Substitutability of menthol cigarette alternatives: a clinical trial

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ABSTRACT

Introduction This study assessed the substitutability of plausible combustible menthol cigarette alternatives (MCAs) for usual brand menthol cigarettes (UBMCs) in adults who smoke menthol cigarettes.

Methods Following three in-lab sampling sessions, 80 adults aged 21–50 who smoke menthol cigarettes chose their preferred MCA: (1) a menthol roll-your-own cigarette (mRYO), (2) a menthol filtered little cigar (mFLC) or (3) a non-menthol cigarette (NMC). Participants were instructed to completely substitute their preferred MCA for their UBMC for 1 week and complete daily diaries documenting adherence and subjective effects. At the final lab visit, participants completed concurrent choice and cross-price elasticity tasks with their substitute product and UBMC as the comparator.

Results Most (65%) participants chose mRYO as their preferred product, followed by NMC and mFLC. Adherence to MCA was high for all products across the week (range: 63%–88%). Positive subjective effects for mRYO decreased over time but remained numerically higher than the other MCA products; craving reduction also decreased for NMC across phases. In the progressive ratio task, participants chose their UBMC in 61.7% of choices; this did not differ by preferred MCA, although the median breakpoint was highest for mRYO and similar for mFLC and NMC. Cross-price elasticity comparing UBMC and the preferred product indicated high substitutability of each MCA at phase 3 (I values −0.70 to −0.82).

Conclusions and relevance mRYOs were the most preferred MCA among the study products, but all MCAs were acceptable substitutes for UBMC using behavioural and economic measures in a short-term trial period.

Trial registration number NCT04844762.

INTRODUCTION

With a proposed product standard to ban menthol cigarettes issued by the U.S. Food and Drug Administration (FDA) in May 2022,1 two states banning the sale of menthol cigarettes since 2020 (California, Massachusetts) and local bans on menthol cigarette sales enacted in six other states in the USA,2 tobacco companies have taken more aggressive measures to counter or delay these public health policies, including litigation3 and disinformation.45 In California, where the most recent state-level menthol cigarette ban has been implemented, companies have begun direct-to-consumer marketing of novel cigarette products with ‘fresh’ and ‘crisp’ descriptors and ingredients that include synthetic cooling agents.6 These tactics underscore the importance of menthol cigarettes to company profits, as evidenced by the stability of menthol cigarette consumption amid significant declines in non-menthol cigarette (NMC) consumption in the USA over the past 20 years.78

Mechanisms by which menthol cigarettes influence the initiation and maintenance of cigarette smoking have been outlined in reviews of tobacco industry documents9–11 and confirmed in independent research. First, menthol’s cooling and analgesic properties mask the harshness and taste of cigarette smoke, making it more appealing.12 Second, menthol’s refreshing sensory qualities increase the degree of nicotine metabolism, causing greater systemic exposure to nicotine.13 14 Third, menthol inhibits nicotine metabolism, causing greater systemic exposure to nicotine.15 Fourth, menthol may change puff topography, causing people who smoke to take more puffs.12 Marketing of menthol cigarettes16 17 has also dramatically shaped use patterns in the USA18–20 and the persistence of menthol use in young adults who smoke cigarettes.21 22

WHAT IS ALREADY KNOWN ON THIS TOPIC

Menthol cigarette consumption has been stable in the USA over the past 20 years amid significant declines in non-menthol cigarette consumption.

Given the importance of menthol cigarettes to company profits, tobacco companies have taken aggressive measures to counter or delay menthol cigarette bans, most recently marketing menthol cigarette alternatives to their consumers.

WHAT THIS STUDY ADDS

In an observational study including ecological momentary assessment, measures of subjective effects and behavioural economic measures, three combustible menthol cigarette alternative products currently available on the market demonstrated substitutability for usual brand menthol cigarettes.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

To maximise the benefits of a menthol cigarette ban, restrictions should extend to plausible substitutes, particularly menthol pipe tobacco and cigarette tubes that can be used to create roll-your-own cigarettes and are not covered in existing policies.

