E-cigarette and smoking cessation: friend or foe?

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Outline

- Tobbaco and e-cigarette use in 2022
- E-cigarettes and smoking cessation: randomized controlled trials
- Who are the actual e-cigarette users outside of RCTs?
- Thoughts for the future

Background

A brief history of tobacco

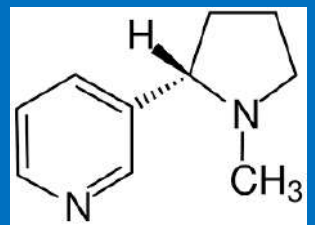
Cured tobacco leaves

Medicinal use of tobacco, 18th century Europe

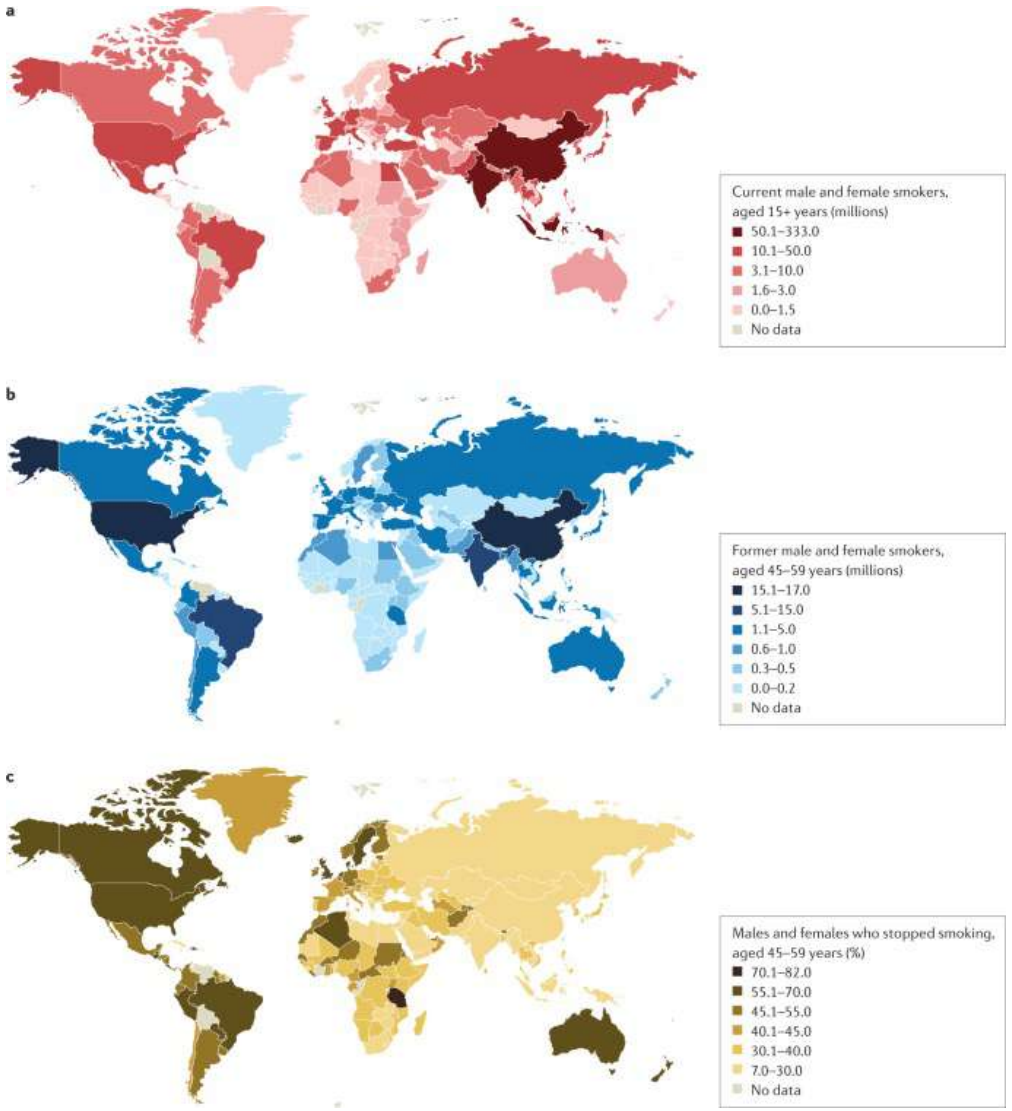
Tobacco plantation, 17th century North America

