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Menthol versus non-menthol flavouring and switching to e-cigarettes in black and Latinx adult menthol combustible cigarette smokers: secondary analyses from a randomised clinical trial

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Abstract

Background—As the US Food and Drug Administration takes regulatory action on menthol cigarettes, debate continues about how restricting menthol e-liquids might impact adult menthol smokers in switching to e-cigarettes.

Methods—Switching patterns and e-cigarette acceptability were assessed at week 6 among 64 black and Latinx menthol cigarette smokers who used JUUL menthol (n=39) or non-menthol e-cigarettes (n=25), primarily mint or mango) as part of a randomised switching trial.

Results—No clear evidence of effects was found between menthol versus non-menthol e-cigarettes on use or subjective effects/acceptability, effect sizes for all comparisons were small

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Trial registration number [NCT03511001](https://clinicaltrials.gov/ct2/show/study/NCT03511001).

Competing interests JA received sponsored funds for travel expenses as a speaker for the 2021 annual GTNF conference. He also serves as a consultant, and has equity, in a start-up company Respira Technologies.

Patient consent for publication Obtained.

Ethics approval This study involves human participants and was approved by the Institutional Review Board at California State University San Marcos (1119341-13) and University of Kansas School of Medicine (STUDY00141776). Written consent was used.

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(effect size=0.0–0.2), and Bayes factor ranged from 0.10 to 0.15. Specifically, 82.1% of participants who used menthol-flavoured e-cigarettes fully or partially switched to e-cigarettes compared with 88.0% of participants who used a non-menthol (p=0.75). Further, both groups demonstrated substantial reductions in cigarettes per day (menthol e-cigarettes: -8.5 ± 10.4 vs non-menthol e-cigarettes: -8.8 ± 5.8 , p=0.87), comparable grams of e-liquid consumed (menthol e-cigarettes: 9.2 ± 9.8 g vs non-menthol e-cigarettes: 11.0 ± 11.0 g, p=0.47), and positive subjective effects, including ‘just right’ throat hit (menthol e-cigarettes: 70.7% vs non-menthol e-cigarettes: 66.7%, p=0.93) and flavour liking (menthol e-cigarettes: 75.6% vs non-menthol e-cigarettes: 66.7%, p=0.32).

Conclusions—Both menthol and non-menthol e-cigarettes were associated with high rates of use and acceptability among menthol smokers. Findings require confirmation in a fully powered non-inferiority or equivalence study but provide preliminary evidence to inform regulatory action on menthol e-cigarettes that could slow youth initiation without impacting black and Latinx menthol cigarette smokers interested in switching to e-cigarettes.

INTRODUCTION

Policies targeting menthol flavouring could positively impact public health.^{1–5} The US Food and Drug Administration’s (FDA) decision to advance the rule-making process to ban menthol cigarettes is a potentially important step toward closing the gap in tobacco-related disease and death disproportionately experienced by racial/ethnic minority smokers.^{6–8} Debate continues about whether comprehensive enforcement priorities inclusive of menthol e-liquids should be enacted. Proponents of a comprehensive flavour ban cite the role of flavouring in fuelling the youth vaping epidemic and assert that a ban on flavoured e-liquids would slow or eliminate youth initiation.^{9–12} For the adult smoker who cannot or is not ready to quit cigarettes, e-cigarettes have emerged as an effective harm reduction strategy.^{13–15} Opponents note concerns that removal of flavours would drive adult smokers who would otherwise switch to e-cigarettes for harm reduction to instead continue smoking combustible cigarettes that are, arguably, the more harmful way of obtaining nicotine.² Targeted tobacco industry marketing of menthol cigarettes has led to disproportionately higher rates of menthol cigarette use, especially among black adults.^{17–20} As a result, racial/ethnic minority smokers are more likely to seek a menthol substitute when switching to e-cigarettes.²¹ Opponents further worry that a ban on menthol e-cigarettes would lead to low rates of switching among predominantly black menthol smokers, disproportionately impacting racial/ethnic minority communities and widening tobacco-related health disparities.²² These empirical questions remain largely unanswered.

This secondary data analysis is, to our knowledge, the first to compare e-cigarette use and acceptability among black and Latinx menthol smokers who used their choice of menthol or non-menthol e-cigarettes (primarily mango or mint) for 6 weeks as part of an e-cigarette switching randomised clinical trial (RCT).²³ Based on observational studies in mostly non-Hispanic white non-menthol smokers,^{21 24–26} we tested under the assumption of the null hypothesis, meaning that no clear evidence would be found for an effect of switching from cigarettes to e-cigarettes, reduction in cigarettes per day (CPD), e-liquid consumption or

subjective effects of vaping (ie, acceptability) between participants who used menthol versus non-menthol e-cigarettes.