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to company profits is industry evidence that people who smoke menthol cigarettes prefer their own brand among other menthol brands.\textsuperscript{11,12} In several studies, quitting smoking, switching to NMCs and switching to other menthol nicotine or tobacco products were identified as potential responses to hypothetical menthol cigarette bans.\textsuperscript{23}

In addition to novel products that might be introduced to mitigate profit losses in the face of menthol cigarette bans,\textsuperscript{6} menthol filtered little cigars (mFLCs), menthol pipe tobacco and cigarette tubes for menthol roll-your-own cigarettes (mRYO), and NMCs are potential menthol cigarette substitutes that tobacco companies could promote.\textsuperscript{24} Neither mRYO nor NMC will be affected by the proposed FDA ban on menthol cigarettes and flavoured cigars. Our prior publication in 98 adults who smoked menthol cigarettes and completed a four-session randomised crossover lab study found that each of these menthol cigarette alternatives (MCAs; ie, mFLC, mRYO and NMC) significantly reduced nicotine craving and withdrawal symptoms, but the combination of mentholated pipe tobacco and tubes in an mRYO resulted in the highest behavioural economic demand and positive subjective experience.\textsuperscript{25} The goal of the current study was to assess the substitutability of these three combustible MCAs in the same sample during an extended observation phase. Consistent with an established framework for abuse liability assessment,\textsuperscript{26} we assessed substitutability using measures of product adherence, craving and withdrawal during self-administration, changes in subjective effects, hypothetical purchase tasks, and a concurrent choice self-administration task. We had three a priori hypotheses: (1) a significantly higher portion of product preference selections will favour NMCs than all other alternatives; (2) participants’ use of MCAs will significantly increase over the 1-week substitution period; and (3) under simulated conditions of a ban on menthol cigarettes, more than 80% of participants will substitute at least 50% of their usual brand menthol cigarette (UBMC) use with the study product.

METHODS

Setting and participants

Participants were 80 adults who currently smoked menthol cigarettes recruited in the Columbus, Ohio metropolitan area from the general community via internet advertisements, flyers and word-of-mouth advertising from January 2020 to August 2021. This sample size provided 81% power to estimate 80% use of the preferred MCA more than half the time during phase 2 with a 95% CI of 66% to 94%.

Potential participants were screened for eligibility via an online questionnaire and then over the telephone. Eligibility criteria included (1) current menthol cigarette use (>90% menthol cigarette use; ≥5 cigarettes per day) for at least the past 6 months; (2) between 21 and 50 years old; (3) willing to abstain from tobacco, nicotine and marijuana use for at least 12 hours prior to each of the study visits; and (4) read and speak English. Exclusion criteria included (1) self-reported diagnosis of lung disease; (2) cardiac event or distress within the past 3 months; (3) pregnancy, breast feeding or planning to become pregnant; (4) use of other tobacco products (eg, electronic cigarette, cigar) >5 days in the past month; (5) currently using one of the study products; (6) any reported use of illicit drugs (other than marijuana) during the last 30 days; and (7) currently engaging in smoking cessation treatment. This study was registered on ClinicalTrials.gov (NCT04844762). All participants provided written informed consent. Findings from phase 1 are reported elsewhere, with the full study protocol provided in the online supplemental materials\textsuperscript{25}; in this publication the results of phase 2 and phase 3 in this publication.

