



Effect of Flavored on!® Nicotine Pouch Products on Smoking Behaviors: A Sequential, Multiple Assignment, Randomized Controlled Trial

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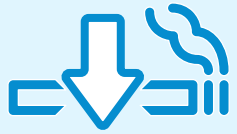
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Key Takeaways



Overall use of on!® nicotine pouch products led to CPD reduction

- Half of participants were able to **reduce CPD by $\geq 50\%$** by end of study
- Magnitude of **reduction was statistically significant** within each Study Arm
- **Rescue effect** for Delayed Access to Flavors
 - May be possible to ascertain need for “rescue” early



Access to Flavors increased incidence of smoke-free days early

Number of smoke-free days was modest

Flavors were used *more*, liked *more*, and had higher purchase intent



Objectives

Objectives were to assess effects of:



VS



on!® nicotine pouch products provided in 4 mg nicotine level



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Measures & Outcomes

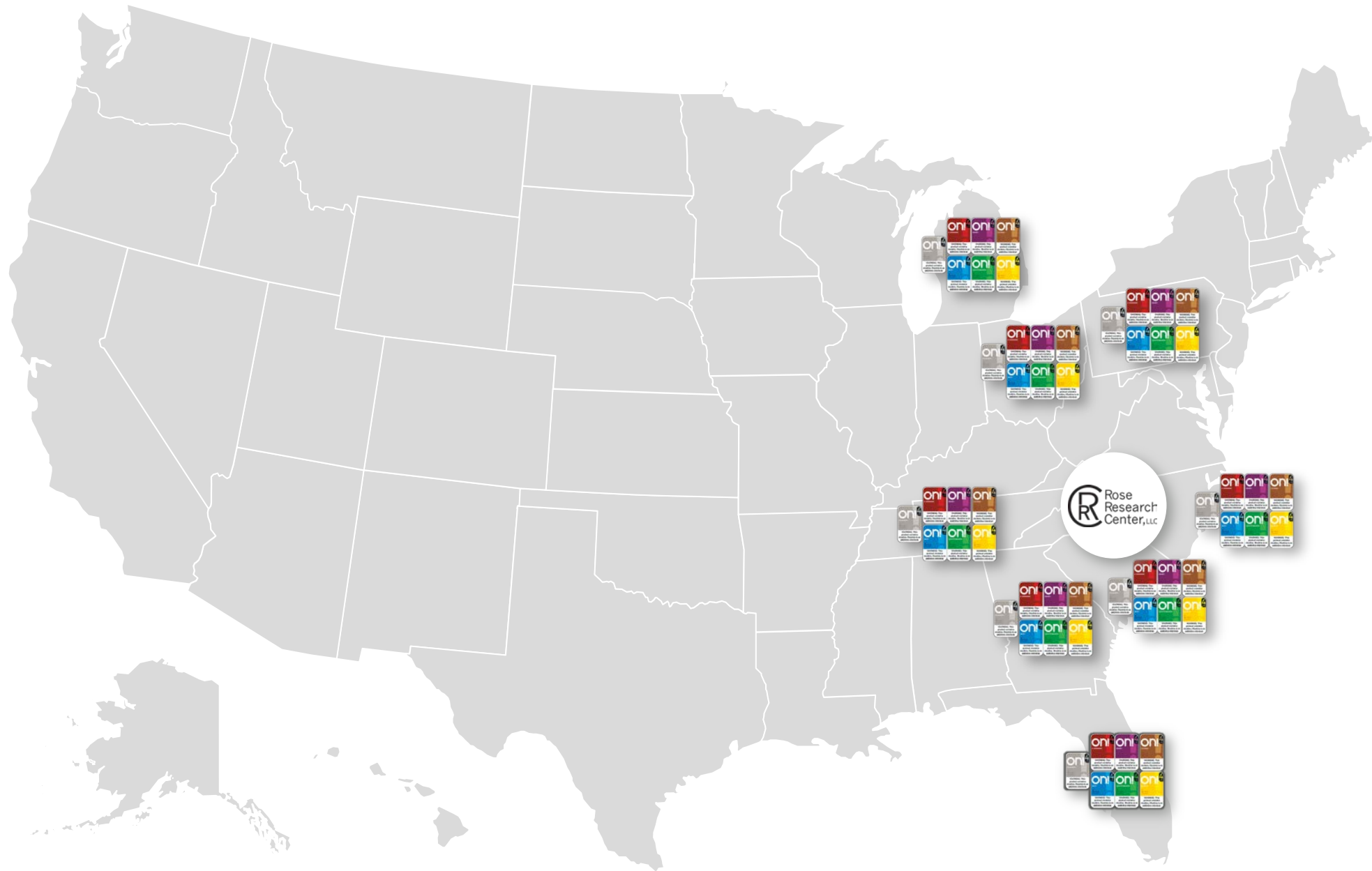
Measure	Frequency Assessed	Binary
Expired-air CO	Every 3 Days	≥50% Reduction from Baseline at Weeks 3 & 6
Number of Cigarettes Smoked	Daily	≥50% Reduction from Baseline at Weeks 3 & 6
Liking	Week 6	N/A
Purchase Intent	Week 6	N/A



Derived Outcomes:

- **Smoking Abstinence:** No cigarettes smoked **and** CO < 6 ppm for a given week
- **Smoke-free Days:** Number of days without smoking for a given week





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JMIR RESEARCH PROTOCOLS

Cheng et al

Protocol

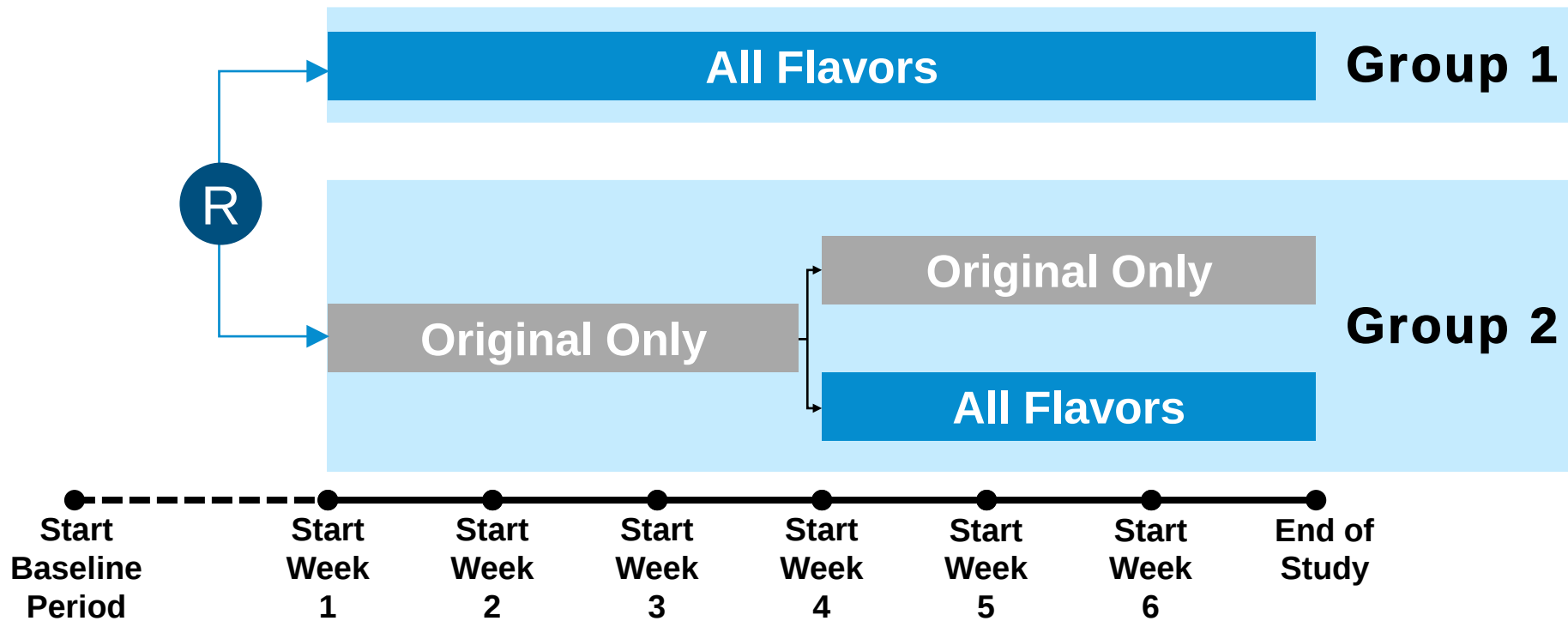
Effect of Flavored on! Nicotine Pouch Products on Smoking Behaviors: Protocol for a Sequential, Multiple Assignment, Randomized Controlled Trial

Hui G Cheng¹, PhD; Jed E Rose², PhD; Joshua L Karelitz¹, PhD; David R Botts², MS; Tanaia L Botts², MS; Perry N Willette², MD; Gal Cohen², PhD