1595

Cigarette rolling machine, end of 19th century

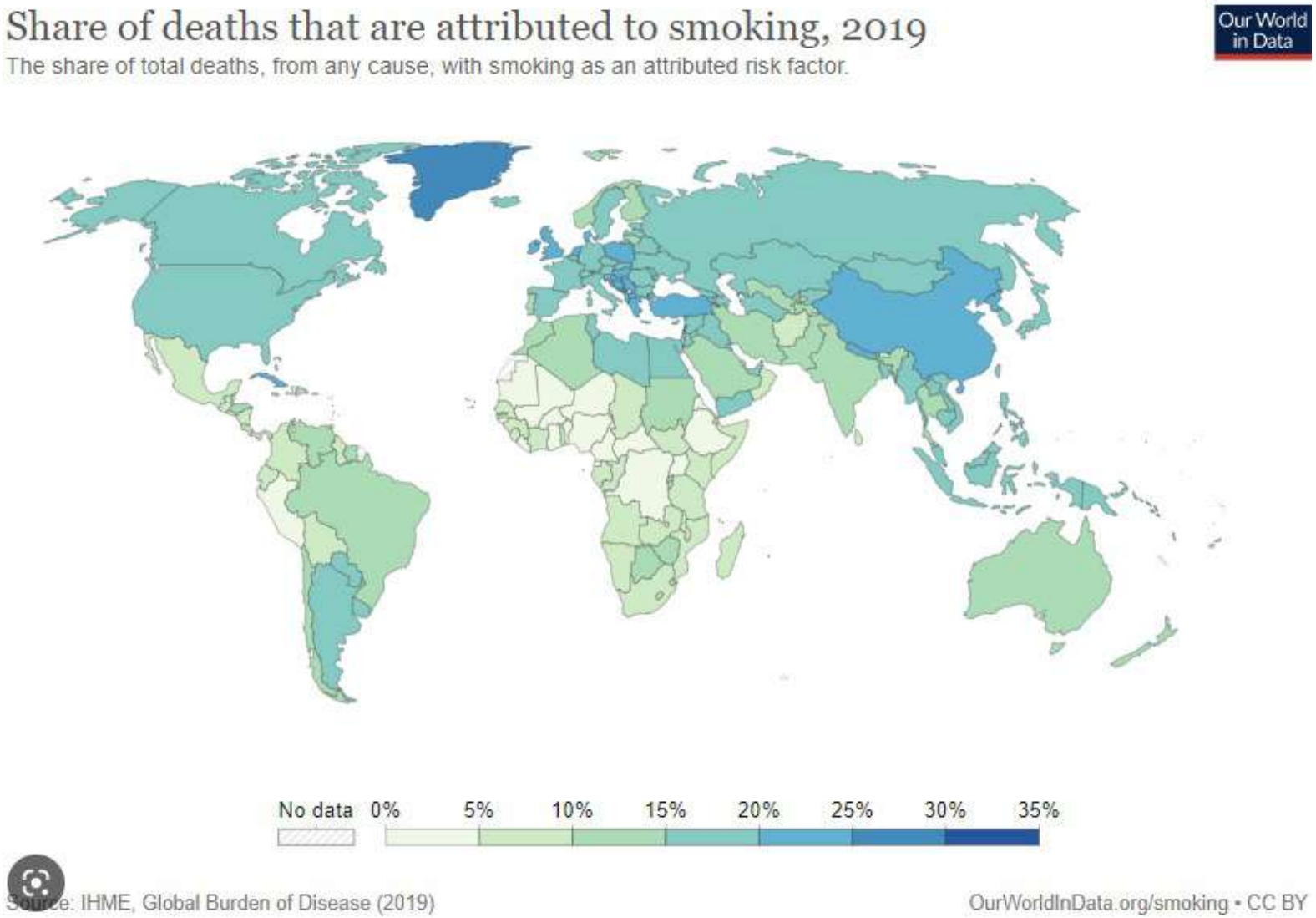


Nicotine addiction today

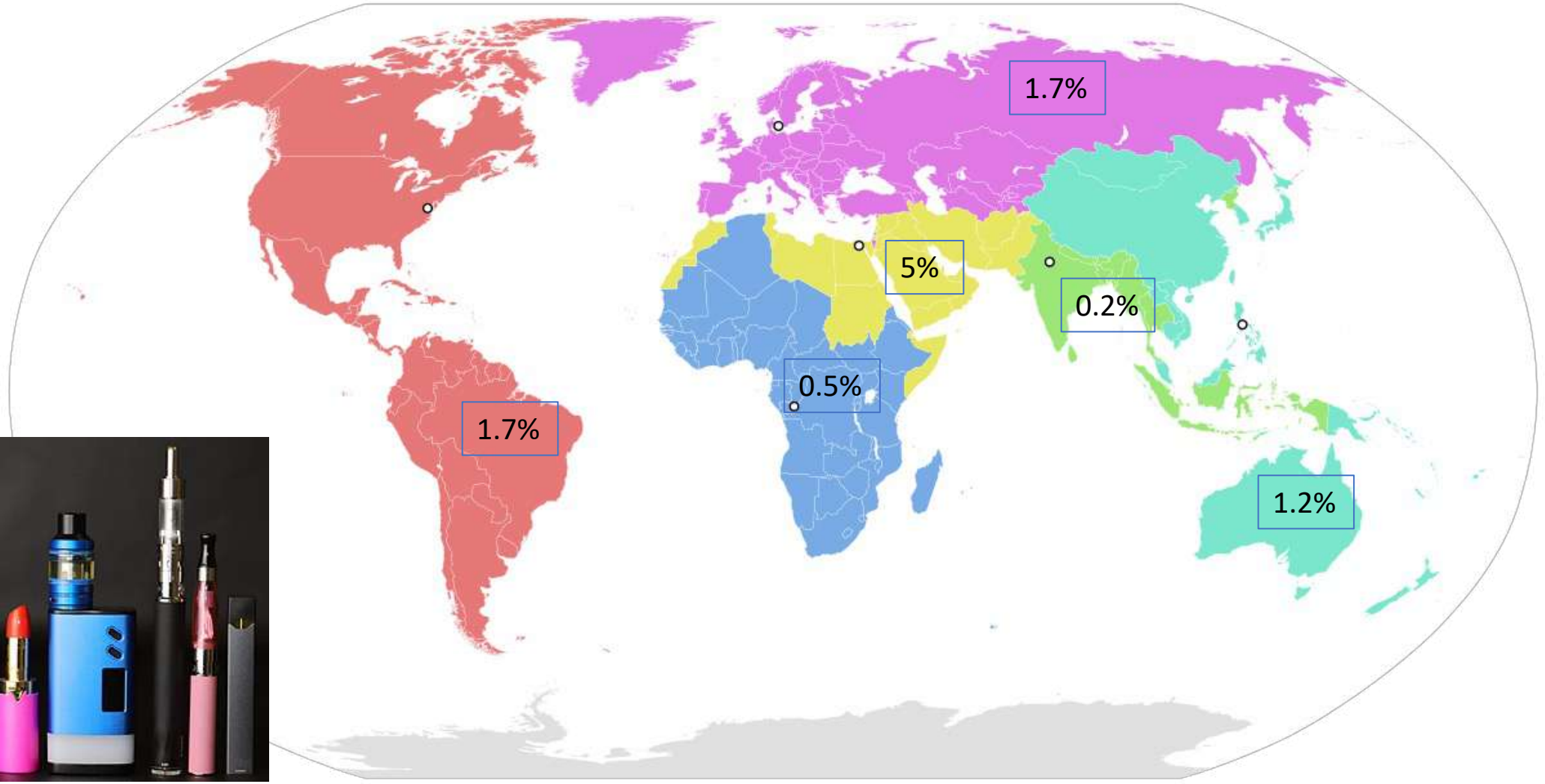


Le Foll et al, Nature reviews, 2022

Tobacco deaths



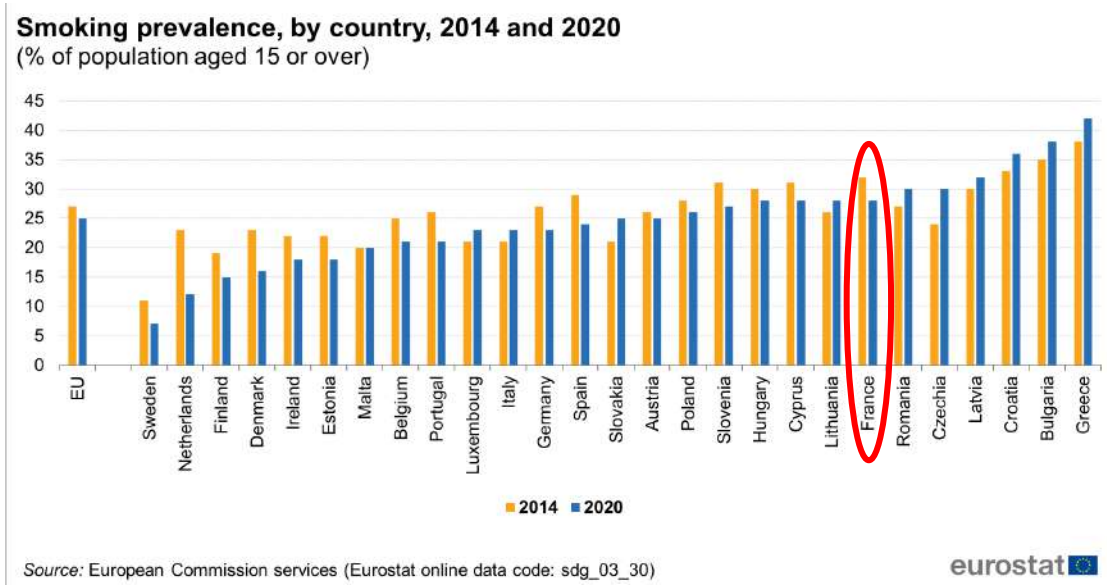
Vaping worldwide



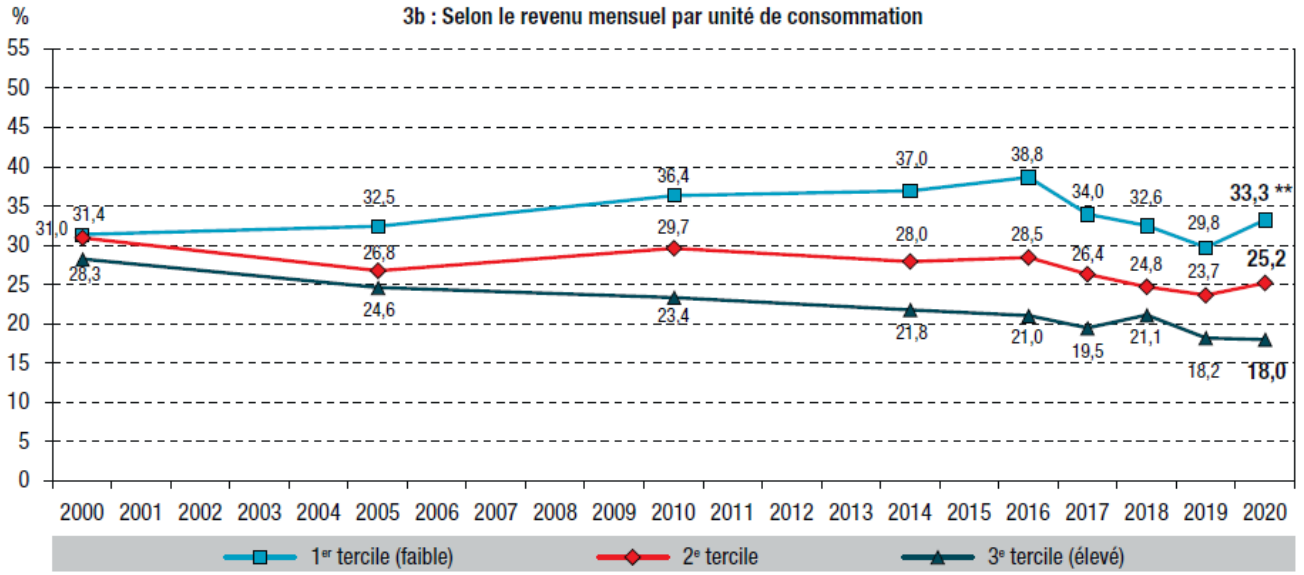
Jerzynski et al, J of Harm Reduction, 2021

Tobacco use patterns in France

Tobacco use 33% of adults in 2020 (25% daily); 3% e-cigarette use



Widening inequalities since 2019



Pasquereau et al, 2021

E-cigarette use and smoking cessation in RCTs

Cochrane review 2022: nicotine EC vs. NRT

Summary of findings 1. Nicotine EC compared to NRT for smoking cessation

Nicotine EC compared to NRT for smoking cessation

Patient or population: People who smoke
Setting: New Zealand, UK, USA
Intervention: Nicotine EC
Comparison: NRT

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with NRT	Risk with Nicotine EC				
Smoking cessation at 6 months to 1 year Assessed with biochemical validation	Study population		RR 1.63 (1.30 to 2.04)	2378 (6 RCTs)	⊖⊖⊖⊖ HIGH	-
	6 per 100	10 per 100 (8 to 12)				
Adverse events at 4 weeks to 6-9 months Assessed by self-report	Study population		RR 1.02 (0.88 to 1.19)	1702 (4 RCTs)	⊖⊖⊖⊖ MODERATE[a]	-
	27 per 100	27 per 100 (24 to 32)				
Serious adverse events at 4 weeks to 1 year Assessed via self-report and medical records	Study population		RR 1.12 (0.82 to 1.52)	2411 (5 RCTs)	⊖⊖⊖⊖ LOW[b]	2 studies reported no events; effect estimate based on the three studies in which events were reported
	6 per 100	7 per 100 (5 to 9)				

Hartmann-Boyce et al, Cochrane Review, 2022

Cochrane review 2022: nicotine EC vs. non-nicotine EC

Summary of findings 2. Nicotine EC compared to non-nicotine EC for smoking cessation

Nicotine EC compared to non-nicotine EC for smoking cessation

Patient or population: People who smoke cigarettes
Setting: Canada, Italy, New Zealand, UK, USA
