Cigarette pack messages about toxic chemicals: a randomised clinical trial

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► Additional material is published online only. To view please visit the journal online (http://dx.doi.org/10.1136/tobaccocontrol-2017-054112).

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Received 20 October 2017
Revised 22 January 2018
Accepted 20 February 2018
Published Online First 13 April 2018

To cite: Brewer NT, Jeong M, Mendel JR, *et al*. *Tob Control* 2019;**28**:74–80.

ABSTRACT

Background The USA can require tobacco companies to disclose information about harmful and potentially harmful chemicals in cigarette smoke, but the impact of these messages is uncertain. We sought to assess the effect of placing messages about toxic chemicals on smokers' cigarette packs.

Methods Participants were 719 adult cigarette smokers from California, USA, recruited from September 2016 through March 2017. We randomly assigned smokers to receive either factual messages about chemicals in cigarette smoke and their health harms (intervention) or messages about not littering cigarette butts (control) on the side of their cigarette packs for 3 weeks. The primary trial outcome was intention to quit smoking.

Results In intent-to-treat analyses, smokers whose packs had chemical messages did not have higher intentions to quit smoking at the end of the trial than those whose packs had control messages (P=0.56). Compared with control messages, chemical messages led to higher awareness of the chemicals (28% vs 15%, P<0.001) and health harms (60% vs 52%, P=0.02) featured in the messages. In addition, chemical messages led to greater negative affect, thinking about the chemicals in cigarettes and the harms of smoking, conversations about the messages and forgoing a cigarette (all P<0.05).

Discussion Chemical messages on cigarette packs did not lead to higher intentions to quit among smokers in our trial. However, chemical messages informed smokers of chemicals in cigarettes and harms of smoking, which directly supports their implementation and would be critical to defending the messages against cigarette company legal challenges.

Trial registration number NCT02785484.

INTRODUCTION

Burning the tobacco in cigarettes creates and concentrates harmful and potentially harmful constituents (chemicals) that smokers inhale.[1] Toxic chemicals and particulate matter in cigarette smoke cause 480 000 deaths a year in the USA,[2] primarily from cancer, cardiovascular disease and respiratory disease.[3 4] However, few people fully understand these risks. The majority of US adults incorrectly believe that most harmful chemicals in cigarette smoke come from tobacco additives, and a third incorrectly believe that cigarette filters remove 'a lot' of these chemicals.[5] Helping people understand how smoking puts their health at risk and motivating them to quit smoking are two compelling public health goals that effective communication with smokers could help to achieve.[6]

Messages on cigarette packs have high reach because smokers see their packs many times a day.[7–10] Over 100 countries require pictorial cigarette pack warnings,[11] which effectively inform smokers about the health risks of smoking[9] and increase quit attempts.[12] The US Family Smoking Prevention and Tobacco Control Act requires the front and back of cigarette packs to have pictorial warnings,[13] which the tobacco industry has stalled through litigation.[14] The Tobacco Control Act also empowers the US government to implement messages about toxic chemicals in cigarette smoke anywhere on cigarette packs.[13] In the past, when US cigarette packs displayed the amount of tar and nicotine, comparisons across brands created the illusion of reduced risk that misled consumers.[15–17] Thus, countries have moved away from including quantitative information about chemicals in messages on packs.[18 19] Several countries including Mexico, Canada and Australia instead require descriptive, non-numerical chemical messages on cigarette packs, which have been associated with increases in knowledge of these chemicals.[20] The USA has yet to identify chemical messages or methods for disclosure.[21] The USA will likely have to defend any required new chemical messages against legal challenges by the tobacco industry. To establish evidence relevant to implementation of chemical messages, we evaluated them in a randomised clinical trial (RCT). We tested our hypothesis that messages on cigarette packs disclosing information about the presence of toxic chemicals in cigarette smoke would motivate smokers to quit. We also examined whether such chemical messages informed smokers.