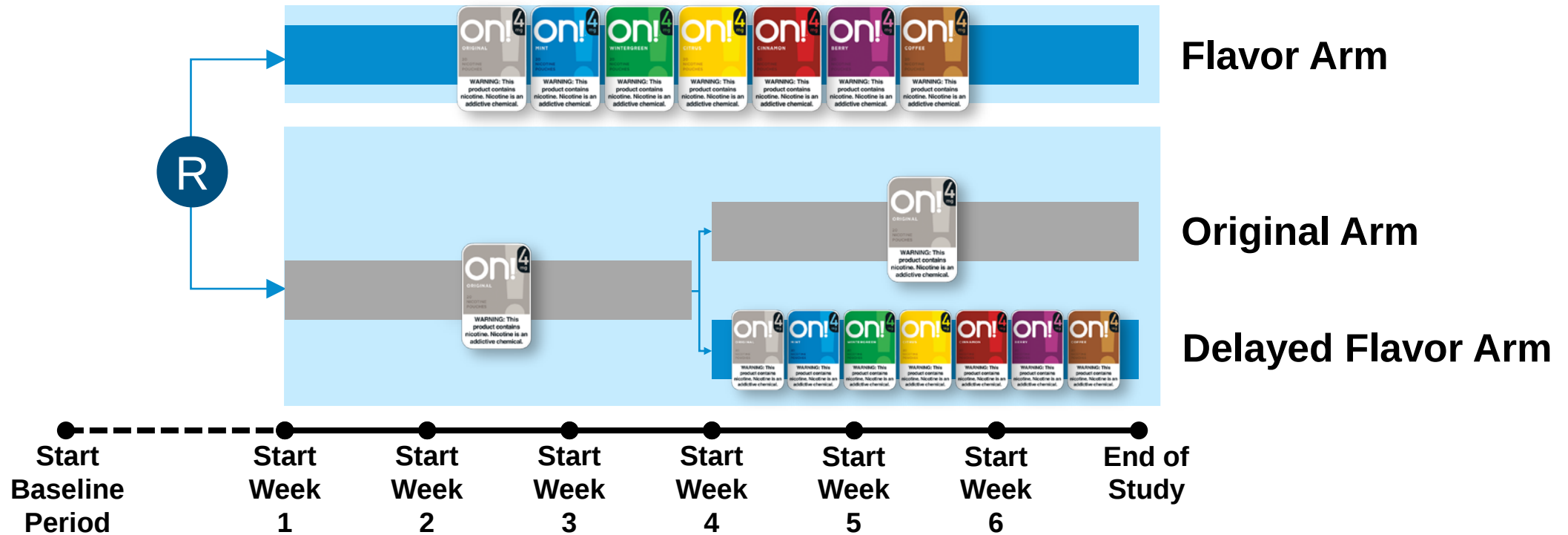
¹Altria Client Services, LLC, Richmond, VA, United States

²Rose Research Center, LLC, Raleigh, NC, United States

Design



Design



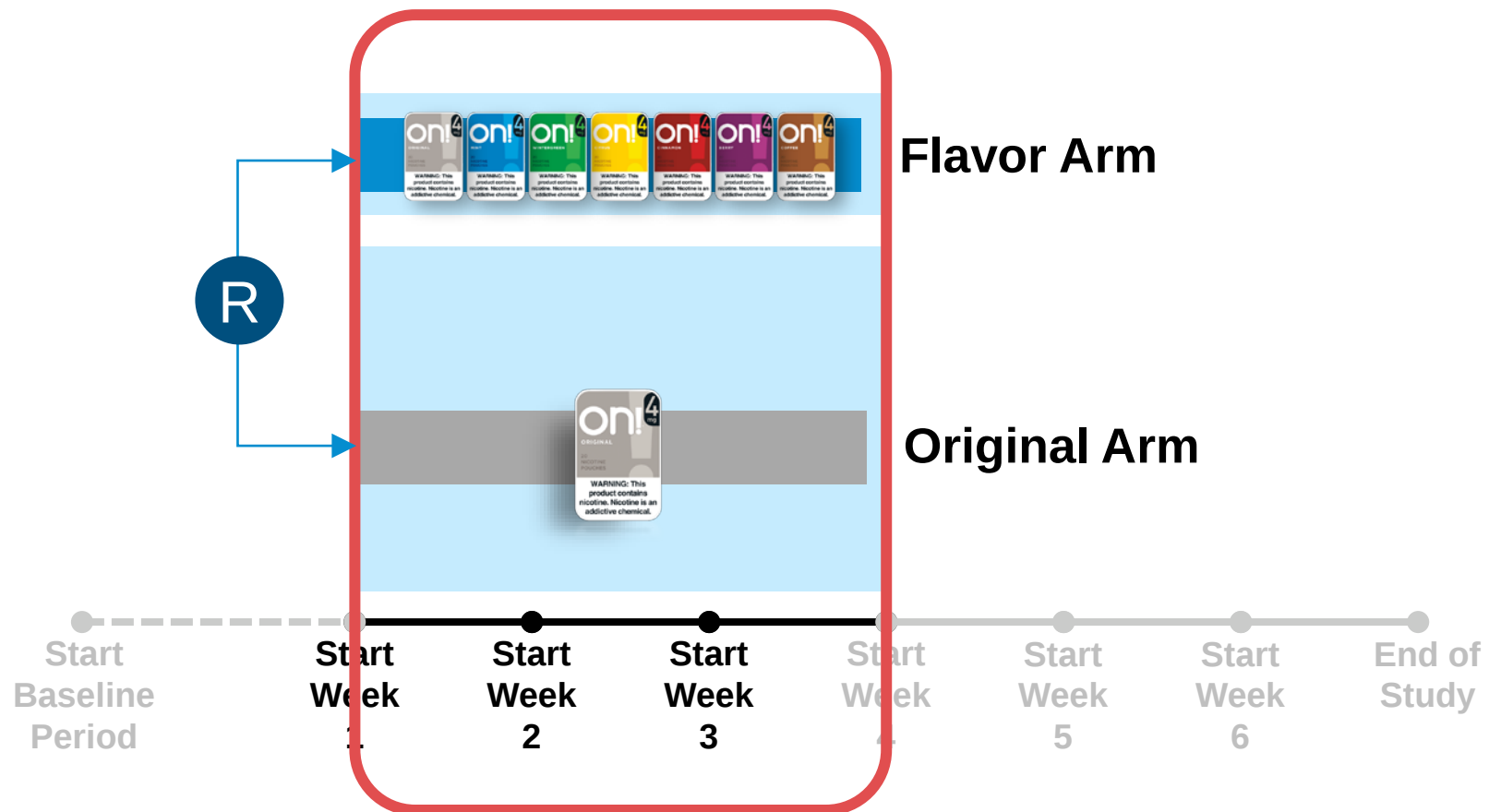
on!® nicotine pouches provided in 4 mg nicotine level



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Design



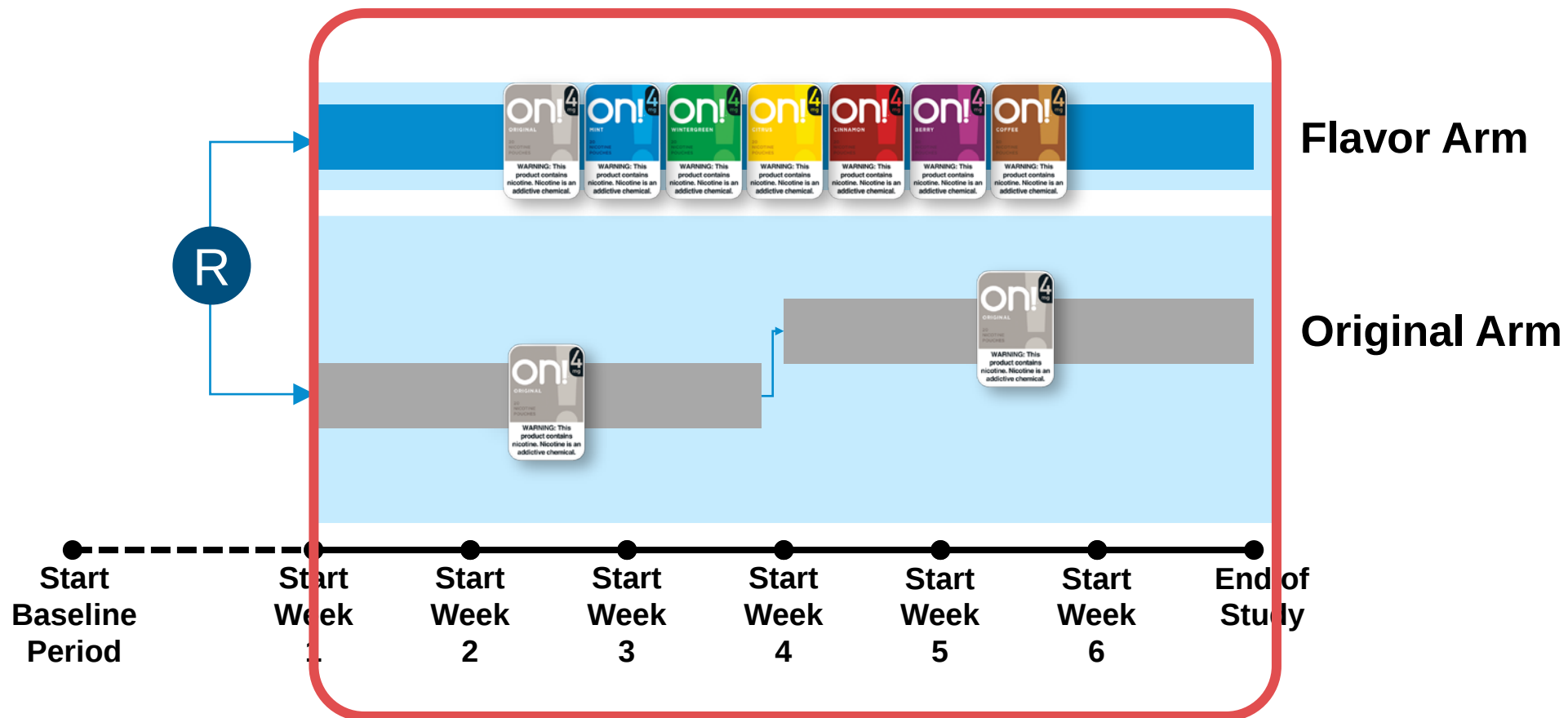
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Design



