NO MEANINGFUL EFFECT OF PROMOTIONAL MATERIALS FOR A NOVEL ORAL NICOTINE POUCH PRODUCT ON BEHAVIORAL INTENTIONS AND RISK PERCEPTIONS

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Abstract

Objective: This study evaluated the effect of promotional materials on behavioral intentions and risk perceptions for on! PLUS™ nicotine pouches (on! PLUS™ NPs) among adults who use and do not use tobacco.
Methods: We conducted an online, quantitative experimental study with 4,723 U.S. adults, who currently used smokeless tobacco (Adult Dippers; AD), used smokeless tobacco and cigarettes (Adult Dual Users; ADU), or did not use any tobacco product (Adult Nonusers). The study sample included a group of underage adults (18-20 years) and an oversample of young adults aged 21-24 years. Participants were randomly assigned to view the on! PLUS™ NPs concept with promotional materials (Test) or the concept only (Control).
Results: Overall, AD and ADU had high intention to try and moderate to high intention to use to on! PLUS™ NPs. Adult Nonusers and underage individuals had low intention to try or use on! PLUS™ NPs. The promotional materials had no effect on behavioral intentions to try or use on! PLUS™ NPs among AD, ADU, Adult Nonusers, and underage adults. AD and ADU accurately perceived using on! PLUS™ NPs as less risky than using cigarettes, using snuff/dip, or dual-use and riskier than using nicotine replacement therapies (NRTs) or quitting altogether. Adult Nonusers and underage adults perceived using on! PLUS™ NPs as similar in risk to using cigarettes and snuff/dip and riskier than using NRTs and completely quitting all tobacco.
Implications: These results suggest that on! PLUS™ NPs can facilitate AD and ADU transition to on! PLUS™ NPs while not increasing risk of initiation among nonusers. Tobacco users and nonusers understand that the on! PLUS™ NPs are not risk-free.

Introduction

Smokeless tobacco (ST) products contain harmful and potentially harmful constituents (HPHCs), of which some are classified as carcinogens by the FDA[1], yet moist smokeless tobacco (MST) products continue to be the predominant (~90%) type of ST products used in the U.S.[2] Novel oral nicotine products may offer a reduced-risk alternative to AD and ADU who are unwilling or unable to quit. To demonstrate that on! PLUS™ NPs are appropriate for the protection of public health, FDA requires information about the effects of the product and promotional materials on perceptions, intentions, and behaviors among intended and unintended audiences, as well as the likelihood of tobacco use initiation by nonusers. We conducted an online quantitative experimental study evaluating the effects of promotional materials on behavioral intentions and risk perceptions on! PLUS™ NP among adults who use and do not use tobacco.

Methods

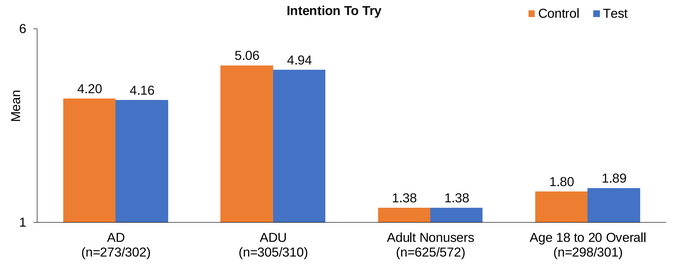
Study Objective:
Evaluate the effect of promotional materials on behavioral intentions (i.e., intention to try, intention to use) and risk perceptions for on! PLUS™ NPs among adults who use and do not use tobacco.

Participants:
The study enrolled 4,723 U.S. adult tobacco users and nonusers, oversampled for ages 21-24 and included a separate cohort of underage (to purchase tobacco products) adults ages 18-20*. Participants were recruited from online panels and central location testing facilities, with demographic quotas based on the 2020 National Health Interview Study (NCHS, NHIS 2020) for gender, age, race/ethnicity, education, and US region (Northeast, Midwest, South, West).

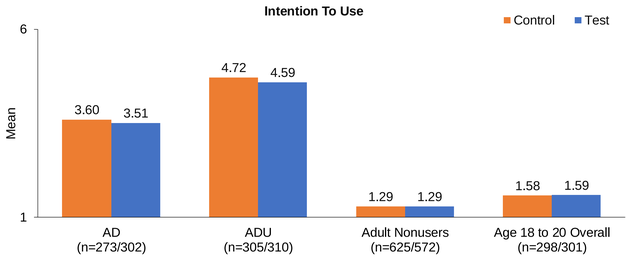
Study Design:
Participants were randomized to one of two study conditions:
- **Control (n=2419; C)** viewed the on! PLUS™ NPs product concept only
- **Test (n=2394; T)** viewed the on! PLUS™ NPs product concept as well as a suite of promotional materials (print materials, website screenshot, and product lineup)

The study instrument contained questions about socio-demographics and prior and current tobacco use behavior. It was followed by the presentation of study stimuli and post-exposure questions, described under Results.
*Note: Age 18-20 Overall includes both tobacco users and tobacco nonusers.