METHODS

Participants

Participants in the RCT were adult smokers from the general population in the Bay Area in California, USA. Eligibility criteria were being age 21 years or older; being a current smoker (defined as having smoked at least 100 cigarettes and currently smoking every day or some days); smoking at least seven cigarettes per week (to exclude very light smokers who might not purchase their own packs); being able to attend five weekly appointments; being able to bring in 8 days' worth of cigarettes to each of the first four weekly visits; and being able to speak English and use a computer to take surveys. We excluded pregnant women from the trial, as well as smokers who used only roll-your-own cigarettes,

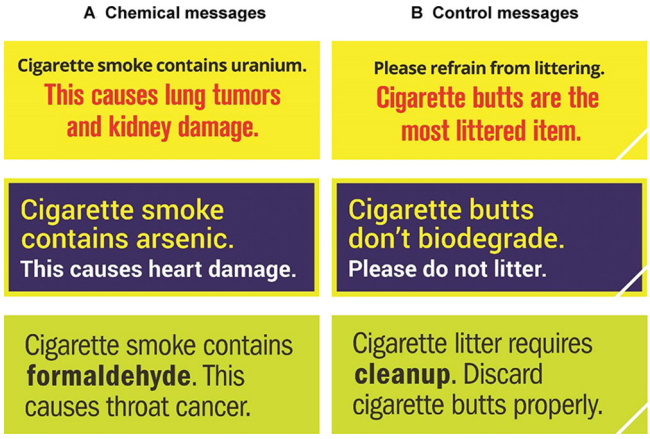

Figure 1 Labels placed on smokers' cigarette packs in intervention arm (A) and control arm (B).

were concurrently enrolled in another tobacco study or lived in the same household as another trial participant. We recruited participants between September 2016 and March 2017 through craigslist, Facebook, in-person recruitment and newspaper advertisements. We screened potential participants for eligibility online and by phone.

Procedures

Trial design

We conducted a parallel group RCT. Each smoker received a label on the side of his or her cigarette packs for a total of 3 weeks. We chose this exposure period because it allowed for sufficient time to observe an effect on our primary outcome of quit intentions based on our previous pictorial warnings trial.[12] Smokers in the intervention arm saw a different label every week, in one of the six possible orders. The control arm followed the same procedure. We chose to label the sides of packs for a conservative estimate of the messages' impact and because the USA might be more likely to place them on the side of packs since pictorial warnings are already required to appear on the front and back of packs.

Message development

We developed chemical (intervention) and litter (control) messages through a multistage process. First, we systematically reviewed the literature on how people think about the chemicals in cigarette smoke.[16] Second, we conducted focus groups on what adults and adolescents believed about chemicals in cigarette smoke.[22] Third, we conducted national surveys to identify chemicals and health effects that smokers thought would discourage them from wanting to smoke.[5 23 24] Fourth, we developed 76 chemical messages and conducted national surveys to evaluate the perceived effectiveness of these messages.[25 26] Fifth, we conducted focus groups to vet the nine most promising chemical messages to ensure that people brought the same meaning to the messages that we intended.[27] Sixth, we evaluated the perceived effectiveness of six chemical messages in a survey with a national probability sample, retaining the three most promising ones for the intervention arm in the trial.[27] Seventh, throughout the message development and testing process, we consulted toxicologists to confirm that the content of our messages was factual. The final chemical messages were 'Cigarette smoke contains formaldehyde. This causes throat cancer.'; 'Cigarette smoke contains uranium. This causes lung tumors and kidney damage.' and 'Cigarette smoke contains arsenic. This causes heart damage.' Eighth, we developed three attention-matched control messages about not littering cigarette butts that mirrored the number and approximate length of words in the chemical messages. The final control messages were: 'Cigarette litter requires cleanup. Discard cigarette butts properly.'; 'Please refrain from littering. Cigarette butts are the most littered item.' and 'Cigarette butts don't biodegrade. Please do not litter.' Finally, we worked with a graphic design firm to develop labels that included the intervention and control messages, optimised for the side of cigarette packs. The intervention and control labels had the same layout, size and colour (figure 1). The control labels had a small white line on the bottom-right corner to distinguish from intervention labels during implementation.

Trial protocol

We adapted the UNC Pack Labeling Protocol,[28] pilot tested it with 28 adult smokers and refined the protocol (online supplement 1). In our trial, we invited participants to attend five trial visits, each 1 week apart, at the trial office in San Francisco, California, USA. At visit 1, we confirmed eligibility, obtained written informed consent and enrolled smokers. Participants then and at each subsequent visit completed a computer survey.