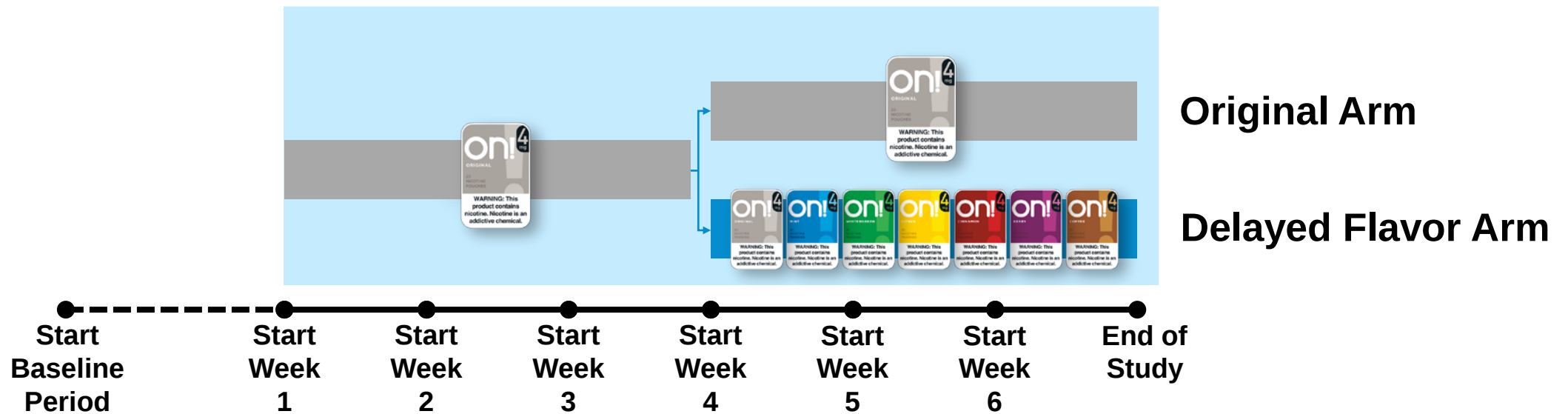
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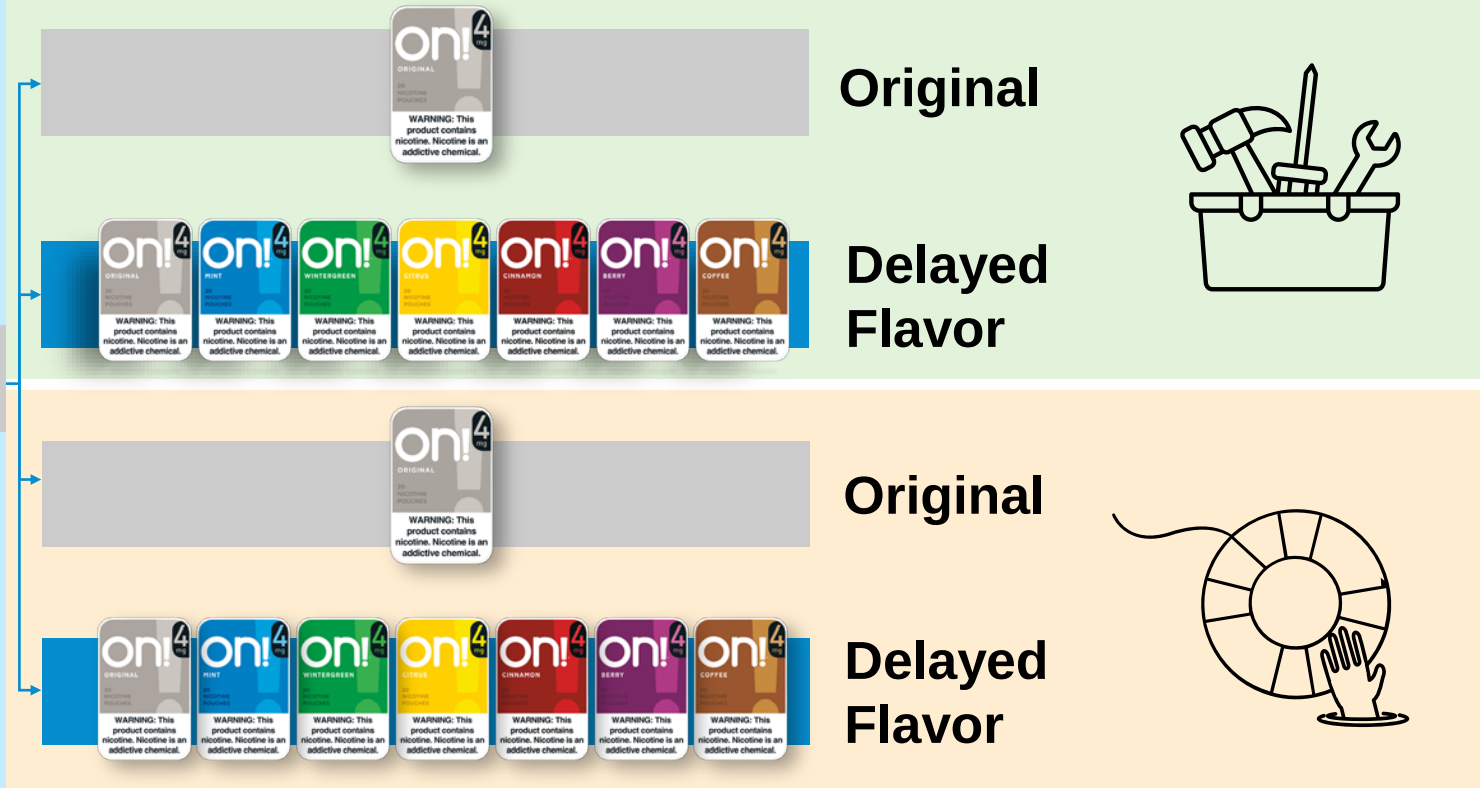
Responders

≥50% CPD reduction from Baseline in Week 3



Non-Responders

<50% CPD reduction from Baseline in Week 3



Start
Week
1

Start
Week
2

Start
Week
3

Start
Week
4

Start
Week
5

Start
Week
6

End of
Study



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Study Population



Select Inclusion Criteria

Aged 22-65 years of age

- Verified via valid government-issued photo identification (e.g., driver's license, passport, etc.)



Smoked ≥ 5 cigarettes daily for ≥ 12 months prior to screening

Did not intend to stop using tobacco products within 60 days of screening

Interested in replacing cigarettes with a smoke-free nicotine/tobacco product at screening



Results



Sample Composition





Demographics

		Overall n=400	Flavor n=151	Original + Delayed Flavor n=249
Sex n (%)	Female	198 (49.5%)	79 (52.3%)	119 (47.8%)
	Male	202 (50.5%)	72 (47.7%)	130 (52.2%)
Age n (%)	Mean (SD)	43.8 (10.0)	44.0 (9.9)	43.6 (10.0)
	21-34	83 (20.8%)	28 (18.5%)	55 (22.1%)
	35-44	130 (32.5%)	56 (37.1%)	74 (29.7%)
	45-49	54 (13.5%)	13 (8.6%)	41 (16.5%)
	50-65	133 (33.3%)	54 (35.8%)	79 (31.7%)
Race / Ethnicity n (%)	White NH	296 (74.0%)	113 (74.8%)	183 (73.5%)
	Black NH	46 (11.5%)	15 (9.9%)	31 (12.5%)
	Other NH	24 (6.0%)	9 (6.0%)	15 (6.0%)
	Hispanic	34 (8.5%)	14 (9.3%)	20 (8.0%)
Education n (%)	Less than College	211 (52.8%)	68 (45.0%)	143 (57.4%)
	Some College	146 (36.5%)	66 (43.7%)	80 (32.1%)
	College or Higher	43 (10.8%)	17 (11.3%)	26 (10.4%)

Abbreviations: n=number; SD=standard deviation



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Baseline Cigarette Use

		Overall n=399	Flavor n=151	Original + Delayed Flavor n=248
Cigarettes Per Day n (%)	Mean (SD)	13.0 (7.4)	13.3 (7.7)	12.8 (7.3)
	≤10 CPD	157 (39.4%)	57 (37.8%)	100 (40.3%)
	>10 CPD	242 (60.7%)	94 (62.3%)	148 (59.7%)

Abbreviations: n=number; SD=standard deviation; CPD=cigarettes per day
Note. One participant in Original+Delayed Flavor Arm missing baseline CPD



