 ppm) at week 23

	MAR (Multiple Imputation)			MI-2[a]			MI-5[b]			Missing=Smoking		
	b	se	P-value	b	se	P-value	b	se	P-value	b	se	P-value
Intercept	-1.048	.136	<.001	-1.133	.086	<.001	-1.229	.086	<.001	-1.311	.084	<.001
Patch	.137	.089	.13	.086	.069	.21	.095	.068	.16	.089	.067	.18
Duration	.032	.077	.68	.036	.068	.59	.047	.068	.49	.060	.067	.37
Patch x Duration	.065	.077	.40	.049	.068	.47	.034	.067	.62	.015	.067	.83
Site	.376	.241	.14	.326	.151	.03	.346	.141	.01	.351	.140	.01

[a] A pattern mixture model in which the odds of abstinence as defined by the probabilities of the multiple imputation model were reduced by a factor of 2 if the outcome was missing

[b] A pattern mixture model in which the odds of abstinence as defined by the probabilities of the multiple imputation model were reduced by a factor of 5 if the outcome was missing

eTable 2B. Results for logistic regression analyses under four assumptions about missing outcomes, biochemically-confirmed 7-day point prevalence abstinence rates (CO cutoff=5 ppm) at week 52

	MAR (Multiple Imputation)			MI-2[a]			MI-5[b]			Missing=Smoking		
	b	se	P-value	b	se	P-value	b	se	P-value	b	se	P-value
Intercept	-1.093	.109	<.001	-1.244	.093	<.001	-1.402	.093	<.001	-1.534	.090	<.001
Patch	-.030	.096	.76	.009	.072	.90	.017	.074	.82	.016	.073	.82
Duration	.006	.086	.95	-.037	.074	.62	-.005	.071	.94	.012	.073	.87
Patch x Duration	.048	.092	.61	.076	.073	.30	.046	.073	.53	.015	.073	.84
Site	.164	.156	.30	.157	.161	.33	.175	.166	.29	.178	.153	.24

[a] A pattern mixture model in which the odds of abstinence as defined by the probabilities of the multiple imputation model were reduced by a factor of 2 if the outcome was missing

[b] A pattern mixture model in which the odds of abstinence as defined by the probabilities of the multiple imputation model were reduced by a factor of 5 if the outcome was missing

eTable 3. Biochemically confirmed (CO ≤ 5 ppm) 7-day point prevalence abstinence rates at weeks 23 and 52, and prolonged abstinence by treatment main effects, with the 4 prespecified covariates

Post-Quit Abstinence Measure	Treatment Main Effect Abstinence Rates, N Abstinent (%)				Abstinence Risk Difference (95% CI) P-Value[a]				Covariate-Adjusted Odds Ratio (95% CI)[b]		
	Medication Type Main Effect		Medication Duration Main Effect		Medication Type Main Effect		Medication Duration Main Effect				
	Varenicline + Active Patch (Combo) (N=625)	Varenicline + Placebo Patch (Mono) (N=626)	24 weeks (N=622)	12 weeks (N=629)	Combo vs Mono	*P* Value[b]	24 weeks vs 12 weeks	*P* Value[b]	Medication Type Main Effect	Medication Duration Main Effect	Medication Type X Duration Interaction
Primary Outcome: 7-Day Point Prevalence Abstinence at 52 Weeks[c]	152 (24.3%)	155 (24.8%)	154 (24.8%)	153 (24.3)	0.4 (-4.3 to 5.2)	.82	0.4 (-5.2 to 4.3)	.75	1.0 (0.9-1.1)	1.0 (0.9-1.2)	1.0 (0.9-1.2)
7-Day Point Prevalence Abstinence at 23 Weeks[c]	156 (25.0%)	136 (21.7%)	152 (24.4%)	140 (22.3%)	-3.2 (-7.9 to 1.5)	.19	-2.2 (-6.9 to 2.5)	.30	1.1 (0.96-1.2)	1.1 (0.9-1.2)	1.0 0.9-1.2)
Prolonged Abstinence (23 Weeks)[d]	139 (22.2%)	137 (21.9%)	138 (22.2%)	138 (21.9)	-0.4 (-5.0 to 4.2)	.94	-0.3 (-4.8 to 4.4)	.81	1.0 (0.9-1.2)	1.0 (0.9-1.2)	1.1 (0.9-1.2)
Prolonged Abstinence (52 Weeks)[e]	104 (16.6%)	101 (16.1%)	103 (16.6%)	102 (16.2)	-0.5 (-4.6 to 3.6)	.87	-0.3 (-4.5 to 3.8)	.77	1.0 (0.9-1.2)	1.0 (0.9-1.2)	1.1 (0.97-1.3)