Procedures

Using an in-laboratory and outpatient mixed design, participants completed a three-phase study lasting approximately 3 weeks. In phase 1, participants completed four smoking session visits, smoking their UBMC during the first visit and randomised to one of the three MCAs at each subsequent visit. They also completed daily assessments of their UBMC use behaviour via ecological momentary assessment (EMA). This phase used multiple methods of assessing addiction potential in a lab-based setting, including an acute dose–effect comparison study, drug self-administration, suppression of craving and withdrawal, behavioural economics, and forced choice of their preferred MCA; phase 1 results have been published elsewhere, including lab characterisations of each of the MCA products.\textsuperscript{23}

During phase 2, participants were provided their most preferred MCA at no cost in standardised packaging (online supplemental figure S1) and instructed to completely switch and exclusively use the MCA during the 1-week trial period. During this period, participants completed evening daily diaries via EMA. Daily diary measures included the number of study products smoked, number of non-study tobacco products used (including UBMC), current smoking urges/craving using the Tiffany-Drobes Questionnaire of Smoking Urges: Brief Form (QSU)\textsuperscript{27} and current nicotine withdrawal using the 15-item version of the Minnesota Nicotine Withdrawal Scale (MNWS).\textsuperscript{28} Each QSU subscale (desire and relief) is composed of the sum of five separate items, each scored from 1 (strongly disagree) to 7 (strongly agree); the MNWS is the mean of seven items, with scores ranging from 1 to 5.

At the end of the week, participants returned to the lab for a study visit (phase 3), where they completed a 90 min concurrent choice self-administration task with differential cost (ie, response effort) required to earn two puffs from their UBMC versus their preferred MCA, which remained at a fixed rate (10 clicks per two puffs). To earn two puffs of the UBMC, the concurrent choice task escalated response requirements (computer mouse clicks) on the following progressive ratio schedule: 10, 160, 320, 640, 1280, 2400, 3600, 4800, 6000, 7200 and 8400. A maximum of 10 reinforcers (20 puffs) per session were allowed. The proportion of reinforcers earned is considered to provide an index of the strength of the reinforcing effects of the product.\textsuperscript{29} Participants were informed of the differential response requirements between products and instructed that the session was 90 min long, no matter how much or how little they responded. Breakpoint was calculated as the highest value completed for UBMC.

Following completion of the concurrent choice task, participants completed an adapted version of the Drug Effects/Liking Questionnaire,\textsuperscript{30} modified Cigarette Evaluation Questionnaire (mCEQ) to assess subjective responses to cigarettes (eg, reward, satisfaction),\textsuperscript{31,32} and behavioural intentions to ‘try this product again’, ‘purchase this product for personal use’ and ‘use this product regularly’ if menthol cigarettes were no longer available to be purchased. Due to small cell sizes, behavioural intention responses were dichotomised as extremely unlikely/unlikely/neutral versus likely/extremely likely for analysis. Participants also completed\textsuperscript{33,34} a cross-price elasticity (CPE) task to estimate the substitutability of the preferred MCA for the UBMC.\textsuperscript{35,36} Substitutability was quantified as the linear slope for the consumption curve of the alternative product, with substitutability indicated by a positive slope. A crossover price, or the point
at which the adjusting amount curve and the substitute curve cross, indicating the price at which the two options are valued approximately equally, was also calculated by determining when the percentage of UBMC cigarettes switched from more than 50% of the total cigarettes purchased to less than 50%. The following demand indices were also calculated: intensity (ie, the number of products consumed when free), breakpoint (ie, the last price consumption was greater than 0) and alpha (ie, change in elasticity).

