

Supplemental Materials for
Effects of Reduced-Nicotine Cigarettes Across Regulatory Environments in the Experimental
Tobacco Marketplace: A Randomized Trial

Submitted to Nicotine and Tobacco Research

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	N/A
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3
	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5-7
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	N/A
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	N/A
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	5
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	N/A
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	5
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	5
	11b	If relevant, description of the similarity of interventions	5-7
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	8
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	8

Results

Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure S1
Recruitment	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure S1
	14a	Dates defining the periods of recruitment and follow-up	5
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Table 1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	9-13
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	9-13
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	9-13
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	16
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	16
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	14-17
Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	1
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	1

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Product Listing and Prices

Table S1. Products and prices available in the Experimental Tobacco Marketplace					Regulatory Environments			
Category	Product	Unit	Price (\$USD)	Current Marketplace	Experimental Control	Proposed Marketplace	Combined Marketplace	
Combusted Cigarette	Investigational cigarette	Single cigarette	0.25 ea (fixed); 0.13, 0.25, 0.50, 1.00, 2.00, 4.00 ea (variable)		X	X	X	
Combusted Cigarette	Usual-brand cigarette	Single cigarette		X			X	
ENDS (disposable e-cigarette)	400 puff V2 tobacco/menthol 1.8%; Blu tobacco/menthol/cherry	Single disposable cigarette	4.99 ea; 7.99 ea	X		X	X	
ENDS (e-liquid)	32 degrees menthol, American red tobacco, crazy grape 6 and 24mg/g	2 mL bottle	0.87 ea	X		X	X	
Snus	Camel frost/mellow/mint	Single pouch	0.23 ea	X		X	X	
Snus	General classic/mint/wintergreen	Single pouch	0.09 ea	X		X	X	
Dip	Skoal straight/mint/wintergreen	Single pouch	0.26 ea	X		X	X	
Dip	Grizzly straight/mint/wintergreen	Single pouch	0.21 ea	X		X	X	
NRT	Nicorette gum fruit/mint 4mg	Single piece	0.40 ea	X		X	X	
NRT	Nicorette lozenge original/mint 4mg	Single piece	0.56 ea	X		X	X	

Pearson Bivariate Correlations

Table S2. Pearson Bivariate Correlations Among Demographic Variables				
	Age	Education	Monthly Income	FTND
Age				
Education	0.24**			
Monthly Income	0.19*	0.30***		
FTND	-0.12	-0.26**	-0.17*	
Cigarettes per Day	-0.08	-0.11	-0.03	0.61****
*p < .05, **p < .01, ***p < .001, ****p < .0001				

Extra Sum-of-Squares F-tests (Investigational Cigarettes)

Table S3. Comparison of α

Regulatory Environment	Log(Q ₀)	Log(Q ₀) Std. Err	K	R ²	Log(α)	Log(α) Std. Err	N	AbsSS	Notes	F-test
Shared										Summary of F-test Conclusion: reject the null hypothesis F(2,2711) = 30.9528, p = 0
Experimental Control	4.964	2.421	2	0.305	-4.944	-8.165	2717	30238	converged	
Proposed Marketplace Combined	4.149	1.443	2	0.305	-4.944	-8.165	2717	30238	converged	
Marketplace	2.053	0.501	2	0.305	-4.944	-8.165	2717	30238	converged	
Not Shared										
Experimental Control	4.875	2.354	2	0.350	-5.047	-7.935	905	13528	converged	
Proposed Marketplace Combined	4.425	2.255	2	0.222	-4.583	-7.138	906	10744	converged	
Marketplace	4.887	4.651	2	0.087	-3.478	-4.828	906	52912	converged	

