

# Potential Effects of a Menthol Ban on Smoking Behavior in Menthol Cigarette Smokers

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# Background

- Following the passage of the Family Smoking Prevention and Tobacco Control Act (FSPTCA), the FDA banned fruit or candy flavored cigarettes but menthol was excluded from this ban
- The Tobacco Products Scientific Advisory Committee (TPSAC) in their report recommended that “removal of menthol cigarettes from the marketplace would benefit public health in the United States”
  - in part because smoking cessation is more difficult for those smoking menthol vs. non-menthol cigarettes, particularly in African Americans
  - Report produced by the FDA evaluating the public health effects of menthol in cigarettes reached similar conclusions (FDA 2013)
- Recently, the FDA taken the initial steps necessary to enact a national ban on menthol characterizing flavor in combustible cigarettes and cigars in the United States

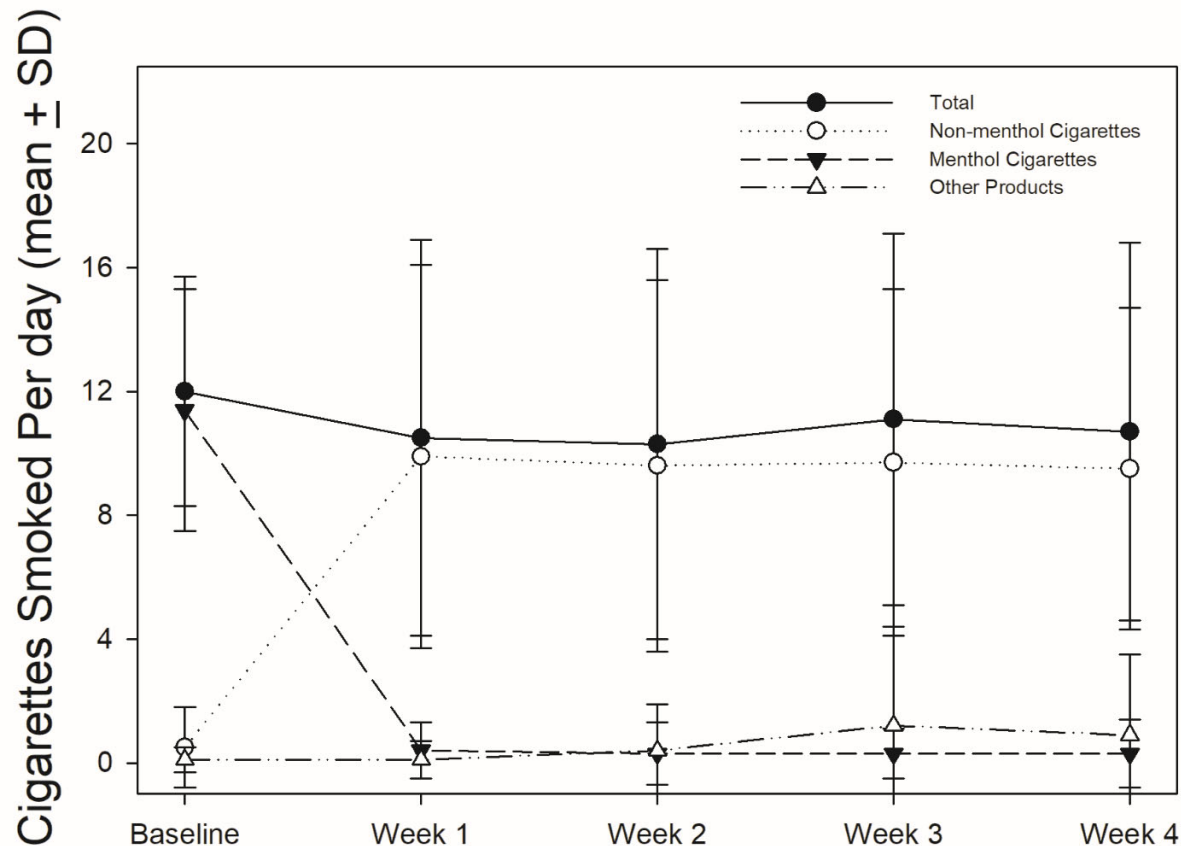
# What do menthol cigarette smokers say they would do if menthol was banned?