METHODS

This study is a secondary analysis of an RCT that was not prospectively designed to examine differences in outcome by e-cigarette flavour. Findings should be considered preliminary and hypothesis-generating. Parent study methods and procedures are described in detail elsewhere.¹³ In brief, eligible participants were black (n=92) or Latinx (n=94) adult (> 21 years) daily smokers who were interested in switching to e-cigarettes. Participants were excluded if they were e-cigarette users, primary users of non-cigarette tobacco products (eg, cigarillos) or had medical contraindications to e-cigarette use (eg, pregnant). Recruitment occurred from May 2018 through March 2019; follow-up was completed in May 2019. The study was approved by the Institutional Review Board at California State University San Marcos and University of Kansas School of Medicine. Written consent was used.

The study was conducted prior to the removal of JUUL mint and mango pods from the market. Participants were randomised 2:1 to 6 weeks of JUUL (5% nicotine) in their choice of mint, menthol, Virginia tobacco or mango pods, or 6 weeks smoking cigarettes as usual. Participants were given the opportunity to try each e-cigarette flavour before making their selection. Pods were allocated in the preferred flavour at baseline and week 2 at a rate of one pod per pack of baseline cigarettes. Used, partial and unused pods were returned at week 6 for weighing.

Measures

E-cigarette flavour was based on participants' choice of e-liquid. Menthol e-cigarette users selected menthol pods at baseline and week 2. Non-menthol e-cigarette users selected mint, mango or Virginia tobacco pods at baseline or week 2.

Switching patterns (ie, exclusive e-cigarette, dual cigarette–e-cigarette, exclusive cigarette use) were based on the Timeline Follow Back Interview (TFLB) of the number of cigarettes and e-cigarettes used each day over the previous 7 days at week 6, confirmed with carbon monoxide in self-reported exclusive e-cigarette users.^{27–29}

Change in CPD from baseline to week 6 was based on the 7-day TFLB.^{27–29}

Total grams of study e-liquid consumed was derived from pods that were weighed prior to their distribution and then upon return.

Rate of substitution represents the proportion of total consumption coming from e-cigarettes at week 6 and was calculated by dividing the total grams of e-liquid consumed in the past 7 days by the sum of total cigarette and e-cigarette consumption (e-cigarette/cigarettes+e-cigarettes).³⁰

Subjective effects of vaping/acceptability was measured at baseline after sampling e-cigarettes using the 12-item Modified Cigarette Evaluation Scale adapted for e-cigarettes.^{31–32} Two additional items assessed throat hit and flavour liking.³³

Demographic and tobacco use history variables were assessed at baseline.

Statistical analyses

The impact of menthol and non-menthol flavouring on switching from cigarettes to e-cigarettes, reduction in CPD, rate of substitution, grams of e-liquid consumed, and subjective effects of vaping were compared at week 6 using X^2 test for categorical and two-sided t-tests for continuous measures. Effect sizes were calculated with Cramer's V for categorical variables and Hedge's g for continuous variables. For continuous outcomes, Bayes factor was also computed to examine strength of evidence for the null versus the alternative hypothesis.³⁴ Analyses were repeated comparing the outcomes by menthol, tobacco and mint/mango e-cigarette flavouring using analysis of variance for continuous variables and X^2 for categorical variables. These analyses can be found in online supplemental materials given space limitations of a brief report and the small proportion of non-menthol e-cigarette users selecting tobacco.

RESULTS

Of the 122 smokers (62 black, 60 Latinx) randomised to e-cigarettes, 68 (55.6%) were menthol cigarette smokers, 64 of whom returned at week 6, representing the final analytical sample. The majority were black (50 of 64, 78.1%), 51.5% female with a mean age of 45.4 years (SD=12.5), 47.0% were unemployed or unable to work, and 79.1% were at 200% Federal Poverty Level (FPL). Participants smoked 12.0 (SD=7.7) CPD at baseline and had been smoking their current menthol cigarettes for 17.4 (SD=12.8) years. The four who did not return were younger (33.0 (SD=5.9) vs 46.2 (12.4), $p=0.01$) but otherwise did not differ from those who returned on race/ethnicity, gender, employment, FPL or smoking characteristics ($p>0.05$).

Menthol e-cigarettes were used throughout the duration of the study by 39 participants; 25 participants used non-menthol e-cigarettes (table 1). Among non-menthol users, mint was the most common flavour, followed by mango and Virginia tobacco.