Table S4. Comparison of Q₀

Regulatory Environment	Log(Q ₀)	Log(Q ₀) Std. Err	K	R ²	Log(α)	Log(α) Std. Err	N	AbsSS	Notes	F-test
Shared										Summary of F-test Conclusion: reject the null hypothesis F(2,2711) = 4.8947, p = 0.0076
Experimental Control	4.784	1.957	2	0.318	-5.086	-8.075	2717	2967	converged	
Proposed Marketplace Combined	4.784	1.957	2	0.318	-4.475	-7.502	2717	2967	converged	
Marketplace	4.784	1.957	2	0.318	-3.443	-5.837	2717	2967	converged	
Not Shared										
Experimental Control	4.875	2.354	2	0.350	-5.047	-7.935	905	13528	converged	
Proposed Marketplace Combined	4.425	2.255	2	0.222	-4.583	-7.138	906	10744	converged	
Marketplace	4.887	4.651	2	0.087	-3.478	-4.828	906	52912	converged	

GEE Predicting Zero Purchasing

Table S5. GEE Predicting All Zero Purchasing

<i>Predictors</i>	All Zero Purchasing		
	<i>Odds Ratios</i>	<i>CI</i>	<i>p</i>
(Intercept)	0.08	0.03 – 0.28	<0.001
Cigarettes per Day	0.96	0.93 – 1.00	0.064
Experimental Control	<i>Reference</i>		
Proposed Marketplace	7.03	3.67 – 13.45	<0.001
Combined Marketplace	36.45	17.17 – 77.36	<0.001
15.8mg/g	<i>Reference</i>		
5.2mg/g	1.53	0.66 – 3.53	0.324
2.4mg/g	1.28	0.56 – 2.94	0.560
1.3mg/g	1.94	0.81 – 4.65	0.139
0.4mg/g	1.12	0.46 – 2.70	0.804
Usual Brand Flavor [Menthol]	<i>Reference</i>		
Tobacco	1.34	0.76 – 2.36	0.312
Monthly Income (\$1000)	0.82	0.59 – 1.14	0.239
Multiuser Status [Multiuser]	1.52	0.81 – 2.86	0.188
N _{id}	150		
Observations	450		

GEE Experimental Cigarette Purchasing

Table S6. GEE Predicting Experimental Cigarette Purchasing

<i>Predictors</i>	Experimental Cigarettes Purchased		
	<i>Estimates</i>	<i>CI</i>	<i>p</i>
(Intercept)	1.10	-11.07 – 13.27	0.860
Cigarettes per Day	0.94	0.48 – 1.39	<0.001
Experimental Control	<i>Reference</i>		
Proposed Marketplace	-9.02	-11.06 – -6.98	<0.001
Combined Marketplace	-19.98	-22.73 – -17.22	<0.001
15.8mg/g	<i>Reference</i>		
5.2mg/g	3.63	-5.24 – 12.50	0.423
2.4mg/g	-0.67	-7.80 – 6.47	0.855
1.3mg/g	-4.11	-11.12 – 2.90	0.250
0.4mg/g	-1.89	-11.24 – 7.46	0.692
Proposed Marketplace x Log(Cigarette price)	18.66	13.20 – 24.13	<0.001
Combined Marketplace x Log(Cigarette price)	41.69	34.93 – 48.44	<0.001
Sex [Female]	<i>Reference</i>		
Male	1.36	-3.98 – 6.70	0.618
Log(Cigarette price)	-52.58	-60.21 – -44.94	<0.001
Monthly Income (\$1000)	2.64	0.50 – 4.78	0.015
Usual Brand Flavor [Menthol]	<i>Reference</i>		
Tobacco	-0.09	-5.42 – 5.24	0.974
N _{id}	150		
Observations	2699		

Extra Sum-of-Squares F-tests (Conventional Cigarettes)