[a]Main effect comparisons of abstinence risk differences were tested via SAS Proc Freq, which provides risk differences (RDs) and 95% confidence limits of RDs. [b]Based on logistic regression analysis controlling for 4 binary prespecified covariates (Site, Gender, Race, and Fagerstrom Test of Cigarette Dependence[26, 27] (FTCD) Item 1). [c]Abstinence self-

report was biochemically confirmed via exhaled carbon monoxide (CO) testing with abstinence confirmed with a CO value of ≤ 5 parts per million (ppm). [d]Prolonged abstinence (23 weeks) = no smoking from Day 7 to Week 23 after the target quit day. [e]Prolonged abstinence (52 weeks) = no smoking from Day 7 to Week 52 after the target quit day.

eTable 4. Biochemically-confirmed 7-day point prevalence abstinence rates (CO cutoff=5 ppm) at weeks 23 and 52, and prolonged abstinence by the 4 treatment conditions, with the 4 prespecified covariates

Post-Quit Abstinence Measure	Treatment Group Abstinence Rates, N Abstinent (%)				Covariate-Adjusted Abstinence Risk Difference (95% CI) P-Value[a]						Covariate-Adjusted Odds Ratio (95% CI)[b]		
	A: Varenicline + Placebo Patch 12 weeks (N=315)	B: Varenicline + Active Patch 12 weeks (N=314)	C: Varenicline + Placebo Patch 24 weeks (N=310)	D: Varenicline + Active Patch 24 weeks (N=309)	Patch Effect (at 12 weeks Duration) A vs. B	P Value	Duration Effect (of Varenicline Only) A vs. C	P Value	24-Week Combo Patch Effect vs. 12-Week monotherapy A vs. D	P Value	A vs. B	A vs. C	A vs. D
Primary Outcome: 7-Day Point Prevalence Abstinence at 52 Weeks[c]	79 (25.1%)	74 (23.6%)	76 (24.5%)	78 (25.2%)	2.1 (-4.4 to 8.7)	.53	0.4 (-6.2 to 7.0)	.91	0.2 (-6.5 to 6.8)	.96	0.9 (0.6-1.3)	1.0 (0.7-1.4)	1.0 (0.7-1.5)
7-Day Point Prevalence Abstinence at 23 Weeks[c]	66 (21.0%)	74 (23.6%)	70 (22.6%)	82 (26.5%)	-1.8 (-8.1 to 4.2)	.58	-1.9 (-8.1 to 4.2)	.54	-4.9 (-11.4 to 1.6)	.14	1.2 (0.8-1.7)	1.1 (0.8-1.6)	1.4 0.9-2.0)
Prolonged Abstinence (23 Weeks)[d]	72 (22.9%)	66 (21.0%)	65 (21.0%)	73 (23.6%)	2.0 (-4.1 to 7.8)	.51	1.7 (-4.3 to 7.8)	.58	-0.2 (-6.5 to 6.0)	.94	0.9 (0.6-1.3)	0.9 (0.6-1.3)	1.0 (0.7-1.5)
Prolonged Abstinence (52 Weeks)[e]	55 (17.5%)	47 (15.0%)	46 (14.8%)	57 (18.4%)	2.3 (-3.1 to 7.7)	.41	2.0 (-3.3 to 7.3)	.46	-0.8 (-6.6 to 5.0)	.79	0.8 (0.5-1.2)	0.8 (0.5-1.3)	1.1 (0.7-1.6)

