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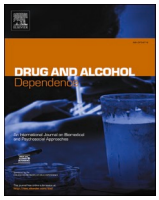

Short communication

Effect of menthol/mint-flavored pods on young JUUL E-cigarette users' subjective experience, puffing behavior, and nicotine exposure: A pilot study

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ABSTRACT

Background: Recent regulations have banned all flavors except menthol/mint and classic tobacco from pod-based e-cigarette devices such as JUUL. However, menthol/mint flavor can present a potential risk given its increasing popularity among young people in the US and its puffing and nicotine-enhancing properties. This study examines the impact of menthol/mint flavor manipulation on users' puffing behavior, subjective experience, and nicotine exposure among young people.

Methods: JUUL users (n = 33, 18–24 years) attended two 60-min ad libitum e-cigarette use sessions (menthol/mint flavor vs. classic tobacco flavor) in a cross-over design. Puff topography and plasma nicotine concentration were measured, and participants completed subjective experience questionnaires.

Results: Following the use of the menthol/mint-flavored pod, increases were observed in measures of satisfaction, pleasurable/interest to use, willingness to use again, enjoyment, urge to vape, product appeal, taste, and concentration ($p < .05$ for all). For example, compared to the classic tobacco flavor, participants experienced significantly more satisfaction of the product (4.24 vs. 3.09; $p = .001$) and sensation enjoyment of the product (3.55 vs. 2.48; $p = .002$) when using the menthol/mint flavor. While means of the plasma nicotine boost and puff parameters were lower in the classic tobacco condition compared to the menthol/mint flavor condition, no statistical significance was observed between the two conditions ($p > .05$ for all).

Conclusions: Results of this pilot study suggest that menthol/mint-flavor increases e-cigarette users' subjective experience significantly. Regulating menthol/mint flavor is a potentially promising strategy to curb e-cigarette use among young people.

1. Introduction

Electronic cigarettes (e-cigarettes) are now the leading tobacco products among young people in the United States (US), where about 20 % of high school students (in 2020) and 8 % of young adults (18–24 years) (in 2018) were current e-cigarette users (Wang et al., 2020; Dai and Leventhal, 2019). Described by former Food and Drug Administration (FDA) commissioner as "nothing short of an epidemic proportion of growth" United States Food and Drug Administration (2018, 2020), this epidemic is propagated by e-cigarettes' appealing design, flavors, and social media marketing.

Flavor is a major factor in attracting young people to e-cigarettes. In 2020, among current e-cigarette users, around 85 % of high school students and 72 % of middle school students reported using flavored e-cigarettes in the US (Wang et al., 2021). Furthermore, evidence shows that youths perceived flavored e-cigarettes as less harmful than tobacco-flavored e-cigarettes (Pepper et al., 2016) and flavored e-cigarette use was associated with increased risks of combustible tobacco use

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(Chen et al., 2017; Dai and Hao, 2016). Therefore, FDA (in 2020) limited flavors of cartridge-based products to menthol and tobacco to reduce the spread of e-cigarettes among young people (US Food and Drug Administration, 2020). Given the recentness of the FDA directive on flavors of cartridge-based products, robust population data about the effect of such policy on e-cigarette use are still unavailable. However, sales data show that menthol-flavored e-cigarettes rose in 2020 to account for more than half of total e-cigarette sales (Diaz et al., 2021).

Mint is the herb plant that produces menthol while menthol is the aromatic organic compound responsible for the sweet and spicy flavor of mint (Truth initiative, 2022). Both are likely to cause similar stimulation of the cold receptors in the respiratory tract, which is the most relevant property related to their effects on e-cigarette users (Truth initiative, 2022). Furthermore, menthol flavor dampens the harshness of tobacco emissions and the irritation caused by nicotine and increases the likelihood of addiction in young people (Wickham, 2020; Azagba et al., 2020). Menthol's sensory effects facilitate deeper inhalation and thus, can enhance nicotine impact and dependence, as well as exposure to other toxicants (Wickham, 2020). Accumulating evidence shows that flavor plays a vital role on various subjective (e.g., satisfaction, harm perception, intention to quit) and objective outcomes (e.g., nicotine exposure, puff topography) related to e-cigarette use (Meernik et al., 2019; Voos et al., 2020; Vargas-Rivera et al., 2020). For example, recent laboratory work suggests that flavors enhance users' experience, product appeal, and motivation to vape in the future (Vargas-Rivera et al., 2020). This study aims to look at the role of menthol/mint flavors on young people's satisfaction, nicotine, and puffing behavior.

