

CigVent Proj-003

Effects of Cigarette Filter Ventilation on Substitution in the Experimental Tobacco Marketplace

in Tobacco Cigarette Smokers: Experiment 1

Statistical Analysis Plan

NCT03306173

02/01/2022

Statistical Analysis Plan

Participants' characteristics, including demographics and smoking-related assessments collected at a baseline session, were described using mean, standard deviation, and percentages, where appropriate. The perceived risk of HVCs was compared to the perceived risk of LVCs using a paired t-test.

Purchasing cigarettes (LVCs and HVCs) is a continuous measure, ie, the number of cigarettes purchased. In practice, participants opted to purchase either LVCs or HVCs and rarely purchased both products in the same trial (11.94% of the trials). As a result, we opted to model the purchasing of cigarettes and alternative tobacco products as a binary indicator; whether or not a participant purchased that type of cigarette in a trial. The purchasing of HVCs was estimated using a mixed-effects logistic regression to model the association between session, ventilation level (30.6% or 22.0% ventilation), and price of a HVC with a random effect for each participant due to the repeated (3) measurements study design. Similarly, the purchasing of LVCs and alternative tobacco products was estimated using a mixed-effects logistic regression to model the association between session, ventilation level (3.0% or 11.6% ventilation), and price of HVCs. Note that we included a variable for ventilation level in both models to quantify if the changes in product specifications over time influenced the overall purchasing patterns.

The proportion of the total budget spent on cigarettes was estimated using a repeated measures analysis of variance (RMANOVA) to evaluate the session's role and the price of HVCs. The total number of cigarettes purchased was also modeled using an RMANOVA, including the session and price of HVCs as independent variables. For these analyses, the price of cigarettes was categorical. Post hoc comparisons were performed using Tukey's correction for multiple testing.

For all analyses, the inclusion of the interaction between session and price of an HVC was determined by the model with the lowest Bayesian Information Criteria (BIC). After model selection, the final model to predict the total quantity of cigarettes purchased included the interaction between session and price, and the final model for all other outcome measures did not include this interaction. R software Version 3.5.1 was used for all data analysis (R Core Team, 2021). All statistical tests were considered significant at the < 0.05 level.

A post hoc power analysis was performed with 1000 simulations using the package SIMR (Green & MacLeod, 2016). This analysis set the effect size to the smallest observed value in the results

(OR: 2.8; Purchasing patterns of low-ventilation cigarettes section). Using this effect size, the sample size of 20 participants, and an alpha of 0.05, we achieved 88% power in this study.