Statistical methods
Differences in demographic and tobacco use characteristics between participants who selected each of the three products were evaluated with analysis of variance (ANOVA), Kruskal-Wallis tests or Fisher exact tests, as appropriate. The change in subjective effects and mCEQ between phase 1 (product visit) and phase 3 (visit 5) was assessed with repeated measures ANOVA, while logistic regression models, accounting for repeated measures within individuals, were fit to assess the difference in behavioural intentions between the three visits; the probability of a likely/extremely likely response was modelled. Detailed methods on behavioural economic measures and analysis are provided in the online supplemental materials. CPE for each study product compared with UBMC of >0.2 indicates substitution, CPE <−0.2 indicates complementarity, and CPE between −0.2 and 0.2 indicates independence of the two products.37 Linear mixed effects models adjusting for sex and baseline UBMC use, defined as the average number of UBMC used daily as reported during the phase 1 daily diary period, were employed to evaluate the trends in the number of chosen MCAs used each day over the phase 2 daily diary period. For QSU desire, QSU relief and MNWS trends over the phase 2 daily diary period, linear mixed effects models containing the main effects for selected product and day, as well as their interaction, were fit. For all models, log transformations were employed as necessary to satisfy assumptions, random subject effects were included (mixed effects models) to account for the correlated within-subject observations, and Tukey’s adjustment for multiple comparisons was made where appropriate. All available daily diary data were used in the modelling; no participants were excluded for poor daily diary completion rates. All analyses were conducted in SAS V9.4.

RESULTS
Participant characteristics
Eighty participants who completed all three study phases were included in the analysed sample. Participants had a mean age of 37.1 years (SD=7.5), were predominantly female (75.0%), white (72.5%) and non-Hispanic or Latino (93.8%; online supplemental table S1). Approximately a quarter (26.3%) of participants had a bachelor’s degree or higher education. Participants reported smoking an average of 11.3 cigarettes per day (SD=5.1) and had smoked at this frequency for the last 15.4 years (SD=10.2), with a median Fagerstrom Test for Nicotine Dependence score of 3 (IQR, 2–5), indicating a moderate level of dependence. At the end of phase 1, 65.0% (n=52) of participants chose mRYO as their preferred menthol alternative to use during phase 2, 22.5% (n=18) chose NMC and 12.5% chose mFLC (n=10). There were no significant differences in socio-demographic or tobacco use history between product groups, although comparisons on specific variables across the mFLC and NMC conditions may be unreliable due to the small subgroup sample sizes. Daily diary completion was high in both phases (phase 1: 89%, phase 2: 91%; online supplemental table S2).

Product self-administration and substitution
Figure 1 depicts the mean number of study products and UBMC used during the 1-week trial period compared with their mean UBMC use from the phase 1 daily diary. Adherence to the study product was high for all products across the 7 days of phase 2 (range: 63%–88%), and there was no significant increase or decrease in the use of study products overall during the 1-week substitution period, controlling for sex and mean UBMC smoked at baseline (b=0.01, 95% CI −0.002, 0.03). However, when considering each of the study products separately, participants who chose mRYO increased their use over the 1-week substitution period (b=0.02, 95% CI 0.0004, 0.03), controlling for sex and baseline UBMC use; the same increase was not seen for NMC or mFLC (NMC: p=0.794; mFLC: p=0.922). Details on the products used each day during the phase 1 and phase 2 daily diary observation periods can be seen in online supplemental table S3. Across the week-long observation period, 82% of the participants substituted at least 50% of their UBMC use with their chosen study product and this was consistent for mRYO (84%), mFLC (80%) and NMC (78%; online supplemental table S4).

Desire for a cigarette decreased over the 7 days of observation for all study products (p=0.0025), controlling for product and the interaction between product and day, and there was no effect of study product on change in QSU desire during phase 2 (figure 2A). There were, however, effects of study product on QSU relief from withdrawal (p=0.0472; figure 2B) and MNWS scores (p=0.0340; figure 2C), controlling for day and the interaction between product and day. QSU relief and MNWS scores across all days were lower in mFLC participants than in mRYO and NMC participants. Comparison of these measures between phase 1 and phase 2 is found in online supplemental figure S2.

Concurrent choice self-administration task
In the phase 3 concurrent choice self-administration task, participants chose their UBMC in 61.7% of choices; this did not differ by preferred MCA (online supplemental figure S3), although the median breakpoint was highest for mRYO and similar for mFLC and NMC (online supplemental figure S4). The median breakpoint was highest for mRYO (median=2400), followed by mFLC (median=1280) and NMC (median=1280). Participants met the highest response requirement for mRYO and mFLC (6000), followed by NMC (3600; online supplemental figure S5).

