A Trial of the Effectiveness of Vaporised Nicotine Products for Tobacco Smoking Cessation amongst NSW Opiate Agonist Treatment Clients

Melissa Jackson, Paul Haber, Nick Lintzerus, Nadine Ezard, Richard Hallinan, Craig Rodgers, Tim Ho, Chris Oldmeadow, Coral Gartner

CIs Billie Bonevski & Adrian Dunlop

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NSW GOVERNMENT Health
Hunter New England Local Health District

Acknowledgement to Country

I acknowledge that we are on the lands of the Ngunnawal people. I pay my respects to Elders past and present and celebrate the diversity of Aboriginal peoples and their ongoing cultures and connections to the lands and waters of the ACT.

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Vaporised Nicotine Products (VNPs)

- Evidence supports vaporised nicotine for tobacco harm reduction[1]
- High certainty evidence that Vapourised nicotine can assist smoking cessation better than NRT (patches, gum, chews)[2]

1. Edwards S et al. Tobacco Harm Reduction with Vaporised Nicotine (THRiVe): A Feasibility Trial of Nicotine Vaping Products for Smoking Cessation Among People Living with HIV. AIDS Behav. 2023 Feb;27(2):618-627.

2 Lindson N et al Electronic cigarettes for smoking cessation. Cochrane Database of Systematic Reviews 2024, Issue 1. Art. No.: CD010216.

Substance use and Tobacco

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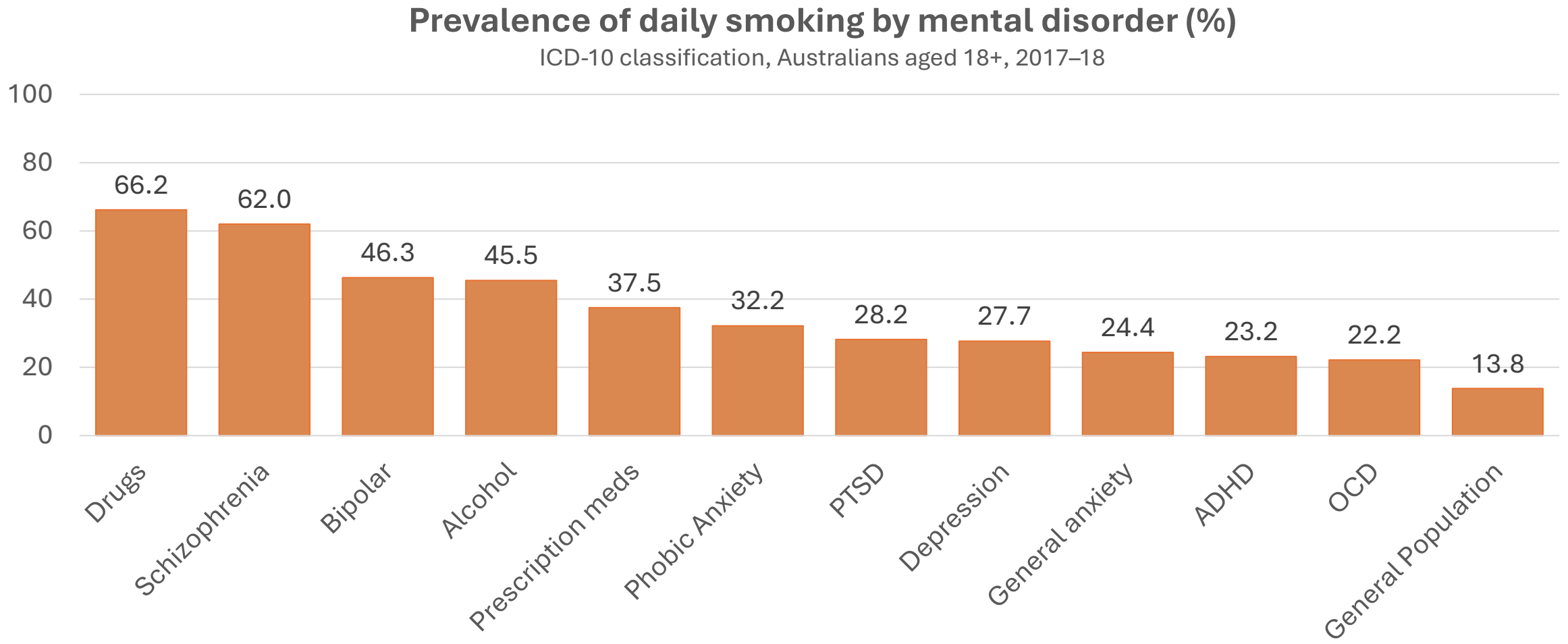


