Switching people who smoke to unfiltered cigarettes: perceptions, addiction and behavioural effects in a cross-over randomised controlled trial

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ABSTRACT

Background Behavioural research is needed to inform a ban on sales of filtered cigarettes that could reduce plastic waste due to discarded filters. This study reports on differences in perceptions, nicotine dependence and behaviour among participants in a cross-over randomised trial of filtered compared with unfiltered cigarettes.

Method This proof-of-concept study involved 43 people who smoke filtered cigarettes (41.9% women, mean age 36.7 years). Participants were provided 2 weeks' supply of filtered cigarettes, 2 weeks of the same brand of unfiltered cigarettes and randomly assigned to starting conditions. Measures included the Modified Cigarette Evaluation Questionnaire; single-item cigarette perception questions; Fagerström Test of Nicotine Dependence; 7-day cigarette consumption, urinary cotinine and intention to quit. Analyses included linear and ordinal repeated measures mixed-effects models and paired t-tests.

Results Filtered cigarettes were perceived as better tasting, more satisfying, more enjoyable, less aversive, less harsh, less potent and less negatively reinforcing than unfiltered cigarettes. Filtered cigarettes were smoked at a higher rate during the trial than unfiltered cigarettes ($p \leq 0.05$). There was no difference in cotinine, dependence or intention to quit between filtered versus unfiltered cigarette conditions ($p > 0.05$).

Conclusion People who smoke perceived unfiltered cigarettes as having greater nicotine effects and less desirable sensory effects than filtered cigarettes, and they smoked fewer of these during the trial. Although cotinine, dependence and intention to quit were similar for smoking unfiltered and filtered cigarettes in this small trial, results suggest that banning the sale of filtered cigarettes might make smoking less attractive overall to people who smoke.

Trial registration number NCT03749876.

INTRODUCTION

There is widespread belief that filters provide a 'safer' cigarette,[1] but there is no evidence that cigarette filters reduce harms for people who smoke.[2–5] In addition, the cellulose acetate filter, found on nearly all commercially sold cigarettes, may have significant environmental impacts, facilitated by decades of tobacco industry misinformation and avoidance of producer responsibility.[6–11] Banning the sale and production of filtered cigarettes is a proposed solution to minimise these impacts by changing the product.[10 12 13] The WHO and other agencies have recommended eliminating plastic filters to reduce the global impact of this waste.[8] Eliminating filters from the tobacco market may help rectify effects of the 'filter fraud' foisted on the public for decades while also eliminating the main source of plastic environmental waste due to discarded cigarette butts.[14]

This study aims to evaluate perceptions, nicotine dependence and smoking behaviour while smoking filtered versus unfiltered cigarettes. We hypothesise that the (1) perception of unfiltered cigarettes will be negative compared with filtered cigarettes, (2) dependence on unfiltered cigarettes will be lower than for filtered cigarettes, (3) average daily consumption of unfiltered cigarettes will be lower than for filtered cigarettes and (4) intention to quit unfiltered cigarettes will be higher than for smoking filtered cigarettes.

METHODOLOGY

This was a proof-of-concept, randomised, cross-over clinical trial in which adults who smoke filtered cigarettes were provided 2 weeks of filtered cigarettes and 2 weeks of the same brand of unfiltered cigarettes (online supplemental figure 1). Participants were randomly assigned (1:1) to a starting condition (filtered or unfiltered). Hence, participants were their own controls. The team statistician randomised participants using a block balance method[15] and individually sealed opaque envelopes for concealment. The trial investigator opened the sealed envelopes to reveal the order of conditions.

The entire trial was 9 weeks and included a 3-week washout period to evaluate changes in toxicant exposure biomarkers (not reported in this paper), and two baseline evaluations (one at study entrance and one following the washout). Measurements in this report were taken at week 1 (study entry), weeks 2 and 3 (treatment condition 1 or 2), and weeks 8 and 9 (treatment condition 1 or 2).

