

Vaporized nicotine products for smoking cessation among people experiencing social disadvantage: A randomized clinical trial

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QUIT
Smoking
Study



Conflicts of Interest

- None to declare
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Vaporized Nicotine Products for Smoking Cessation Among People Experiencing Social Disadvantage: A Randomized Clinical Trial

This article has been corrected. [VIEW CORRECTION](#)

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Smoking in Australia

In Australia:

- approx. **1.8 million people** smoke daily (8.3% of Australians aged 14+)
 - 9% male vs 7.7% female
 - No decreases from earlier survey wave (2019) for those aged 60-69 and 70+
- Individuals living in low socioeconomic areas are **over 3 times more likely to smoke daily** than those living in high socioeconomic areas (13.4% compared with 4.1%)
- People from low-socioeconomic populations are disproportionately affected by the harms of smoking
- More effective interventions needed

National Drug Strategy Household Survey 2024

Calls for further research



- Further research is needed in many areas and NHMRC is currently funding a number of studies investigating e-cigarettes.



NSW Health

More research is needed to confirm the harms and benefits of using e-cigarettes as a smoking cessation aid (2). There are other proven safe and effective options to help people to quit smoking such as behavioural therapies, nicotine replacement therapy (NRT) including patches, gums, lozenges, mouth spray, inhalators, and some prescription medicines. NSW Health recommends people use approved medications to help them quit smoking, in consultation with their doctors or other health professionals.

VNPs for smoking cessation



Trusted evidence.
Informed decisions.
Better health.

Cochrane Database of Systematic reviews | Review - Intervention

New search

Electronic cigarettes for smoking cessation

Nicola Lindson, Ailsa R Butler, Hayden McRobbie, Chris Bullen, Peter Hajek, Angela Difeng Wu, Rachna Begh, Annika Theodoulou, Caitlin Notley, Nancy A Rigotti, Tari Turner, Jonathan Livingstone-Banks, Tom Morris,

✉ Jamie Hartmann-Boyce Authors' declarations of interest

Version published: 29 January 2025 Version history

- Living review
- Last update (29 Jan 2025) included 49 RCTs
- There is **high certainty** that nicotine VNP increases quit rates compared to nicotine replacement therapy (NRT) (RR 1.59, 95% CI 1.30 to 1.93; 7 studies, 2544 participants)
- Most often reported **adverse effects** with VNP were throat or mouth irritation, headache, cough and nausea

In absolute terms, out of
100 people using...

VNP: 8-10

NRT: 6

No support: 4

...are likely to quit smoking
long term

Policy in context

- Use initially required access via Special Access Scheme
- During trial, classification of VNPs shifted to prescription-only medicine and only available through doctor's prescription with purchase from an Australian pharmacy or imported from overseas via the TGA Personal Importation Scheme
- No e-liquid flavour restriction
- Initially RACGP/NHMRC did not authorize/endorse VNPs for smoking cessation
- But towards end trial provided a “conditional” endorsement for use if patient had failed to quit with other frontline treatments e.g. varenicline or NRT