Ref: Greenhalgh, EM and Scollo, MM 9A.3 People with substance use and mental disorders In Greenhalgh, EM, Scollo, MM and Winstanley, MH [editors]. Tobacco in Australia: Facts and issues. Melbourne : Cancer Council Victoria; 2022.

Population

Opiate Treatment Clients

- People receiving treatment for opiate dependence have the highest rates of smoking.[4]
- Mortality rate 18 x higher due to tobacco smoking[5]
- Reported tobacco smoking rates between 73% to 94%[4]

4. Guydish J et al. An international systematic review of smoking prevalence in addiction treatment. Addiction. 2016 Feb;111(2):220-30

5. Engstrom A et al. Mortality in patients with substance abuse: a follow-up in Stockholm County, 1973-1984. International Journal of the Addictions. 1991;26(1):91-106

Design

Design: Randomised single blinded parallel group trial

Intervention: Vaporised Nicotine vs Combination NRT

Duration: 12-week treatment + 12-week follow-up

Target Recruitment: 572

Participating Sites: DACRIN NSW Health OAT clinics

- Hunter New England LHD
- Sydney LHD
- South West Sydney LHD
- Western Sydney LHD
- St Vincent's LHN
- South East Sydney LHD

Participants

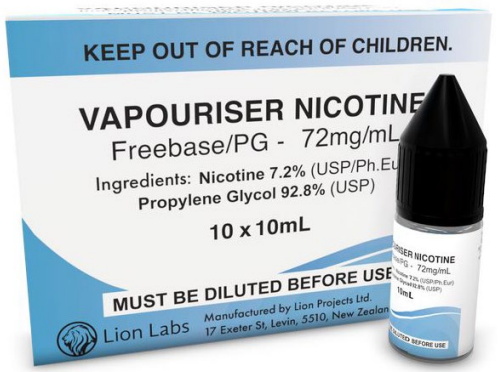
- Aged 18+ years
- Accessing opioid agonist treatment from a participating service
- Self-report daily tobacco smoking
- Wanting to quit or cut down
- Not vaping (no more than 1 day/week in past 30 days)

Participants

Intervention

VPN group received:

- Innokin Endura T18-II starter kit + 5 spare coils
- 12-weeks supply unflavoured e-liquid nicotine
- 1-week supply of NRT patches
- Instructions for correct use



