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

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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 ≥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:

Availability of all flavors

+

Early vs. delayed availability of all flavors

on smoking reduction

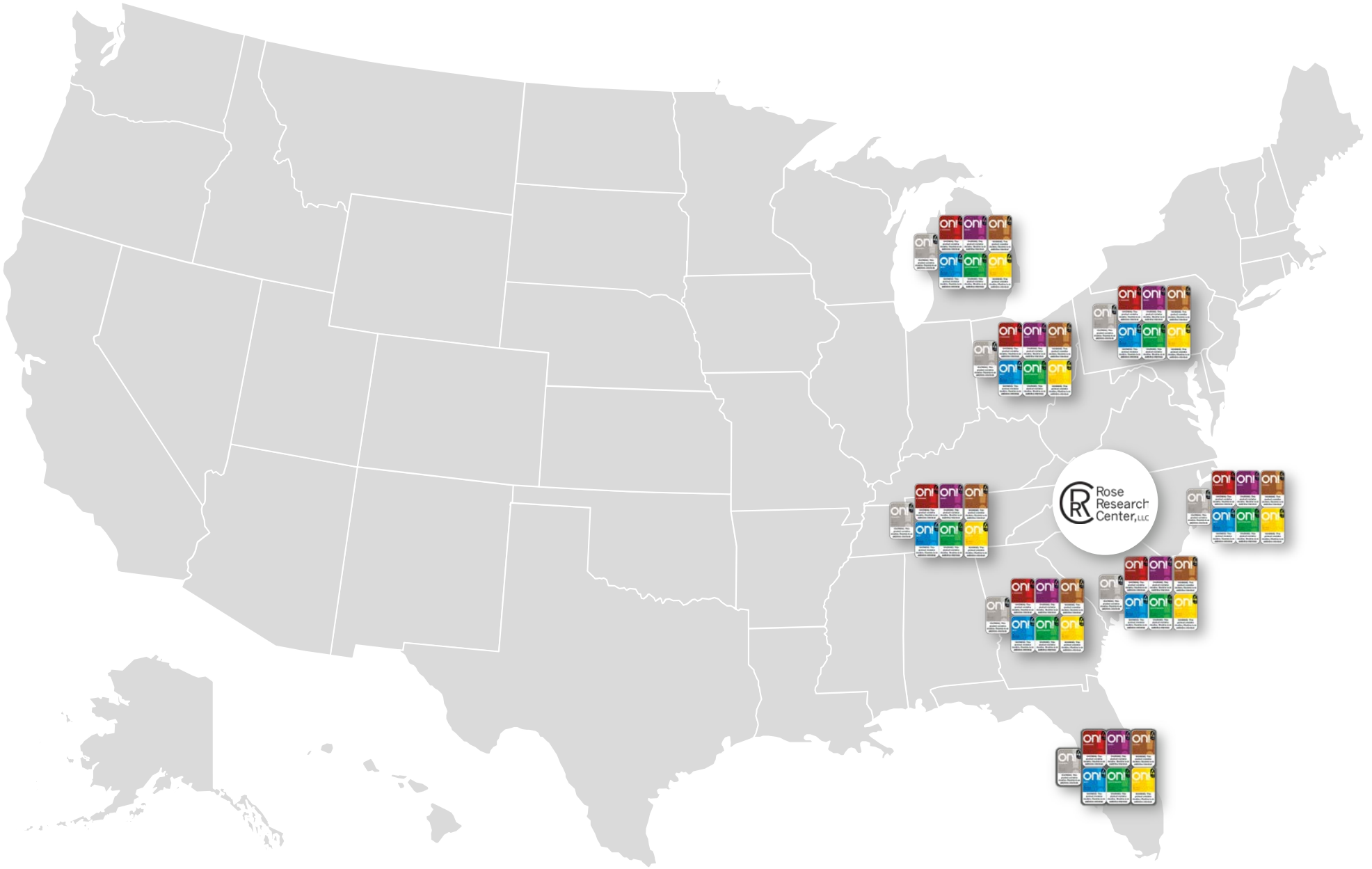
on!® nicotine pouch products provided in 4 mg nicotine level

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


Rose
Research
Center, LLC

Design

Protocol

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

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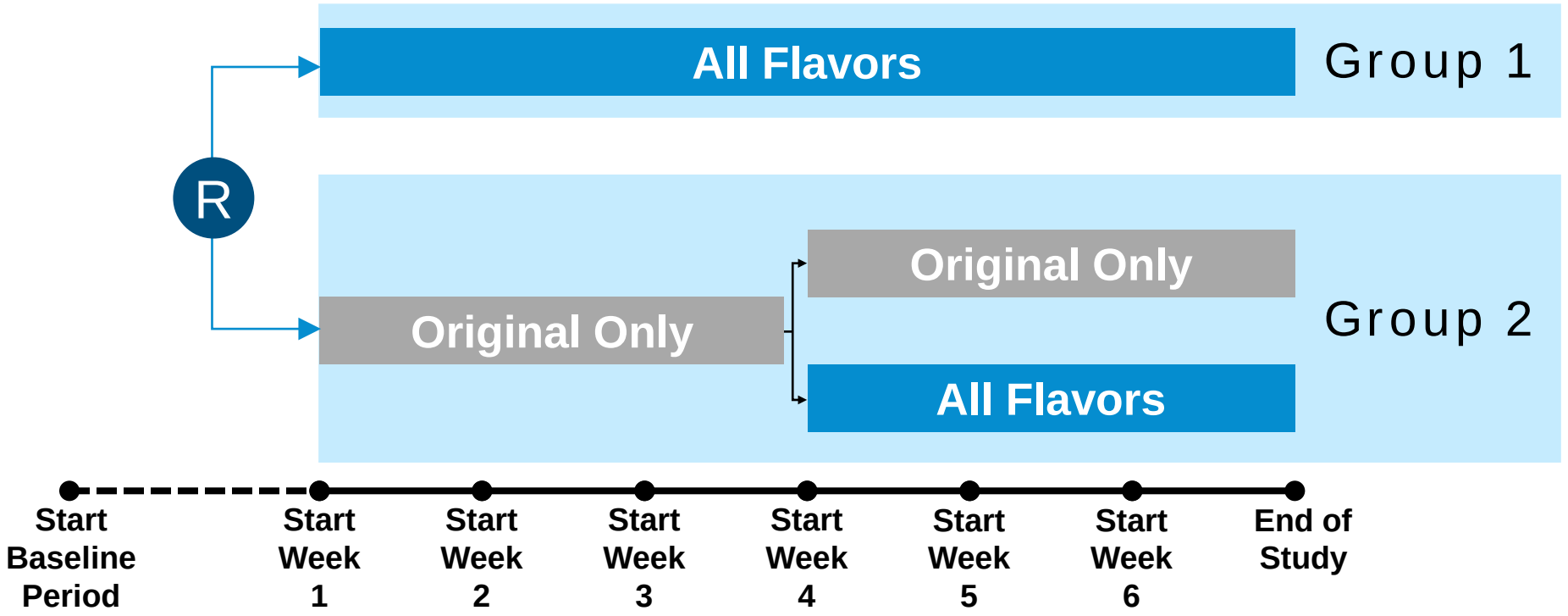
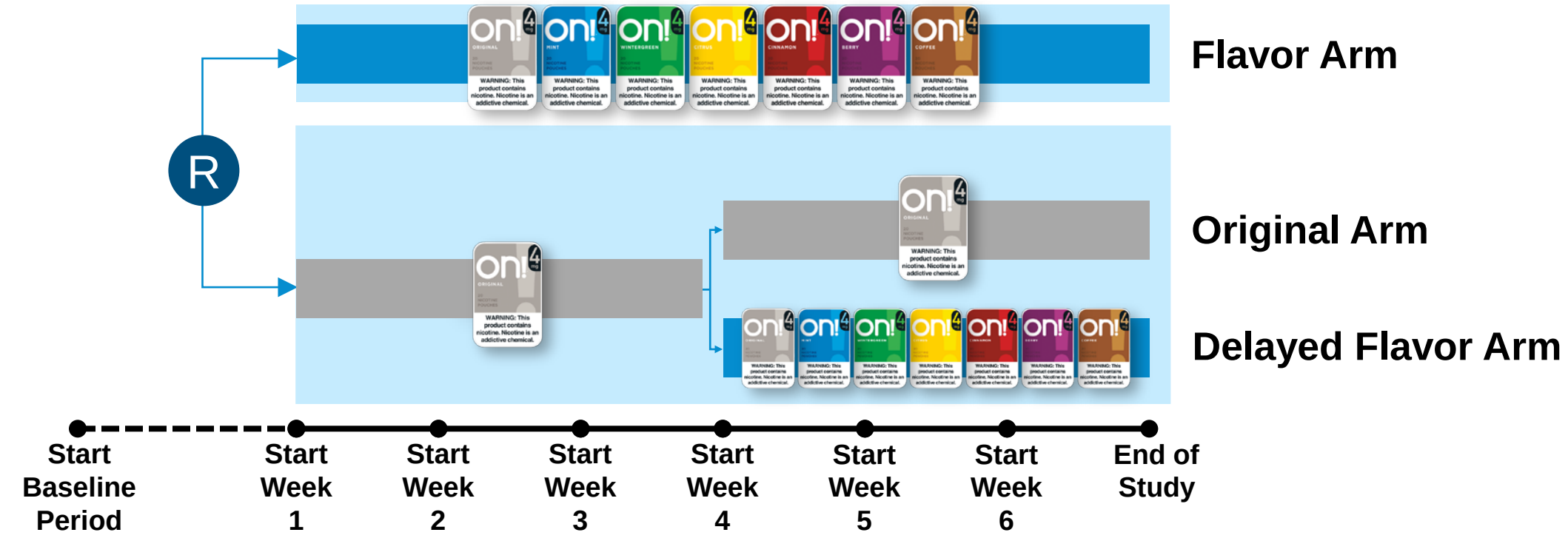
Design