2. Methods

2.1. Study design and procedures

JUUL-a small, USB flash drive shaped device, was the most popular e-cigarette product among young adults at the time of this study (early 2019) (Herzog and Kanada, 2019). Therefore, thirty-three current (past 30-day) JUUL users (18–24 years old) were recruited via flyers and word-of-mouth from the Florida International University campus-a large public university in Miami, and all provided informed consent for this IRB-approved study. Subsequently, they attended two ~2-h lab sessions that involved 60-min of JUUL use ad libitum and differed by the flavor condition (menthol/mint vs. classic tobacco, 5 % of nicotine strength in both). For the flavored condition, participants were asked to select the preferred flavor, and this study sample included those who reported menthol or mint. Around half of the participants (n = 16) were randomly assigned to either menthol or mint flavor in the first session. Sessions were counterbalanced and separated by a 48-h washout period to avoid carryover effects between conditions and preceded by 12-h nicotine abstinence of all tobacco products validated by pre-session plasma nicotine levels ($\leq$ 5 ng/ml) (Vargas-Rivera et al., 2020; Li et al., 2021). Participants were excluded if they: (1) self-reported history of chronic health problems, psychiatric conditions, or regular use of prescription medications (other than vitamins or birth control); (2) current use of $>$ 5 cigarettes/month, other tobacco/nicotine products ($>$ 5 times/month) in the past year because substantial use of other tobacco/nicotine products can potentially bias the measurement of e-cigarette associated outcomes (e.g., dependence measures) (Hiler et al., 2017); or (3) were pregnant (assessed via urinalysis) or breastfeeding. Participants were compensated with a total of 150 USD at the end of the study.

2.2. Measures

Plasma nicotine boost was assessed by subtracting pre-session plasma nicotine concentration from post-session (Maziak et al., 2020). Blood (~10 ml) was drawn before and after the session at each lab visit. Blood samples were centrifuged, plasma was stored at −80 °C, and analyzed for nicotine concentration using the gas chromatography-mass spectrometry (GC-MS) (Jacob et al., 2000).

E-cigarette puff topography was assessed using a validated topography instrument adapted for JUUL pods (Shihadeh et al., 2005). Similar to our previous work (Vargas-Rivera et al., 2020; Li et al., 2021), the JUUL device was connected through an adapter to the puff topography instrument, which monitored and recorded the participant's puffing behavior throughout the lab session. The topography software converts signals to airflow (ml/s) and integrates the flow data, producing measures of total use time, total puff volume, puff duration, number, inter puff interval (IPI), numbers of puffs, total volume inhaled, and average puff volume (Shihadeh et al., 2005).

2.2.1. Subjective measures

A 10-item Visual Analog Scale (VAS) (Leavens et al., 2018) was used to measure the participants' perception of the product they used (e.g., pleasant, urge to vape, etc.) and rated on a (0 not at all to 100 extremely) scale. Eleven items (e.g., urges to vape, irritability/frustration/anger, etc.) were used to assess Minnesota Nicotine Withdrawal Scale (MNWS) (Hughes and Hatsukami, 1986) and the answers were rated on a (0 not at all to 100 extremely) scale. JUUL modified e-cigarette evaluation questionnaire (mCEQ) was measured by 11 items (e.g., "Did JUUL calm you down?") (Arger et al., 2017). The Duke Sensory Questionnaire (DSQ) with nine items (e.g., puff liking, puff satisfaction, etc.) in this study was adapted from previous cigarette literature (Pickworth et al., 2002) to evaluate the appeal and sensory experience of the inhaled JUUL. The answers of mCEQ and DSQ were all rated on a 7-point Likert scale (1 not at all to 7 extremely).