Intervention

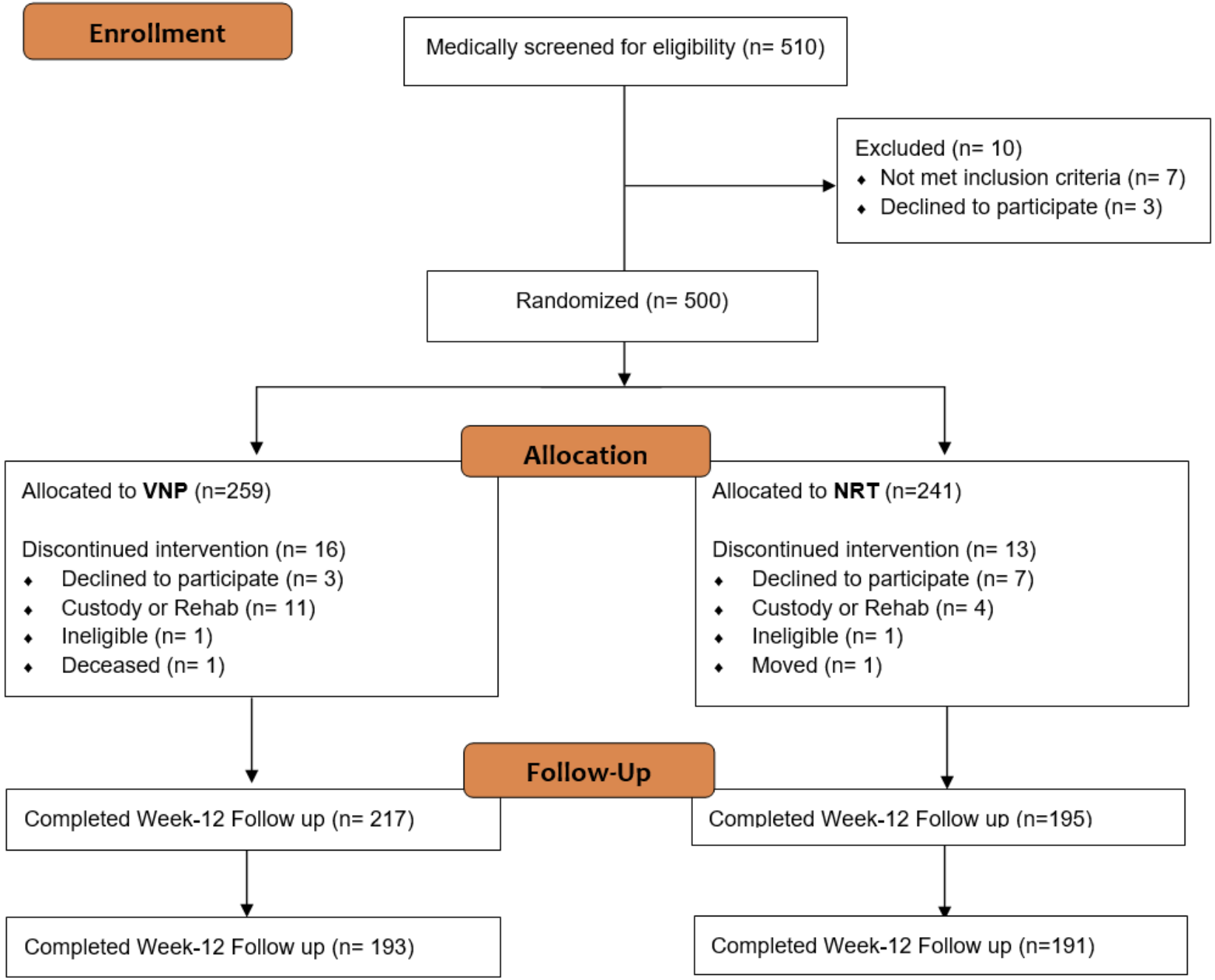
NRT group received:

- 12 weeks combination NRT
  - Patch (Step 1/21mg)
  - Inhalator (15mg)
  - Gum (4mg)
  - Lozenge (4mg)
  - QuickMist (150sprays @ 1mg)
- Pre-packaged, not customizable
- Instructions for correct use

Outcomes

- Self-reported 7-day point prevalence abstinence from tobacco (12 weeks)
- CO verified 7-day pp abstinence from tobacco (12-weeks)
- Self-reported 7-day pp abstinence from tobacco (24 weeks)
- Number of cigarettes smoked daily
- Treatment adherence
- Self-reported 30-day continuous abstinence from tobacco (24 weeks)
- Safety of liquid nicotine (adverse events)
- Quit attempts & relapse
- Study retention

Participant Flow



Results

Demographics

Characteristic	VNP N = 259	NRT N = 241	Overall N = 500
Gender: Male	157 (61%)	151 (63%)	308 (62%)
Aboriginal or Torres Strait Island origin	63 (24%)	553 (22%)	116 (23%)
Age (mean, SD)	46 (10)	46 (9)	46 (10)
Education up to & including year 10	183 (71%)	171 (71%)	354 (71%)
Income: Government benefit or pension	212 (82%)	203 (84%)	415 (83%)