Intervention: Nicotine EC
Comparison: Non-nicotine EC

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with non-nicotine EC	Risk with Nicotine EC				
Smoking cessation at 6-12 months Assessed with biochemical validation	Study population 7 per 100	14 per 100 (9 to 23)	RR 1.94 (1.21 to 3.13)	1447 (5 RCTs)	⊖⊖⊖⊖ MODERATE[a,b]	-
Adverse events at 1 week to 6 months Assessed via self-report	Study population 9 per 100	9 per 100 (8 to 10)	RR 1.01 (0.91 to 1.11)	840 (5 RCTs)	⊖⊖⊖⊖ MODERATE[b]	-
Serious adverse events at 1 week to 1 year Assessed via self-report and medical records	Study population 3 per 100	3 per 100 (2 to 6)	RR 1.00 (0.56 to 1.79)	1272 (8 RCTs)	⊖⊖⊖⊖ LOW[c]	4 studies reported no events; effect estimate based on the 3 studies in which events were reported

Cochrane review 2022: nicotine EC vs. behavioral/ no intervention

Summary of findings 3. Nicotine EC compared to behavioural support only/no support for smoking cessation

Nicotine EC compared to behavioural support only/no support for smoking cessation

Patient or population: People who smoke
Setting: Canada, Italy, UK, USA
Intervention: Nicotine EC
Comparison: Behavioural support only/no support

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with behavioural support only/no support	Risk with Nicotine EC				
Smoking cessation at 6 to 12 months Assessed using biochemical validation	Study population 1 per 100	3 per 100 (2 to 5)	RR 2.66 (1.52 to 4.65)	3126 (7 RCTs)	⊕⊖⊖⊖ VERY LOW[a,b]	-
Adverse events at 12 weeks to 6 months Assessed via self-report	Study population 66 per 100	80 per 100 (74 to 87)	RR 1.22 (1.12 to 1.32)	765 (4 RCTs)	⊕⊕⊖⊖ LOW[a]	-
Serious adverse events at 4 weeks to 8 months Assessed via self-report and medical records	Study population 2 per 100	2 per 100 (1 to 4)	RR 1.03 (0.54 to 1.97)	1993 (9 RCTs)	⊕⊖⊖⊖ VERY LOW[a,c]	5 of the 9 studies reported no SAEs; MA is based on pooled results from 4 studies.