The study protocol and inclusion/exclusion criteria are reported elsewhere.[16] After obtaining written informed consent, we conducted the study in San Diego County, California, USA from January 2019 to June 2020.

Sample size

The trial (required n=40) was designed with $\geq 80\%$ power to detect moderate within-subject effect

sizes ($f=0.35$) with a moderate correlation between repeated measures ($r>0.50$).

Measures

Perceptions

The 11-item Modified Cigarette Evaluation Questionnaire (mCEQ)[17] was administered immediately after smoking a study cigarette at each visit. This includes five subscales: Smoking Satisfaction, Psychological Reward, Aversion, Enjoyment of Respiratory Tract Sensations and Craving Reduction. Each item was measured on an ordinal Likert scale ranging from 1 (not at all) to 7 (extremely likely).

Five single-item questions assessed addiction, taste, harshness, draw ease and drug potency (scale 0–100). For addiction, the range was 'I am not addicted to cigarettes at all' to 'I am extremely addicted to cigarettes'. For taste, the range was 'Tastes terrible' to 'Tastes great'. For harshness, the range was 'Not harsh at all' to 'Extremely harsh'. For draw ease, the range was 'Very hard to draw' to 'Very easy to draw'. For drug potency, the range was 'No drug effect' to 'Very strong drug effect'.[18]

Nicotine dependence

We used the six-item Fagerström Test of Nicotine Dependence (FTND) to assess dependence at each visit, with score range 0–10.[19]

Smoking behaviour

Consumption

At baseline, participants were asked how many of the past 30 days they smoked cigarettes and how many cigarettes they smoked on those days. At each visit, participants were asked how many of the past 7 days they smoked cigarettes and how many cigarettes they smoked on those days.[20]

Biomarker verification

We measured creatinine-adjusted urinary cotinine[21] at condition 1 baseline, end of condition 1, condition 2 baseline and end of condition 2. Measurement methods included isotope-dilution liquid chromatography/tandem mass spectrometry.[22–24]

Intention to quit

Intention to quit was measured with the item, 'What best describes your intentions to stop smoking completely, not even a puff?',[20] at each visit. Responses included never expect to quit, may quit in the future but not in the next 6 months, will quit in the next 6 months and will quit in the next 30 days, coded on a 4-point ordinal scale.

Statistical analysis

Descriptive analyses included all protocol measures (mean daily consumption, mean butt counts, urinary cotinine/creatinine ratio and quit intentions). We used linear repeated measures, mixed-effects models to analyse mCEQ, single-item perception questions, FTND and consumption. Df for the factor t-tests was estimated using the Satterthwaite approximation.[25] We analysed the quit intention questionnaire using an ordinal logistic repeated measures model. Estimates were tested using a Wald X^2 test. All models included study arm (FU=filtered first, unfiltered second, or UF=unfiltered first, filtered second), treatment (exposure status at time of measurement), visit, sequence (condition 1 or 2), and sex as fixed effects, and participant number as a random effect. Missing observations on questionnaires

(14%–20% at week 7 or later) were omitted in these models (online supplemental table 1).

The ratio of log-transformed cotinine/creatinine was used to correct for variability in cotinine concentrations at all four measurements. Tests for differences between treatments and differences between baseline and post-baseline visits were performed using a paired t-test (omitted when post-baseline values were missing).

Analyses were performed using SAS V.9.4,[26] R V.3.6.2 and RStudio V.1.2.5033.[15] Unless specified, all analyses were performed for the intent-to-treat population that included all randomised participants.

RESULTS

Of 210 people screened for eligibility, 164 were eligible, and 43 were randomised (21 to filtered condition first and 22 to unfiltered condition first) (online supplemental figure 2). Study completion was 17 of 21 (81%) and 19 of 22 (86%) in the FU and UF arms, respectively. The mean (SD) age was 36.7 years (9.9), and 18 (41.9%) were women. At baseline, participants reported smoking an average (SD) of 14.5 (6.7) cigarettes per day in the past 30 days (online supplemental table 2). No serious adverse events occurred during the study.