[a]Pairwise comparisons of abstinence risk differences were tested via SAS Proc Genmod, which provides least squares risk differences and 95% confidence limits for the risk differences controlling for 4 binary prespecified covariates (Site, Gender, Race, and Fagerstrom Test of Cigarette Dependence[26, 27] (FTCD) Item 1. [b]Based on logistic regression analysis controlling for 4 a priori covariates. [c]Abstinence self-report was biochemically confirmed via exhaled carbon monoxide (CO) testing with abstinence confirmed with a CO value of ≤ 5 parts per million (ppm). [d]Prolonged abstinence (23 weeks) = no smoking from Day 7 to Week 23 after the target quit day. [e]Prolonged abstinence (52 weeks) = no smoking from Day 7 to Week 52 after the target quit day.

Note: Statistically significant covariates for each of the primary and secondary outcomes:
Week 52 Abstinence: Race (p=.007); FTCD Item 1(p=.009)
Week 23 Abstinence: Race (p<.001)
Prolonged Abstinence (Week 23): Site (p=.007); Race (p<.001); FTCD Item 1 (p=.002)
Prolonged Abstinence (Week 52): Race (p<.001); FTCD Item 1 (p<.001)

eTable 5. Moderation analyses for post hoc covariates and week 52 biochemically confirmed point prevalence abstinence (CO cutoff=5 ppm)[a]

Moderator	Model Interaction Effects			
	Patch X Moderator		Duration X Moderator	
	P-value	Odds Ratio (95% CI)	P-value	Odds Ratio (95% CI)
Gender (n=1251) Female (n=675) Male (n=576)	.62	1.1 (0.8 to 1.4)	.82	1.0 (0.8 to 1.4)
Race (n=1250) White (n=867) Non-White (n=383)	.35	0.9 (0.6 to 1.2)	.69	0.9 (0.7 to 1.3)
Income (n=1174) <$20,0000 (n=311) ≥$20,000 (n=863)	.28	1.2 (0.8 to 1.8)	.64	0.9 (0.6 to 1.3)
FTCD Total Score (n=1247) 0-4 (n=492) 5-10 (n=755)	.63	0.9 (0.7 to 1.2)	.69	1.1 (0.8 to 1.4)
Age (years) (n=1251) 18-49 (n=622) 50+ (n=629)	.37	1.1 (0.9 to 1.5)	.54	1.1 (0.8 to 1.5)
Carbon Monoxide (ppm) (n=1251) 5-14 (n=609) 15+ (n=642)	.25	1.2 (0.9 to 1.6)	.95	1.0 (0.8 to 1.3)

Moderator	Model Interaction Effects			
	Patch X Moderator		Duration X Moderator	
	P-value	Odds Ratio (95% CI)	P-value	Odds Ratio (95% CI)
Home Smoking[b] (n=1250) No (n=770) Yes (n=480)	.83	1.0 (0.7 to 1.3)	.43	1.1 (0.8 to 1.5)
Prior Use of Cessation Medications[c] (n=1250) No (n=258) Yes (n=992)	.61	1.1 (0.8 to 1.5)	.78	1.0 (0.7 to 1.3)
Menthol Smoking (n=1250) No (n=568) Yes (n=682)	.10	0.8 (0.6 to 1.0)	.86	1.0 (0.8 to 1.4)
FTCD Item 1 (n=1248) Smoke > 30 Min (n=224) Smoke Within 30 Min of Waking (n=1024)	.41	1.2 (0.8 to 1.6)	.85	1.0 (0.7 to 1.4)
WISDM37 Primary Dependence Motives (n=1248) Low (n=634) High (n=614)	.19	0.8 (0.6 to 1.1)	.06	1.3 (0.99 to 1.8)
WISDM37 Secondary Dependence Motives (n=1243) Low (n=634) High (n=614)	.20	0.8 (0.6 to 1.1)	.12	1.3 (0.9 to 1.7)

Abbreviation: FTCD=Fagerstrom Test of Cigarette Dependence[26, 27]. WISDM37=Wisconsin Inventory of Smoking Dependence Motives, Brief Version[28].