Change in subjective effects and behavioural intentions
Positive subjective effects for mRYO were highest among the preferred MCA but decreased between phase 1 and phase 3, as did smoking satisfaction, aversion and enjoyment (table 1). Craving reduction also decreased for NMC across phases. The odds of being extremely likely or likely to try this product again, purchase this product for regular use and use this product regularly at phase 3 compared with phase 1 were similarly low across all study products, although none of the estimates differed from the null.

CPE task
Figure 3 depicts aggregate CPE data for each of the alternative products, with the corresponding demand indices related to UBMC presented in online supplemental table S5. Demand
intensity for UBMC decreased slightly from phase 1 to phase 3 for mFLC (n=9; pre-\(Q_0=12.3\), post-\(Q_0=11.7\)), mRYO (n=49; pre-\(Q_0=13.6\), post-\(Q_0=13.4\)) and NMC (n=15; pre-\(Q_0=17.6\), post-\(Q_0=16.9\)). Breakpoint decreased from phase 1 to phase 3 for mFLC (pre=US$7.11, post=US$3.58) and mRYO (pre=US$3.40, post=US$2.66) and increased slightly for NMC (pre=US$1.57, post=US$1.79). The alpha increased for mFLC and mRYO products from phase 1 to phase 3. However, the alpha decreased slightly for NMC from phase 1 to phase 3. The changes in intensity, breakpoint and alpha for mFLC and mRYO indicate a slightly lower abuse liability in phase 3 compared with phase 1. For NMC, there were small decreases in intensity and alpha and a small increase in breakpoint, indicating a slightly greater abuse liability for NMC in phase 3 as compared with phase 1.

DISCUSSION

Findings from this study highlight significant potential for MCAs to substitute for UBMCs in the context of a menthol cigarette ban, particularly menthol pipe tobacco and cigarette tubes used to make roll-your-own cigarettes, and NMCs. Adherence to preferred MCA was high during the 1-week product trial period, with more than 80% of participants substituting at least 50% of their UBMC use with their preferred MCA; this did not differ based on the MCA chosen. Counter to study hypotheses, most participants chose the menthol roll-your-own product (65%) to substitute for the UBMC rather than the NMC (22.5%), and MCA use did not increase over the trial period. Consistent with study hypotheses, 82% of participants substituted at least 50% of their UBMC use with their MCA, and desire for cigarettes decreased across the product trial week for all groups, supporting that all three MCAs suppressed craving. Moreover, CPE comparing UBMCs and the preferred MCAs indicated high substitutability of each MCA following a week of use (\(I\) values, \(-0.7\) to \(-0.8\)).

There were, however, some product-level differences. mFLC participants reported lower levels of withdrawal than mRYO and NMC across all days of the 7-day MCA trial period. This is especially surprising since mFLC also demonstrated lower nicotine delivery than mRYO and NMC. In addition, while still reporting higher levels of positive subjective experience than the other MCA, mRYO participants reported waning product appeal over the product trial week, with decreases in most measures of subjective effects; this was a similar pattern across all MCAs.
although small cell sizes for mFLC and NMC limited inferences about significant change in these measures. Waning appeal was also evident in mRYO having the highest median breakpoint compared with NMC and mFLC in a concurrent choice self-administration task that occurred following the product trial week.