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Results

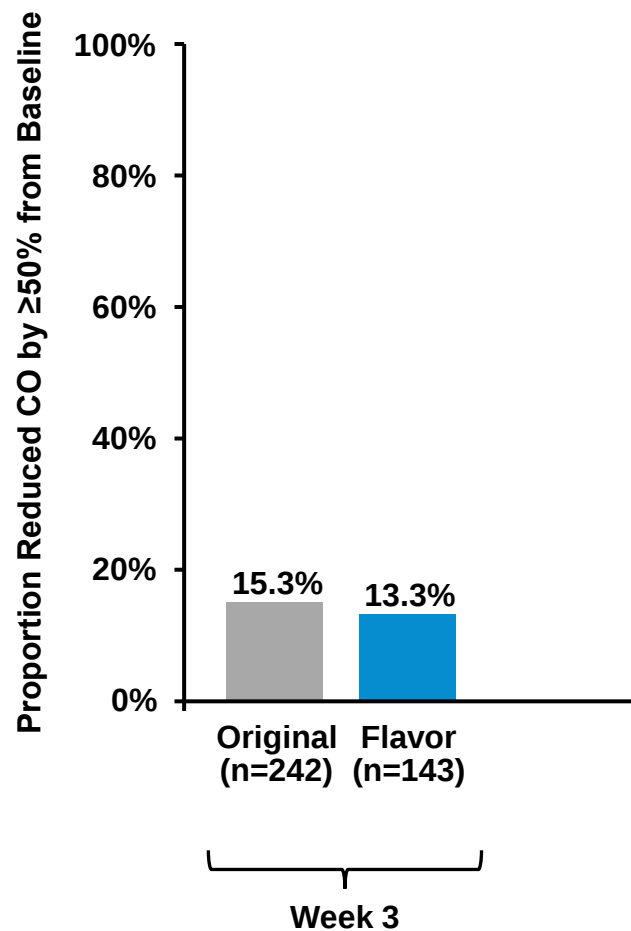


Smoking Reduction:

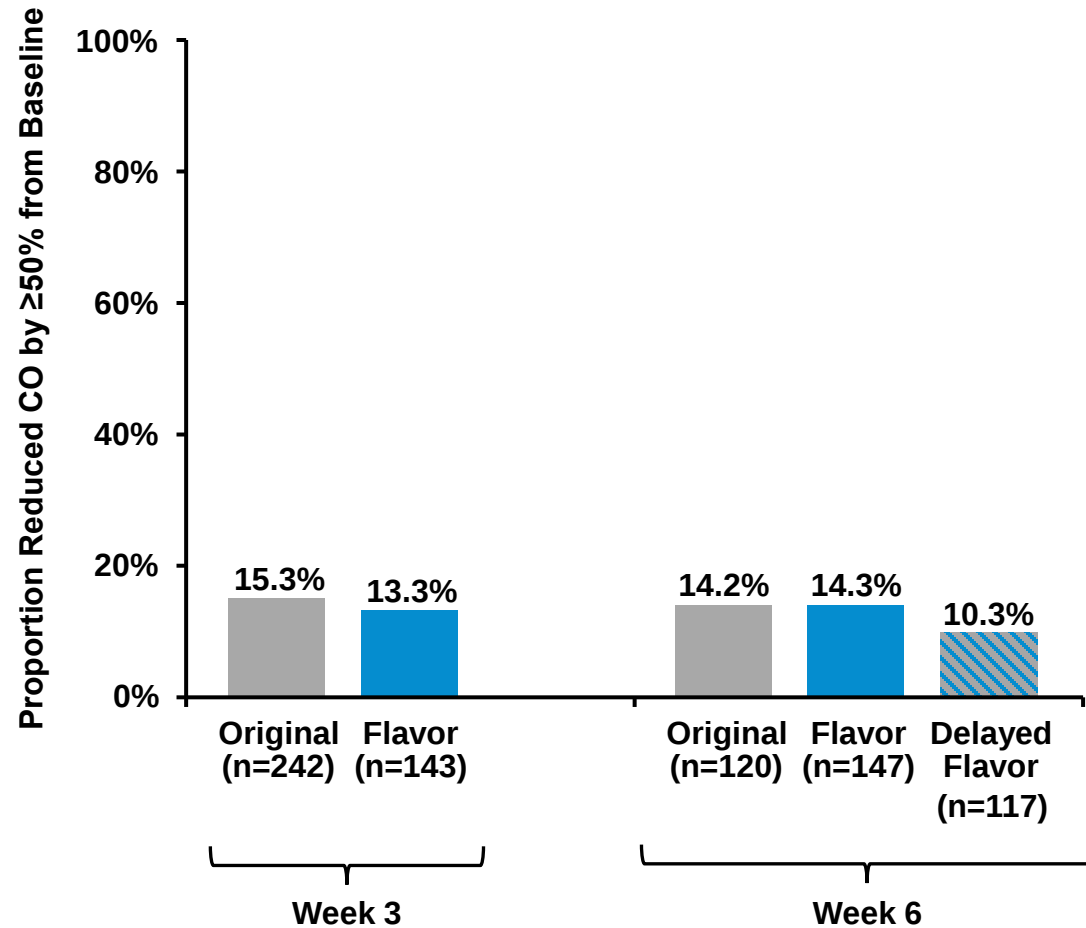
- CO Reduction
- CPD Reduction



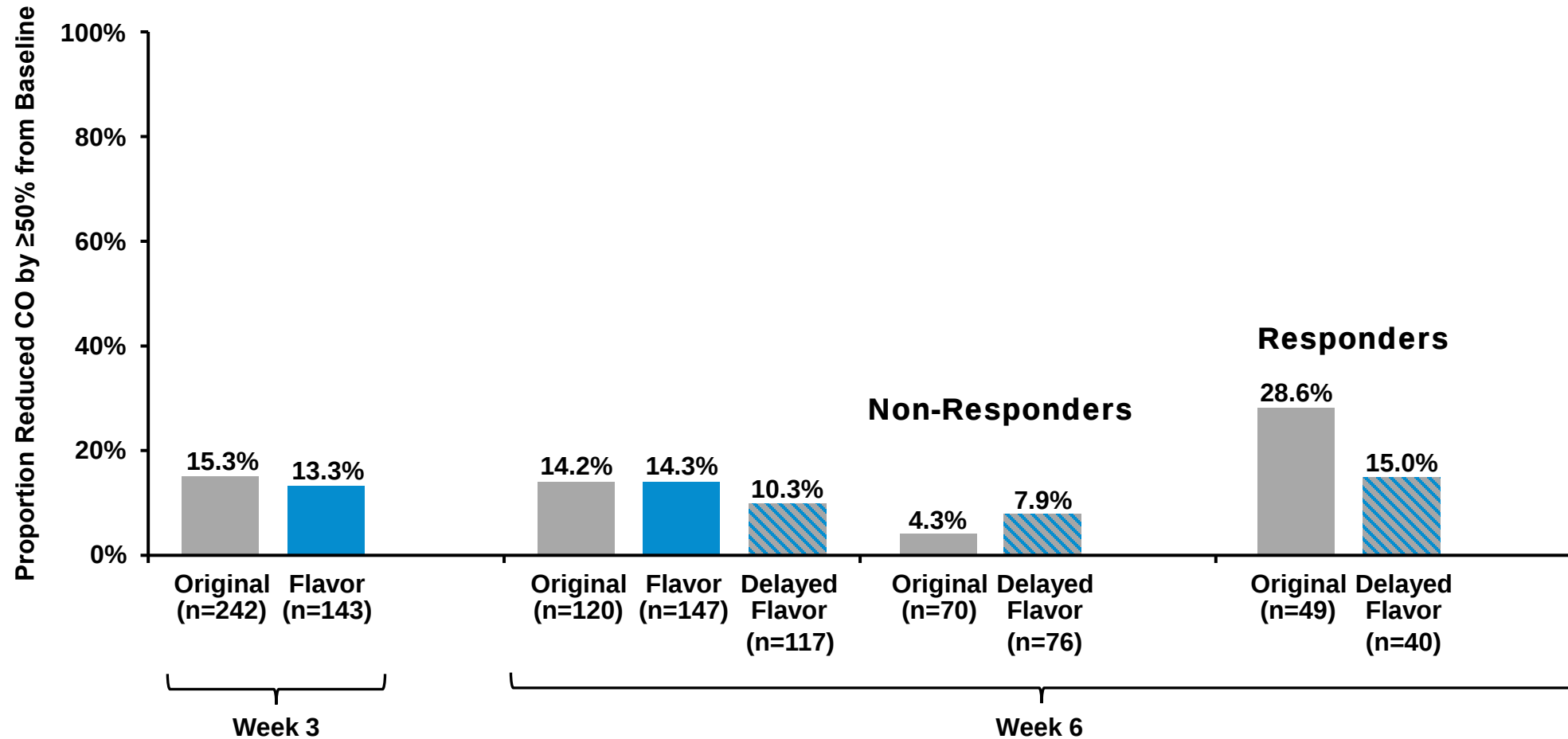
No Differences for $\geq 50\%$ CO Reduction