Study	n	Intention if menthol cigarettes banned
D'Silva et al 2015	1,158	46% would quit smoking; 27% switch to non-menthol cigarettes
Hartman et al 2011	2,887	39% would quit smoking and not switch to alternative product
O'Connor et al 2012	170	35% report intention to quit smoking
Pacek et al 2019	126	25% would plan to quit smoking
Pearson et al 2012	465	39% would try to quit smoking; 13% switch to non-menthol cigarettes; 25% would switch and try to quit
Rose et al 2019	806	24% would quit smoking; 32% switch to non-menthol cigarettes
Wackowski et al 2014	619	64% would quit smoking; 18% switch to non-menthol cigarettes
Wackowski et al 2015	187	28% would try to quit smoking; 46% switch to non-menthol cigarettes

# Assessing Response to Hypothetical Ban on Menthol Cigarettes

- African American smokers of menthol cigarettes were asked to abstain from menthol cigarettes for a four week period
- No specific instructions given regarding how to cope with the inability to smoke menthol cigarettes
- Visits occurred at baseline, week 1, week 2 and week 4
- At final visit, participants were asked their level of support for a menthol ban

# Results



- 32 participants completed the study
  - 17 Men; 15 women
  - Average age = 46.4 (range 27 – 61)
  - Average cigs per day at screening = 13.5
- Three smokers attempted to quit
  - One smoker quit for 4 weeks
  - Two others decreased to 1 to 2 cigarettes per day
- Those who smoked switched to non-menthol cigarettes
- Number of cigarettes smoked decreased from 11.9 cigs per day at baseline to 9.8 cigs per day at week 4 ( $p < 0.001$ )

# Results / Conclusions

Measure	Baseline	Week 1	Week 2	Week 4
Exhaled CO (ppm)	13.4 (10.9, 16.3)	12.1 (9.9, 14.8)	13.9 (11.3, 16.9)	11.1 (9.1, 13.6)*
Motivation to Quit	5.3 $\pm$ 3.0	5.8 $\pm$ 2.7	5.1 $\pm$ 2.9	6.3 $\pm$ 3.1*

- At the conclusion of the study, participants indicated that quitting menthol cigarettes was difficult (average score = 7.2) but that they were supportive of banning menthol (average score = 7.1)

## Conclusions

- During a simulated ban on menthol cigarettes, most smokers switch to non-menthol cigarettes
- Smoking patterns do not suggest increased harm as a result of the switch to non-menthol cigarettes (e.g. number of cigarettes smoked decreased, exhaled CO decreased, motivation to quit increased)

# Effects of Menthol Smokers Switching to Non-Menthol Cigarettes

- 29 non-treatment seeking menthol cigarette smokers switched from usual brand to non-menthol cigarettes for 2 weeks (one week of menthol and two weeks of non-menthol cigarettes provided to participants)

Measure	Baseline	End of Study
Cigarettes per day	12.2 ± 5.6	10.0 ± 5.0*
Urinary Cotinine (ng/ml)	1786 ± 1160	1440 ± 1007*
Exhaled CO (ppm)	32.0 ± (20.3)	28.2 ± (19.4)
motivation to quit smoking	3.3 (2.4)	5.4 (2.5)*
confidence in ability to quit smoking	4.2 (2.9)	5.5 (2.7)*
Craving (from Wisconsin Smoking Withdrawal Scale)	3.3 (0.6)	2.8 (0.8)*
Nicotine Dependence	45.0 (10.7)	36.8 (10.9)*

- Results generally consistent with previous study
  - Fewer cigarettes smoked per day
  - Increase in motivation to quit smoking