Consistent with tobacco industry research, findings from our behavioural concurrent choice task support that one’s UBMC outperforms an alternative product even when a greater response effort is needed to obtain the usual brand product. These findings, however, may have limited predictive value in the face of an actual menthol cigarette ban. Despite tobacco company arguments about the growth of an illicit market for menthol cigarettes following a ban,\textsuperscript{9,10} evaluations of menthol cigarette bans in Canada have shown no surge in illicit cigarette seizures,\textsuperscript{10} no increase in illicit purchases of cigarettes (menthol or non-menthol)\textsuperscript{10,21} and significantly lower rates of brand-verified menthol cigarette use than self-reported menthol cigarette use postban.\textsuperscript{10} Further, data from England document substantial decreases in the proportion of youth who smoke menthol cigarettes following the menthol cigarette ban,\textsuperscript{41} and in Canada the Ontario menthol ban resulted in a significant reduction in menthol cigarette and total cigarette sales\textsuperscript{42} and promoted greater cessation among adults who smoked menthol cigarettes than NMCs.\textsuperscript{43-45} However, short-term outcomes following Ontario’s menthol cigarette ban support that adults who smoked menthol cigarettes occasionally were more likely to use other flavoured tobacco products and flavoured cigars postban, with daily menthol cigarette users also more likely to use flavoured cigars postban.\textsuperscript{46}

The strengths of this study include the use of multiple methods of estimating substitutability of MCAs in a clinical laboratory sample of adults who currently smoke menthol cigarettes and inclusion of a 1-week MCA trial period. This study sample was recruited from a single midwestern city, but findings may be generalisable to a broader population of people who smoke menthol cigarettes in the USA, including women and people of lower socioeconomic status who have a higher prevalence of menthol cigarette use.\textsuperscript{19,20} However, our sample largely identified as white and heterosexual and we were unable to explore differences in substitutability by race/ethnicity or sexual orientation, both of which are known correlates of menthol cigarette use among people who smoke cigarettes.\textsuperscript{20} Imbalance in product choice limits our ability to draw inferences about differential substitutability of these three MCAs; however, high adherence to MCAs across the observation phase and performance in the CPE tasks suggest that mRYO, mFLC and NMC are acceptable substitutes for UBMCs. Future research examining the extent to which these products remain suitable substitutes for UBMCs when adults are required to obtain the products in a real-world setting will inform the longer-term acceptability of these MCAs.

Findings from this study suggest that mRYOs, mFLCs and NMCs are potential acceptable substitutes for UBMCs during a short-term trial period. However, even after a week-long trial with one’s chosen alternative product, UBMCs remained preferred in a concurrent choice self-administration experiment. Consistent with our prior work,\textsuperscript{25} this study supports including menthol pipe tobacco and tubes (roll-your-own) in flavoured tobacco bans. Future studies examining potential MCAs should address menthol-flavoured non-combusted nicotine products and cigarette products containing synthetic cooling agents that have emerged in response to flavoured tobacco policies.

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**Contributors** ACV and TLW conceived of and designed the study. TM managed the study and was overseen by TYW and ACV. AH, JS and TE conducted and are responsible for the data analysis. ACV wrote the initial draft of the manuscript, and AH, JS, TE, TM, DR, MB, JT and TLW reviewed, edited and approved the final version. ACV, AH and TLW had full access to all the data in the study and take responsibility for the data analysis.
Table 1  Change in subjective effects and behavioural intentions from phase 1 (study product visit) to phase 3 (visit 5)