Table S7. Comparison of α

Regulatory Environment	Log(Q ₀)	Log(Q ₀) Std. Err	K	R ²	Log(α)	Log(α) Std. Err	N	AbsSS	Notes	F-test
Shared										Summary of F-test Conclusion: reject the null hypothesis F(1,1807) = 9.9752, p = 0.0016
Current Marketplace Combined	5.187	2.561	2	0.470	-5.076	-8.607	1811	21560	converged	
Marketplace	4.880	2.100	2	0.470	-5.076	-8.607	1811	21560	converged	
Not Shared										
Current Marketplace Combined	5.124	2.418	2	0.508	-5.147	-8.404	906	10631	converged	
Marketplace	4.987	2.491	2	0.430	-4.960	-8.071	905	10810	converged	

Table S8. Comparison of Q₀

Regulatory Environment	Log(Q ₀)	Log(Q ₀) Std. Err	K	R ²	Log(α)	Log(α) Std. Err	N	AbsSS	Notes	F-test
Shared										Summary of F-test Conclusion: fail to reject the null hypothesis F(1,1807) = 1.7176, p = 0.1902
Current Marketplace Combined	5.072	2.115	2	0.473	-5.163	-8.419	1811	21462	converged	
Marketplace	5.072	2.115	2	0.473	-4.939	-8.221	1811	21462	converged	
Not Shared										
Current Marketplace Combined	5.124	2.418	2	0.508	-5.147	-8.404	906	10631	converged	
Marketplace	4.987	2.491	2	0.430	-4.960	-8.071	905	10810	converged	

GEE Conventional Cigarette Purchasing

Table S9. GEE Predicting Conventional Cigarette Purchasing

<i>Predictors</i>	Conventional Cigarettes Purchased		
	<i>Estimates</i>	<i>CI</i>	<i>p</i>
(Intercept)	-4.93	-16.19 – 6.33	0.391
Cigarettes per Day	1.25	0.81 – 1.69	<0.001
Current Marketplace	<i>Reference</i>		
Combined Marketplace	-4.77	-6.73 – -2.81	<0.001
15.8mg/g	<i>Reference</i>		
5.2mg/g	-0.21	-9.25 – 8.83	0.964
2.4mg/g	-3.51	-12.64 – 5.62	0.451
1.3mg/g	-4.52	-13.68 – 4.63	0.333
0.4mg/g	-7.27	-16.80 – 2.26	0.135
Combined Marketplace x Log(Cigarette price)	9.21	3.70 – 14.73	0.001
Sex [Female]	<i>Reference</i>		
Male	5.10	-0.22 – 10.41	0.060
Log(Cigarette price)	-63.64	-70.51 – -56.76	<0.001
Monthly Income (\$1000)	3.48	1.33 – 5.62	0.001
Usual Brand Flavor [Menthol]	<i>Reference</i>		
Tobacco	2.97	-2.42 – 8.37	0.280
N _{id}	150		
Observations	1799		

GEE Cigarette Substitution

Table S10. GEE Predicting Cigarette Substitution

<i>Predictors</i>	Cigarettes Purchased		
	<i>Estimates</i>	<i>CI</i>	<i>p</i>
(Intercept)	-18.92	-35.00 – -2.84	0.021
Cigarettes per Day	1.54	0.92 – 2.15	<0.001
15.8mg/g	<i>Reference</i>		
5.2mg/g	-3.54	-16.59 – 9.51	0.595
2.4mg/g	-0.70	-11.95 – 10.55	0.903
1.3mg/g	-9.32	-20.55 – 1.91	0.104
0.4mg/g	-10.75	-23.98 – 2.47	0.111
Investigational Cigarette	<i>Reference</i>		
Usual Brand Cigarette	33.78	28.06 – 39.51	<0.001
Usual Brand Cigarette x Log(Cigarette price)	-9.10	-13.38 – -4.81	<0.001
Sex [Female]	<i>Reference</i>		
Male	3.10	-4.80 – 11.01	0.441
Log(Cigarette price)	13.09	8.56 – 17.62	<0.001
Monthly Income (\$1000)	6.33	3.06 – 9.60	<0.001
Usual Brand Flavor [Menthol]	<i>Reference</i>		
Tobacco	5.32	-3.42 – 14.05	0.233
N _{id}	150		
Observations	1799		