2.3. Data analysis

Plasma nicotine concentration values below the limit of quantitation were replaced with 1.0 ng/ml (Vargas-Rivera et al., 2020; Li et al., 2021). This approach is more conservative than assuming values below the LOQ were zero (Spindle et al., 2015). Descriptive statistics for the study sample's characteristics were summarized as proportions or means with standard deviations. For the outcomes, using two-tailed paired samples t-tests, means and standard deviations were compared by flavor sessions for puff topography. Means and standard errors of the post-session were compared by flavors for subjective measures. The differences (post-pre) of means and standard errors were compared by flavor sessions for plasma nicotine boost. All analyses were performed in SAS 9.4 version, and p-value$<$ .05 was considered statistically significant.

3. Results

Among a total number of 33 study participants, more than half of them were male (54.6 %) and Hispanic/Latino (78.8 %). The mean age of the participants was 21.0 years$\pm$ 1.6 years. Around half of them (48.5 %) reported mint flavor of JUUL e-cigarette was the first time they ever used. (Supplemental table 1).

In the flavored condition, 4 participants chose menthol flavor, and 29 participants used mint flavor. Although no statistical significance (p $>$ .05) was noticed between the two conditions, the mean (standard error) nicotine boost observed in the tobacco condition of 7.43 ng/ml (1.17) was lower than 9.39 ng/ml (1.32) in the menthol/mint condition. Eight participants were missing topography data for the classic tobacco flavor due to technical issues. Regarding puff topography, there was a consistent tendency toward higher values in the menthol/mint condition among most of the puffing parameters, although none of these comparisons were statistically significant (Supplemental table 2).

3.1. Subjective measures

Analysis revealed significantly lower mean scores ($p < .05$ for all) for the tobacco condition compared to the menthol/mint condition for 8 of