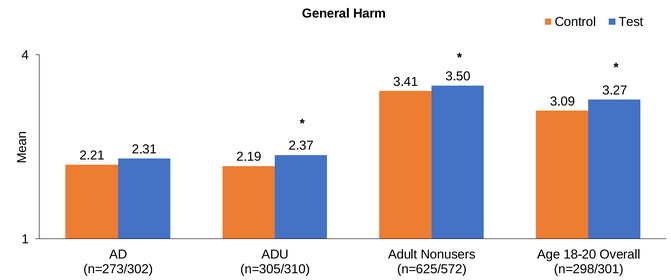
Results



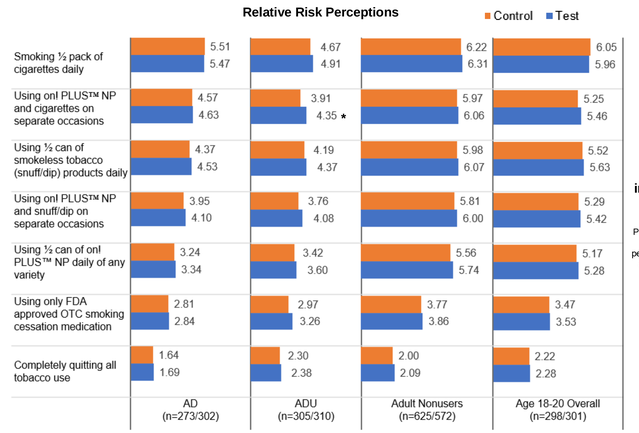
(Test vs. Control; * indicates statistically significant differences).
"I am open to trying on! PLUS™ NP in the next 30 days." (6-pt scale, Strongly disagree to Strongly agree); "Based on what you know about on! PLUS™ NP, how likely or unlikely are you to try on! PLUS™ NP?" (6-pt scale, Definitely Not to Definitely); "Based on what you know about on! PLUS™ NP, how likely or unlikely are you to try on! PLUS™ NP if one of your best friends were to offer on! PLUS™ NP to you?" (6-pt scale, Definitely Not to Definitely). Composite Score calculated by averaging across the three measures, at the individual level.
Note: The promotional materials did have an effect on intention to try for Age 21-24 Nonusers. Their intention to try was significantly higher however, the score reflected low intentions.



(Test vs. Control; * indicates statistically significant differences)
"I would consider using on! PLUS™ NP more than once." (6-pt scale, Strongly disagree to Strongly agree); "I expect to use on! PLUS™ NP." (6-pt scale, Strongly disagree to Strongly agree); "It is likely that I will regularly use on! PLUS™ NP in the next 6 months." (6-pt scale, Strongly disagree to Strongly agree). "on! PLUS™ NP will be my regular brand of tobacco in the next 30 days." (6-pt scale, Strongly disagree to Strongly agree). Composite Score calculated by averaging across the four measures, at the individual level.
Note: The promotional materials did have an effect on intention to try for Age 21-24 Nonusers. Their intention to use was significantly higher however, the score reflected low intentions.



(Test vs. Control; * indicates statistically significant differences)
"How harmful is using on! PLUS™ NP to a person's health?" (4-pt scale, Not At All Harmful to Very Harmful).



(Test vs. Control; * indicates statistically significant differences).
Please rate each item for the risk you feel it could pose to a person's health. (7-pt scale, 1 Not at all risky, 7 Extremely risky).

Conclusions

The study results suggest that the proposed promotional materials for on! PLUS™ NPs had no meaningful effect on behavioral intentions and risk perceptions.

- Both AD and ADU reported high intention to try on! PLUS™ NPs and moderate to high intention to use on! PLUS™ NPs. Adult Nonusers and underage young adults age 18-20 reported low intention to try or use.
- The promotional materials had no effect on intention to try or use on! PLUS™ NPs among AD, ADU, Adult Nonusers, and underage young adults age 18-20.
- All groups indicated that using on! PLUS™ NPs carried some level of harm to a person's health, regardless of study condition and accurately perceived the risk of on! PLUS™ NPs relative to other tobacco use behaviors.

Limitations:

- This research involved a non-probability-based sample and, therefore, may not provide true population estimates. However, we used sample quotas derived from national surveys to align key demographic characteristics of the sample with nationally representative samples of groups of interest.
- Study participants may rate risk perceptions for the candidate products in the context of incoming beliefs and attitudes that may create bias. To minimize this, we included a Control condition, with the assumption that the incoming beliefs and attitudes are comparable across the Control and Test conditions.
- Outcome measures were self-reported by study participants based on a single exposure to the stimuli in an experimental setting and may not reflect real-world use behaviors.

References

1. FDA Draft Guidance 2012: Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under Section 904(a)(3) of the Federal Food, Drug, and Cosmetic Act; 77 Fed. Reg. 20034 (April 3, 2012). FDA, Silver Spring, MD.
2. Federal Trade Commission Smokeless Tobacco Report for 2022.Retrieved from https://www.ftc.gov/system/files/ftc_gov/pdf/2022-Smokeless-Tobacco-Report.pdf. Accessed January 18, 2024. FTC, 2023, Washington D.C.

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