Estimated Marginal Means Nicotine By Regulatory Environment and Cigarette Group

Table S11. Estimated Marginal Means of Nicotine from Alternate Product Purchasing			
Regulatory Environment	Estimated Marginal Mean	Standard Error	Degrees of Freedom
<i>15.8mg/g</i>			
Current Marketplace	15.25	3.31	219.86
Proposed Marketplace	14.93	3.31	219.86
Combined Marketplace (UB Price Increasing)	7.17	3.31	219.86
Combined Marketplace (IC Price Increasing)	6.67	3.31	219.86
<i>5.2mg/g</i>			
Current Marketplace	13.67	3.19	220.73
Proposed Marketplace	16.92	3.19	220.73
Combined Marketplace (UB Price Increasing)	13.30	3.19	221.39
Combined Marketplace (IC Price Increasing)	11.36	3.19	220.73
<i>2.4mg/g</i>			
Current Marketplace	15.25	3.26	219.42
Proposed Marketplace	17.42	3.26	219.42
Combined Marketplace (UB Price Increasing)	8.34	3.26	219.42
Combined Marketplace (IC Price Increasing)	8.81	3.26	219.42
<i>1.3mg/g</i>			
Current Marketplace	12.29	3.47	213.70
Proposed Marketplace	25.54	3.47	213.70
Combined Marketplace (UB Price Increasing)	11.27	3.47	213.70
Combined Marketplace (IC Price Increasing)	9.62	3.47	213.70
<i>0.4mg/g</i>			
Current Marketplace	4.07	3.13	221.60
Proposed Marketplace	12.70	3.13	221.60
Combined Marketplace (UB Price Increasing)	4.58	3.13	221.60
Combined Marketplace (IC Price Increasing)	3.50	3.13	221.60