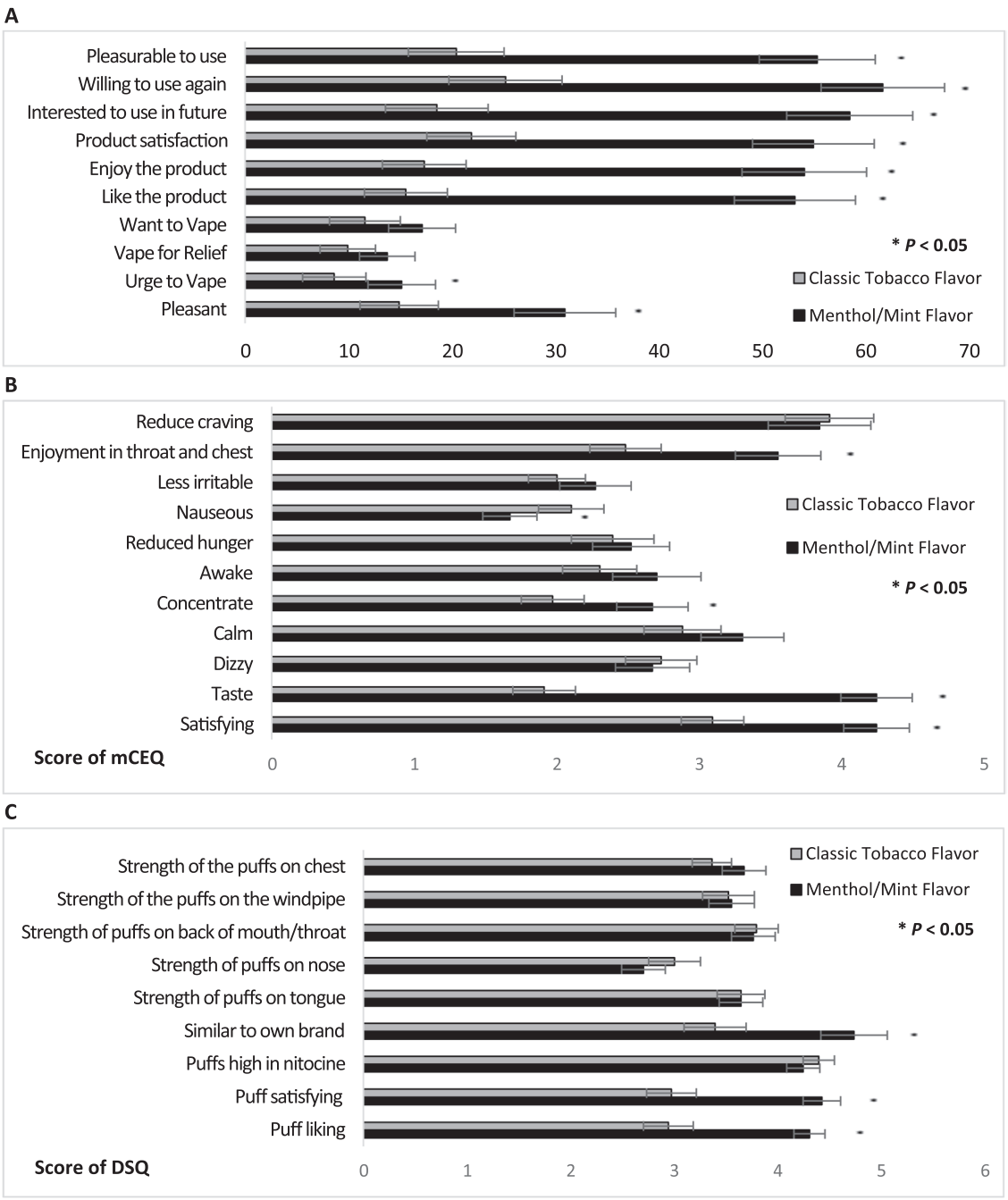

Fig. 1. Means (standard errors) for post-session of participant's response to 3 of the subjective measures by flavor condition (n = 33): Subjective measures presented as Visual Analog Scale (VAS) (panel A, 0 not at all to 100 extremely); JUUL modified cigarette evaluation questionnaire (mCEQ) (panel B, 1 not at all to 7 extremely); and JUUL Duke Sensory Questionnaire (DSQ) (panel C, 1 not at all to 7 extremely).

the 10 VAS items (Fig. 1A). Specifically, means (menthol/mint flavor vs. tobacco flavor) of VAS items for pleasurable to use (55.24 vs. 20.39; $p <$ .001), willing to use again (61.58 vs. 25.15; $p <$ .001), interested to use in the future (58.39 vs. 18.52; $p <$ .001), product satisfaction (54.88 vs. 21.85; $p <$ .001), product enjoyment (54.00 vs. 17.30; $p <$ .001), product liking (53.09 vs. 15.52; $p <$ .001), urge to vape (15.12 vs. 8.61; $p <$ .001), and pleasant (30.88 vs. 14.88; $p <$ .001) were significantly reduced in the tobacco condition compared to the menthol/mint condition. 5 lower mean scores of the 11 JUUL mCEQ items [satisfaction (4.24 vs. 3.09; $p =$ .001), taste (4.24 vs. 1.91; $p <$ .001), helping concentration (2.67 vs. 1.97; $p =$ .015), feeling nauseous (1.67 vs. 2.06; $p =$ .046) and sensation enjoyment (3.55 vs. 2.48; $p =$ .002)] were noticed in the classic tobacco flavor condition compared to the menthol/mint flavor condition (Fig. 1B). Additionally, significant mean differences in 3 of 9 items [puff liking (4.30 vs. 2.94; $p <$ .001), puff satisfaction (4.42 vs. 2.97; $p <$ .001) and similarity of product to their own brands (4.73 vs. 3.39; $p =$ .002)] between the two conditions were also found in the JUUL DSQ (Fig. 1C). For the JUUL MNWS, there were no significant differences between the two conditions ($p >$ .05 for all).

4. Discussion

This is the first cross-over clinical lab study to compare, in young e-cigarette users, the effects of menthol/mint- and tobacco-flavored JUUL e-cigarette aerosol on plasma nicotine concentration, puffing behavior, and subjective experience. While plasma nicotine boost and puff

topography measures showed a tendency for a difference across conditions, no statistically significant differences were observed on these measures. In contrast, menthol/mint produced greater ratings on a variety of subjective effect measures, including VAS items (e.g., product liking, product enjoyment, willingness to use and urge to use, etc.); the items from mCEQ (e.g., satisfaction, taste, and sensation enjoyment, etc.); and DSQ items (puff liking, puff satisfaction and similarity of product to their own brands). These latter results suggest that menthol/mint flavor may play a crucial role in appealing to young users for e-cigarette use, and regulating menthol/mint flavor is a potentially promising strategy to curb e-cigarette use among young people.