E-cigarette use in real-life settings

E-cigarette use and smoking trajectories: the French CONSTANCES cohort study

Research

JAMA Internal Medicine | Original Investigation

Association Between Electronic Cigarette Use and Smoking Reduction in France

Ramchandar Gomajee, MSc; Fabienne El-Khoury, PhD; Marcel Goldberg, MD; Marie Zins, PhD; Cédric Lemogne, MD; Emmanuel Wiernik, PhD; Emeline Lequy-Flahault, PhD; Lucile Romanello, PhD; Isabelle Kousignian, PhD; Maria Melchior, ScD

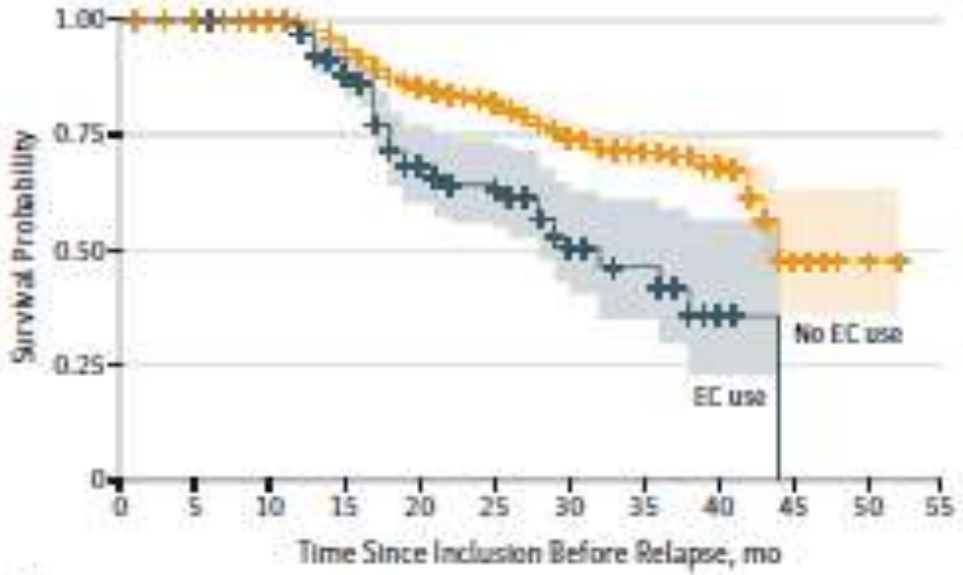
CONSTANCES

Table 2. Longitudinal Changes in Cigarette Smoking as a Function of EC Use CONSTANCES Cohort Study, 2012-2017[a]

Analysis	Estimate (95% CI)		P Value
	EC Users (n = 822)	Nonusers (n = 4578)	
Univariate			
No. of cigarettes smoked per day, β	11.2 (10.8 to 11.7)	9.8 (9.6 to 10.0)	<.001
Difference in No. of cigarettes per day between baseline and follow-up, β	−4.0 (−5.1 to −2.8)	−1.8 (−2.9 to −0.7)	<.001
Smoking cessation, RR	1.59 (1.45 to 1.76)	1 [Reference]	<.001
Adjusted[b]			
No. of cigarettes smoked per day, β	11.2 (10.5 to 11.8)	12.2 (11.6 to 12.8)	<.001
Difference in No. of cigarettes per day between baseline and follow-up, β	−4.4 (−4.8 to −3.9)	−2.7 (−3.1 to −2.4)	<.001
Smoking cessation, RR	1.67 (1.51 to 1.84)	1 [Reference]	<.001

EC use and time to smoking relapse: the French CONSTANCES cohort study

Figure. Time to Smoking Relapse According to Current Regular Electronic Cigarette (EC) Use Among Former Smokers (n = 2025), CONSTANCES Cohort Study, 2012-2017



No. at risk

EC use	176	173	56	23	3	0
No EC use	1849	1835	830	300	84	2

The shaded area indicates 95% CIs. CONSTANCES indicates Consultants des Centres d'Examens de Santé.

EC use and smoking relapse: PATHS

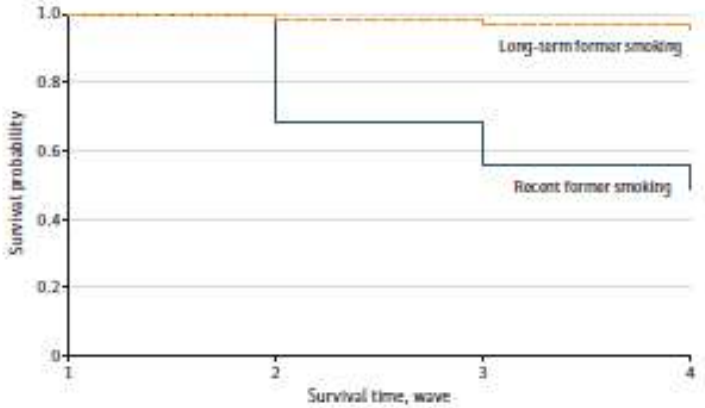
JAMA Network Open.

Original Investigation | Substance Use and Addiction

Association of Electronic Nicotine Delivery System Use With Cigarette Smoking Relapse Among Former Smokers in the United States

Colm D. Everard, PhD; Marushka L. Silveira, PhD, MPH, BDS; Heather L. Kimmel, PhD; Daniela Marshall, PhD; Carlos Blanco, MD, PhD; Wilson M. Compton, MD, MPE

Figure. Kaplan-Meier Survival Curves of Cigarette Smoking Relapse for Recent Former Smokers and Long-term Former Smokers



No. at risk

Recent former smoking	3 154 000	2 165 000	1 751 000	1 552 000
Long-term former smoking	34 933 000	34 265 000	33 769 000	33 386 000

Numbers at risk are weighted and rounded nearest thousand.

Table 4. Cox Proportional Hazards Models With Covariates Assessing Associations of Characteristics With Cigarette Smoking Relapse[a]

	Former smokers, AHR (95% CI)[c]		
Covariate[b]	All	Recent	Long-term
Unweighted, No.	1858	304	1554
Past 12 mo[d]			
Use of ENDS	2.98 (1.93-4.60)*	1.63 (1.04-2.53)*	3.79 (1.75-8.2)*
Use of OTP	2.74 (1.86-4.04)*	1.97 (1.27-3.05)*	3.82 (1.91-7.66)*
GAIN-SS internalizing problems	1.08 (0.81-1.44)	1.16 (0.83-1.63)	1.02 (0.68-1.54)
GAIN-SS externalizing problems	0.89 (0.66-1.19)	1.01 (0.70-1.46)	0.90 (0.52-1.54)
GAIN-SS substance use problems	0.90 (0.63-1.29)	0.73 (0.45-1.19)	0.96 (0.53-1.76)
Days quit cigarettes	NA	0.998 (0.996-1.00)*	NA
Years quit cigarettes	0.87 (0.83-0.91)*	NA	0.93 (0.90-0.96)*

Abbreviations: AHR, adjusted hazard ratio; ENDS, electronic nicotine delivery systems; GAIN-SS, Global Appraisal of Individual Needs-Short Screener; NA, not applicable to this study; OTP, other tobacco products.