Figure S1

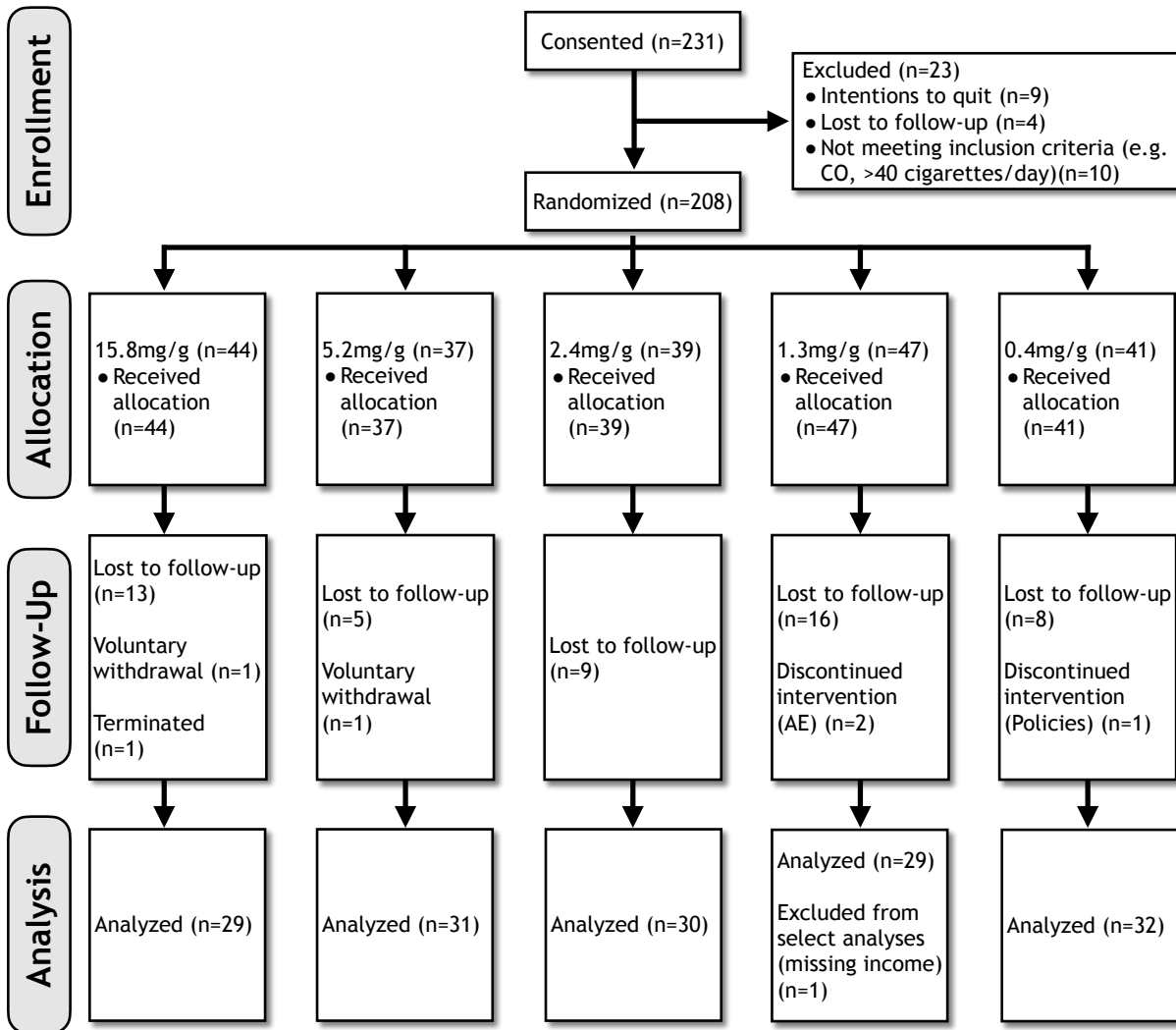


Figure S1. CONSORT diagram for this between subjects, double-blind experimental design, where randomized allocation is the between-subjects factor, and repeated measurements over time is the within-subjects factor.

Figure S2

The screenshot displays the 'Tobacco Marketplace' catalog interface. At the top left is the ARRC logo. The main header includes 'Tobacco Marketplace' and 'Catalog'. On the top right, a blue box shows a shopping cart icon, 'Empty', and '\$31.25 Remaining'. Below this, it says 'Items 1-28 Displayed'. The catalog lists five products, each with a small image, a title, a description, price, unit, quantity selector, and an 'Add to Cart' button.

Product Name	Description	Price	Unit	Quantity	Action
Experimental Cigarette	An investigational tobacco product (experimental cigarette) that you have recently used for this study. This price is for 1 cigarette. Flavor: Tobacco	\$0.13	single cigarette	1	Add to Cart
400 Puff V2 Menthol Disposable	1 400 Puff V2 Disposable E-cigarette in Menthol flavor. Flavor: Menthol Nicotine: 18 mg/mL nicotine.	\$4.99	single disposable e-cigarette	1	Add to Cart
400 Puff V2 Tobacco Disposable	1 400 Puff V2 Disposable E-cigarette in Tobacco flavor. Flavor: Tobacco Nicotine: 18 mg/mL nicotine.	\$4.99	single disposable e-cigarette	1	Add to Cart
Blu Disposable Cherry	1 Blu Disposable e-cigarette in Cherry flavor. Flavor: Cherry Nicotine: 24 mg/mL nicotine	\$7.99	single disposable e-cigarette	1	Add to Cart
Blu Disposable Menthol	1 Blu Disposable e-cigarette in Menthol flavor. Flavor: Menthol Nicotine: 24 mg/mL nicotine	\$7.99	single disposable e-cigarette	1	Add to Cart

Figure S2. Actual screenshot of the Experimental Tobacco Marketplace.