There was no clear evidence of an effect of menthol versus non-menthol e-cigarette flavour on any of the outcomes of interest. Effect sizes were small for all comparisons (effect sizes=0.0–0.2) (table 1). The Bayes factor ranged from 0.098 to 0.148, indicating that the null hypothesis was 6.7–10.2 times more likely than the alternative hypothesis on the outcomes of interest. E-cigarette flavour was not significantly associated with switching pattern ($X^2(2, n=64)=0.57, p=0.75$); 82.1% of participants who used menthol-e-cigarettes fully or partially switched to e-cigarettes at week 6 compared with 88.0% of participants who used non-menthol e-cigarettes ($p=0.75$). Further, both groups demonstrated substantial reductions in CPD ($p=0.87$), a high rate of substitution ($p=0.98$), comparable e-liquid consumption ($p=0.47$), and positive subjective effects, including 'just right' throat hit ($p=0.93$) and 'just right' flavour liking ($p=0.32$). The same trends were found for analyses comparing menthol, tobacco, and mint or mango e-cigarettes (see online supplemental table 1).

DISCUSSION

To our knowledge, this is the first study to compare menthol versus non-menthol e-liquid choice on switching patterns, e-cigarette use, and acceptability among black and Latinx menthol cigarette smokers interested in switching. No clear evidence of effects was found in switching from tobacco cigarettes to e-cigarettes, reduction in CPD, rate of substitution of cigarettes for e-cigarettes, e-liquid consumption or subjective effects of vaping between those who used menthol versus non-menthol e-cigarettes. Importantly, both menthol and non-menthol e-cigarettes led to high rates of biochemically verified exclusive e-cigarette use, substantial reduction in CPD and comparable grams of e-liquid consumed.

Findings build on a growing body of evidence from cross-sectional and longitudinal cohort studies of predominantly non-Hispanic white, non-menthol smokers suggesting that nicotine—not flavour—drives use in adults who currently use e-cigarettes. Specifically, across Population Assessment of Tobacco and Health Study, the International Tobacco Control (ITC) Four Country Smoking and Vaping Survey, and a large longitudinal cohort study of adult smokers using JUUL, no differences have been found between pod flavour and rate of switching, reduction in CPD, plans to quit or making a recent attempt to quit cigarettes after accounting for factors known to impact e-cigarette use (eg, device type, vaping frequency, age, sex, race/ethnicity).^{21 25 26 35 36} Another study by Yingst *et al* examined response to the removal of mint, mango, crème, fruit, and cucumber e-liquids in adult JUUL users and found that removal of these popular flavours did not impact overall e-cigarette use.³⁷ Rather, smokers perceived the shift to Virginia tobacco or menthol as relatively easy and cited nicotine, not flavour, as the driver of their continued use. Findings are consistent with data suggesting that, while menthol smokers prefer menthol e-cigarettes, less than one-fourth use menthol e-cigarettes exclusively.³⁸ Combined findings from the literature and the current study appear to indicate that factors other than flavouring are the primary drivers of switching in adult e-cigarette users.

Findings cannot be generalised to non-menthol cigarette smokers or smokers of other races/ethnicities. Further, the sample was primarily black menthol smokers so care should be taken to not overgeneralise results to Latinx menthol smokers. The parent RCT was not prospectively designed to examine the impact of e-cigarette flavouring on switching and the sample size for the current study was small; however, effect size and Bayes factor for all comparisons were small, indicating that flavouring had no clear evidence of impact on the outcomes of interest independent of sample size. Participants were not randomised to e-cigarette flavouring, although allowing participants to choose their preferred flavour represents ‘real-world’ behaviour. The study was conducted prior to the removal of mango, crème, fruit, cucumber and mint JUUL pods from the market, and the subsample of those selecting Virginia tobacco was too small to conduct meaningful comparisons that reflect the current regulatory environment for closed system e-cigarettes. A prospectively designed RCT directly comparing tobacco versus menthol e-cigarettes is underway ([NCT05023096](#)) and will be critically important as FDA contemplates further regulatory action on flavoured e-cigarettes. Finally, very few participants chose tobacco-flavoured e-cigarettes. Findings might be negated if a comprehensive ban on flavoured e-liquids inclusive of menthol dissuaded menthol smokers from being willing to initiate e-cigarette use altogether if

tobacco is the only flavour option available. This possibility has been suggested in ‘hypothetical choice’ experiments but has not been confirmed with ‘real-world’ behaviour.³⁹

In conclusion, both menthol and non-menthol e-cigarettes led to high rates of switching, positive subjective effects, and comparable grams of e-liquid consumed in black and Latinx menthol smokers who used their choice of menthol or non-menthol e-cigarettes for 6 weeks as part of an e-cigarette switching RCT. Findings require confirmation in a fully powered and prospectively designed non-inferiority or equivalence study but provide preliminary data to inform regulatory action on menthol e-cigarettes that could slow youth and young adult initiation without impacting black and Latinx menthol cigarette smokers interested in transitioning to e-cigarettes.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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What this paper adds

What is already known on this subject

- Racial/ethnic minority smokers, especially black people, are more likely to use menthol flavouring when switching to e-cigarettes.