[a]Covariate effects were tested in a series of multivariable logistic regression analyses with the primary outcome (7-day point-prevalence abstinence at 52 Weeks post-target quit day [carbon monoxide ≤5 ppm]) as the dependent variable, with effect coding for Patch and Duration. Moderators were dummy-coded. The multivariable model included Patch and

Duration main effects, the moderator main effect, the Patch X moderator interaction, and the Duration X moderator interaction. [b]Defined as presence of anyone who smokes living in the home of the participant. [c]Prior use of varenicline or nicotine patch, gum, or lozenge.

eTable 6. Patch and varenicline adherence data (n's and percentages) among participants in the four treatment conditions

Assessment Timepoint	Patch Adherence Rates,[a] N (%) by Treatment Condition[b]					Varenicline (Pill) Adherence Rates,[a] N (%) by Treatment Condition[b]				
	A: Varenicline + Placebo Patch - 12 weeks (N=315)	B: Varenicline + Active Patch - 12 weeks (N=314)	C: Varenicline + Placebo Patch - 24 weeks (N=311)	D: Varenicline + Active Patch - 24 weeks (N=311)		A: Varenicline + Placebo Patch - 12 weeks (N=315)	B: Varenicline + Active Patch - 12 weeks (N=314)	C: Varenicline + Placebo Patch - 24 weeks (N=311)	D: Varenicline + Active Patch - 24 weeks (N=311)	
Target Quit Day	238 (75.6)	247 (78.7)	244 (78.5)	234 (75.2)		241 (75.2)	254 (80.9)	252 (81.0)	285 (75.6)	
Week 2	211 (67.0)	209 (66.6)	219 (70.4)	213 (68.5)		219 (69.5)	214 (68.2)	240 (77.2)	213 (68.5)	
Week 4	207 (65.7)	203 (64.6)	211 (67.8)	196 (63.0)		228 (72.4)	216 (68.8)	223 (71.7)	201 (64.6)	
Week 8	170 (64.0)	162 (51.6)	178 (57.2)	155 (49.8)		195 (61.9)	184 (58.6)	201 (64.6)	163 (52.4)	
Week 11	163 (51.7)	152 (48.4)	167 (53.7)	147 (47.3)		181 (57.5)	173 (55.1)	193 (62.1)	160 (51.4)	
Week 23	128 (40.6)	132 (42.0)	142 (45.7)	138 (44.4)		149 (47.3)	148 (47.1)	173 (55.6)	142 (45.7)	

[a]Past week adherence for the patch was defined as using one patch per day for 6 or 7 days; adherent use of the pill was defined as taking 1 or 2 pills per day for 6 or 7 days. Missing adherence data were re-coded as non-adherent.

[b]All participants received active varenicline (pill); standard duration of pill and patch medications=12 weeks; extended duration of pill and patch medications=24 weeks post-quit

eTable 7. Pre-quit and post-quit counseling call and visit attendance (n's and percentages) among participants in the four treatment conditions

Assessment Timepoint	Attendance Rates, N (%) by Treatment Condition[a]				
	A: Varenicline + Placebo Patch 12 weeks (N=315)	**B: Varenicline + Active Patch 12 weeks (N=314)**	**C: Varenicline + Placebo Patch 24 weeks (N=311)**	**D: Varenicline + Active Patch 24 weeks (N=311)**	
Pre-Quit Call and Visit Attendance (Maximum=2 Sessions)[b]					
0-1 Sessions	49 (15.6)	50 (15.9)	39 (12.5)	48 (15.4)	
2 Sessions	266 (84.4)	264 (84.1)	272 (87.5)	263 (84.6)	
Post-Quit Call and Visit Attendance (Maximum=4 Sessions)[c]					
0-2 Sessions	94 (29.8)	83 (26.4)	86 (27.7)	96 (30.9)	
3-4 Sessions	221 (70.2)	231 (73.6)	225 (72.3)	215 (69.1)	

[a]All participants received active varenicline (pill); standard duration of pill and patch medications=12 weeks; extended duration of pill and patch medications=24 weeks post-quit.