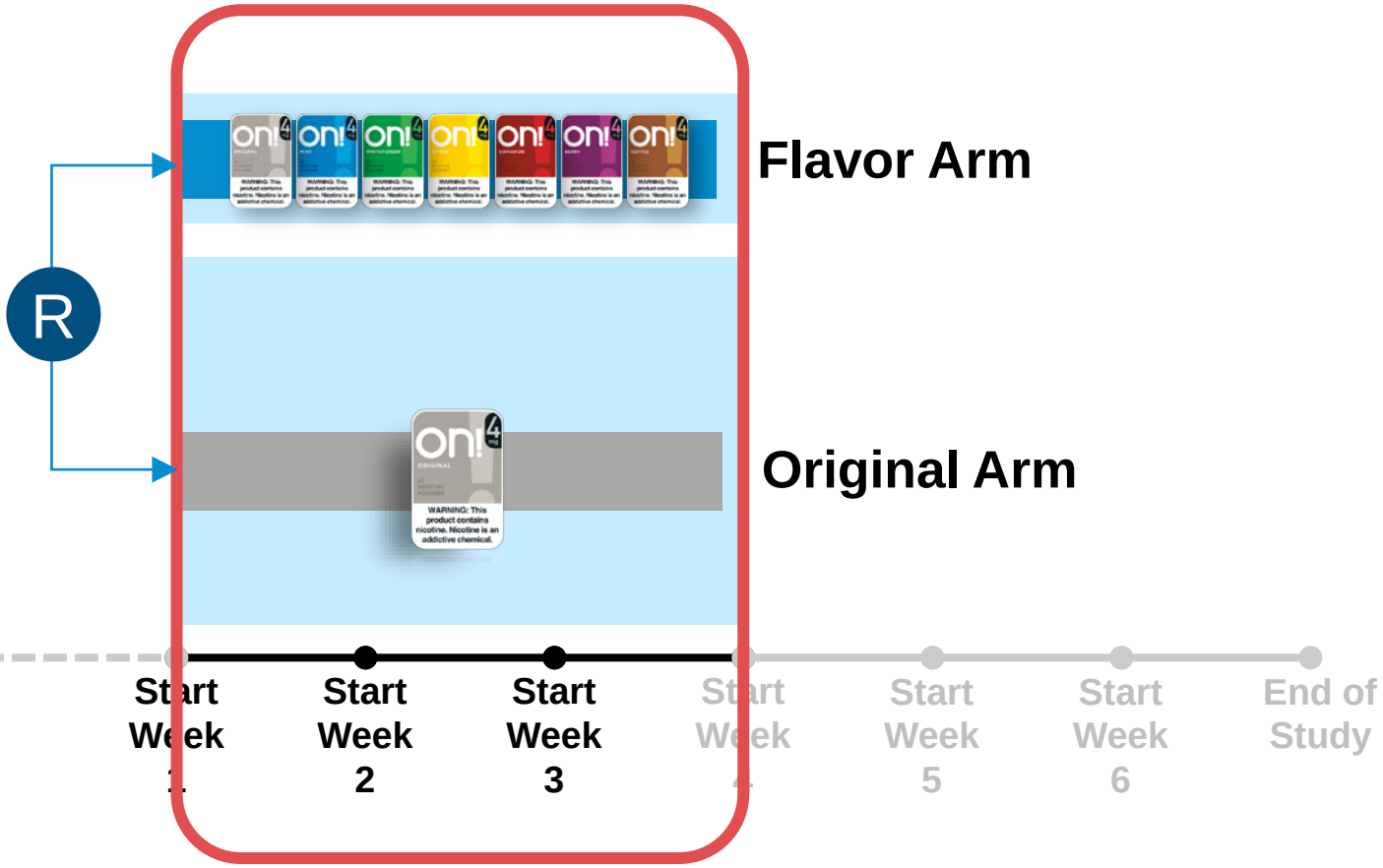

All Flavors
Group 1
R
Original Only
Original Only
All Flavors
Group 2
Start Baseline Period
Start Week 1
Start Week 2
Start Week 3
Start Week 4
Start Week 5
Start Week 6
End of Study

Design



on!® nicotine pouches provided in 4 mg nicotine level

Design



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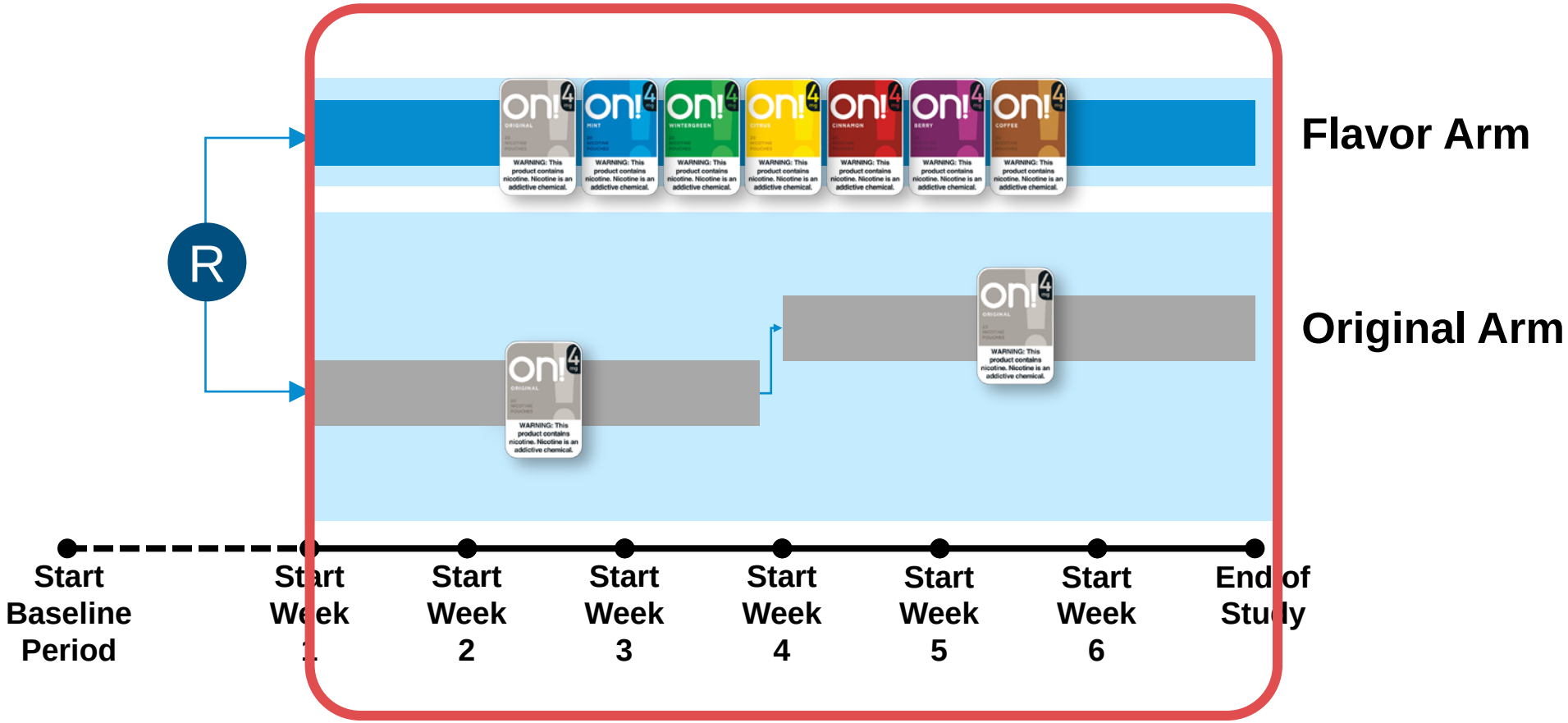