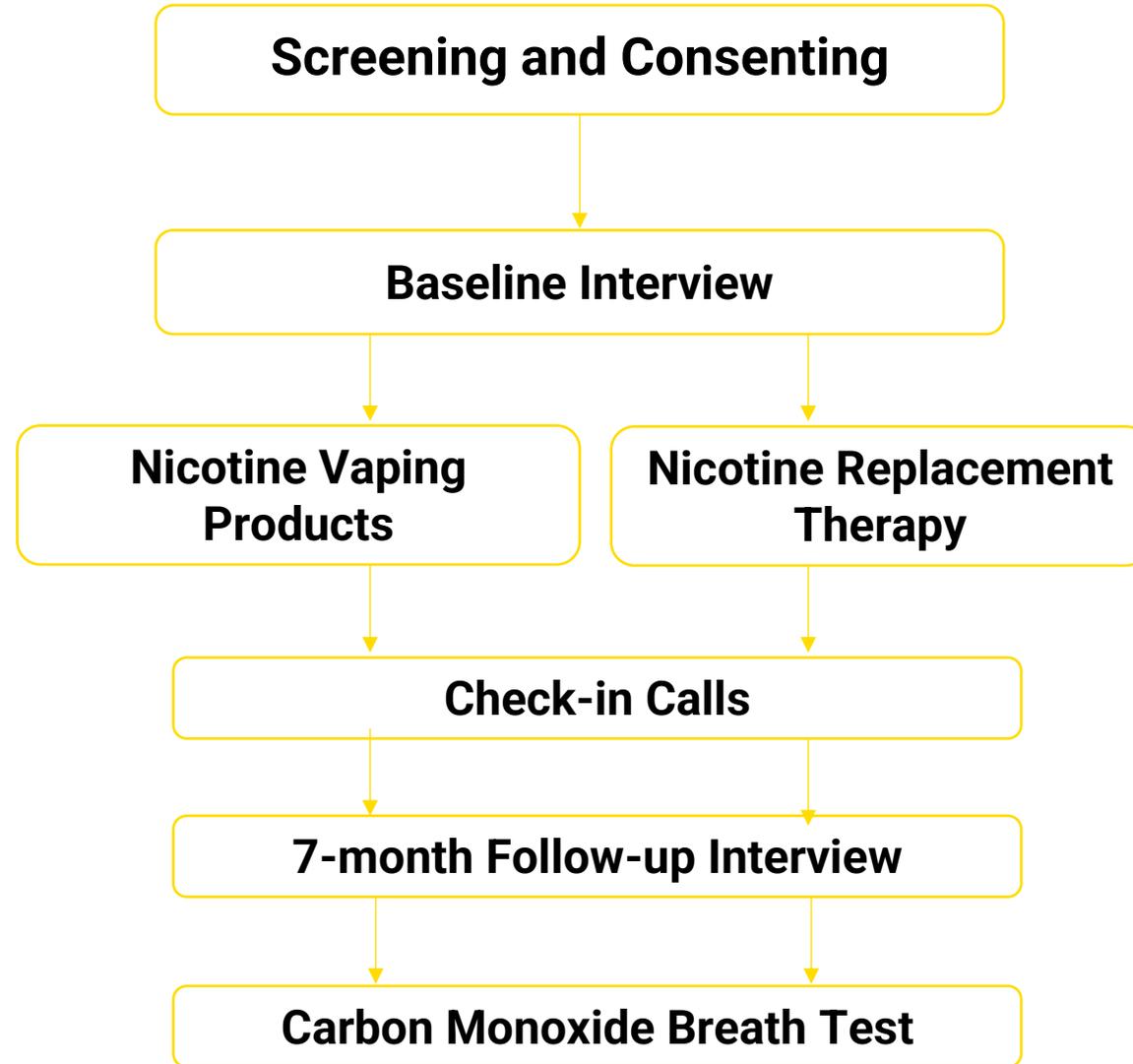
Vaporised Nicotine Products versus Nicotine Replacement Therapy

Design

- RCT, Australia between March 2021 and Dec, 2022
- 1,045 participants were randomised and analysed
- 8 weeks supply of free quit smoking products
- Inclusion criteria
 - ✓ aged 18+
 - ✓ in receipt of a govt. pension/allowance
 - ✓ current daily smoker
 - ✓ interested in quitting
- Participants were followed up for a period of 7 months
- Primary outcome = 6-month continuous biochemically verified smoking abstinence