[b]The pre-quit visit was two weeks before the Target Quit Date (TQD); the pre-quit call was one week before the TQD.

[c]The post-quit visits occurred on the TQD and at week 2 post-quit; the post-quit calls occurred at weeks 4 and 8 post-quit.

eTable 8. Means of first week post-quit non-craving withdrawal and craving with statistical adjustment for baseline pre-quit score

	Withdrawal Measures[a]	
Condition (Number of Participants Providing Withdrawal Data)	**Non-Craving Withdrawal[b]**	**Craving[c]**
	Mean (SD)[d]	**Mean (SD)[d]**
12-week Varenicline + Placebo Patch (N=276)	2.7 (0.7)	3.5 (1.2)
12-week Varenicline + Active Patch (N=289)	2.6 (0.7)	3.3 (1.0)
24-week Varenicline + Placebo Patch (N=84)	2.6 (0.7)	3.3 (1.0)
24-week Varenicline + Active Patch (N=276)	2.6 (0.7)	3.4 (1.2)

[a]Withdrawal and craving measures consisted of items rated with the following instructions: "Please rate how much you have felt each of the following over the past 24 hours on a scale from 1 to 7 where 1 is Not at all and 7 is Extremely" assessed via interactive voice response (IVR) calls.

[b]Non-Craving Withdrawal = mean of four items: anxious, worried or stressed; angry or irritated; sad or unhappy; can't concentrate or think clearly.

[c]Craving = means of two items: bothered by desire to smoke; trouble getting cigarettes off your mind.

[d]Means and SDs are based on least squares means from a regression model that included the baseline (pre-quit) score as a covariate.