on!® nicotine pouches provided in 4 mg nicotine level

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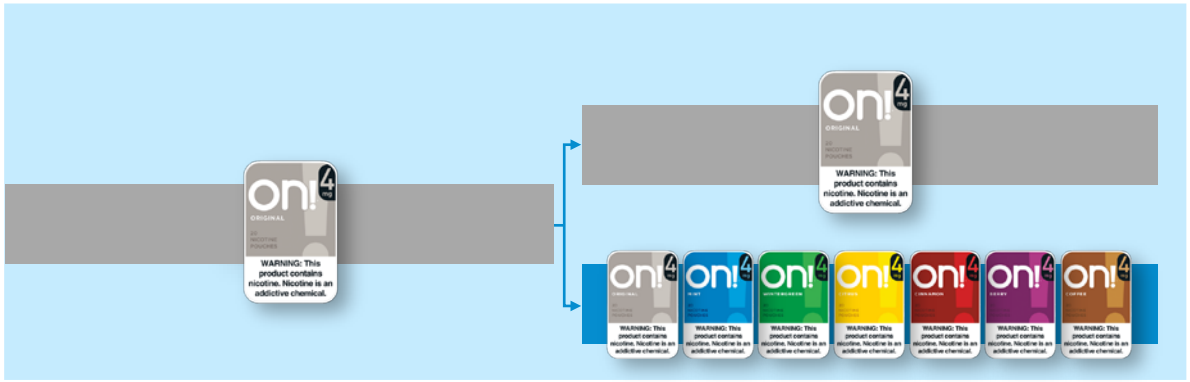


Original Arm

Delayed Flavor Arm

Start Baseline Period | **Start Week 1** | **Start Week 2** | **Start Week 3** | **Start Week 4** | **Start Week 5** | **Start Week 6** | **End of Study**

on!® nicotine pouches provided in 4 mg nicotine level

Design

Responders

≥50% CPD reduction from Baseline in Week 3

Non-Responders

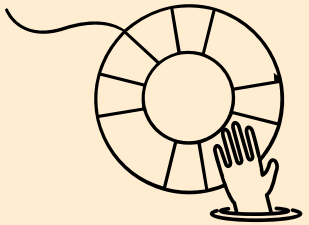
<50% CPD reduction from Baseline in Week 3

Original

Delayed Flavor

Original

Delayed Flavor



Start Week 1 | Start Week 2 | **Start Week 3** | Start Week 4 | Start Week 5 | Start Week 6 | End of Study

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

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%)

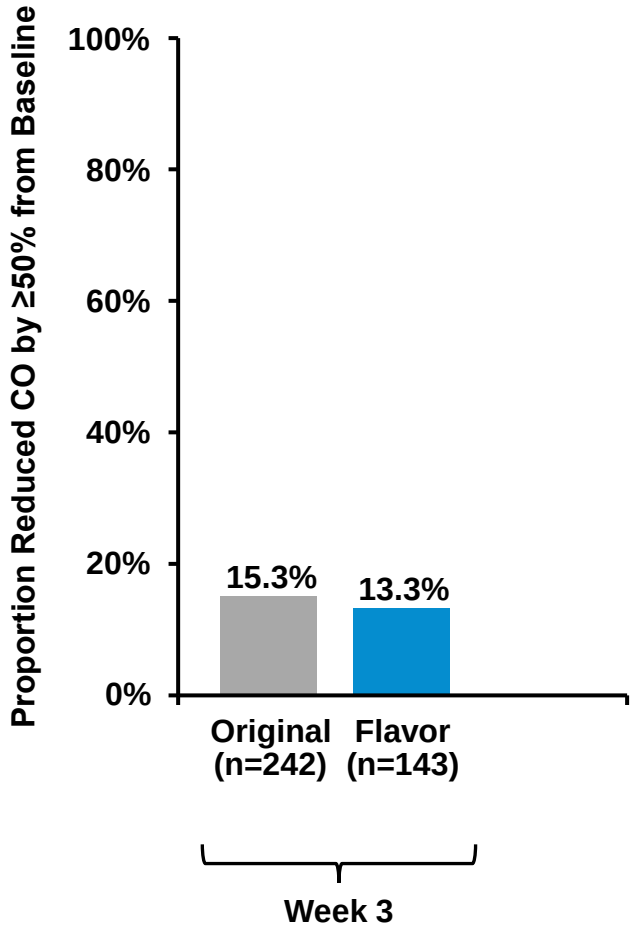
Abbreviations: n=number; SD=standard deviation; CPD=cigarettes per day
Note. One participant in Original+Delayed Flavor Arm missing baseline CPD

Results

Smoking Reduction:

- CO Reduction
- CPD Reduction

No Differences for ≥50% CO Reduction



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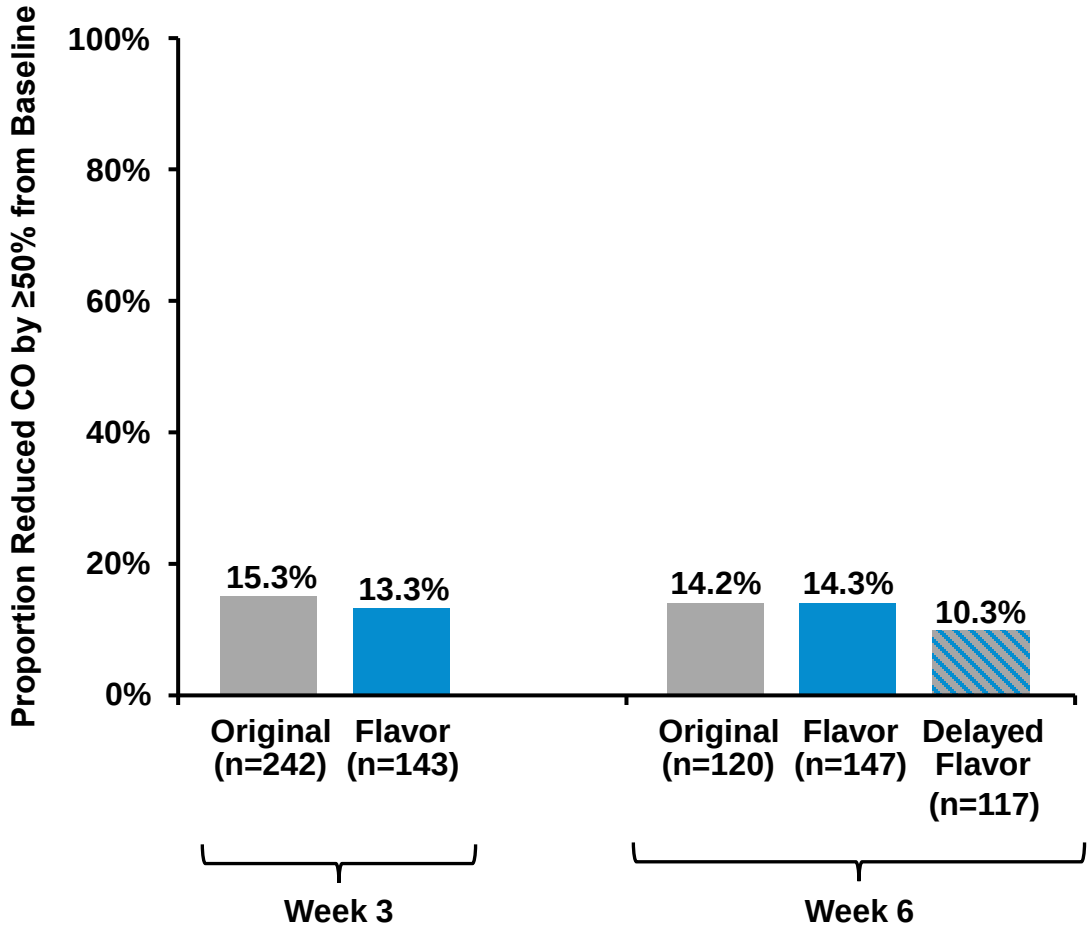