We asked participants to bring 8 days' worth of cigarettes to visits 1–4. While participants took the survey, research staff removed the cellophane from the packs and marked the bottom of the packs with the visit date. At visit 1, participants brought in their cigarette packs to demonstrate that they could adhere to the trial protocol, but we did not label the packs.

To randomise participants, a statistician generated a prepopulated list of assignments randomly ordered in blocks of 12 conditions (2 arms × 6 label orders), prior to the start of the trial. This permuted block randomisation approach allowed the statistician to use a single allocation ratio to randomly assign smokers to 1 of 12 conditions while also maintaining balanced trial arms. When participants returned for visit 2, study staff assigned them to condition using this list.

At visits 2–4, research staff applied a self-adhesive label with an intervention or control message to the right side of each participant's cigarette packs (ie, on the side opposite from the existing Surgeon General's warning), covering most of that side. Participants who missed a visit after randomisation were able to complete the corresponding survey online; participants who missed visits 3 or 4 did not have their packs labelled for that week. At the end of each visit, on completion of the survey, participants received a cash incentive that totalled up to $300 across the trial. At the end of the trial, we offered participants information and resources about smoking cessation.

The trial's registration is available at clinicaltrials.gov, identifier NCT02785484.

Measures

A survey at visit 5 assessed the trial outcomes (eTable 1 in online supplement 2). The primary trial outcome was intention to quit smoking, assessed using a three-item scale that has high reliability[12 29] and correlates with smoking behaviour (Brewer *et al*, under review). The first item was, 'How interested are you in quitting smoking in the next month?', with responses that ranged from 'not at all interested' (coded as 1) to 'very interested' (4). The second item was, 'How much do you plan to quit smoking in the next month?', with responses that ranged from 'not at all' (1) to 'very much' (4). The third item was, 'How likely are you to quit smoking in the next month?', with responses that ranged from 'not at all likely' (1) to 'very likely' (4). We averaged these

intention items to create an intention score that ranged from 1 to 4 (Cronbach's α=0.94).

We conceptualised secondary trial outcomes related to being *informed* as a continuum from having heard information to actively thinking about it and changing one's risk beliefs. Measures of being informed were awareness of chemicals in cigarette smoke (ie, arsenic, uranium, formaldehyde) and health effects of smoking (ie, lung tumours, throat cancer, kidney damage, heart damage) that were in the intervention messages; awareness of chemicals (ie, ammonia, benzene, lead) and health effects (ie, lip cancer, strokes) *not* in the messages; thinking about the chemicals in cigarette smoke, the harms of smoking, the messages and quitting[30 31]; and perceived likelihood of smoking-related illnesses mentioned in the intervention messages (absolute chance of harm to the respondent).[12] We conceptualised secondary trial outcomes related to *motivation* as constructs that predict quitting smoking, based on the UNC Tobacco Warning Model (Brewer *et al*, under review) and other models[32 33] as well as prior empirical research.[34–37] Measures of motivators were negative affect (ie, fear, anxiety, disgust, sadness, guilt)[38–40]; number of conversations about the label in the past week[41 42]; number of times butting out or forgoing a cigarette in the past week[43 44]; attempt to quit smoking for 1 day or longer in the past 3 weeks, which included weekly and end-of-trial recall of quit attempts[45]; and quitting smoking (ie, did not smoke in the past 7 days as of the end of the trial).[46] We conceptualised thinking about the messages and their implications as related to both being informed and motivated.

The visit 1 survey assessed many of the same outcomes as well as participant demographics and smoking behaviours. Most survey items were previously validated; we cognitively tested newly developed measures either in person (n=7) or online (n=311).

Statistical analysis

Power analyses showed that enrolling 672 smokers would provide >80% power to detect a difference in quit intentions of d=0.22 (a small effect) or larger in analyses with α=0.05. To check whether random assignment created trial arms that were equivalent on demographic and outcome variables at visit 2 (the randomisation visit), we used χ^2 tests for categorical variables and t-tests for continuous variables. We used logistic regression to assess differential attrition.