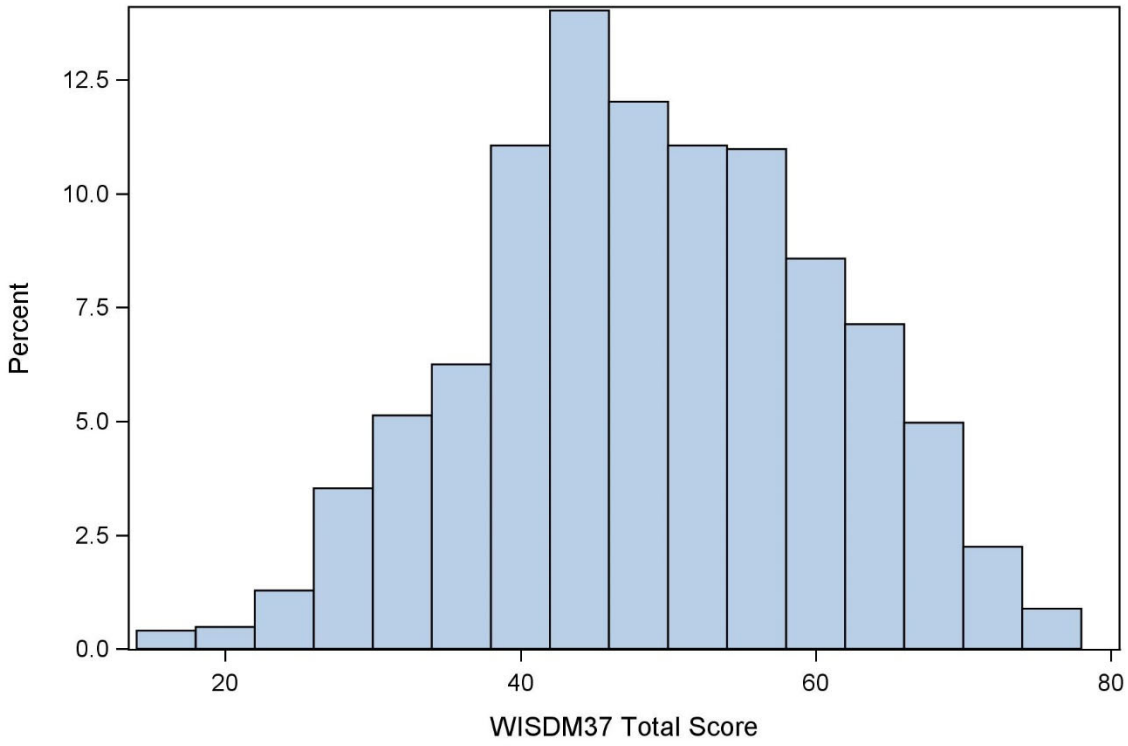
eMethods

A sensitivity analysis evaluated estimated treatment effects when making different assumptions about the 7-day point-prevalence abstinence at Weeks 23 and 52 for subjects with missing outcomes. The assumptions ranged from a missing-at-random (MAR) assumption, in which case a multiple imputation strategy was used, to a missing not-at-random (MNAR) condition in which missingness = smoking (no abstinence), as is commonly assumed in tobacco cessation studies. Additional conditions of MNAR were implemented using a pattern mixture model[1,2,3] whereby the odds of abstinence as defined by the probabilities of the multiple imputation model were reduced by factors of 2 and 5 if the outcome was missing versus not. These latter two conditions can be viewed as intermediate conditions on a continuum defined by MAR on one end to missing = smoking at the other end.

The multiple imputation strategy was applied using ten imputed datasets. The imputation model included as predictors the treatment variables and the site covariate as well as the variables gender, race, ethnicity, income, education, marital status, cigarettes smoked/day, heaviest smoking, years of smoking, age when first smoked a cigarette, age that daily smoking started, items from the Fagerstrom Tests of Cigarette Dependence[4,5] at baseline, the Heaviness of Smoking Index,[6] use of menthol cigarettes, total number of quit attempts, the longest prior quit attempt, any cessation medications previously used, prior use of nicotine replacement therapy (NRT), prior use of varenicline, smokers in the home, being around smokers, motivation to quit, confidence in quitting, positive affect and negative affect scales from the Positive and Negative Affect Schedule,[7] and scores from the Depression Anxiety Stress Scales questionnaire .[8] The imputation analyses were conducted using SPSS version 27.[9]

Supplemental Tables 2a and 2b display the results for the four analyses ordered in terms of the degree to which missingness was assumed to reflect smoking. Estimates for the first three analyses are based on the application of Rubin's rules[10] to provide pooled results across the imputed datasets.

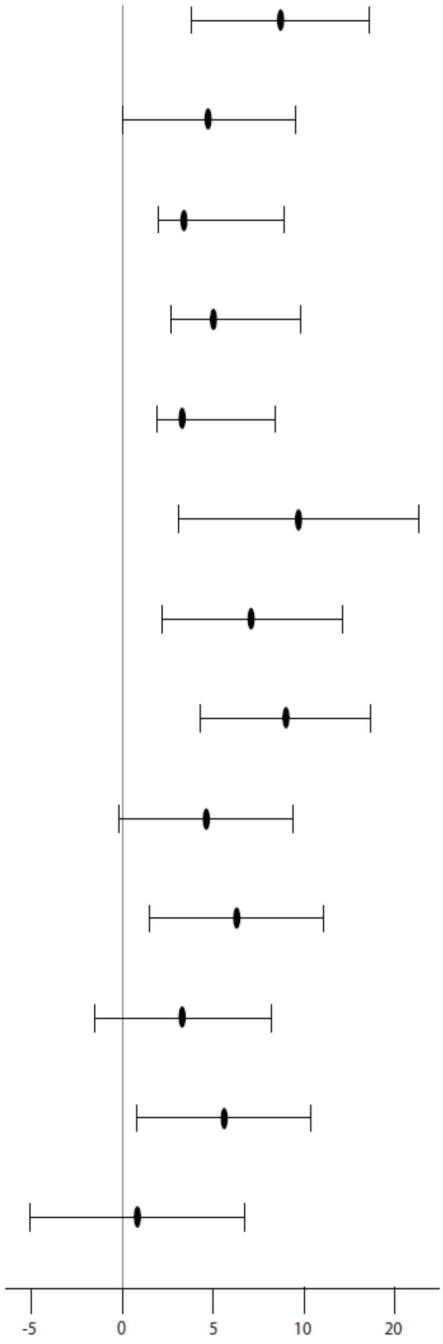
eFigure 1. Histogram of the Wisconsin Inventory of Smoking Dependence Motives, brief version[11] total score



eFigure 2. Associations of demographic and smoking variables with 52-week abstinence