<table>
<thead>
<tr>
<th></th>
<th>Menthol roll-your-own cigarettes (n=51)</th>
<th>Menthol filtered little cigars (n=10)</th>
<th>Non-menthol cigarettes (n=18)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Phase 1 Mean (SD)</td>
<td>Phase 3 Mean (SD)</td>
<td>Phase 1 Mean (SD)</td>
</tr>
<tr>
<td><strong>Subjective effects</strong>†</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Want</td>
<td>66.57 (25.02)</td>
<td>44.90 (30.52)**</td>
<td>58.80 (33.59)</td>
</tr>
<tr>
<td>Like</td>
<td>71.90 (24.92)</td>
<td>54.39 (32.07)**</td>
<td>62.50 (33.86)</td>
</tr>
<tr>
<td>Enjoy</td>
<td>70.33 (24.90)</td>
<td>53.33 (31.45)**</td>
<td>63.30 (31.34)</td>
</tr>
<tr>
<td>Pleasurable</td>
<td>71.06 (25.73)</td>
<td>52.18 (32.09)**</td>
<td>63.80 (33.25)</td>
</tr>
<tr>
<td>Satisfying</td>
<td>71.86 (27.39)</td>
<td>57.55 (31.65)*</td>
<td>55.30 (38.52)</td>
</tr>
<tr>
<td><strong>mCEQ</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoking satisfaction</td>
<td>4.58 (1.56)</td>
<td>3.89 (1.74)*</td>
<td>3.80 (1.74)</td>
</tr>
<tr>
<td>Psychological reward</td>
<td>3.13 (1.49)</td>
<td>2.90 (1.66)</td>
<td>2.40 (1.98)</td>
</tr>
<tr>
<td>Aversion</td>
<td>2.01 (1.20)</td>
<td>1.62 (1.23)*</td>
<td>1.15 (0.34)</td>
</tr>
<tr>
<td>Enjoyment of respiratory tract sensations</td>
<td>4.27 (1.74)</td>
<td>3.63 (1.88)*</td>
<td>3.80 (2.39)</td>
</tr>
<tr>
<td>Craving reduction</td>
<td>4.75 (1.62)</td>
<td>4.31 (1.73)</td>
<td>4.10 (1.52)</td>
</tr>
<tr>
<td><strong>Behavioural intentions</strong>‡</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Try purchase this product again</td>
<td>0.40 (0.16 to 1.00)</td>
<td>0.25 (0.03 to 2.47)</td>
<td>0.22 (0.04 to 1.23)</td>
</tr>
<tr>
<td>Purchase this product for personal use</td>
<td>0.68 (0.28 to 1.65)</td>
<td>0.41 (0.05 to 3.61)</td>
<td>0.75 (0.15 to 3.76)</td>
</tr>
<tr>
<td>Use this product regularly</td>
<td>0.76 (0.32 to 1.79)</td>
<td>0.20 (0.02 to 2.25)</td>
<td>0.75 (0.15 to 3.76)</td>
</tr>
</tbody>
</table>

†P<0.05, **P<0.001.  
‡Logistic regression models account for repeated measures within individuals and model the probability of response as ‘extremely likely/likely’ (vs ‘neutral/unlikely/extremely unlikely’) at phase 3 compared with phase 1 (reference).

ANOVA, analysis of variance; mCEQ, modified Cigarette Evaluation Questionnaire.

for the integrity of the data and the accuracy of the data analysis. ACV and TLW accept full responsibility for the work and/or the conduct of the study, and controlled the decision to publish.

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**Conflict of interest**  None declared.

**Patient consent for publication**  Not required.

**Ethics approval**  This study involves human participants and was approved by The Ohio State University Institutional Review Board (2019C0107). Participants gave informed consent to participate in the study before taking part.

**Provenance and peer review**  Not commissioned; externally peer reviewed.

**Data availability statement**  Data are available upon reasonable request. The authors will make deidentified participant data and the data dictionary available following publication. Institutions and individuals wishing to access any resources or data must contact Dr Theodore Wagener (theodore.wagener@osumc.edu). Data will only be made available to those whose proposed use of the data has been approved by TLW. Data will be made available for the sole purpose of replicating the analyses reported in the manuscript. The recipient must agree to not transfer the data to other users and that the data are only to be used for research purposes. The private investigators will require requestors of the data to sign a data sharing agreement that will ensure (1) use of the data only for research purposes, (2) data security using appropriate technology/firewalls, (3) destruction of data after data analysis and (4) proper citation in publications or other written materials. A record of transfer of data and a copy of the data set that was distributed will be kept by The Ohio State University.

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**REFERENCES**


Figure 3  Change in cross-price elasticity from Phase 1 to Phase 3, by menthol cigarette alternative (n = 73). Note: mFLC, menthol filtered little cigar; mRYO, menthol roll-your-own cigarette; NMC, non-menthol cigarette.

Original research

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