[a] eTables 4, 5, and 6 in the Supplement detail these results. Sex, age, race/ethnicity, educational attainment, and household income are also adjusted for in these models.

[b] See Table 1 for characteristic variable descriptions.

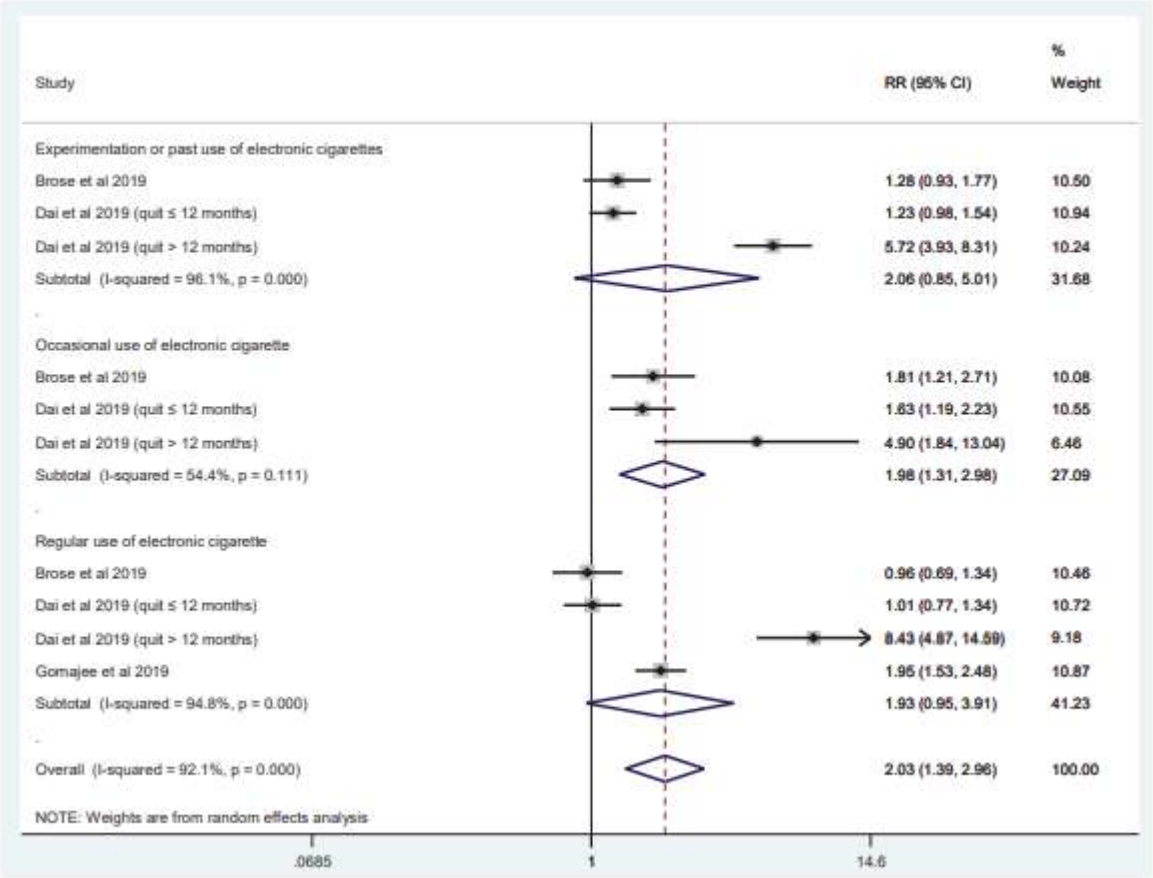
[c] All former indicates former established cigarette smokers who were not current users of any tobacco product at their wave 1 interview; recent former indicates former established cigarette smokers who became former cigarette smokers within the past 12 months of their wave 1 interview and were not current users of any tobacco product at that interview; and long-term former indicates former established cigarette smokers who became former cigarette smokers more than 12 months before their wave 1 interview and were not current users of any tobacco product at that interview.

[d] Time-dependent variables.

* Significant at $P < .05$.

EC use and long-term smoking cessation

Figure 2. Meta-analysis of the risk of smoking relapse associated with electronic cigarette use (experimentation or past use, current occasional use and current regular use)



Barufaldi et al, Tobacco Prevention and Cessation, 2021

E-cigarette use trajectory and smoking patterns

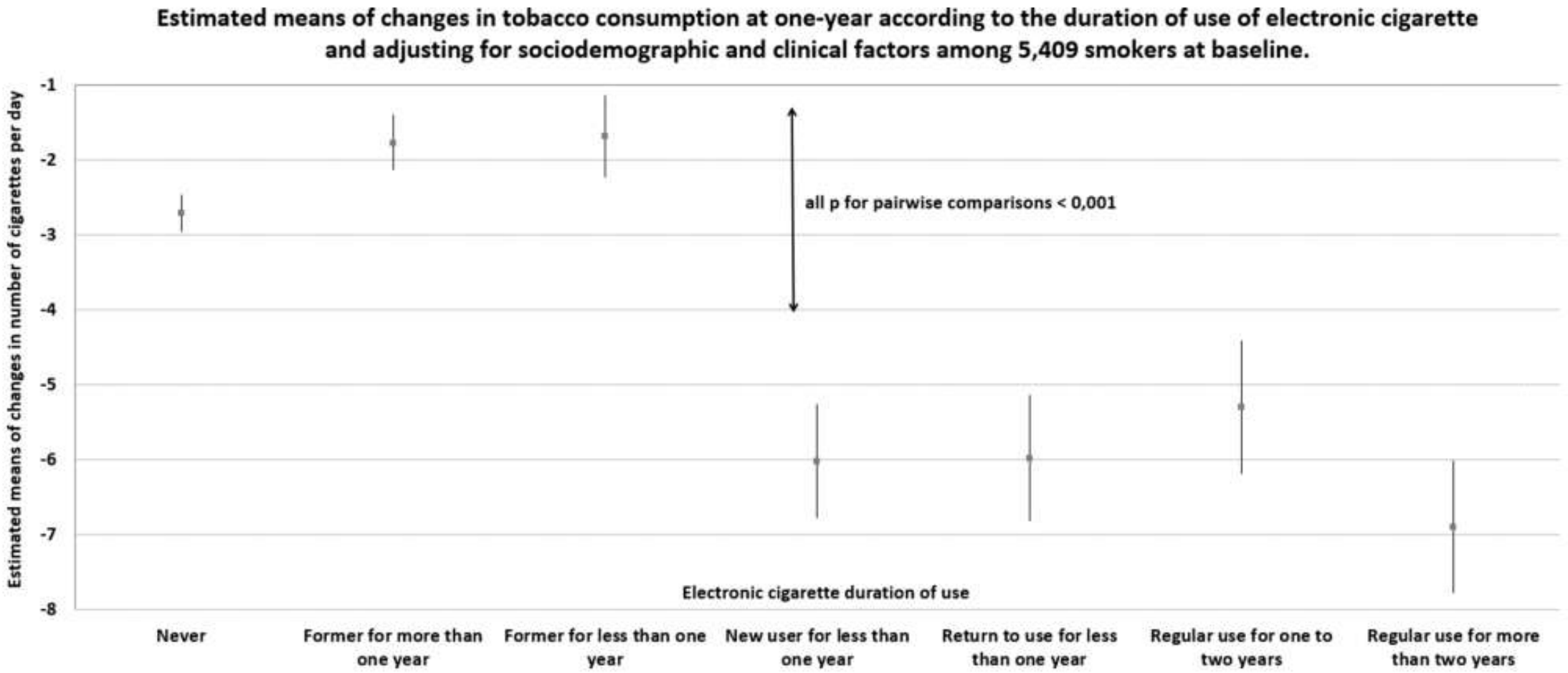


Fig. 1.