Figure S3

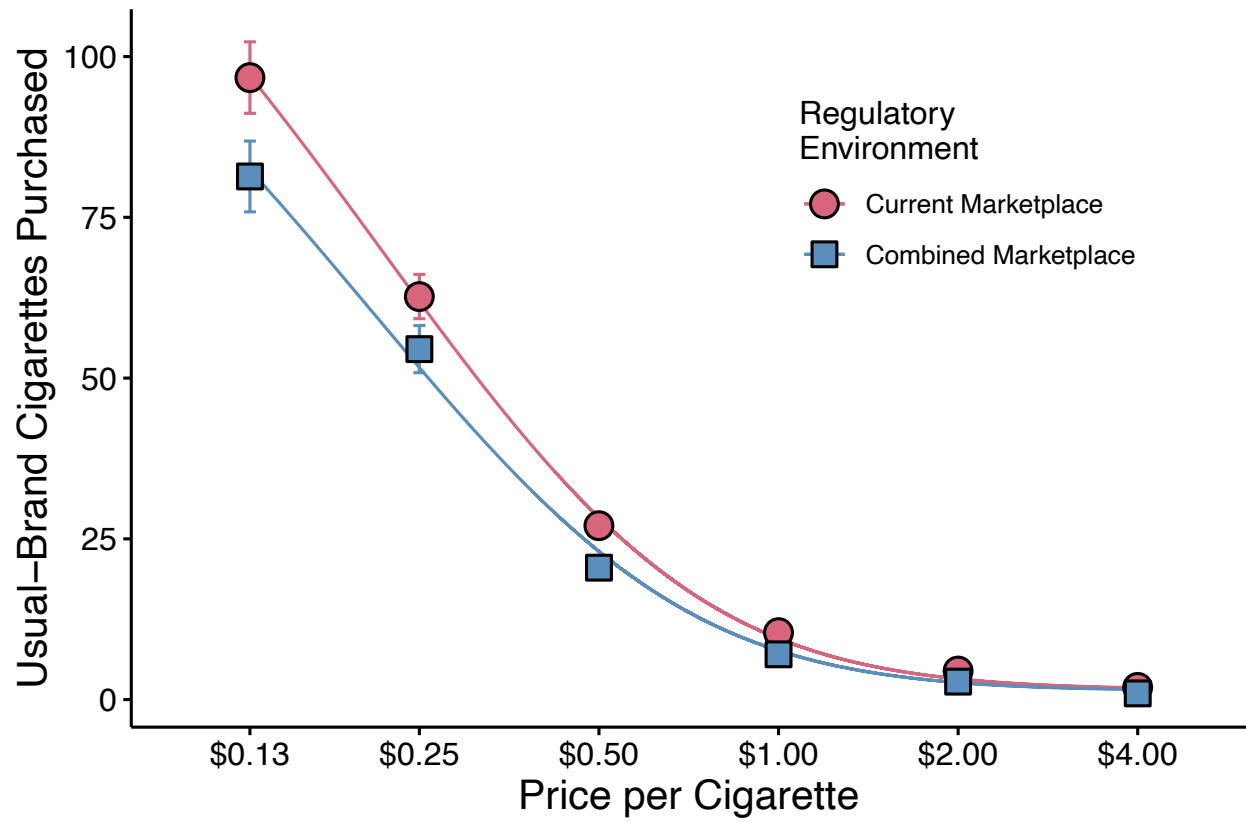


Figure S3. Usual-brand cigarettes purchased across each regulatory environment condition. Symbols represent mean and standard error of the mean.