Results

Characteristics

Characteristic	VNP N = 259	NRT N = 241	Overall N = 500
Opiate Treatment: Methadone	145 (56%)	122 (51%)	267 (53%)
Years of treatment (mean, SD)	5.7 (7.0)	5.4 (6.8)	5.5 (6.9)
Anxiety/Depression (PHQ4): Mod + Severe	186 (72%)	173 (71%)	359 (71%)
Nicotine Addiction (HIS): Mod + High	210 (81%)	192 (79%)	402 (80%)
Quit attempts in past year: Zero	142 (55%)	139 (58%)	281 (56%)
Previous quit method: Willpower	81 (70%)	81 (79%)	162 (75%)

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Results

Substance Use

Substance	VNP N = 259	NRT N = 241	Overall N = 500
Cannabis	94 (36%)	84 (35%)	178 (76%)
Alcohol	80 (31%)	67 (28%)	147 (29%)
Benzodiazepine	48 (19%)	48 (20%)	96 (20%)
Amphetamine	45 (17%)	38 (16%)	83 (17%)
Heroin	46 (18%)	35 (15%)	81 (16%)
Illicit Opioid	8 (3%)	8 (3%)	16 (3%)
Cocaine	3 (1%)	5 (2%)	8 (2%)

Analysis

Bayesian Framework

- Effects included:
  - Treatment group
  - Timepoint
  - Treatment group x Timepoint
  - Cannabis use at baseline
  - Random intercept to account for repeated measures within participants
- Used vague priors [N(0,1000)]

Analysis

Bayesian Framework

- Treatment effects reported as:
  - Mean posterior rate ratio
  - Absolute difference between treatment groups with 95% credible intervals (CrI)
  - Bayes Factor
  - Probability of direction (treatment effect >0)
- Missing data multiply imputed

Results

Primary Outcome

Effect of treatment on 7-day abstinence from tobacco at week 12.

VNP	NRT	Posterior risk ratio	Mean difference	Bayes factor[1]	Posterior p
52/217 (24%)	24/195 (12%)	1.99 (CrI 1.32, 2.98)	0.12 (CrI 0.05, 0.18)	1,719	>0.99

Bayes Factor (BF_{10})	Interpretation
> 100	Extreme evidence for VNP compared to NRT
30 – 100	Very strong evidence for VNP compared to NRT
10 – 30	Strong evidence for VNP compared to NRT
3 – 10	Moderate evidence for VNP compared to NRT
1 – 3	Anecdotal evidence for VNP compared to NRT
1	No evidence for VNP compared to NRT

Secondary Outcomes

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Abstinence

Outcome	Time	VNP	NRT	Ratio (RR or OR)[3]	Mean difference	Bayes factor[4]	Posterior p[5]
7-day pp tobacco abstinence (CO verified)	**Week 12**	**29/32 (91%)**	**9/13 (69%)**	**1.16 (CrI 0.93, 1.65)**	**0.12 (CrI −0.07, 0.37)**	**7.95**	**0.88**

Secondary Outcomes

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30-day continuous tobacco abstinence (self-report)	**Week 24**	**35/193 (18%)**	**17/191 (9%)**	**1.96 (CrI 1.14, 3.45)**	**0.09 (CrI 0.02, 0.15)**	**159.80**	**>0.99**

Secondary Outcomes

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Abstinence

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30-day continuous tobacco abstinence (self-report)	Week 24	35/193 (18%)	17/191 (9%)	1.96 (CrI 1.14, 3.45)	0.09 (CrI 0.02, 0.15)	159.80	>0.99
7-day pp tobacco abstinence (self-report)	**Week 24**	**49/193 (25%)**	**23/191 (12%)**	**2.02 (CrI 1.37, 3.15)**	**0.13 (CrI 0.06, 0.2)**	**2,975.7**	**>0.99**