Airagnes et al, Addictive Behaviors, 2021

What drives differences between RCTs and real-life settings?

Participant characteristics

Table 1. Characteristics of Smokers and Former Smokers According to EC Use Status, CONSTANCES Cohort Study, 2012-2017

Characteristic	Active Smokers at Study Baseline			Former Smokers Since 2010		
	EC Users (n = 822)	Nonusers (n = 4578)	P Value	EC Users (n = 176)	Nonusers (n = 1849)	P Value
Sociodemographic characteristics						
Male sex, No. (%)	423 (51.5)	2071 (45.2)	.001	111 (63.1)	910 (49.2)	<.001
Age at inclusion period, mean (SD), y	45.9 (11.6)	44.7 (12.5)	.01	44.6 (10.6)	43.5 (12.2)	.23
Duration of follow-up, mean (SD), mo	26.2 (9.5)	22.9 (9.1)	<.001	21.9 (8.9)	22.2 (8.6)	.65
Marital status: in a civil partnership or married, No. (%)	403 (49.0)	2142 (46.8)	.02	94 (53.4)	1018 (55.1)	.79
Educational level: no tertiary education, No. (%)	377 (45.9)	2092 (45.7)	.93	63 (35.8)	682 (36.9)	.77
Citizenship: non-French, No. (%)	14 (1.7)	117 (2.6)	.29	2 (1.2)	38 (2.1)	.26
Monthly household income: <€1500 [$1695], No. (%)	132 (16.1)	752 (16.4)	.85	14 (8.0)	177 (9.6)	.52
Financial difficulties, No. (%)	269 (32.7)	1277 (27.9)	.05	61 (34.7)	534 (28.9)	.17
Alcohol and Tobacco use						
Alcohol abuse, No. (%)[a]	134 (16.4)	621 (13.6)	.09	24 (13.6)	136 (7.4)	.05
No. of cigarettes smoked at baseline, median (IQR)	11.0 (8-17)	10.0 (5-15)	<.001	0	0	NA
Cigarette pack-years, median (IQR)[b]	15.0 (7-25)	9.0 (4-18)	<.001	14.5 (8-23)	9.0 (4-18)	<.001
Made previous attempt to quit smoking, No. (%)	594 (72.3)	3147 (68.7)	.04	NA	NA	NA
Stopped smoking during follow-up, No. (%)	339 (41.2)	1180 (25.8)	<.001	NA	NA	NA
Relapsed smoking during follow-up, No. (%)	NA	NA	NA	55 (31.3)	297 (16.1)	<.001
Health characteristics						
Depressive symptoms (CES-D score), median (IQR)	12.0 (7-19)	10.0 (5-17)	<.001	10.0 (5-17)	9.0 (5-15)	.01
History of depression, No. (%)	199 (24.2)	911 (19.9)	.005	34 (19.4)	316 (17.3)	.47
Respiratory problems, No. (%)	646 (78.6)	3116 (68.1)	<.001	103 (58.5)	1035 (56.0)	.52
History of cardiovascular problems, No. (%)	137 (16.7)	655 (14.3)	.07	23 (13.1)	272 (14.8)	.55
History of cancer, No. (%)	28 (3.4)	157 (3.4)	.97	6 (3.4)	79 (4.3)	.57

Abbreviation: CES-D, Center for Epidemiologic Studies–Depression scale; CONSTANCES, Consultants des Centres d'Examens de Santé; EC, electronic cigarette; IQR, interquartile range; NA, not applicable.

[a] Determined via Alcohol Use Disorders Identification Test score.

[b] Lifetime tobacco exposure: a pack-year is defined as 20 cigarettes smoked every day for 1 year.

Generalizability of clinical trials?

Generalizability of Clinical Trial Results for Adolescent Major Depressive Disorder

Carlos Blanco, MD, PhD,[a] Nicolas Hoertel, MD, MPH,[b,c,d] Silvia Franco, MD,[e] Mark Olfson, MD, MPH,[e] Jian-Ping He, MSc,[f] Saioa López, MD,[g] Ana González-Pinto, MD, PhD,[g] Frédéric Limosin, MD, PhD,[b,c,d] Kathleen R. Merikangas, PhD[f]

abstract

BACKGROUND: Although there have been a number of clinical trials evaluating treatments for adolescents with major depressive disorder (MDD), the generalizability of those trials to samples of depressed adolescents who present for routine clinical care is unknown. Examining the generalizability of clinical trials of pharmacological and psychotherapy interventions for adolescent depression can help administrators and frontline practitioners determine the relevance of these studies for their patients and may also guide eligibility criteria for future clinical trials in this clinical population.

METHODS: Data on nationally representative adolescents were derived from the National Comorbidity Survey: Adolescent Supplement. To assess the generalizability of adolescent clinical trials for MDD, we applied a standard set of eligibility criteria representative of clinical trials to all adolescents in the National Comorbidity Survey: Adolescent Supplement with a *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition* diagnosis of MDD ($N = 592$).

RESULTS: From the overall MDD sample, 61.9% would have been excluded from a typical pharmacological trial, whereas 42.2% would have been excluded from a psychotherapy trial. Among those who sought treatment ($n = 412$), the corresponding exclusion rates were 72.7% for a pharmacological trial and 52.2% for a psychotherapy trial. The criterion leading to the largest number of exclusions was "significant risk of suicide" in both pharmacological and psychotherapy trials.

CONCLUSIONS: Pharmacological and, to a lesser extent, psychotherapy clinical trials likely exclude most adolescents with MDD. Careful consideration should be given to balancing eligibility criteria and internal validity with applicability in routine clinical care while ensuring patient safety.

ORIGINAL CONTRIBUTION

Are Participants in Pharmacological and Psychotherapy Treatment Trials for Social Anxiety Disorder Representative of Patients in Real-Life Settings?

