



Strong preference for mint snus flavor among research participants



Liane M. Schneller^a, Bruce R. Lindgren^b, Peter G. Shields^c, Dorothy K. Hatsukami^b,
Richard J. O'Connor^{a,*}

^a Roswell Park Cancer Institute, Department of Health Behavior, Elm and Carlton Streets, Buffalo, NY 14263, United States

^b University of Minnesota, Tobacco Research Programs, 717 Delaware St. SE, Minneapolis, MN 55414, United States

^c Ohio State University, College of Medicine, 460 W. 10th Avenue, Columbus, OH 43210-1240, United States

A B S T R A C T

Introduction: The Family Smoking Prevention and Tobacco Control Act of 2009 allows the US FDA to regulate tobacco products, including the banning of characterizing flavors, such as fruit and candy, cigarettes. The availability of mint flavored snus may facilitate the use of the product if consumers find it more palatable with respect to taste, odor, pleasantness, and intensity.

Methods: This study assessed product evaluation (PES), odor identification, odor intensity, and odor hedonics among 151 smokers enrolled in a clinical trial of snus substitution for cigarettes.

Results: Far more participants selected Winterchill (N = 110) than Robust (N = 41), regardless of their menthol cigarette smoking status. Nicotine dependence was higher among those who selected Winterchill (4 vs 3 on Fagerstrom scale, $p = 0.017$). Those who found Winterchill to be more satisfying, less aversive, and having a more intense, more pleasant odor than Robust were substantially more likely to select Winterchill for their one week trial.

Conclusions: Findings indicate that subjective effect measures such as the PES and DEQ are capable of differentiating products in terms of flavor preference, and that smokers express a strong preference for mint flavored snus.

1. Introduction

The Family Smoking Prevention and Tobacco Control Act of 2009 allows the US Food and Drug Administration (FDA) to regulate tobacco products, including the banning of characterizing flavors, such as fruit and candy, in cigarettes (US Food and Drug Administration, 2009). These products were of concern to public health advocates because of the appeal of the enticing names, package design and pleasing flavors to youth (Klein et al., 2008; Kostygina & Ling, 2016). Menthol flavoring, however, was not included in the Tobacco Control Act (US Food and Drug Administration, 2009). Econometric evaluations suggest that this ban was effective in reducing the probability of adolescent tobacco use by 6%, even though some substitution with remaining legal flavored products (menthol cigarettes, little cigars, pipes) was observed (Courtemanche, Palmer, & Pesko, 2017). Characterizing flavors were not banned in non-cigarette tobacco products at the federal level, though several localities (e.g., Providence, New York City, Chicago, and Santa Clara) have done so (Board of Supervisors of the County of Santa Clara, 2014; City of Providence, 2012; Commissioner of Health and Mental Hygiene, 2010; Emanuel, Thompson, & Mitts, 2013). Still, data

from the Population Assessment of Tobacco and Health study suggests that flavored tobacco use remains particularly common among youth and young adults (Villanti et al., 2017) and may serve to aide initiation to tobacco use. Consumer initiation and continued use of a tobacco product is dependent upon many factors including nicotine content, as well as pH of the product and palatability of the product (US Department of Health and Human Services, 2010). Chemical additives, such as menthol, can alter the taste and flavor of the product, creating a more pleasurable taste and making it more acceptable among consumers (US Department of Health and Human Services, 2010).

The favorable perceptions of flavorings may have important implications for regulatory science, particularly with respect to modified risk tobacco products (MRTP). The population health effect of an MRTP in part depends on uptake, which is influenced in part by the palatability and acceptability of the product. For example, prior studies suggest that cigarette smokers have a preference for flavored snus products (Meier et al., 2016). A similar pattern is also observed for smokeless users (Oliver, Jensen, Vogel, Anderson, & Hatsukami, 2013). The availability of flavored snus may facilitate its use in place of more toxic cigarettes, if consumers find it more palatable with respect to

* Corresponding author.

E-mail address: richard.oconnor@roswellpark.org (R.J. O'Connor).

taste, odor, pleasantness, and intensity (Meier et al., 2016). Therefore, these products may be of public health importance if research demonstrates that these products reduce exposure or risk in individuals (Meier et al., 2016). And, conducting such research is dependent on participants using the product being studied.

The question whether smokeless tobacco (ST) products, such as snus, is a potential modified risk tobacco product has been debated (Meier et al., 2016). First, smokeless tobacco has been established as toxic and carcinogenic, but it is thought that it will reduce population harm from tobacco by preventing smoking initiation, promoting smoking cessation and partially replacing the use of cigarettes among current smokers (Kozlowski, 2007; Tomar, 2007). Second, the advertisement of smokeless tobacco as less harmful than cigarettes may increase the prevalence of all tobacco use (Tomar, 2007). Final, there is concern that it will only provide temporary reduced risk, and act as a gateway to cigarette use (Tomar, 2007). With respect to ST, surveys suggest that 59% of current ST users under aged 18 are using a flavored ST product, as are 51% of current adult ST users. A systematic review suggests that flavored tobacco products may be perceived more favorably overall (Feirman, Lock, Cohen, Holtgrave, & Li, 2016), and that their use is more common among the young.