[See next page for full page figure]

Variable[a]	Week 52 CO-Confirmed Abstinence No. (%)	Risk Difference (95% CI)	Univariate Risk Difference (95% CI)	P-Value for Covariate Effect[b] From Logistic Regression: Bivariable Model	Multivariable Model
Race (n=1250)		8.7 (3.8 to 13.6)		.001	.004
White (n=867)	236 (27.2%)				
Non-White (n=383)	71 (18.5%)				
Gender (n=1251)		4.7 (0.0 to 9.5)		.05	.05
Male (n=576)	156 (27.1%)				
Female (n=675)	151 (22.4%)				
Income (n=1174)		3.4 (2.0 to 8.9)		.23	.64
≥$20,000 (n=863)	221 (25.6%)				
<$20,0000 (n=311)	69 (22.2%)				
Age (years) (n=1251)		5.0 (2.7 to 9.8)		.04	.01
50+ (n=629)	170 (27.0%)				
18-49 (n=622)	137 (22.0%)				
Site (n=1251)		3.3 (1.9 to 8.4)		.21	.61
Madison (n=400)	107 (26.8%)				
Milwaukee (n=851)	200 (23.5%)				
FTCD Item 1 (n=1248)		9.7 (3.1 to 16.3)		.002	.35
Smoke > 30 Min (n=224)	73 (32.6%)				
Smoke Within 30 Min of Waking (n=1024)	234 (22.9%)				
FTCD Total Score (n=1247)		7.1 (2.2 to 12.1)		.004	.64
0-4 (n=492)	142 (28.9%)				
5-10 (n=755)	164 (21.7%)				
WISDM37 Primary Dependence Motives (n=1248)[c]		9.0 (4.3 to 13.7)		.0002	.07
Low (n=634)	184 (29.0%)				
High (n=614)	123 (20.0%)				
WISDM37 Secondary Dependence Motives (n=1243)[d]		4.6 (-0.2 to 9.4)		.06	.76
Low (n=634)	168 (27.0%)				
High (n=614)	139 (22.4%)				
Menthol Smoking (n=1250)		6.3 (1.5 to 11.1)		.01	.42
No (n=568)	159 (28.0%)				
Yes (n=682)	148 (21.7%)				
Home Smoking (n=1250)		3.3 (-1.5 to 8.2)		.18	.36
No (n=770)	199 (25.8%)				
Yes (n=480)	108 (22.5%)				
Carbon Monoxide (ppm) (n=1251)		5.6 (0.8 to 10.4)		.02	.004
5-14 (n=609)	167 (27.4%)				
15+ (n=642)	140 (21.8%)				
Prior Use of Cessation Medications (n=1250)		0.8 (-5.1 to 6.7)		.79	.36
No (n=258)	65 (25.2%)				
Yes (n=992)	242 (24.4%)				



Note: For each variable, two groups or variable values were compared on week 52 CO-confirmed abstinence. For purposes of display, the first (top) group of each of the two groups formed by variable coding was the one that was associated with an increase in abstinence.

Abbreviation: FTCD=Fagerstrom Test of Cigarette Dependence[28, 29]. WISDM37=Wisconsin Inventory of Smoking Dependence Motives, Brief Version [23] ; see eFigure 1 for a histogram of WISDM37.

[a]See Table 1 for definitions of variables.

[b]Covariate effects were tested in a series of bivariable and multivariable logistic regression analyses with the primary outcome (7-day point-prevalence abstinence at 52 Weeks post-target quit day [CO ≤ 5 ppm]) as the dependent variable, with no treatment coding. The multivariable model included all the covariates in the table.

[c]Low and high values on the WISDM37 Primary Dependence Motives scale were based on a median split (Median=5.1875).

[d]Low and high values on the WISDM37 Secondary Dependence Motives scale were based on a median split (Median=4.0).

eReferences

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