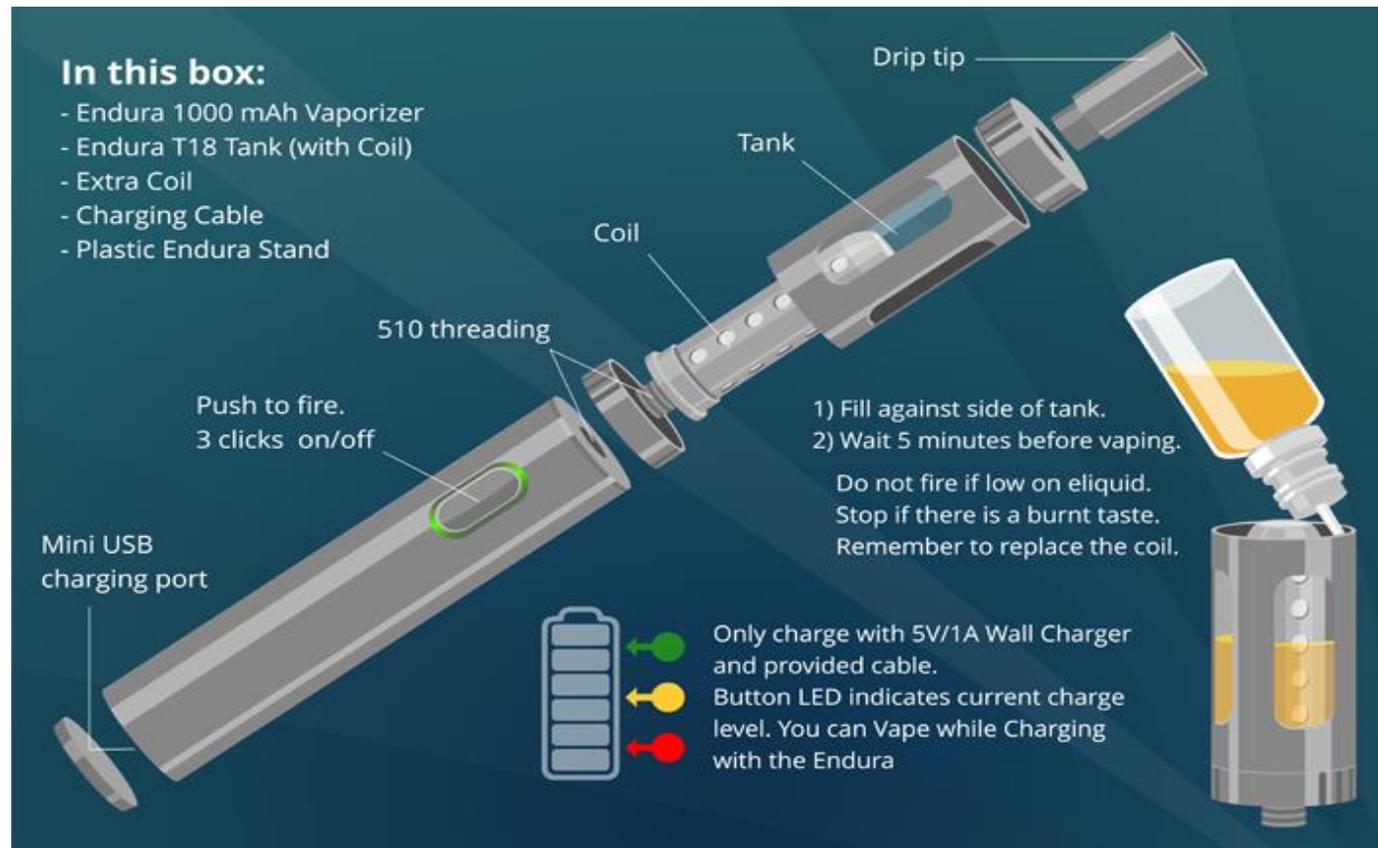
QUIT
Smoking
Study

Study Flow Diagram



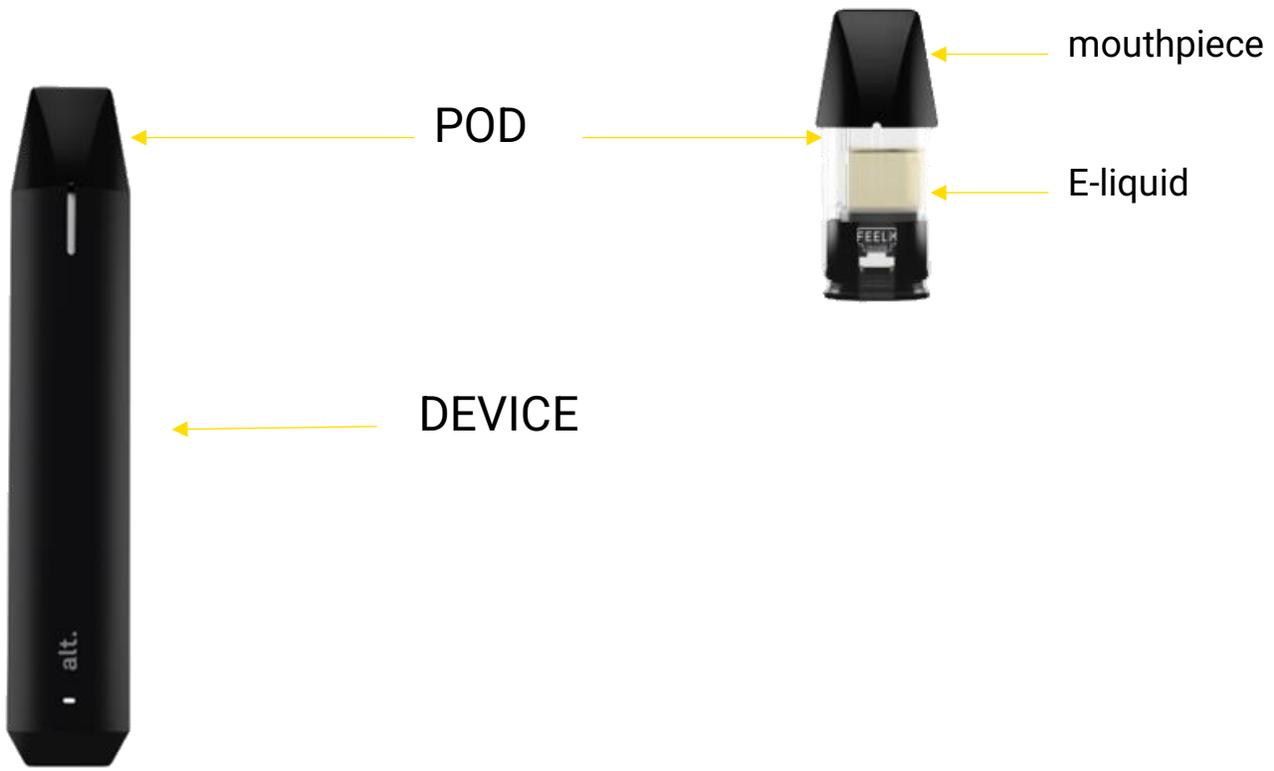
Study Products – VNPs

Alpha vape (with 18mg/mL freebase nicotine e-liquid in Tobacco, Menthol and Berry flavours)



Study Products – VNPs

Alt vape (with 40mg/mL nicotine salt e-liquid in Tobacco, Menthol and Mango flavours)



Study Products – VNPs

Pack 1	Pack 2
<ul style="list-style-type: none">• Alpha tank device (and pack of replacement coils)• Bottles of e-liquid in 3 flavours• Alt pod device (and replacement battery)• Alt pre-filled pods in 3 flavours• Wall adaptor and chargers	<p>Device and flavour preference considered:</p> <ol style="list-style-type: none">1. Choose between Alt or Alpha or both2. Choose one flavour or all 3 flavours

Study Products – Nicotine Replacement Therapy (NRT)

Choice of nicotine gum or lozenge (both 4mg and mint flavour). Participants could change their preference in their second pack.



Behavioural Support – Text Message Program

- 5-week program
- 112 messages in total (93 general and 19 treatment-specific)
- “Quit Buddy” persona
- Ranges in frequency from 2-5 texts per day
- Includes text, emojis, weblinks, videos and GIFs

“Hi, my name is Lou and I will be your quit buddy for the next 5 weeks. Let’s help you quit, one day at a time!”