What important gaps in knowledge exist on this topic

- As the US Food and Drug Administration considers regulatory action inclusive of menthol-flavoured e-liquids, debate continues about whether a ban on menthol e-cigarettes could lead to low rates of switching in these groups, disproportionately impacting racial/ethnic minority communities, and widening tobacco-related health disparities.
- This secondary data analysis is, to our knowledge, the first to compare e-cigarette use and acceptability among black and Latinx menthol smokers who used their choice of menthol or non-menthol flavouring (primarily mint or mango) while switching to e-cigarettes.

What this study adds

- No clear evidence of effects was found for any of the outcomes of interest. Use of both menthol and non-menthol e-cigarettes led to high rates of switching, reduction in cigarettes per day, acceptability and comparable e-liquid consumption.
- Findings require confirmation in a fully powered non-inferiority or equivalence study but provide preliminary data to inform regulatory action on menthol e-cigarettes that could slow youth and young adult initiation with no resulting negative impact in black and Latinx adult menthol cigarette smokers interested in switching to e-cigarettes.

Smoking outcomes among black and Latinx adult menthol smokers who used menthol versus non-menthol-flavoured e-cigarettes for switching

Table 1

Measure	Menthol e-cigarettes (n=39)	Non-menthol e-cigarettes (n=25)	P value	Effect size*	Bayes factors
Rate of switching [‡] , n (%)					
Exclusive e-cigarettes	10 (25.6)	8 (32.0)	0.75	0.09	NA
Dual cigarettes—e-cigarettes	22 (56.4)	14 (56.0)			
Exclusive cigarettes (no e-cigarettes)	7 (17.9)	3 (12.0)			
CPD reduction from baseline, mean (SD) [‡]	-8.5 (10.4)	-8.8 (5.8)	0.87	0.03	0.10
CPD at week 6, mean (SD)	3.6 (5.3)	2.9 (3.6)	0.55	0.15	0.11
E-cigarette product use, grams, mean (SD) [§]	9.2 (9.8)	11.0 (11.0)	0.49	0.18	0.12
Rate of substitution, mean (SD) [¶]	72.7% (34.7%)	73.0% (37.9%)	0.98	0.01	0.10
Subjective effects of vaping, mean (SD)**					
Total	4.6 (1.4)	4.6 (1.3)	0.86	0.00	0.10
Subscale 1: vaping satisfaction	5.0 (1.3)	5.2 (1.5)	0.56	0.14	0.12
Subscale 2: psychological reward	4.3 (1.8)	3.9 (1.8)	0.35	0.22	0.15
Throat hit, n (%)					
Too harsh	9 (23.1)	7 (25.9)	0.93	0.04	NA
Not light	3 (7.7)	2 (7.4)			
Just right	27 (69.2)	18 (66.7)			
Flavour, n (%)					
Wish it was sweeter	9 (23.1)	6 (22.2)	0.32	0.10	NA
Wish it was less sweet	1 (2.6)	3 (11.1)			
Just right	29 (74.4)	18 (66.7)			

* Calculated with Cramer's V for categorical variables and Hedge's g for continuous variables.

[‡] *Exclusive e-cigarette use* was defined as any use of e-cigarettes, no use of cigarettes, confirmed with exhaled carbon monoxide (CO) <6 ppm. *Dual use* was defined as concurrent self-reported use of cigarettes and e-cigarettes. Those who reported exclusive e-cigarette use but who had a CO of 6 ppm (determined a priori) were also classified as dual users.¹⁴ *Exclusive cigarette use* was defined as no use of e-cigarettes and only use of cigarettes in the past 7 days.

[¶] CPD did not differ at baseline in the menthol e-cigarette (12.1±8.8) or non-menthol e-cigarette groups (11.9±5.8) (p=0.96).

[§] Represented as the grams of e-liquid consumed over the 6-week study period (one pod=0.57 g).

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Represents the proportion of consumption derived from e-cigarettes. Calculated by dividing the total amount of e-liquid consumed in the past 7 days at week 6, derived by taking the weight of returned JUUL pods and converting grams of e-liquid into cigarette equivalents (one pod=0.57 g and is equivalent to 20 cigarettes) and dividing by the sum of total cigarette and e-cigarette consumption (e-cigarette/cigarette+e-cigarette). A proportion of 73%, for example, means that 73% of total tobacco consumption at week 6 was from e-cigarettes.

** Measured at baseline (n=68) after trying e-cigarettes. Range is from 1 to 7 with higher scores indicating greater (ie, more satisfying) subjective effects.

CPD, cigarettes per day; NA, Not Applicable.