

Cancer Center Support Grant
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Abstract:

The Food and Drug Administration (FDA) is considering a policy mandating that all cigarettes reduce their nicotine content to a point that, is hoped, would dramatically reduce smoking. This intervention is already being tested in daily smokers (DS), because of concern that lowering nicotine could cause smokers to increase their smoking (compensation). However, those tests exclude a large and growing segment of smokers: 25-33% of adult US smokers are non-daily, or intermittent smokers (ITS). ITS suffer significant health risks from smoking, and (surprisingly) have great difficulty quitting. ITS appear to smoke for the immediate acute effects of nicotine in particular situations, often in bouts of concentrated smoking. Findings from DS may not apply to ITS. It is not known whether ITS would benefit from a nicotine-limiting policy or potentially be harmed by it, should ITS increase their smoking in order to achieve acute nicotine effects. Therefore, it is essential to evaluate the effect of very-low-nicotine content cigarettes (VLNCCs) on ITS smoking. The study assesses the effects of switching to VLNCCs among ITS. In a two-arm study, 455 ITS will first be assessed for 2 weeks while smoking their own cigarettes, and then be randomized (double blind) to one of two matched research cigarettes (menthol if preferred) for 10 weeks: (1) VLNCCs (0.07 mg nicotine delivery.), or (2) normal-nicotine content cigarettes (0.8 mg). Change in cigarette consumption (baseline to end of study.) is the primary end-point, with 80% power to detect changes of +/-20% (after attrition). Cigarette consumption will be recorded in real time using Ecological Momentary Assessment. Additional outcomes include biomarkers (urinary cotinine - nicotine's major metabolite, and NNAL - a carcinogen with a long half-life) and changes in per-cigarette smoking intensity (size and weight of cigarette butts, solanesol - a chemical measure of inhalation, and measures of smoking topography). Changes in cigarette satisfaction, craving, and nicotine dependence are also assessed, and the analysis explores potential moderators of the effects of VLNCCs, including race, baseline dependence, and history of prior daily smoking. Findings of this study will have important implications for the FDA's regulation of nicotine in cigarettes.