Perceptions

Filtered cigarettes were rated as more satisfying (0.56 points higher (95% CI: 0.32 to 0.81), $p<0.01$), less aversive (0.28 points lower (95% CI: −0.52 to −0.03), $p=0.03$), more enjoyable (0.52 points higher (95% CI: 0.25 to 0.79), $p<0.01$) and less negatively reinforcing (0.38 points lower (95% CI: −0.70 to −0.06), $p=0.02$) than unfiltered cigarettes (table 1; online supplemental figure 3). Filtered cigarettes were perceived as better tasting (13.4 points higher (95% CI: 8.4 to 18.3)), less harsh (21.3 points lower (95% CI: −27.0 to −15.5)) and less potent (14.8 points lower (95% CI: −19.8 to −9.8)), compared with unfiltered cigarettes, $p<0.01$ (table 1; online supplemental figure 4). Additional results are reported in online supplemental tables 3 and 4.

Smoking behaviour

There was no difference in nicotine dependence score for filtered versus unfiltered cigarettes (0.15 points (95% CI: −0.22 to 0.52), $p=0.42$) (table 1). Average cigarettes smoked per day were 0.66 higher for filtered cigarettes compared with unfiltered cigarettes ((95% CI: 0.01 to 1.30), $p=0.05$) (table 1). The log-transformed creatinine-adjusted urinary cotinine level for participants was comparable when smoking filtered and unfiltered cigarettes (mean difference=−135 ng/mg lower (95% CI: −330.40 to 60.49), $p=0.17$) (table 1). There was no intention to quit difference for filtered and unfiltered conditions (OR=0.96 (95% CI: 0.56 to 1.66), $p=0.89$) (table 1). Additional results are provided in online supplemental tables 5–7 and online supplemental figure 5.

DISCUSSION

This randomised cross-over trial found that unfiltered cigarettes were perceived less favourably than filtered cigarettes. People who smoke rated unfiltered cigarettes as more harsh, worse tasting, less enjoyable and less satisfying. Participants also rated unfiltered cigarettes as more potent, aversive and negatively reinforcing compared with filtered cigarettes (dizziness and nausea are nicotine effects[17]). Positive subjective effects such as satisfaction are linked with greater risk of cigarette use,

Table 1 Cigarette evaluation, nicotine dependence and behaviours during filtered versus unfiltered smoking conditions

Outcome measure	Filtered vs unfiltered cigarettes MD or OR	SE	95% CI	P value
Cigarette evaluation†				
Smoking Satisfaction, 1–7	0.56*	0.12	0.32 to 0.81	**<0.01**
Psychological Reward, 1–7	0.15*	0.11	−0.06 to 0.37	0.16
Aversion, 1–7	−0.28*	0.13	−0.52 to 0.03	**0.03**
Enjoyment Respiratory Sensations, 1–7	0.52*	0.14	0.25 to 0.79	**<0.01**
Craving Reduction, 1–7	−0.38*	0.16	−0.70 to 0.06	**0.02**
Smoking perception				
Addiction, 0–100	0.95*	1.64	−2.28 to 4.19	0.56
Draw ease, 0–100	−5.08*	3.34	−11.66 to 1.51	0.13
Potency, 0–100	−14.80*	2.53	−19.79 to 9.81	**<0.01**
Taste, 0–100	13.35*	2.50	8.43 to 18.28	**<0.01**
Harshness, 0–100	−21.26*	2.92	−27.01 to 15.51	**<0.01**
Smoking behaviours and biomarker				
Cigarettes per day	0.66*	0.33	0.01 to 1.30	**0.05**
Cotinine, ng/mg‡	−135.0*	256.3	−303.40 to 60.49	0.18
Quit intention	0.96**	0.27	0.56 to 1.66	0.89
Nicotine dependence				
FTND, 0–10§	0.15*	0.19	−0.22 to 8.47	0.42