One of the potential implications from this study is to reduce US young e-cigarette users' access to menthol/mint-flavored e-liquids, which will substantially curtail the e-cigarette use and ultimately protect the population's health. Since menthol's effect on e-cigarette users can be multi-faceted, a comprehensive assessment of the pros and cons of regulating mentholated e-cigarette for different users is needed. For example, limiting menthol in e-cigarettes can affect cigarette smokers who prefer mentholated e-cigarette to help them quit or reduce their harm (Ashley et al., 2020). We approach this issue from a consumer rights and safety perspective, meaning that e-cigarette users are entitled to trustworthy information about the risk profile of different vaping products on the market. It is also consistent with the FDA's mandate to "ensure that the marketing of new tobacco products is appropriate for the protection of the public health" (US Food and Drug Administration, 2018).

Limitations of this study include a small sample size. Although this is a pilot study with a limited number of participants, it was able to demonstrate clear subjective and nicotine exposure differentials and consistent topography change patterns that make it informative despite this limitation. Also, because of a small sample size of the menthol and mint users, we had to combine them to conduct a meaningful analysis. However, this is not likely to introduce bias as these two flavors are very close in chemical properties as well as the effect on tobacco users (Truth initiative, 2022). Further, as these two flavors are also close to each other in terms of stimulating cold receptors in the respiratory tract and vaping experience, we wanted to test how e-cigarette users of these popular flavors would react to a market reality where the only flavor available is tobacco. This is of important regulatory implications because menthol is the only flavor allowed in the popular pre-filled cartridge e-cigarettes (e.g., JUUL), and many e-cigarette users with other flavor preferences migrated to menthol when other flavors were banned for pre-filled cartridge e-cigarettes (Diaz et al., 2021). Larger samples perhaps will be needed to assess the effect of the flavored condition on similar subjective outcomes as well as plasma nicotine and topography parameters in future studies. Additionally, a separation of menthol and mint flavor may help identify which flavor has a greater effect on the outcomes.

5. Conclusions

Our results reveal that menthol/mint flavors play a role in enhancing the use and addictiveness of e-cigarettes by young people. We suggest that limiting access to such flavors may be an effective regulatory strategy to curtail youth vaping. However, our results are preliminary and therefore more comprehensive studies of the short- and long-term effects of menthol/mint e-cigarettes on a variety of outcome measures are needed to inform policymakers who are tasked with ensuring that e-cigarettes are regulated appropriately to protect the targeted population's health.

Contributions

The authors gratefully acknowledge the participants and interviewers that are involved in this study. Author contributions are as follows: Mayra Vargas-Rivera, Thomas E. Eissenberg, Alan Shihadeh, Soha Talih, and Wasim Maziak: conceptualized the study concept, design, writing, review and editing. Wei Li and Mayra Vargas-Rivera guided data extraction, cleaning, analysis, and original draft writing. Wei Li, Mayra Vargas-Rivera, and Wasim Maziak collected and coded the data. Wasim Maziak supervised the study. All authors have approved the manuscript before submission.

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Disclaimer

The content is solely the responsibility of the authors and does not necessarily represent the views of the FIU-RCMI, the FDOH, the NIH or the FDA.

Ethics approval

This study was approved by Florida International University Institutional Review Board.

Declaration of Competing Interest

Dr. Eissenberg is a paid consultant in litigation against the tobacco industry and the electronic cigarette industry and is named on one patent for a device that measures the puffing behavior of electronic cigarette users, on another patent application for a smartphone app that determines electronic cigarette device and liquid characteristics, and a third patent application for a smoking cessation intervention.

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N/A.

Conflict of interest

The authors declare that they have no competing interests or conflicts.

Financial disclosure

No financial disclosures were reported by the authors of this paper.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.drugalcdep.2022.109516.

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