Baseline characteristics

- 2348 EOIs
- 1295 completed screening
- 1045 participants randomised and analysed
- Sample predominately middle-aged (median 50 years) and female (67%)
- Median 20 cigarettes smoked per day
- 42% had reported either a recent diagnosis or treatment for mental health disorder in last 12 months

Primary abstinence outcome

- 9.6% quit in the NRT group compared to 28.4% in the VNP group
- The Bayesian posterior treatment effect estimate of the risk difference between NRT and VNP was 18.7% (95%CrI, 14.1% to 23.3%; >99% posterior probability that VNP is superior)
- The estimated posterior probability of superiority of VNP over NRT was greater than 99.9% with a uniform beta prior
- Sensitivity analysis using Cochrane review data (power priors @ 20, 30, 40 and 50%) also showed clinically significant difference in favour of VNP
- Per-protocol analysis also favoured VNP

Primary abstinence outcomes - subgroup

Characteristic	Subgroup	NRT	VNP	Posterior Risk difference (95% CrI)*
Age	<40 years	8%	25%	17.1% (8.5% to 25.8%)
	≥40 years	10%	30%	19.3% (13.9% to 24.8%)
Sex	Female	10%	29%	19% (13.3% to 24.7%)
	Male	10%	28%	18.2% (10.2% to 26.2%)
Heaviness of Smoking Index (2-item)	High	7%	25%	17.4% (11.2% to 23.6%)
	Low/Med	12%	32%	20.2% (13.4% to 27%
Mental health disorder (last 12 months)	Yes	9%	26%	16.4% (9.5% to 23.3)
	No	10%	30%	20.3% (14.1% to 26.4%)

*Posterior probability VNP > NRT 99.99%

Secondary abstinence outcomes

	NRT (n=523)	VNP (n=522)	OR (n=1045) 95%CI
Self-reported 6-months continuous abstinence at 7-mth follow-up	85 (16%)	192 (37%)	2.82 (2.09-3.81)
Point prevalence (7-day) at 7-mth follow-up	124 (24%)	246 (47%)	2.75 (2.08-3.65)
Point prevalence (7-day) at check-in call 2	76 (15%)	222 (43%)	3.74 (2.76-5.05)

- No significant difference between groups for cigarettes smoked per day or proportion that had reduced smoking from baseline to 7-mth follow-up

Continued use of products*

Participants	NRT, n/N %	VNP, n/N%	OR (95% CI)
All completing follow-up (n = 866)	129/417 (31%)	253/449 (56%)	2.88 (2.18-3.81)
Those meeting primary outcome	17/50 (34%)	86/148 (58%)	2.69 (1.38-5.26)
Those not meeting primary outcome	112/367 (31%)	167/301 (56%)	2.84 (2.06-3.90)

*Continued use defined as self-reporting at least weekly use of allocated/study-supplied product at 7-month follow-up

Adverse events & Respiratory outcomes

- Self-reported adverse events occurred less frequently in the VNP group (355 events among 237 participants) compared with the NRT group (442 events among 278 participants; incident rate ratio, 0.75 [95% CI, 0.65 to 0.88]; $P < 0.001$).

Most frequent ($\geq 5\%$ of all events)	NRT n (%)	VNP n%
COVID-19	38 (8.6)	50 (14.1)
Cough	7 (1.6)	36 (10.1)
Headache	18 (4.1)	32 (9)
Nausea	60 (13.6)	6 (1.7)

- No difference in respiratory outcomes as measured by LRTI-VAS or MRC Dyspnoea scale between baseline, check-in call or follow-up

Implications

- VNP's were more effective than NRT alongside minimal behavioural support
- What we know for the general population also applies for those experiencing social disadvantage
- Few trials had evaluated multiple flavours/devices and nicotine pods
- Sufficient nicotine delivery
- Partial replication of routine setting
- Continued use of vaping at long-term follow-up may be problematic

Limitations

- Open-label trial and treatment assignment not blinded
- Participants in NRT group had choice of gum or lozenge, but trials with wider choice have not found improved quit rates
- Most peak health bodies had cautioned against/discouraged VNP use vs NRT with unanimous endorsement
- Not equal pathways for on-going supply between NRT and VNP
- Continued use data confined to allocated product
- CO testing – practical and cost-effective but detects exposure to smoking in previous 24-hours

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- Stakeholders for dispensing medications and completing interviews
- Study Physician
- Data Safety Monitoring Committee Members

Thankyou for listening

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