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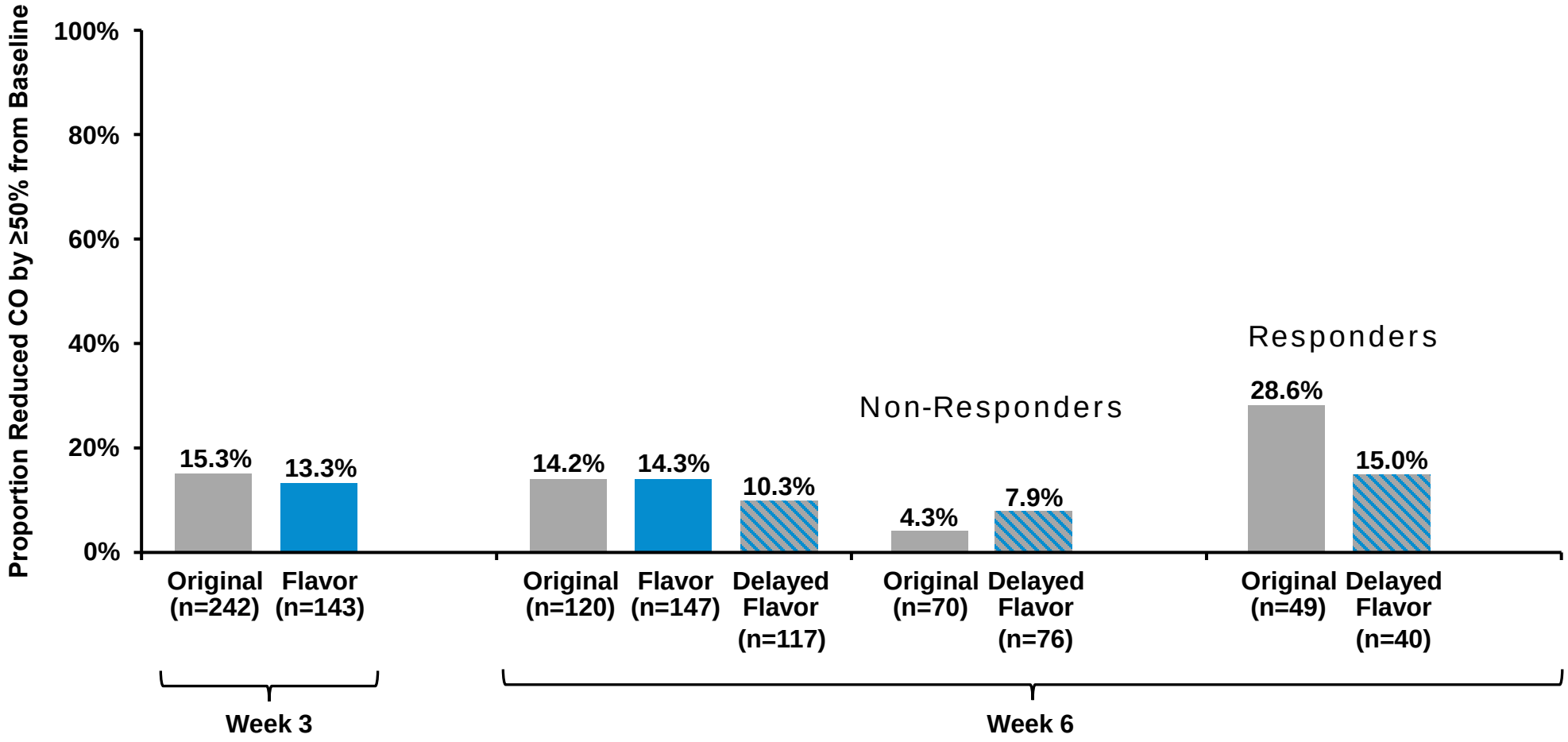
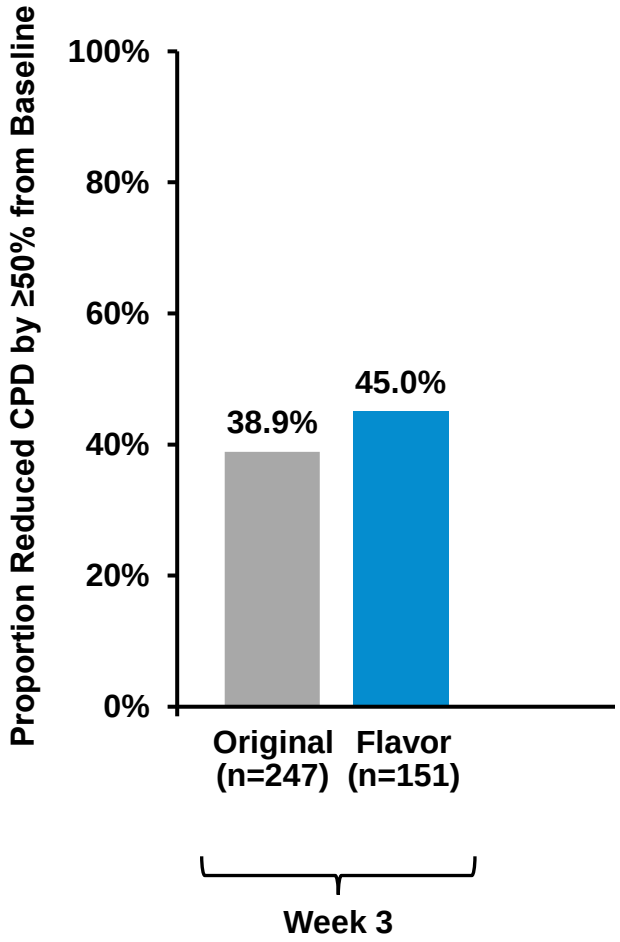
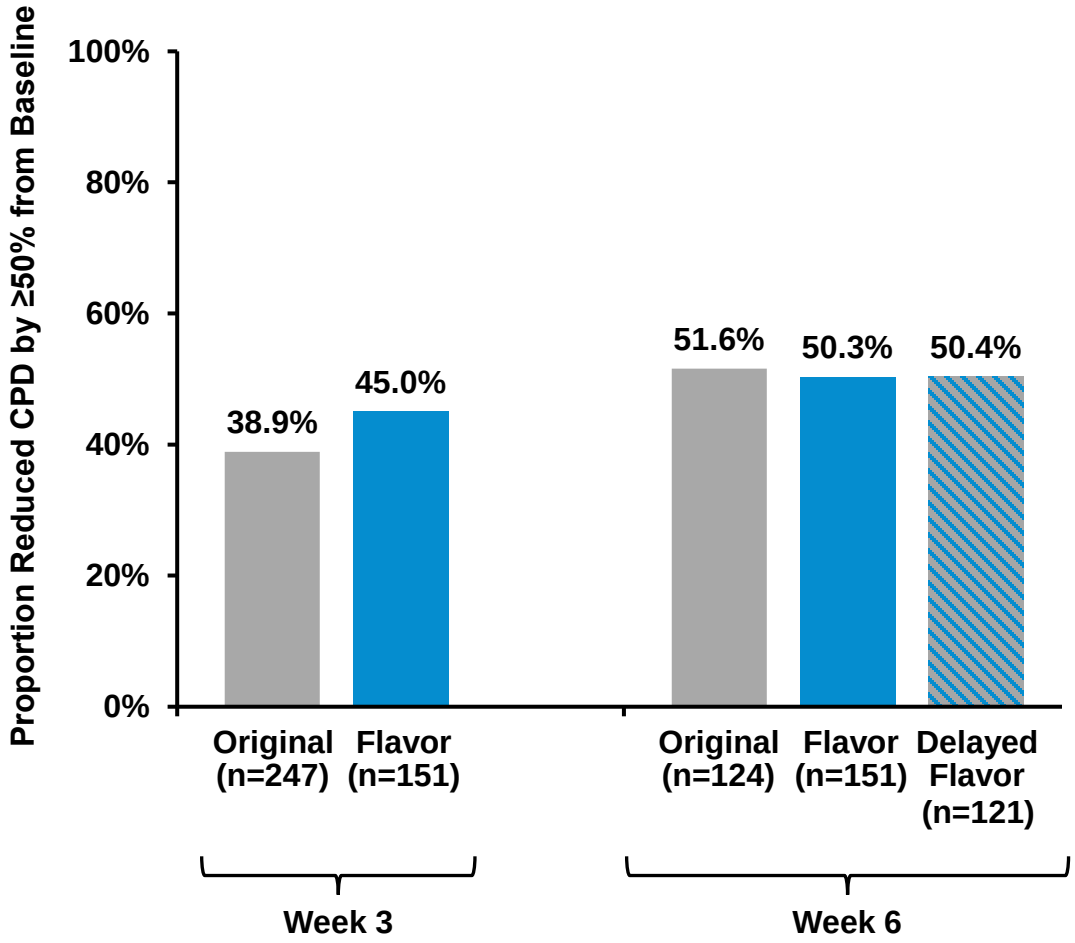