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Research report

Are subjects in treatment trials of panic disorder representative of patients in routine clinical practice? Results from a national sample

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ABSTRACT

Background: Research on the generalizability of clinical trials in panic disorder is limited. The present study sought to quantify the generalizability of clinical trials' results of individuals with DSM-IV panic disorder (PD) to a large community sample.
Methods: Data were derived from the National Epidemiological Survey on Alcohol and Related Conditions (NESARC), a large national representative sample of 43,093 adults of the United States population. We applied a standard set of eligibility criteria representative of PD clinical trials to all adults with past 12 months PD ($n=907$), and then to a subgroup of participants seeking treatment ($n=105$). Our aim was to determine the proportion of participants with PD who would have been excluded by typical eligibility criteria.
Results: We found that more than 8 out of ten participants (80.52%; 95% CI=77.13–83.52%) with PD were excluded by at least one criterion. In the subgroup of participants who sought treatment, the exclusion rate by at least one criterion was higher (92.40%; 95% CI=84.60–96.42%). For the full sample and the treatment-seeking subsample, having currently a depression and a diagnosis of alcohol or drug abuse/dependence were the criteria excluding the highest percentage of participants. Having a lifetime history of bipolar disorder and a current significant medical condition also excluded a substantial proportion of individuals in both samples. Exclusion rates were similar when considering panic disorder with and without agoraphobia.
Conclusions: Clinical trials, that exclude a majority of adults with panic disorder, should carefully consider the impact of eligibility criteria on the generalizability of their results. As required by CONSORT guidelines, reporting exclusion rate estimate and reasons of eligibility should be mandatory in both clinical trials and meta-analyses.

Health characteristics associated with vaping

Table 2. Factors associated with lifetime or current e-cigarette use (TEMPO cohort study, 2015, $n = 368$, multivariate logistic regression).

	Lifetime e-cigarette use OR (95% CI)	Current e-cigarette use OR (95% CI)
Sex		
M	1	1
F	0.96 (0.53-1.74)	0.85 (0.43-1.66)
Age		
23-35 years old	1	1
36-41 years old	1.00 (0.56-1.80)	0.71 (0.36-1.38)
Living with a partner		
No	1.26 (0.65-2.45)	1.35 (0.63-2.87)
Yes	1	1
Socioeconomic position		
Low	**2.20 (1.17-4.15)**	1.44 (0.70-2.96)
Intermediate/High	**1**	1
Depression		
No	1	1
Yes	0.95 (0.44-2.03)	1.08 (0.47-2.49)
Migraine		
No	1	1
Yes	1.77 (0.79-3.97)	2.18 (0.90-5.27)
Asthma		
No	1	1
Yes	2.14 (0.94-4.86)	1.80 (0.72-4.49)
Obesity		
No	1	1
Yes	2.54 (0.94-6.87)	2.77 (0.95-8.03)
Regular smoking		
Neither in 2011 nor in 2015 *(former smokers)*	**1**	**1**
In 2011 and 2015	**13.06 (5.24-32.58)**	**3.91 (1.25-12.21)**
In 2011 only	**10.84 (3.59-32.69)**	**6.78 (1.93-23.74)**
In 2015 only	**7.32 (2.48-21.62)**	**8.50 (2.57-28.12)**
Cannabis use		
No	1	1
Yes	1.25 (0.65-2.39)	1.33 (0.61-2.90)
Perception of e-cigarettes		
Non positive	**1**	**1**
Positive	**4.43 (2.44-8.05)**	**4.38 (2.28-8.40)**

?tempo

Aljandaleh et al, Substance Use and Misuse, 2020

Co-use of e-cigarettes, tobacco and cannabis

(54.2%) of adults using e-cigarettes vaped nicotine only, 7.4% vaped cannabis only, 23.8% vaped nicotine and cannabis, and 14.6% vaped nonnicotine/non-cannabis e-liquid

Table 2
Multivariable Multinomial Logistic Regression Models of Associations Between Sociodemographic Characteristics and Proportions of Nicotine and Cannabis Vaping Among Adults Who Currently Use Electronic Vapor Products (EVPs) (n = 3795).

	Proportions of Nicotine and Cannabis Vaping[a]					
	Cannabis Only		Nicotine & Cannabis		Non-Nicotine/Non-Cannabis E-liquid	
Sociodemographic Characteristics	AOR[b]	95% CI	AOR[b]	95% CI	AOR[b]	95% CI
Sex						
Female	1.11	0.75, 1.65	0.72	0.57, 0.92	1.04	0.79, 1.37
Male	REF		REF		REF	
Age group						
18–24	**3.19**	**1.89, 5.39**	**3.13**	**2.46, 3.98**	**3.18**	**2.50, 4.01**
25–34	1.30	0.74, 2.27	**2.08**	**1.63, 2.65**	1.20	0.84, 1.71
35+	REF		REF		REF	
Race/ethnicity						
Hispanic	**3.73**	**2.47, 5.61**	**1.50**	**1.11, 2.01**	**3.11**	**2.24, 4.33**
NH White	REF		REF		REF	
NH Black	**2.59**	**1.55, 4.31**	0.99	0.67, 1.45	**3.23**	**2.34, 4.46**
NH Other	1.38	0.67, 2.85	1.29	0.80, 2.07	1.50	0.94, 2.40
Sexual orientation						
Heterosexual	REF		REF		REF	
Lesbian, gay, or bisexual+	1.18	0.70, 1.98	**1.51**	**1.12, 2.04**	0.89	0.63, 1.26
Highest educational attainment						
High school or less	0.70	0.50, 1.00	**0.80**	**0.65, 0.98**	0.97	0.77, 1.23
Some college or more	REF		REF		REF	
Annual household income						
<$50,000	0.80	0.54, 1.19	1.07	0.87, 1.31	1.22	0.91, 1.65
$50,000+	REF		REF		REF	

Data come from Wave 4 of the Population Assessment of Tobacco and Health (PATH) Study.
Bold values denote statistical significance ($p < 0.05$). AOR: adjusted odds ratio.
[a] The outcome referent group: vaping nicotine only.
[b] Odds ratios and 95% confidence intervals were adjusted for all sociodemographic characteristics.

Mattingly et al, Preventive Medicine Reports, 2022

Variety of models, uses..

Thoughts for the future

E-cigarettes are already used for smoking cessation

- An estimated 15% of smokers attempt to quit
- Among recent quitters:
  - 69.1% use no aid/ medical advice
  - 14.8% use an electronic cigarette
  - 11.7% use nicotine replacement therapy (NRT)
  - 2.8% use both an electronic cigarette and (NRT)

~4% daily use

marginal

Guignard et al, Bulletin Epidémiologique Hebdomadaire, 2018

Interventions integrating e-cigarettes

- STOP

A personalized intervention with free access to NRT and electronic cigarettes for persons who smoke and experience disadvantage: multicentric RCT (PI. Fabienne El Khoury-Lesueur, INCA)