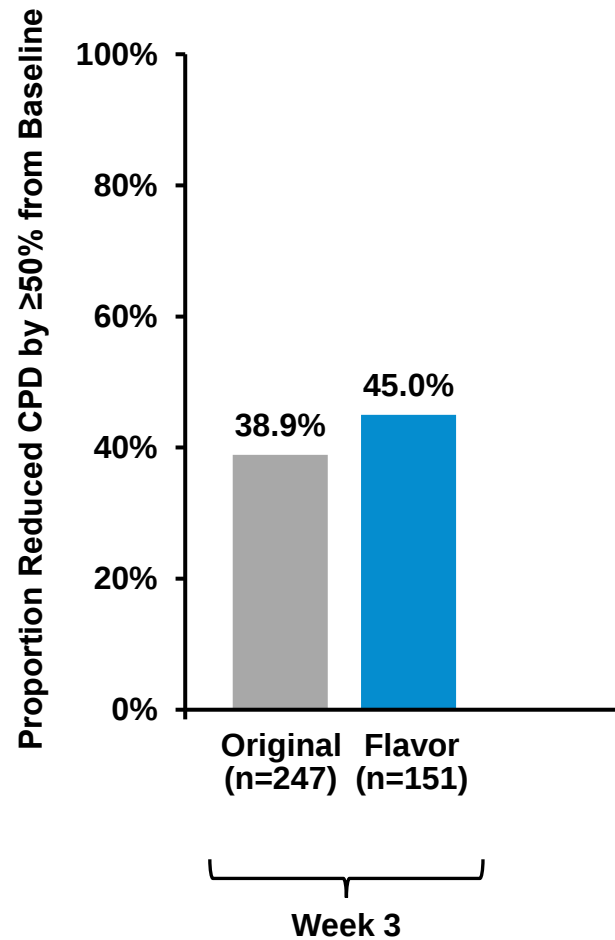
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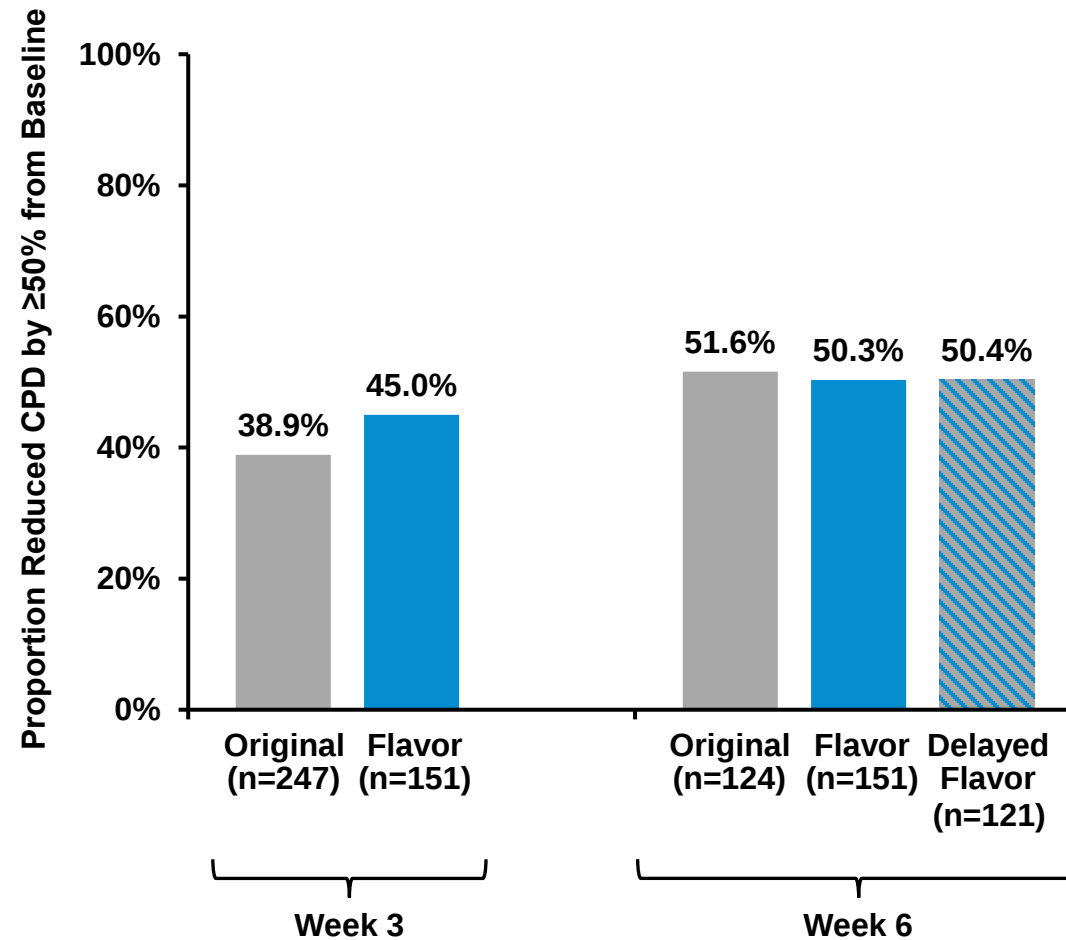
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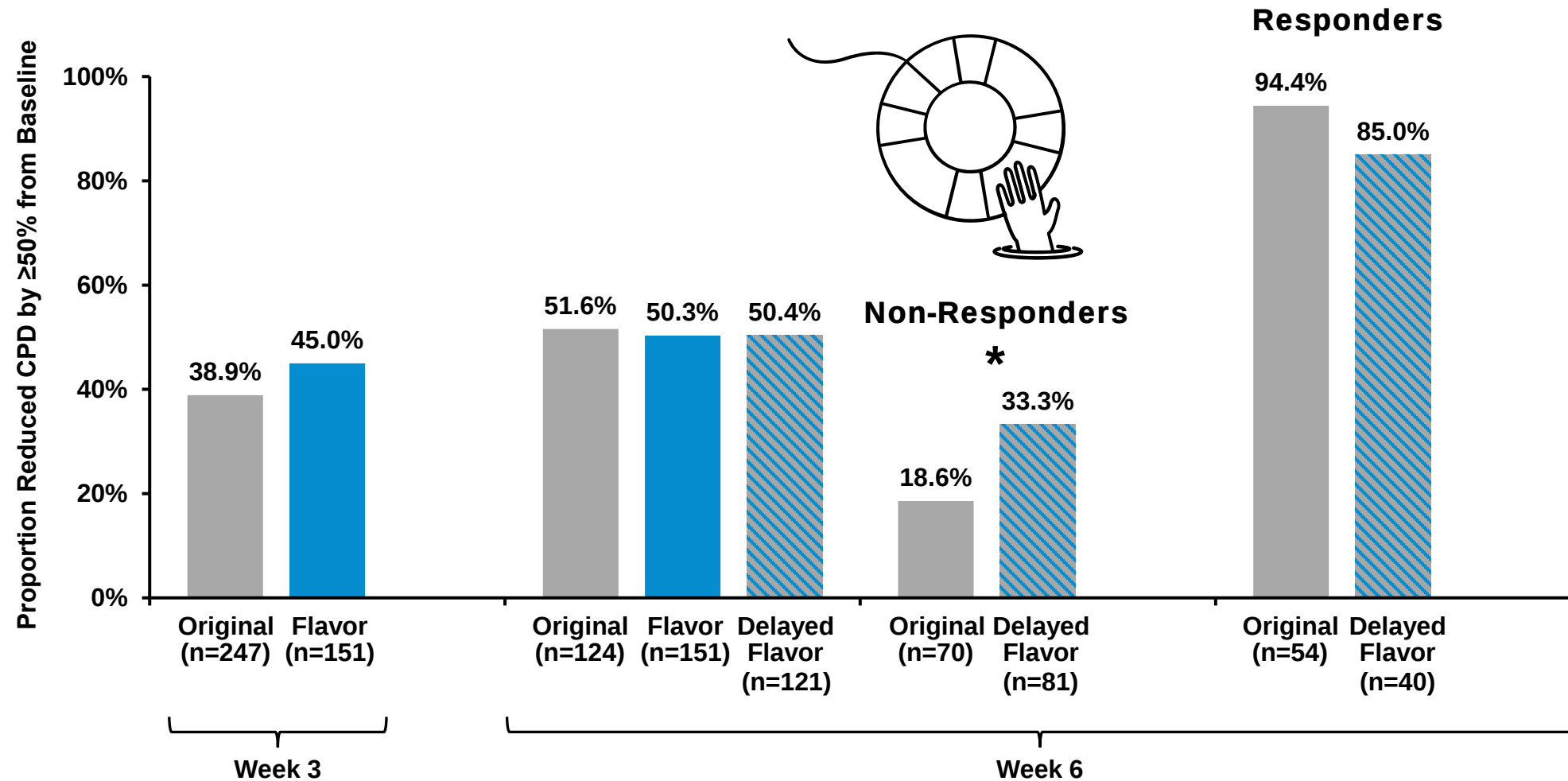
Rescue Effect for $\geq 50\%$ CPD Reduction