Rescue Effect for ≥50% CPD Reduction



Rescue Effect for ≥50% CPD Reduction



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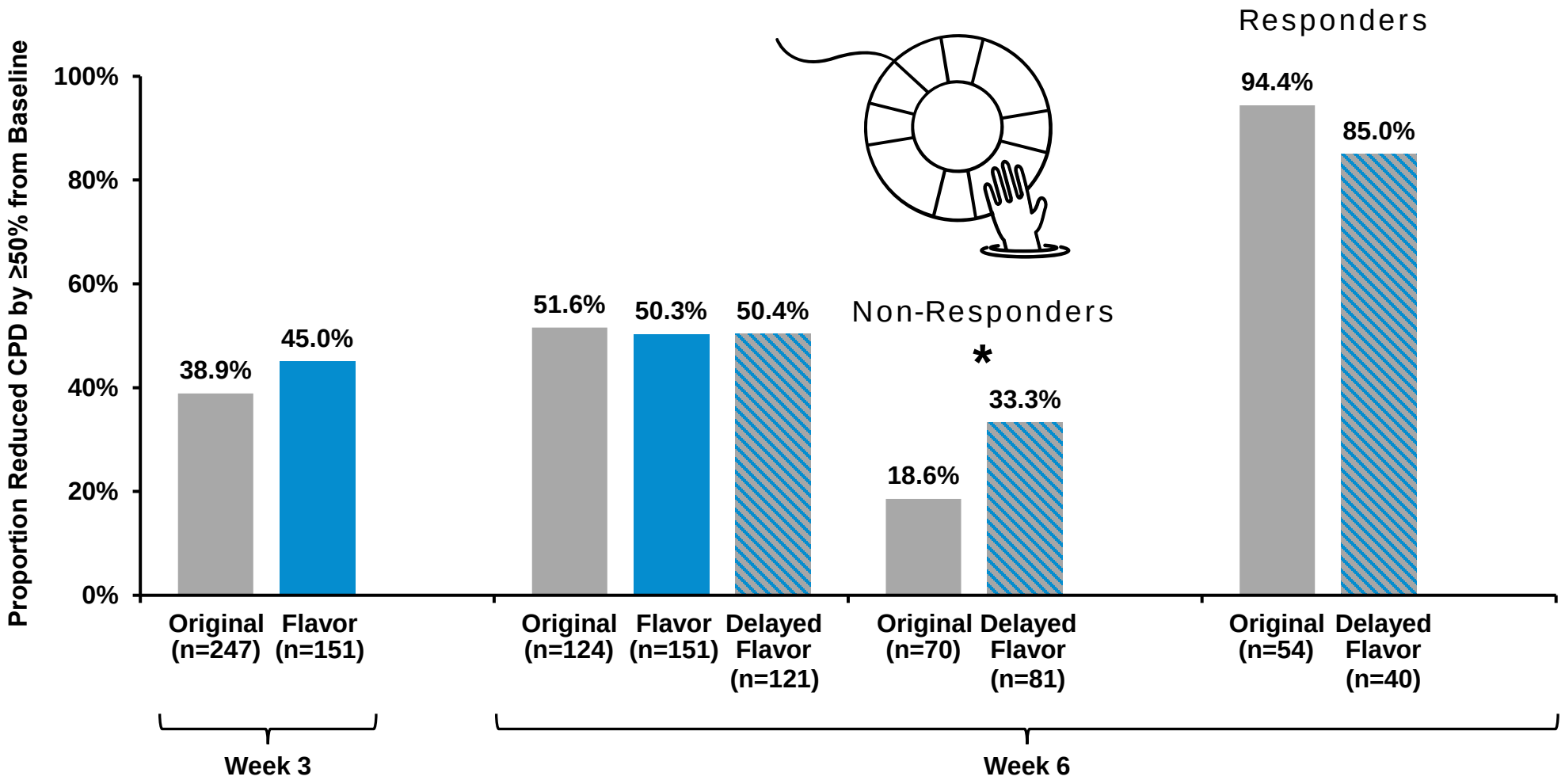
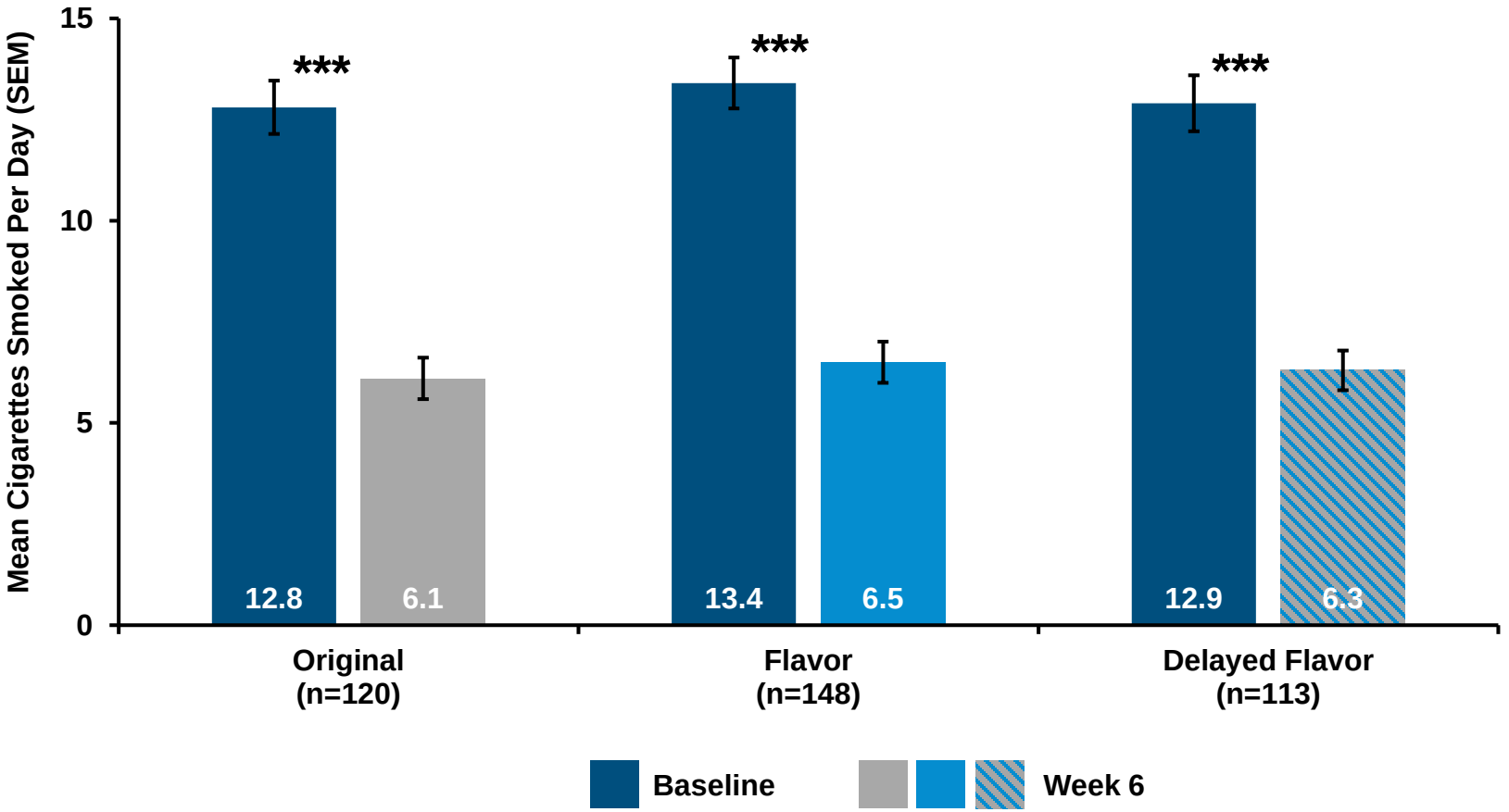