Figure S4

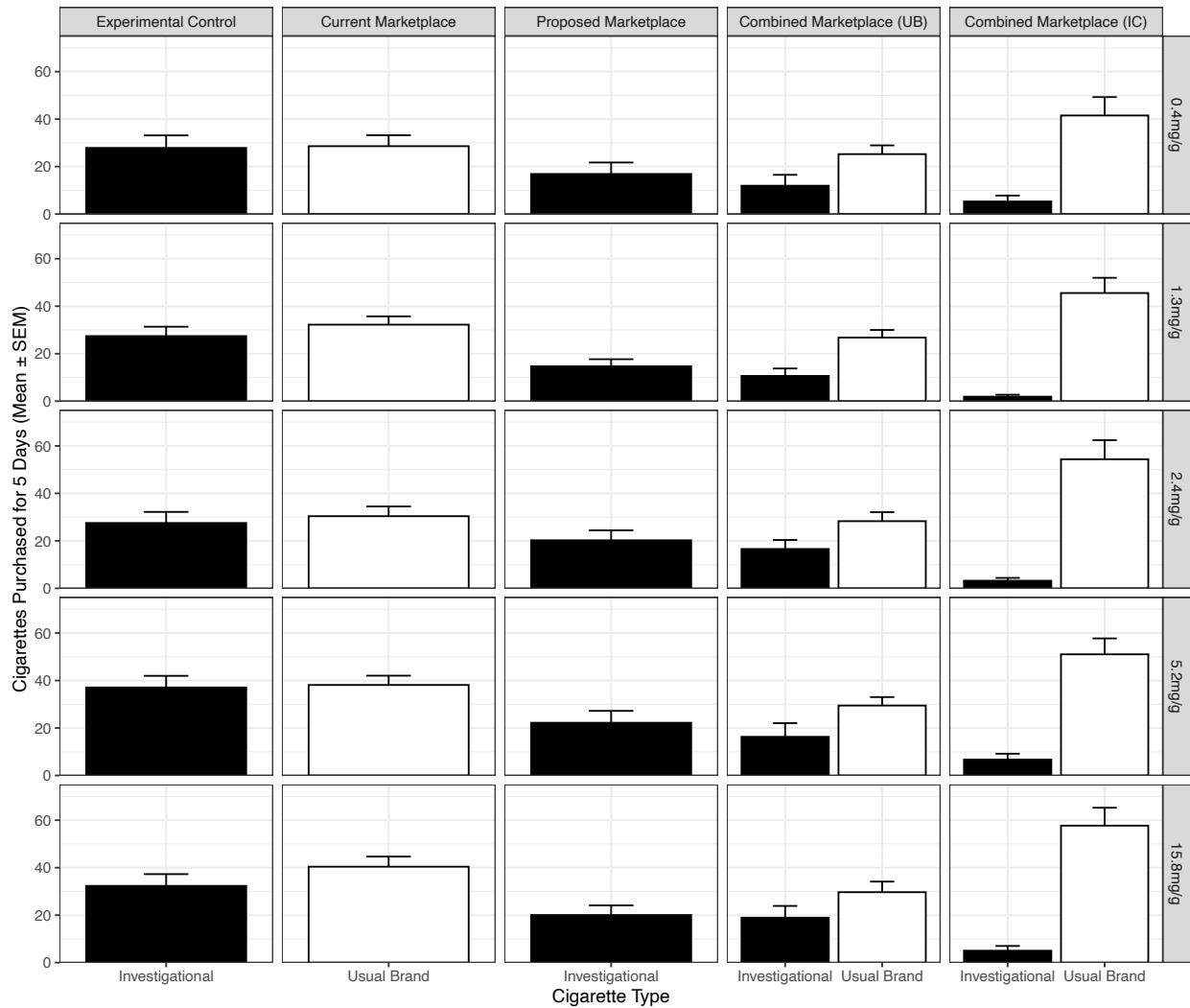


Figure S4. Investigational and usual-brand cigarettes purchased across each regulatory environment condition and within each cigarette group. Combined Marketplace (UB) indicates usual-brand cigarette increasing in price, whereas Combined Marketplace (IC) indicates investigational cigarette increasing in price. In both regulatory environments, the alternate cigarette was fixed at \$0.25 per cigarette.