Rescue Effect for $\geq 50\%$ CPD Reduction



Rescue Effect for $\geq 50\%$ CPD Reduction



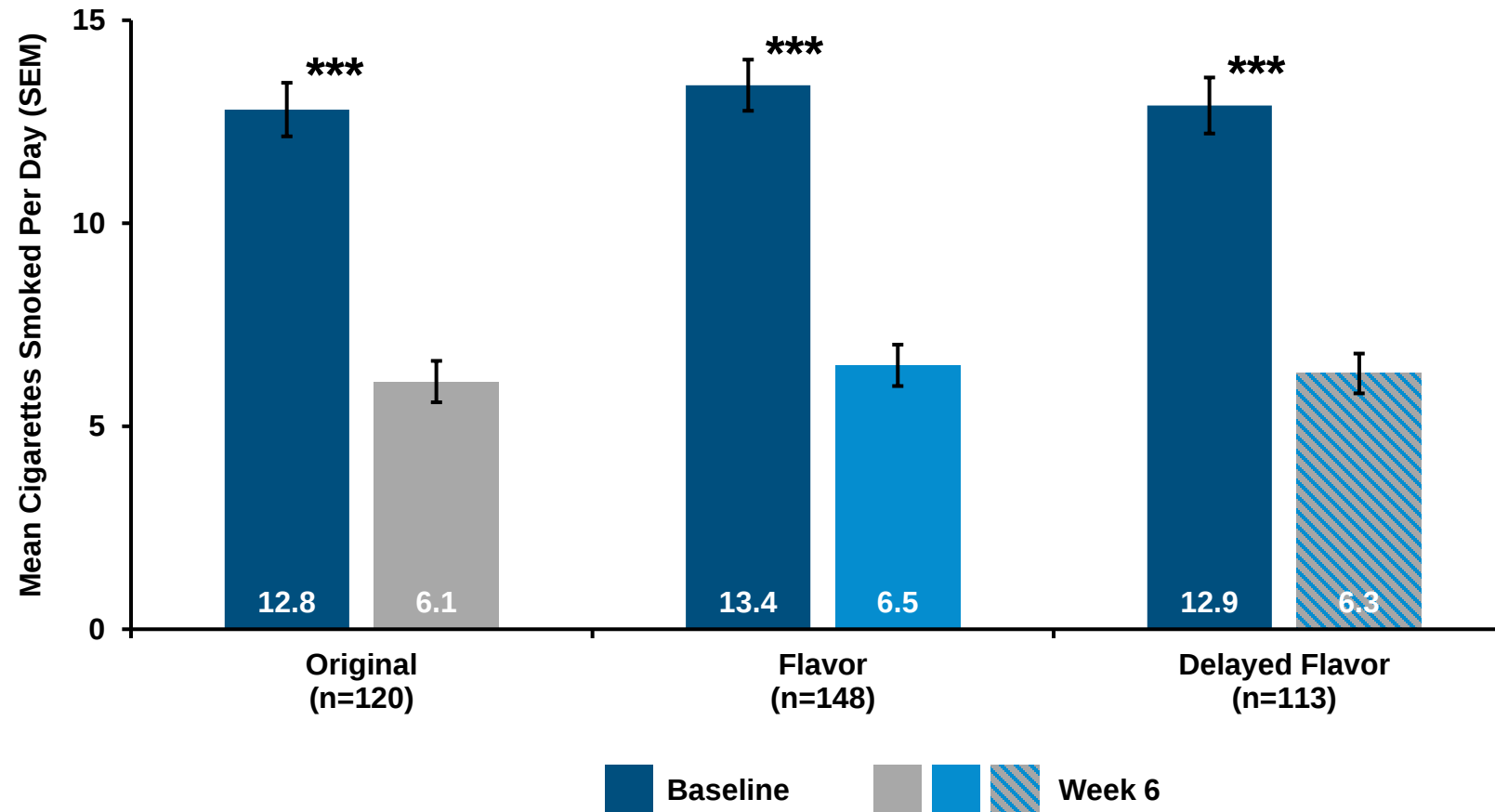
* Indicates p<0.05



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CPD Significantly Reduced Among Those Smoking in Week 6



Among Those
Smoking in Week 6:

Statistically
**significant CPD
reduction**
within each Group

*** Indicates $p < 0.001$



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Results

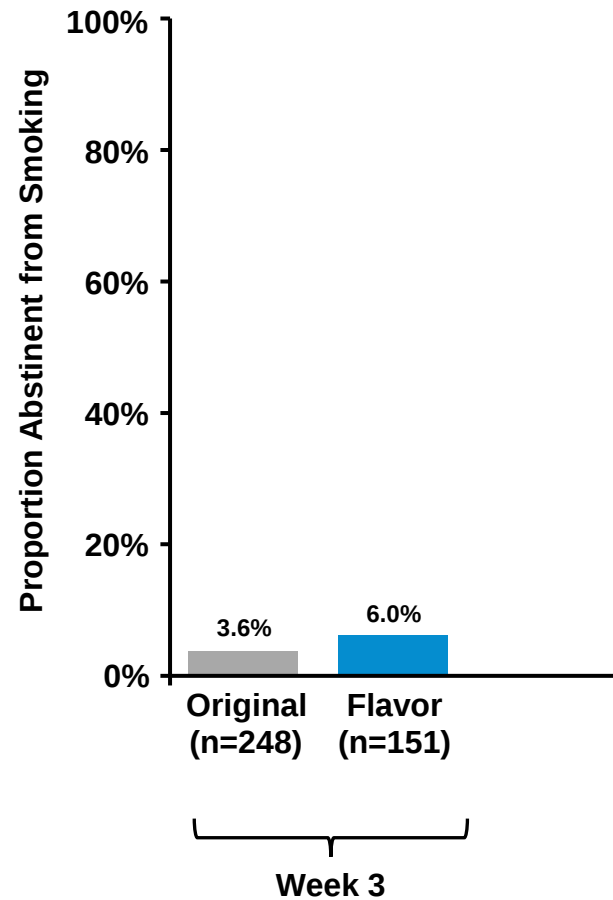


Smoking Abstinence:

- **CO-Verified**
- **Self-Reported Smoke-free Days**



No Differences for CO-verified Smoking Abstinence



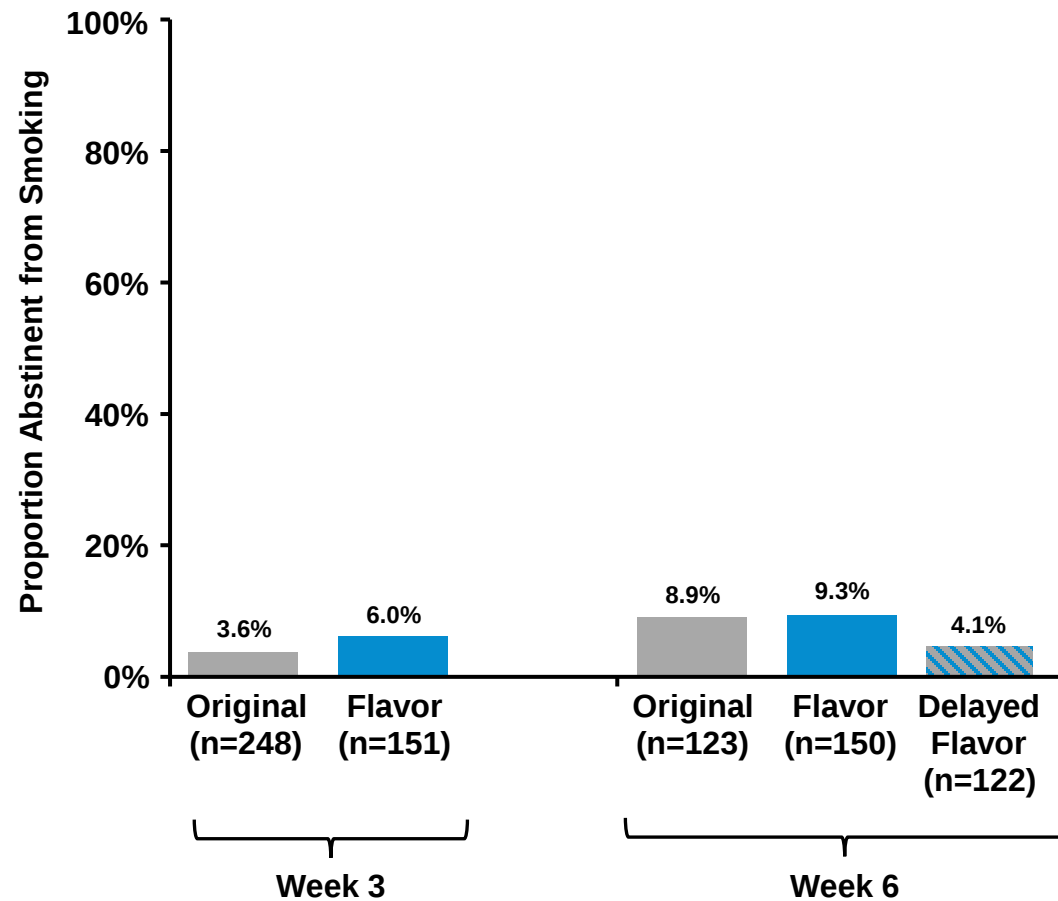
Smoking Abstinence defined as meeting both criteria: no self-reported cigarettes smoked and mean CO < 6 ppm for given week



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No Differences for CO-verified Smoking Abstinence