Bolded entries are statistically significant.
*MD (filtered–unfiltered); **OR.
†Cigarette evaluation included the five domains of the mCEQ
‡Adjusted for creatinine.
§A higher score indicates greater nicotine dependence.
FTND, Fagerström Test of Nicotine Dependence; mCEQ, Modified Cigarette Evaluation Questionnaire; MD, mean difference; OR, odds ratio; SE, standard error.

higher consumption, more nicotine exposure and increased dependence.[27–29] Negative nicotine effects such as aversion are associated with lower cigarette use risk, lower consumption, lower nicotine exposure and less dependence.[27 29] Thus, it was surprising that nicotine exposure, dependence, and quit intention were comparable between filtered and unfiltered cigarettes, despite different sensory perceptions and perceived nicotine effects. It is possible that nicotine exposure did not vary between filtered versus unfiltered cigarettes, because the difference in filtered and unfiltered cigarettes smoked was small. Also, our 2-week treatment period may have been insufficient to detect changes in dependence or smoking behaviour.[30]

Measuring changes in cigarette perceptions may provide valuable consumer insights in reaction to environmental tobacco product regulatory actions[31] such as banning the sale of filtered cigarettes.[32 33] Modifying or removing products with higher reinforcement value from the market may lead to reduced cigarette consumption and/or smoking cessation.[29 31 34 35] A longer study period and larger sample size will help determine whether banning filtered cigarettes may result in these effects. Additional research is needed to determine the possible environmental benefits of using unfiltered cigarettes.

Our findings must be viewed in light of limitations. The sample size was smaller than planned due to study interruption by COVID-19. In addition, we had missing questionnaire (14%–20%) and urine data (~30%) due to participant loss to follow-up and/or completing the study remotely. The drop-out rate was comparable between those who completed some visits remotely (2 out of 9 partially remote participants lost to follow-up (22%), vs 6 out of 34 never-remote participants lost to follow-up (18%)). Loss to follow-up was comparable between study arms (19% filtered vs 14% unfiltered). Additionally, we found that the return rate of cigarette butts was comparable between filtered (56.5%) and unfiltered (59.5%) conditions. However, we did not systematically document the number of butts returned which were filtered versus unfiltered. It is possible that participants did not exclusively use study cigarettes and a lack of difference in nicotine exposure between filtered and unfiltered groups could be due to non-adherence to using unfiltered cigarettes.[36]

Nevertheless, there are several strengths of this trial. To our knowledge, this is the first randomised, cross-over trial of participants smoking filtered or unfiltered cigarettes to assess perceptions, dependence and cigarette usage. This trial collected data on multiple participant-reported measures, biochemical measures and cigarette use at numerous time points, which collectively help to better define the cigarette user experience. The design ensured that participants served as their own control, thereby greatly reducing confounding in outcome assessments. Another strength is that we employed statistical models to analyse the data longitudinally, while accounting for treatment cross-over, which lends to more accurate measures of effect.

CONCLUSIONS

Unfiltered cigarettes were perceived by people who smoke as having greater nicotine effects and less desirable sensory effects than filtered cigarettes and were consumed at lower quantities than filtered cigarettes. However, there was no difference in nicotine exposure, dependence or intention to quit. Our findings provide proof of concept for a larger and longer clinical trial of filtered versus unfiltered cigarettes to provide more definitive evidence of the potential impact on people who smoke of legislation banning the sale of filtered cigarettes.

What this paper adds

► This is the first randomised trial testing the effects of filtered compared with unfiltered cigarettes on cigarette perceptions, nicotine dependence and smoking behaviour.

► People who smoke perceived unfiltered cigarettes as less desirable and smoked fewer of these during the trial. Nicotine dependence and intention to quit were comparable when using filtered and unfiltered cigarettes.

► Findings provide proof of concept for a larger and longer trial to provide more definitive evidence of the potential impact of tobacco product regulatory legislation to ban the sale of filtered cigarettes.

► Banning the sale of filtered cigarettes as an environmental concern may also support behavioural interventions toward the tobacco endgame.

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