* Indicates p<0.05

CPD Significantly Reduced Among Those Smoking in Week 6



Among Those Smoking in Week 6:

Statistically significant CPD reduction within each Group

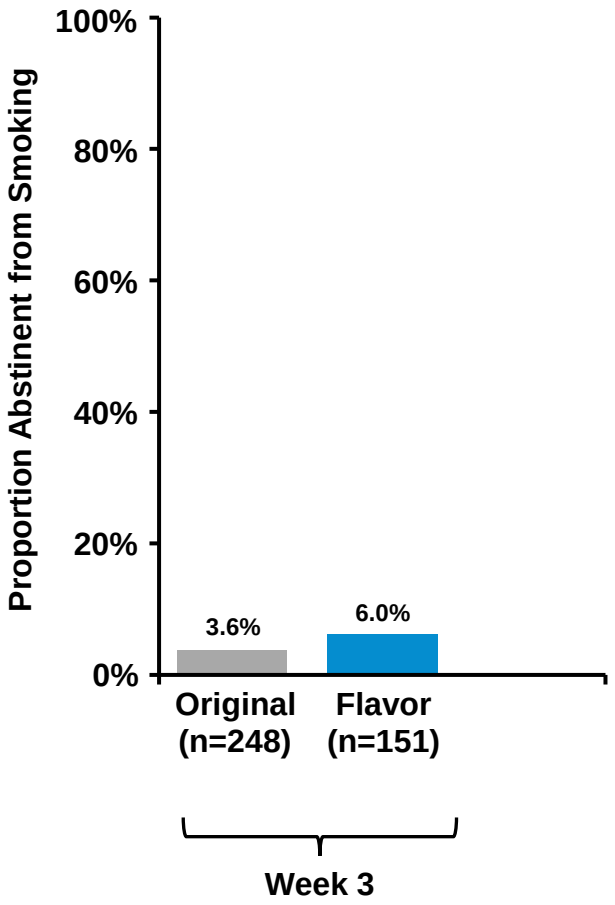
*** Indicates p<0.001

Results

Smoking Abstinence:

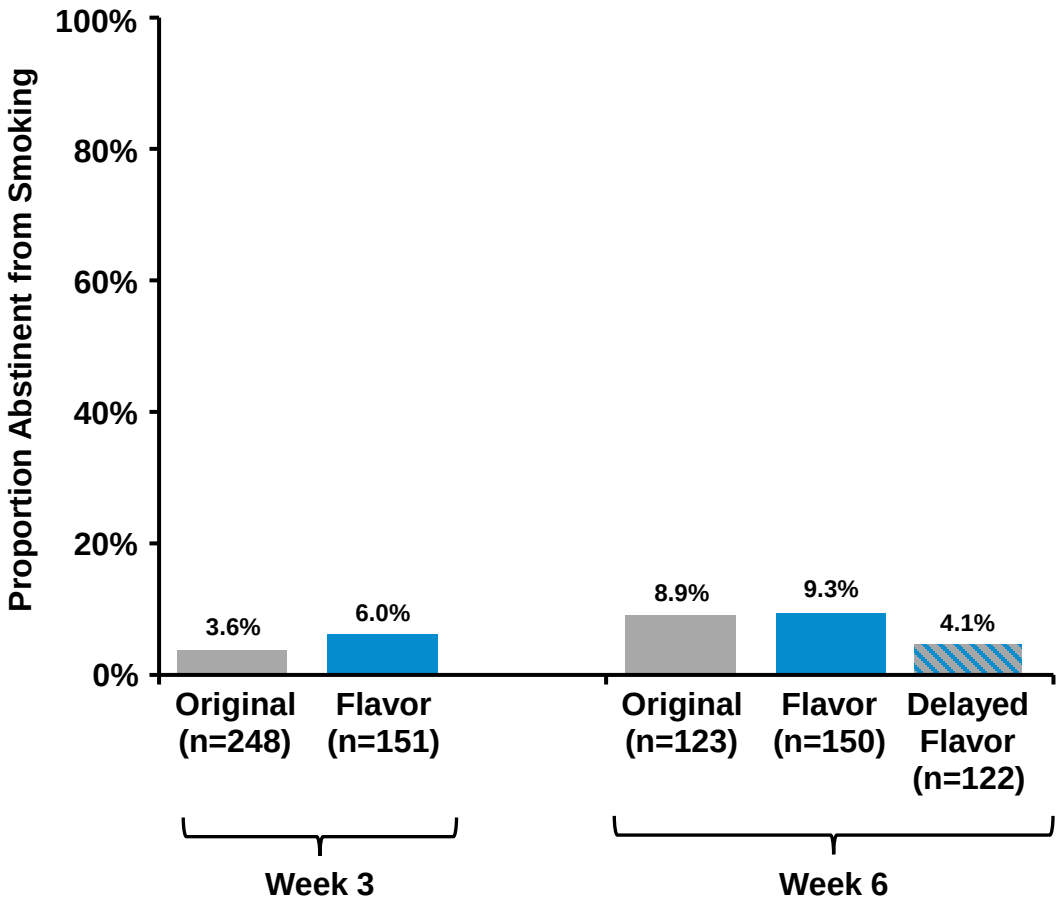
- CO-Verified
- Self-Reported Smoke-free Days

No Differences for CO-verified Smoking Abstinence



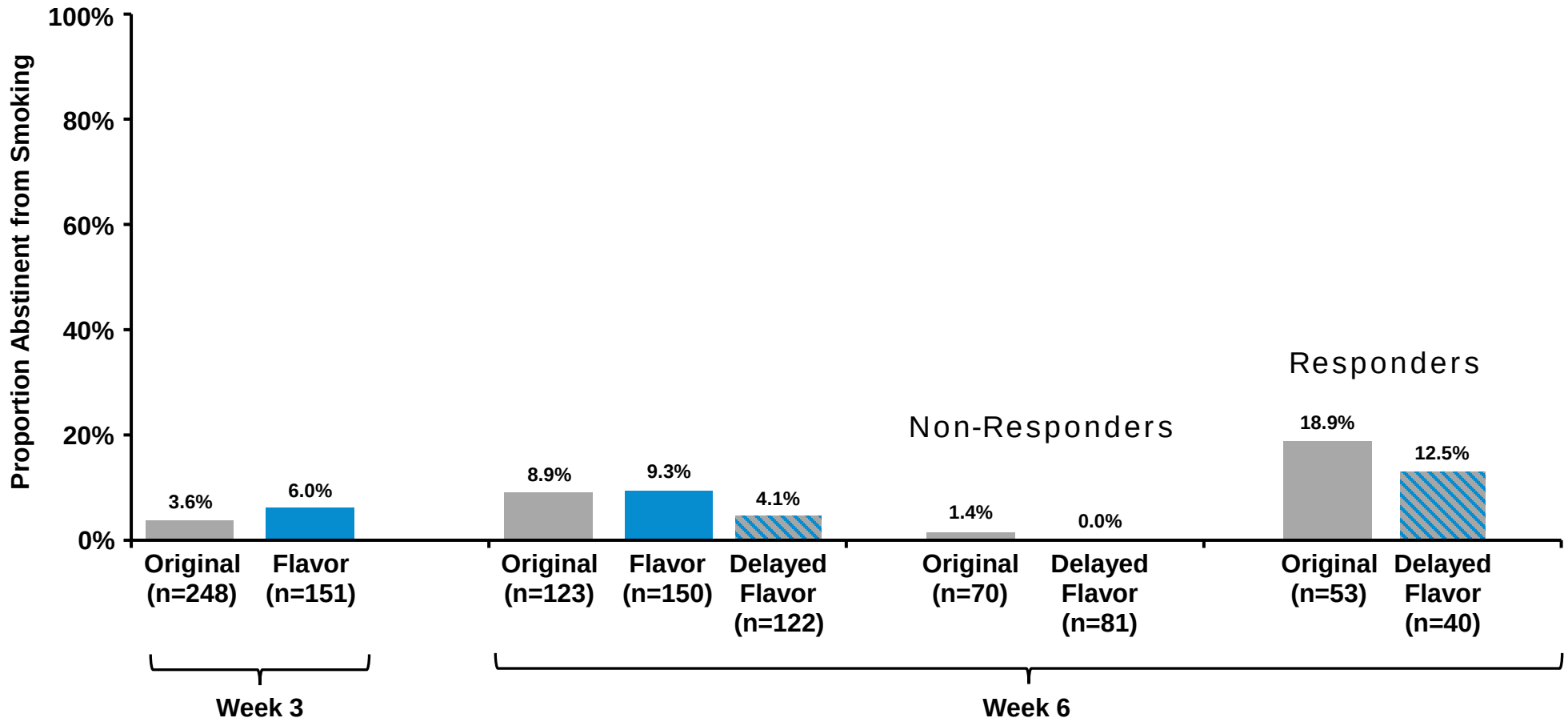
Smoking Abstinence defined as meeting both criteria: no self-reported cigarettes smoked and mean CO < 6 ppm for given week