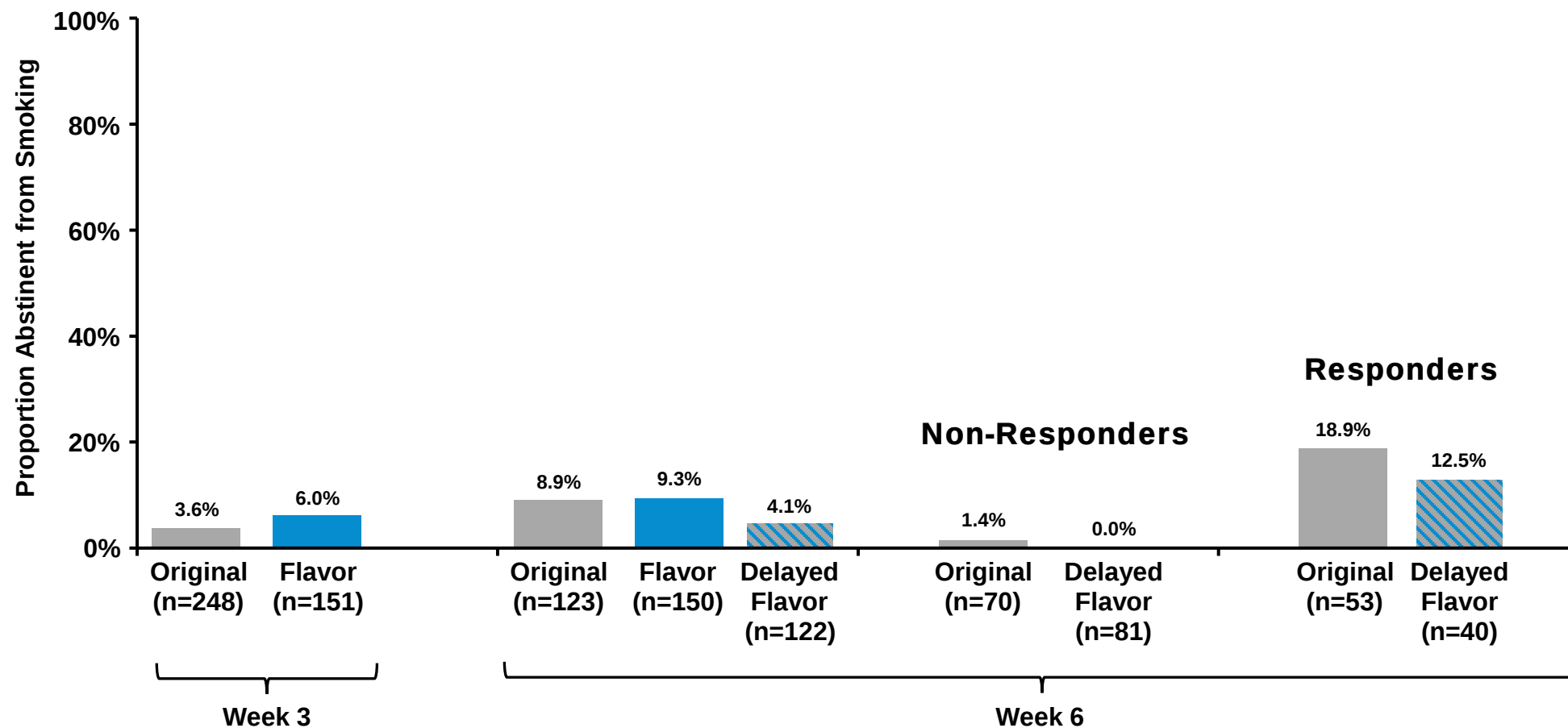
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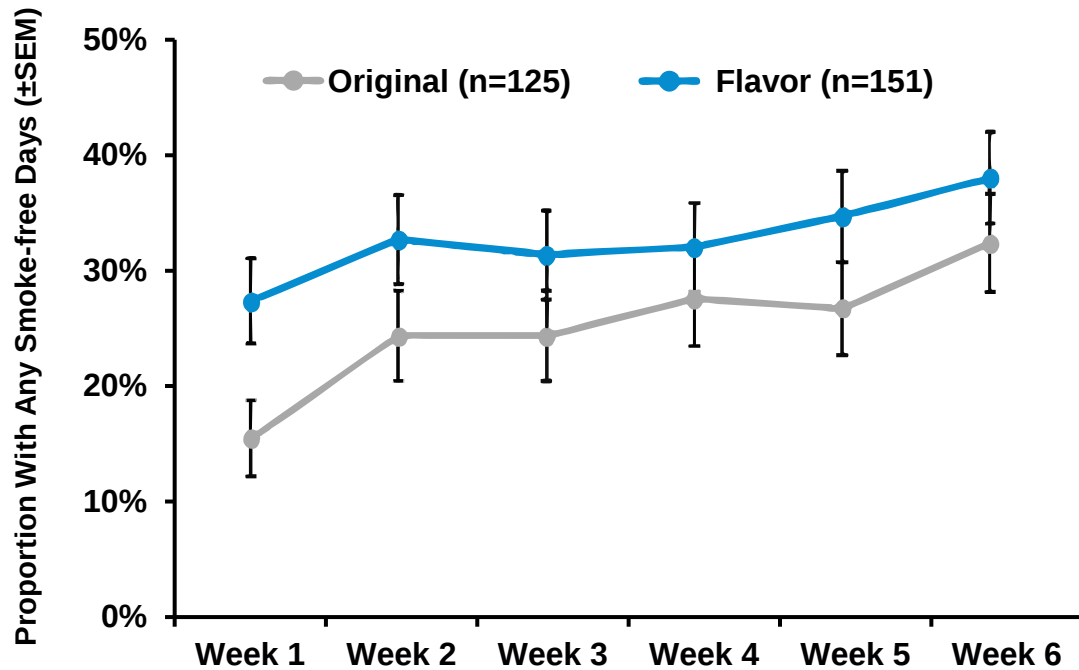
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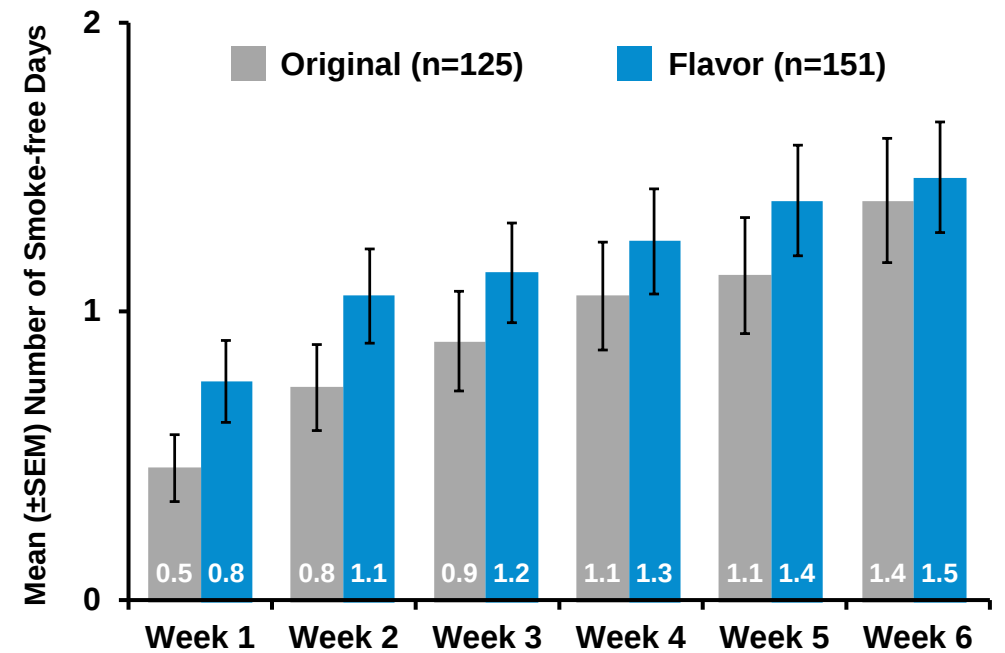
Flavor Availability Increased Incidence of Smoke-free Days

Stronger Effect for Flavor Earlier

- Larger proportion of Flavor Group reported Smoke-free Days
- Original lower at Week 1; caught up in Week 3



Similar Pattern for Number of Smoke-free Days



Results

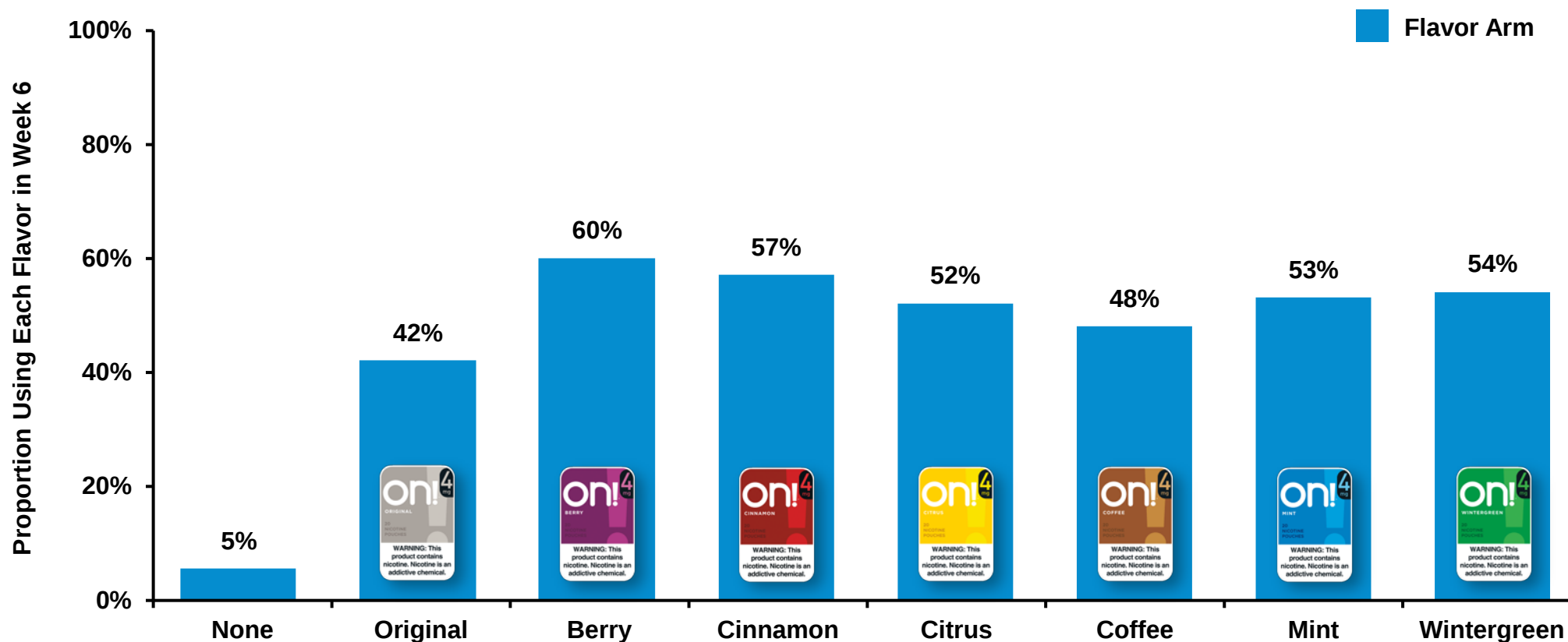


Week 6 Results:

