

The Impact of Waterpipe Tobacco Flavors on Waterpipe Smoking Intentions, Perceptions, Patterns and Toxicant Exposure
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Abstract:

Proposed Administrative Supplement Additions.

In the parent study (1 R03 DA041928-01A1), we proposed a randomized crossover design where participants completed three WP smoking sessions (flavored-sweetened, unflavored-sweetened, and unflavored-very low sweetened). For this administrative supplement proposal, we would like to add a fourth session (flavored-very low sweetened) to complete the full factorial design (see figure 1). With the addition of the fourth session, we will be able to fully examine the unique and, combined contribution of flavors and sweeteners, which our original design does not completely allow. This fourth session will be conducted in the same manner as the three other sessions originally described in the parent study.

Participants will complete all of the same baseline and outcome measures, and all aspects of the study will be able to be completed within the original timeline of the parent study. Finally, this administrative supplement will add 6 additional participants to the parent study for a total of 82 participants to ensure that we have enough statistical power to analyze the main and secondary outcomes given that we anticipate we will have already recruited and completed the three-session study with 16 participants. Therefore, 66 participants will complete the four-session protocol, which will be sufficiently powered.

The parent study with the addition of the administrative supplement will address several critical FDA CTP research areas. It will investigate 1) the initiation, use, perceptions, dependence and toxicity of WP use among waterpipe tobacco users; 2) the impact of waterpipe tobacco flavors and sweeteners on waterpipe initiation and continued use; and 3) examine waterpipe users' perceptions of waterpipe products with respect to flavor and sweeteners. This novel study will contribute knowledge urgently needed by the FDA and health officials to effectively regulate waterpipe tobacco in a way that best serves public health.

Table 1. Proposed and requested additional waterpipe smoking study sessions.

WP Tobacco Flavoring	Flavored	Unflavored
Sweetened	flavored-sweetened	unflavored-sweetened
Very low Sweetened	*flavored-very low sweetened	unflavored-very low, sweetened

Note: green font = approved sessions
 red font = proposed additional session