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

No Differences for CO-verified Smoking Abstinence

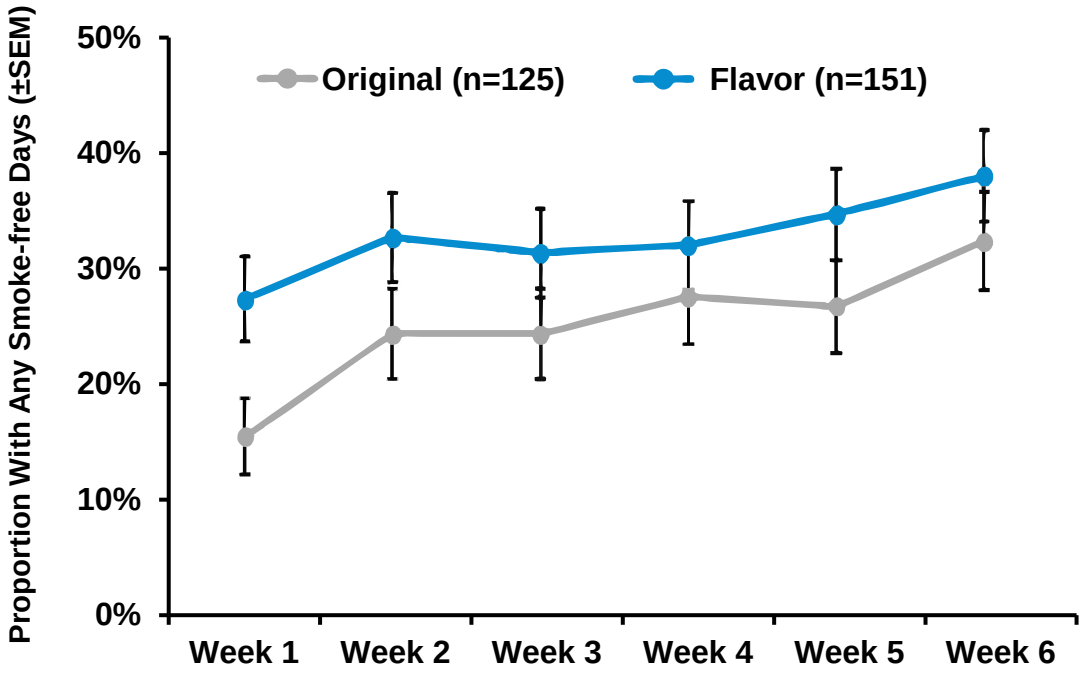


Smoking Abstinence defined as meeting both criteria: no self-reported cigarettes smoked and mean CO < 6 ppm for given week

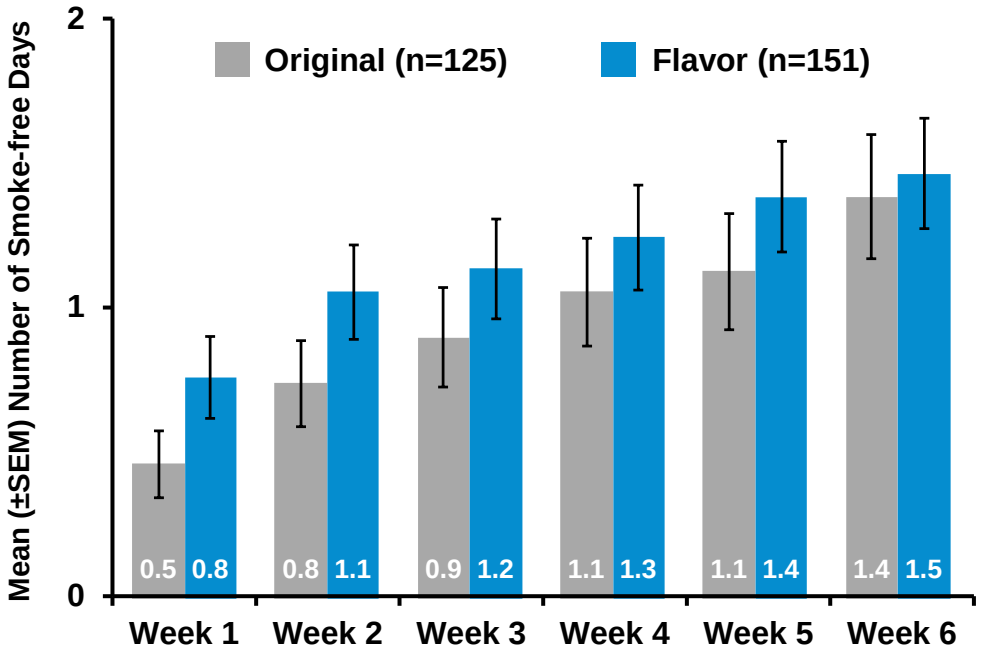
Flavor Availability Increased Incidence of Smoke-free Days