# Does Switching to non-menthol cigarettes facilitate cessation?

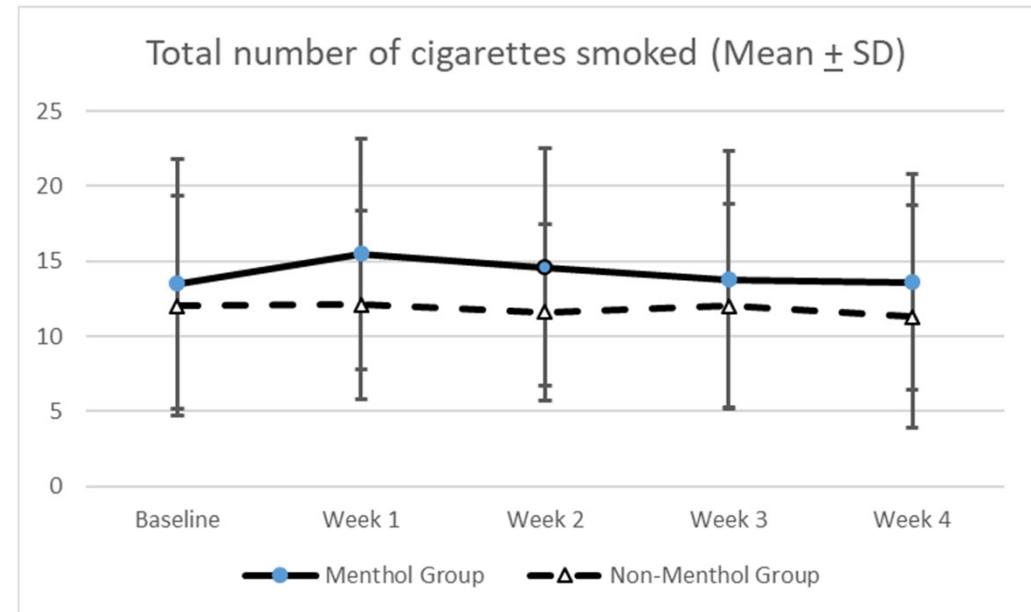
- Smoking cessation is more difficult for those smoking menthol vs. non-menthol cigarettes, particularly in African Americans (TPSAC 2011, Villanti et al 2017, Smith et al 2020)
- Several studies suggest that if menthol cigarettes are not available, many smokers of menthol cigarettes switch to non-menthol cigarettes
- Is switching to non-menthol cigarettes prior to a cessation attempt results is an effective initial step to cessation?
  - Recent study evaluating data from PATH found that switching from menthol (vs maintaining menthol use) was associated with a 58% increased the probability of 30+ day abstinence and 97% increase the the probability of 12-month abstinence (Leas et al 2021)

# Does Switching to non-menthol cigarettes facilitate cessation?

- Randomized study of African American menthol smokers
- Randomized to 4 weeks of their usual brand cigarettes or non-menthol cigarettes before a quit attempt (cigarettes provided to participants)
  - Referred to quit line for assistance with their quit attempt (to approximate the natural environment)
- Participants were generally healthy menthol cigarette smokers ( $\geq 5$  cigarettes per day for a period longer than 1 year) who expressed an interest in quitting smoking (rate themselves  $\geq 7$  on a 10 point scale assessing motivation to quit smoking)
- Outcomes include
  - Time to lapse (time to 1<sup>st</sup> cigarette smoked from quit date)
  - Time to relapse (number of days from quit attempt until the 1<sup>st</sup> of 7 consecutive smoking days)
  - Number of cigarettes smoked
  - Motivation to quit (pre-quit visits)
  - Support for menthol cigarette ban

# Pre-Cessation Results

- 122 participants completed baseline visit (60 in menthol group, 62 in non-menthol group)
  - 107 (54 menthol; 53 non-menthol) completed 4 week pre-cessation period
  - Mean (SD) age: 47 (10) vs. 45 (11)
- Pre-Cessation Results
  - Fewer cigarettes smoked per day in non-menthol group (mean ratio: 0.86; 95% confidence interval [CI]: 0.76, 0.98;  $p = .02$ )
  - Perceived effectiveness of their skills for quitting smoking higher in the non-menthol group
  - Withdrawal symptom severity lower in non-menthol group
  - Support for ban on menthol in cigarettes similar between group