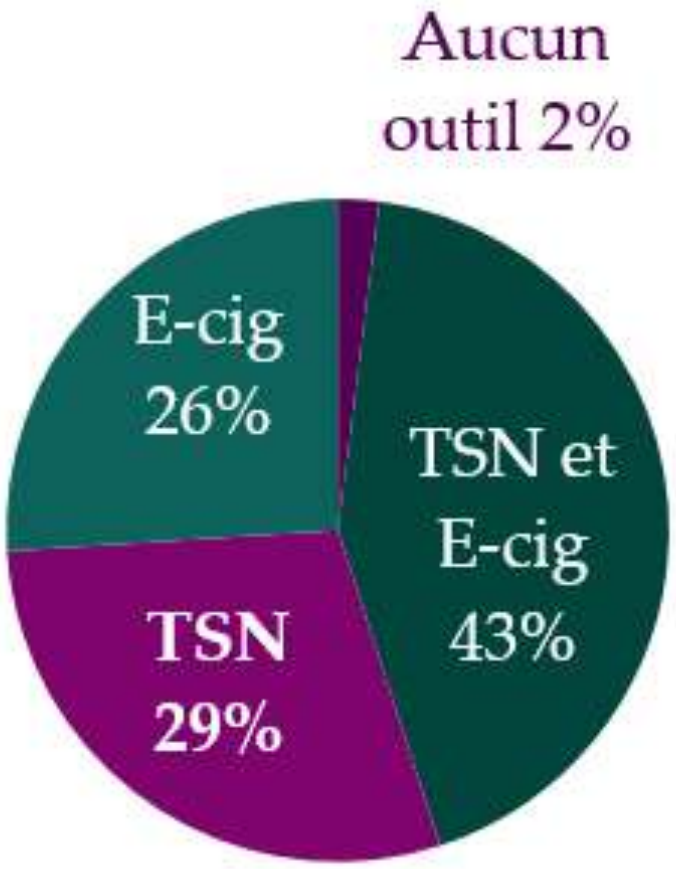
- 520 participants, 16 recruitment centers (GPs, addiction specialists), 6 months follow-up
- Quantitative assessment, qualitative interviews, process evaluation, economic analyses




Participating centres (primary care, ambulatory addiction treatment)

16 active recruitment centres

Results of the STOP pilot study



T0 : Inclusion — 49

Average n cigarettes smoked/day: 19.2 (sd=11)

T0 + 7 - 10 days — 37

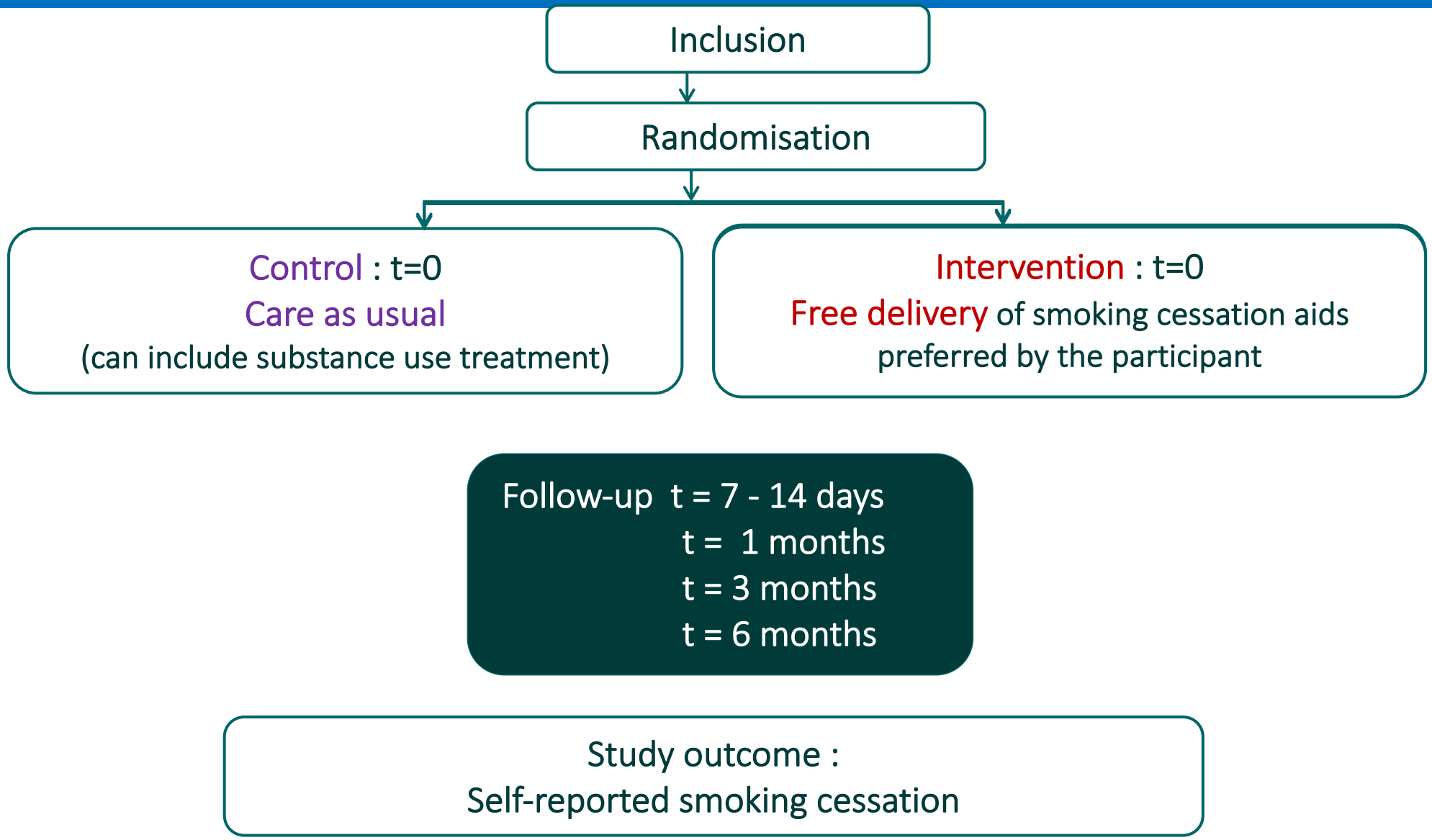
Reduction in tobacco use: N=22 (7.7, sd=7)
Cessation : N=12
Unchanged tobacco status: N=3

T0 + 4 - 6 weeks — 24

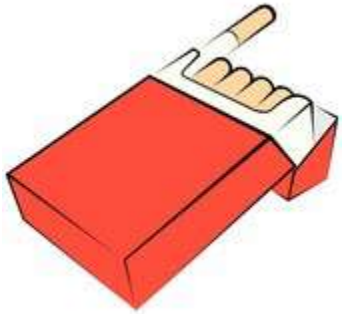
Reduction in tobacco use: N=10 (10.3, sd=5)
Cessation: N=13
Unchanged tobacco status: N=1

Héron et al, Addiction Science and Clinical Practice, 2018

STOP intervention study design



Inclusion criteria

-  ≥18 years
- 

  ≥ 5 cigarettes/day
  - willingness to quit smoking,
  - or reduce level of smoking,
- Low socio- economic position
- Aim: 520 participants

Results expected in 2024

RÉPUBLIQUE FRANÇAISE
Liberté Égalité Fraternité

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Thank you for your attention

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