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

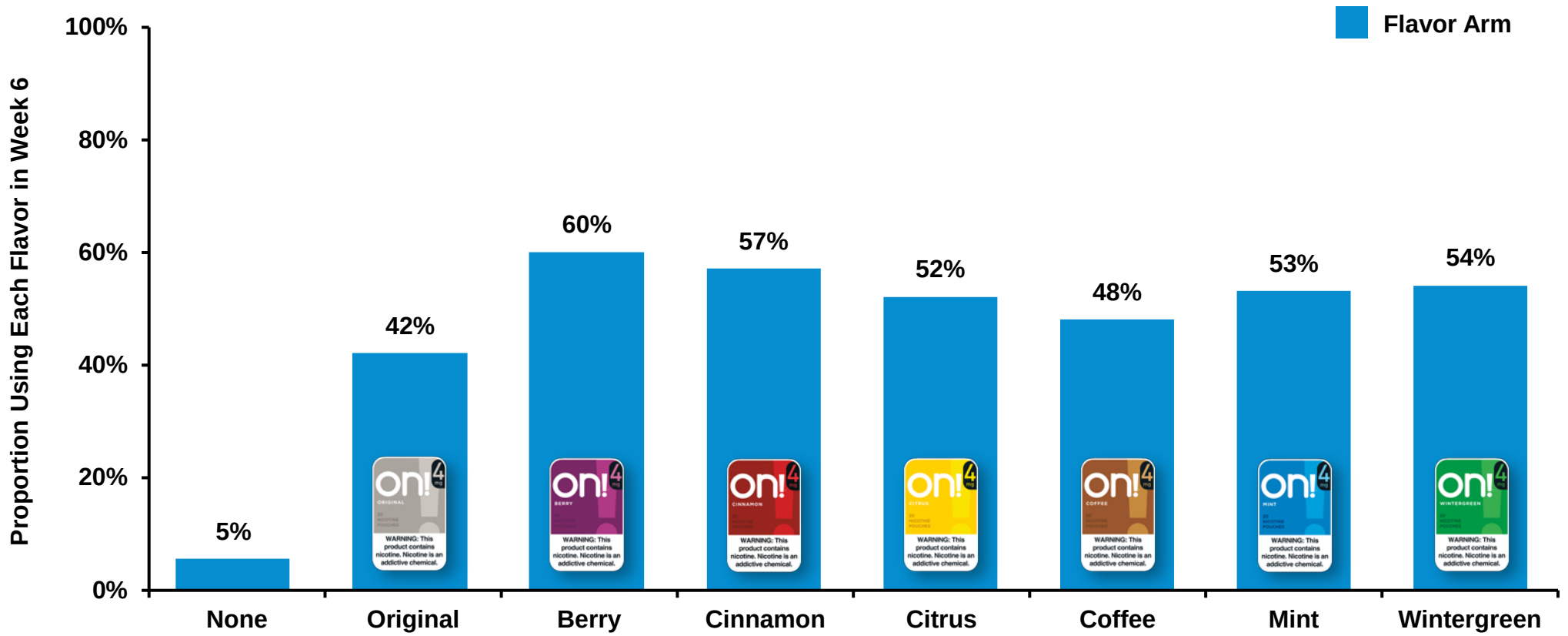


Results

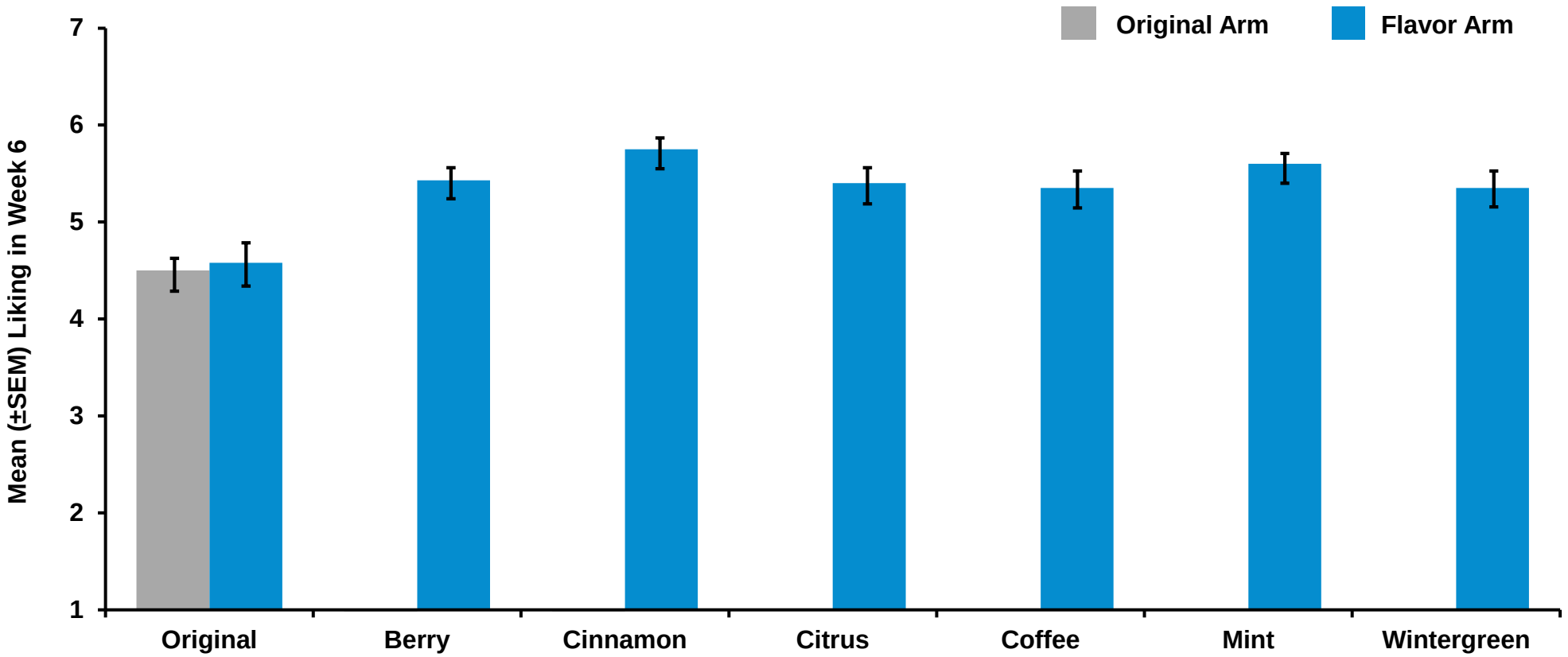
Week 6 Results:

- Flavor Use
- Product Liking
- Purchase Intent

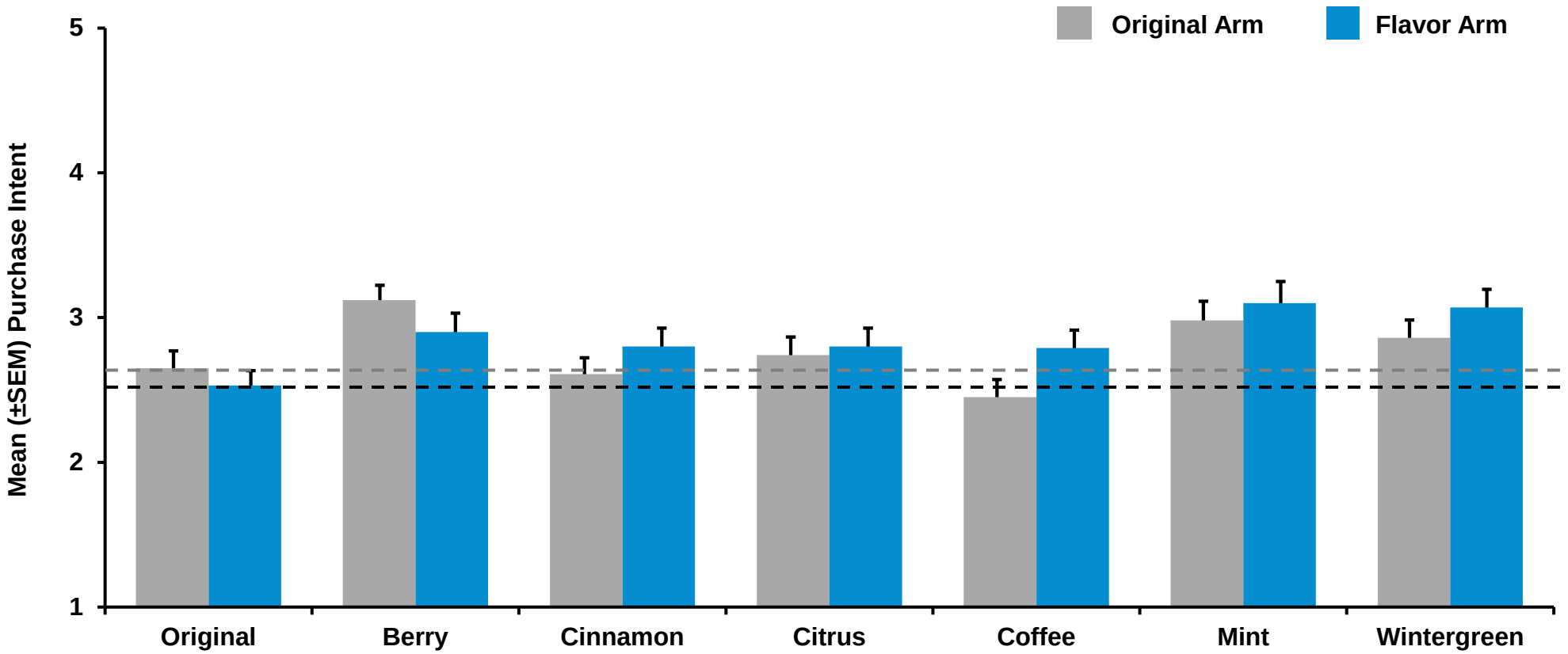
Flavors Used More than Original in Week 6



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 ≥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

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!