# Pre-Cessation Results

Measure	Menthol Group		Non-menthol Group		Non-menthol vs. menthol
	Baseline	Week 4	Baseline	Week 4	Mean (95% CI)
Exhaled CO (ppm)	15.3 (8.1)	14.2 (7.9)	15.3 (7.8)	12.4 (8.7)	GMR: 0.92 (0.80, 1.1)
Withdrawal (from MNWS)	7.0 (6.3)	6.4 (6.0)	6.7 (6.0)	4.9 (4.7)	-1.29 (-2.6, -0.01)
QSU total score	133 (32.4)	109 (30.3)	129 (38.7)	95 (38.6)	-6.99 (-15.42, 1.44)
Motivation to quit	7.8 (2.2)	8.3 (2.0)	8.0 (2.3)	8.7 (2.1)	0.34 (-0.12, 0.81)
Confidence in ability to quit	6.5 (2.5)	7.5 (2.2)	7.2 (2.3)	8.2 (2.3)	0.39 (-0.16, 0.93)
Effectiveness of quitting skills	6.2 (2.3)	7.1 (2.7)	6.4 (2.6)	7.7 (2.6)	0.56 (0.02, 1.10)
Effort put toward quitting	9.0 (1.9)	8.9 (1.9)	8.8 (2.1)	9.0 (1.8)	0.07 (-0.43, 0.57)
Support for menthol ban	5.5 (3.4)	5.9 (3.3)	5.7 (3.4)	6.3 (3.3)	0.22 (-0.78, 1.21)

Kotlyar et al. Nicotine Tobacco Research 2021;23:1921-1927.

# Cessation Results

## Cessation Results

- 95 (45 menthol, 50 non-menthol) completed 12 week post-cessation visit
- Hazard Ratio for time to lapse was 0.82 (non-menthol vs menthol) (95% CI 0.55 to 1.22;  $p=0.33$ )
  - Median time to lapse in the non-menthol group was 2.55 days versus 1.07 days in the menthol group ( $p=0.08$ , post hoc test)
- Hazard Ratio for time to relapse was 0.67 (non-menthol vs menthol) (95% CI 0.42 to 1.06;  $p=0.09$ )
  - Difference primarily due to lower rates of early relapse in the non-menthol group
  - 21% of the non-menthol group relapsed within the first day versus 40% of the menthol group ( $p=0.05$ , post hoc test)

# Conclusions

- Results of pre-cessation phase of the study similar to previous studies in which smokers switched to non-menthol cigarettes
  - Number of cigarettes smoked decreased modestly
  - Few differences between groups in most measures, however perceived effectiveness of quitting skills was modestly higher in those switching to non-menthol cigarettes (vs. continuing to smoke menthol)
  - Support for a menthol ban did not decrease during study participation
- Switching to non-menthol cigarettes may have positive effects on short-term cessation measures largely by decreasing the proportion of relapses occurring within the first day of quitting
  - More intensive interventions may be necessary to sustain early abstinence

# Overall Conclusions

- Following a ban of menthol characterizing flavor, many menthol smokers would likely switch to non-menthol cigarettes
  - Those who switch do not change their smoking behavior in a way that is likely to be more hazardous, with some indicators suggesting that there may be some benefit (e.g., decreased smoking, increases in measures of motivation to quit)
- Switching to non-menthol cigarettes may be an effective first step to short-term cessation but effects are small – more research is needed regarding how to sustain any early success achieved
- Data from longitudinal studies and from localities that have banned menthol will help inform effects of menthol bans (Chung-Hall et al 2021; Chaiton et al 2020)
- More research needed on effects of either including or excluding menthol bans for other tobacco products (e.g., e-cigarettes) on overall tobacco use patterns
  - Some data suggests that decreasing access to flavored e-cigarettes may increase combustible cigarette use (Denlinger-Apte et al 2021; Buckell et al 2019)

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