

Center for the Study of Tobacco Products

Randomized Control Trial Methods for MRTP Evaluation (Project 3)

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Abstract:

Project 3 of this Center is part of a four-project effort with the overarching goal of providing an empirical demonstration of an integrated, iterative model of MRTP evaluation that uses analytic lab, human lab, randomized control trial (RCT), and quantitative/qualitative methods to inform tobacco regulation. Project 3 will show how RCT methods can inform pre-market evaluation by examining the influence of real-world product use on biomarkers of toxicant exposure and disease risk, reports of adverse events, and concurrent use of traditional tobacco products. Thus, Project 3 will demonstrate how regulatory science is advanced by an integrated, iterative model of MRTP evaluation that includes RCT methods. We begin our demonstration with a systematic evaluation of a novel and increasingly popular tobacco product: "electronic cigarettes" (ECIGs). Despite their popularity, little robust evidence is available regarding ECIG safety or effectiveness. Instead, assertions are made that ECIGs likely will reduce tobacco toxicant exposure, probably produce no adverse events, and therefore may lessen the risk of tobacco-caused disease by reducing cigarette use. In fact, the data addressing how long-term ECIG use influences toxicant exposure, user health, and concurrent cigarette smoking are very limited. However, each of these issues can be addressed empirically using an RCT. This project's goal is to demonstrate how RCT methods can be used to evaluate MRTPs generally and ECIGs particularly. To achieve this goal we will recruit 520 ECIG-naïve tobacco cigarette smokers (>10 cigs/day) who are interested in reducing their tobacco use and assign them randomly to one of four 6-month conditions (N=130/condition): High-nicotine dose ECIG, Mid-nicotine dose ECIG, Zero-nicotine dose (placebo) ECIG, or a control condition that includes use of a non-combustion, non-nicotine, non-vapor, imitation cigarette substitute. The exact ECIG device and doses will be guided by Projects 1 and 2. Participants will be instructed to use products ad libitum, with the goal of reducing the number of cigarettes smoked/day with an initial reduction of 50% suggested. Outcome measures will allow us to address the following specific aims: 1) Characterize product influence on toxicants biomarkers, health indicators, and disease risk; 2) Determine the tobacco abstinence symptom and adverse event profile associated with real-world product use. 3) Examine the influence of novel product use on conventional tobacco product use. Project 3 demonstrates the role of RCT methods in an integrated, iterative model of MRTP evaluation that will advance science-based FDA tobacco product regulation.