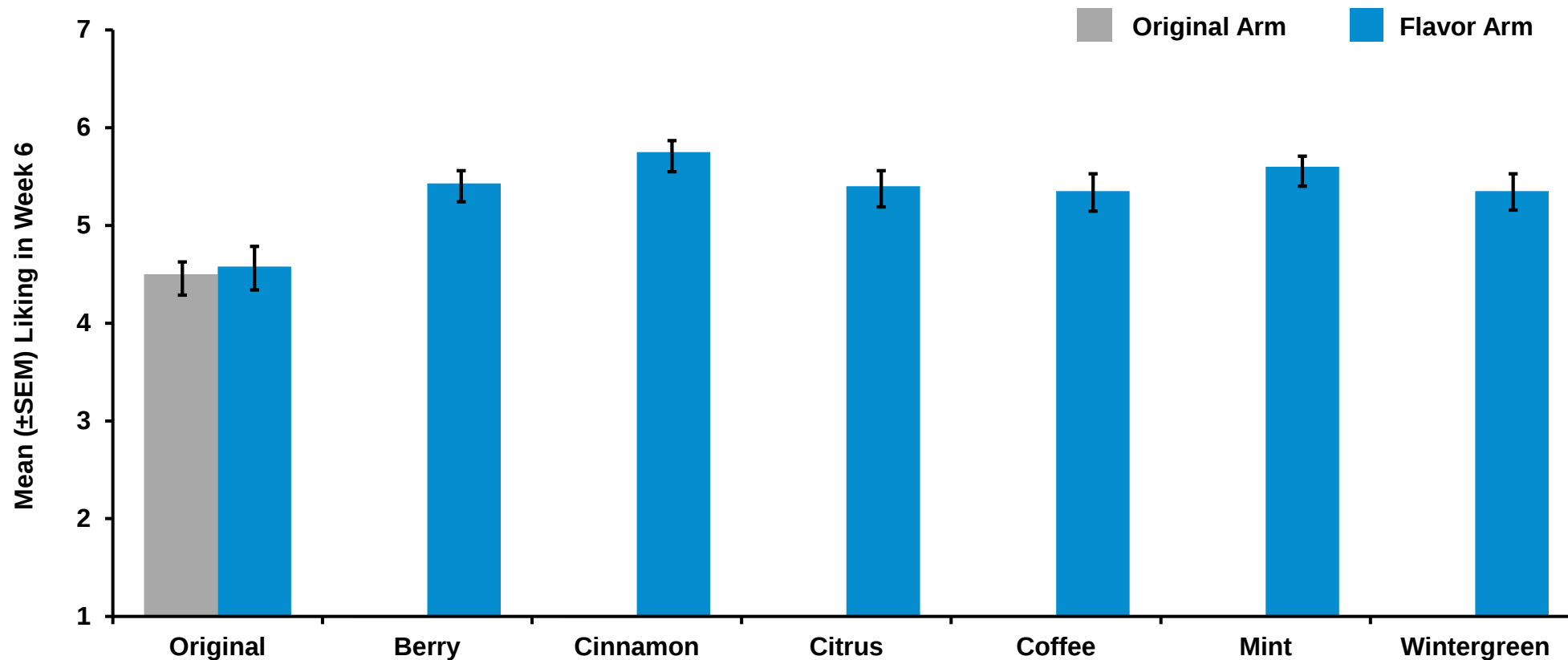
- Flavor Use
- Product Liking
- Purchase Intent



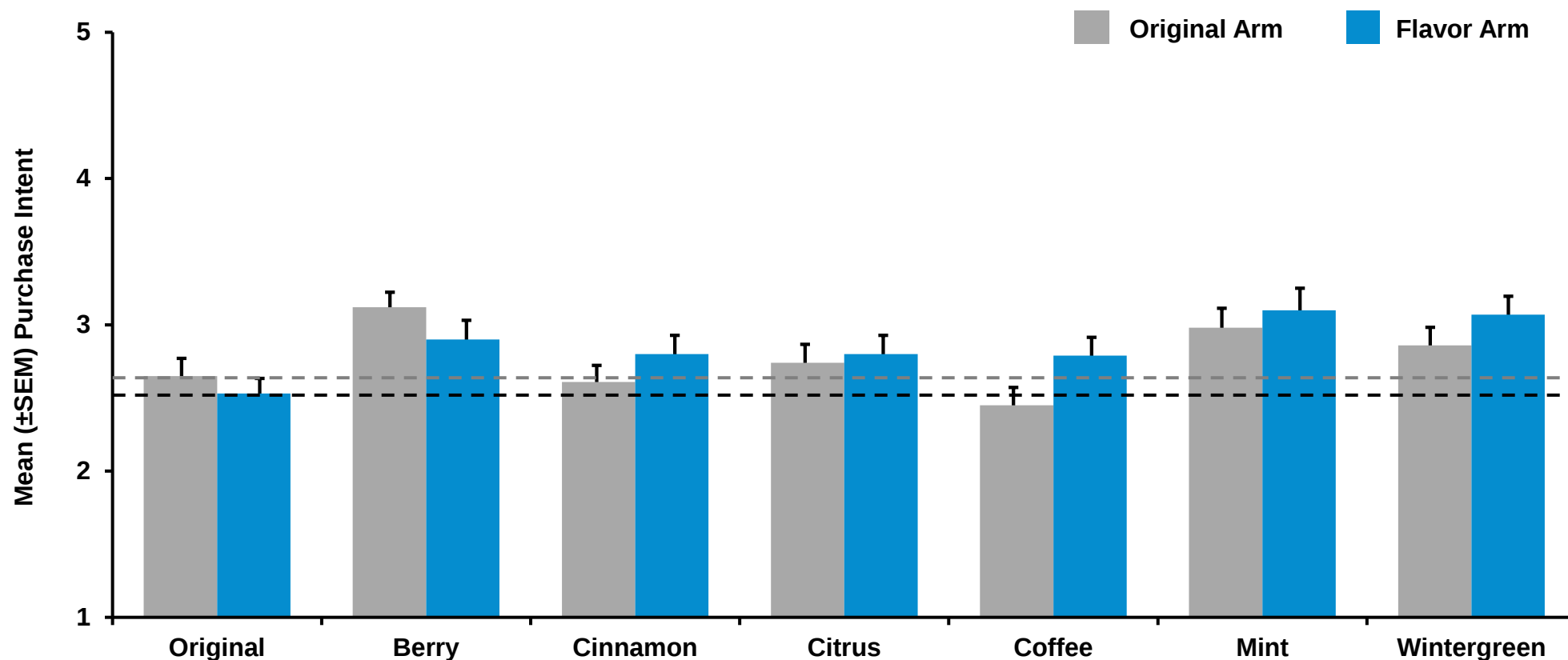
Flavors Used More than Original in Week 6



Flavors Liked More than Original



Higher Purchase Intent for Flavors



Original Arm was not provided flavors during the study, but they were asked about purchase intent for all flavors at end of study



Study Limitations



⊗ Study product provided at no charge

- Could have artificially inflated use

⊗ Only one nicotine level provided (4 mg)

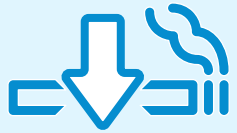
- May not have met expectations for all participants
- Could have limited smoking reduction or abstinence

⊗ Expired-air CO measured once every three days

- Averaging CO across measurements separated by multiple days may not be a valid representation of smoking behavior
 - Half-life of CO is 2-8 hours (depending on physical activity level)



Key Takeaways



Overall use of on!® nicotine pouch products led to CPD reduction

- Half of participants were able to **reduce CPD by $\geq 50\%$** by end of study
- Magnitude of **reduction was statistically significant** within each Study Arm
- **Rescue effect** for Delayed Access to Flavors
 - May be possible to ascertain need for “rescue” early



Access to Flavors increased incidence of smoke-free days early

Number of smoke-free days was modest

Flavors were used *more*, liked *more*, and had higher purchase intent



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Implications



Continued use of on!® nicotine pouch products can reduce cigarette smoking or lead to smoke-free days

Access to flavors had a stronger impact earlier

Occurs with **access to Original**, but takes longer and requires persistence

For adults who smoke cigarettes in the real world:

- Persistent use is unlikely if they do not like the product and are not seeing results
- Access to a variety of products that are liked and lead to desired results is critical
 - e.g., smoking reduction or complete switching away from cigarettes
- Actual Use or Longitudinal Cohort Studies may better characterize real-world use behaviors than an RCT





THANK YOU!



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