Given the regulatory interest in characterizing flavors in the USA and EU, developing methods to assess flavor awareness and preference is important (Henkler & Luch, 2015; Talhout, van de Nobelen, & Kienhuis, 2016). This report aimed to determine the preference of menthol vs. tobacco flavored snus among smokers, and to provide validation of sensory measures of product preference and adoption. Data was collected for a randomized, multi-site open-label trial examining the ability to predict who enrolls in a clinical trial of Camel Snus (O'Connor, Lindgren, Schneller, Shields, & Hatsukami, 2017).

2. Methods

2.1. Eligibility criteria

Participants were eligible if they were at least 18 years of age, currently smoked at least 10 cigarettes per day, had not used ST for at least 3 months, were able to provide consent and read and understand study documents, and had no medical contraindications such as pregnancy, breastfeeding, uncontrolled hypertension, uncontrolled diabetes, recent myocardial infarction, or cancer. A total of 151 individuals were eligible for the study across 3 sites: University of Minnesota (UMN; Minneapolis, MN), Ohio State University (OSU; Columbus, OH), and Roswell Park Cancer Institute (RPCI; Buffalo, NY) (O'Connor et al., 2017).

2.2. Sampling phase procedure

Eligible participants completed a core questionnaire on tobacco use and behaviors at an initial orientation visit. Participants were then shown the two snus products, Camel Snus Winterchill and Camel Snus Robust in blinded tins. A coin flip determined which product was given to the participant first. The nicotine content was 8.9 mg/g in Camel Snus Winterchill and 9.5 mg/g in Camel Snus Robust (wet weight of product), and the levels of unprotonated nicotine were 1.6 mg/g and 2.1 mg/g, respectively. Participants were asked to smell each of the products and to try them for up to 5 min. Participants indicated their preferred flavor (Winterchill vs. Robust) of which they were given 4 tins to use at home. Participants were instructed to use as much or as little of the product as they wanted over a 7 day period. During these 7 days, participants were allowed to smoke. Participants could request more snus if needed.

2.3. Sensory assessments

In addition to the tobacco use and nicotine dependence (FTND), this study incorporated a number of sensory measures designed to tap into participants' subjective responses to the products themselves. Some dimensions of interest include odor identification, odor intensity (measured on a Likert-type scale), and odor hedonics (pleasantness-unpleasantness), as well as touch sensations and hedonics drawn from approaches used in the food, cosmetics, tobacco, and textile industries for assessing sensory responses (Dravnieks, 1982; Meilgaard, Civille, Carr, & Civille, 2006; Pederson & Nelson, 2007). Our Odor/Haptics scale consisted of a list of 31 odor descriptors (i.e., sweet, peppermint, bitter, etc.) that preliminary work showed some response for smokeless tobacco products, each rated on a 1–6 ('not at all' to 'very much') scale. Odor intensity was rated on a 0–6 (none to intolerable) scale, and odor pleasantness was assessed on a 1–5 ('extremely pleasant' to 'extremely unpleasant') scale. In addition, participants rated the products using the Product Evaluation Scale (PES), which is a 7-point Likert scale (Hatsukami, Zhang, O'Connor, & Severson, 2013), as well as the Drug Effects Questionnaire (DEQ), a 100 mm visual analog scale with descriptive anchors including "not at all" and variants of "extremely" (de Wit & Phillips, 2012; Morean et al., 2013).

Frequency distributions were used to initially characterize the data and statistical comparisons were carried out by the Chi-square and Fisher's exact test, and non-parametric methods including the two-sample Wilcoxon rank-sum test, the Kruskal-Wallis test and the bivariate Spearman correlation coefficient given non-normal distributions. Multivariate logistic regression was performed to identify subject characteristics and subjective measures related to product preference. *p*-values < 0.05 were considered statistically significant. All analyses were carried out using SAS 9.3 (SAS Institute, Inc., Cary NC).

3. Results

3.1. Flavor selection and participant demographics

Table 1 describes the profile of participants by preferred flavor. Most participants were White males, averaged about 39 years of age, about half had lifetime experience with smokeless tobacco, and about 40% used menthol cigarettes. Only FTND was significantly different between preferred flavors, the median score for those who chose Winterchill higher compared to those who chose Robust (4 vs. 3, Wilcoxon rank sum *p*-value = 0.017). On average, participants smoked about 17 cigarettes per day, and have been smoking for 12 to 15 years.

3.2. Ratings that differentiate menthol flavored vs. tobacco flavored products

Participants clearly distinguished the characteristic odors of Winterchill and Robust products. Winterchill scored much higher than Robust on mint- and coolness-related odors, while Robust scored higher than Winterchill on plant-related odors (see Fig. 1). Within each product flavor, the rated intensity of Winterchill was marginally predictive of Winterchill selection (*p* = 0.055). Though there was no apparent difference in the group medians, those who selected Robust tended to have higher scale values on intensity (range 3–6) than those who selected Winterchill (range 1–6). Intensity ratings of Robust were not significantly related to Robust selection (*p* = 0.18), though the median score for those who chose Robust was lower (3, range 2–5) than for those who chose Winterchill (4, range 0–6). Ratings of odor pleasantness were also predictive of product selection. Those who selected Winterchill were more likely to rate its odor as pleasant or extremely pleasant (80%) than those who selected Robust (43.9%; *p* < 0.001). This also held for ratings of Robust, though pleasantness was lower for this product overall. Those who selected Robust were more likely to have rated it pleasant or extremely pleasant (39.0%) versus those who

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