Safety

Adverse Events

Characteristic	VNP N = 84	NRT N = 64
Dry mouth	7 (9.1%)	0 (0%)
Throat irritation	7 (9.1%)	1 (1.6%)
Cough	6 (7.8%)	4 (6.3%)
Headache	6 (7.8%)	6 (9.4%)
Shortness of breath	5 (6.5%)	4 (6.3%)
Device event	5 (6.5%)	0 (0%)
Nausea	1 (1.3%)	10 (16%)
Severity of event	**VNP**	**NRT**
Mild	62 (79%)	53 (84%)
Moderate	9 (12%)	6 (9.5%)
Severe	7 (9.0%)	4 (6.3%)
Probable relationship to the intervention	39 (52%)	33 (57%)

Discussion

- Vaporised nicotine is effective for assisting opioid agonist treatment clients to stop tobacco use
- Findings could significantly impact tobacco smoking prevalence in priority populations.
- Endorses an alternative approach for tobacco dependence in substance use populations
- Assist development of tobacco strategies for substance use treatment sector.

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Thank You

Contact:

Adrian.Dunlop@health.nsw.gov.au

Billie.Bonevski@Flinders.edu.au

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Secondary Outcomes

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Study Retention

Outcome	Time	VNP	NRT	Ratio (RR or OR)[3]	Mean difference	Bayes factor[4]	Posterior p[5]
Retention in Study	Week 12	217/259 (84%)	195/241 (81%)	1.02 (0.95, 1.11)	0.02 (-0.04, 0.09)	2.52	0.716
	Week 24	193/259 (75%)	191/241 (79%)	0.93 (0.85, 1.03)	-0.05 (-0.13, 0.02)	0.07	0.069

Secondary Outcomes

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Tobacco Withdrawal

Outcome	Time	VNP	NRT	Mean difference	Bayes factor[4]	Posterior p[5]
Withdrawal Symptoms	Week 12	0.98 (0.67)	1.03 (0.73)	-0.02 (CrI -0.18, 0.12)	1.62	0.619

Secondary Outcomes

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Cigarette Craving

Outcome	Time	Frequency	VNP	NRT	Ratio (RR or OR)[3]	Bayes factor	Posterior p[5]
Craving frequency	Week 12	Hourly or more often	51 (32%)	69 (42%)	1.86 (CrI 1.07, 3.21)	76.60	0.987
		Several times a day	56 (35%)	52 (31%)			
		At least once a day	32 (20%)	35 (21%)			
		Less than daily	13 (8%)	7 (4%)			
		Never	6 (4%)	3 (2%)			

Secondary Outcomes

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Cigarette Craving

Outcome	Time	Strength	VNP	NRT	Odds Ratio	Bayes factor	Posterior p[5]
Craving Strength	Week 12	No urge	6 (6%)	2 (2%)	0.78 (CrI 0.49, 1.23)	6.77	0.871
		Slight	19 (18%)	16 (17%)			
		Moderate	49 (47%)	51 (53%)			
		Strong	26 (25%)	20 (21%)			
		Very strong	4 (4%)	4 (4%)			

Secondary Outcomes

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Quit attempts

Outcome	Time	VNP	NRT	Ratio (RR or OR)[3]	Mean difference	Bayes factor[4]	Posterior p[5]
Attempted to quit	Week 12	87/157 (55%)	97/165 (59%)	1.02 (0.89, 1.18)	0.02 (CrI -0.08, 0.11)	1.77	0.639
	Week 24	55/139 (40%)	69/166 (42%)	1.05 (0.83, 1.3)	0.02 (CrI -0.09, 0.12)	1.84	0.648

Secondary Outcomes

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Treatment Adherence

Outcome	Time	VNP	NRT	Ratio (RR or OR)[3]	Mean difference	Bayes factor[4]	Posterior p[5]
Treatment adherence	Week 12	77/90 (86%)	112/159 (70%)	1.13 (0.83, 1.34)	0.08 (-0.12, 0.21)	4.03	0.801
	Week 24	123/193 (64%)	87/190 (46%)	1.36 (1.05, 1.73)	0.16 (0.02, 0.27)	115.58	0.991

Secondary Outcomes

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Cigarette Reduction

Outcome	Time	VNP	NRT	Ratio (RR or OR)[3]	Mean difference	Bayes factor[4]	Posterior p[5]