Intention-to-treat analyses[47] of trial outcomes included all smokers randomised to trial arms (n=719). For smokers lost to follow-up, we used the last observation available to fill in any missing outcome values, allowing us to maintain the sample size and power of the study. We examined the effect of trial arm on the primary trial outcome (intentions to quit smoking) using linear regression. To assess whether the impact of trial arm differed among subgroups, exploratory analyses used linear regression models with interaction terms between trial arm and demographics or smoking frequency. We examined whether secondary outcomes differed by trial arms using χ^2 tests for dichotomous variables and t-tests for continuous variables. We did not plan or conduct interim analyses or other analyses beyond those reported here. Analyses used two-tailed tests in Stata V.14 (StataCorp, 2015) with a critical alpha of .05.

RESULTS

Participant characteristics

From September 2016 to March 2017, 784 adult current smokers enrolled in the trial (figure 2). We randomised all 719 smokers who returned to visit 2 (368 men, 320 women and 31 transgender people). Smokers in the trial were diverse, including a substantial number of African American, sexual minority, low-education, and low-income smokers (table 1). The trial arms

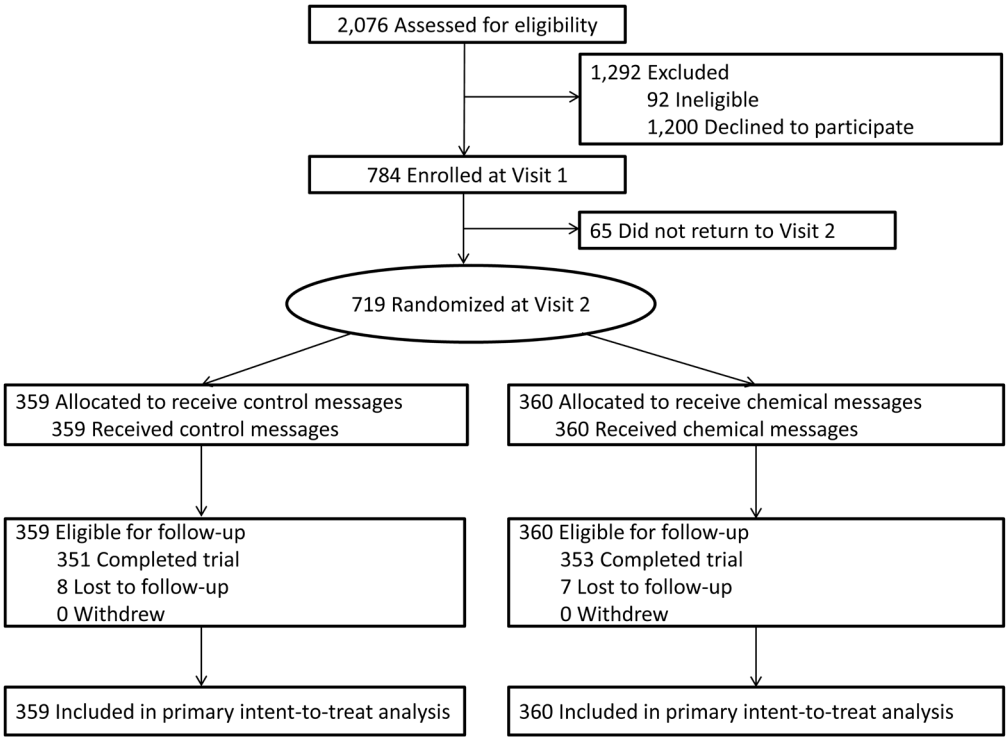

Figure 2 Flow diagram of trial enrollment, randomisation and retention.

Table 1 Participant characteristics

	Control messages (n=359)	Chemical messages (n=360)
	n (%)	n (%)
Age (years)		
21–29	81 (22.6)	83 (23.1)
30–39	86 (24.0)	78 (21.7)
40–49	59 (16.4)	75 (20.8)
50–59	90 (25.1)	91 (25.3)
60+	43 (12.0)	33 (9.2)
Mean (SD)	42.8 (13.6)	42.1 (13.2)
Gender		
Male	172 (47.9)	196 (54.4)
Female	169 (47.1)	151 (41.9)
Transgender (includes other gender identity)	18 (5.0)	13 (3.6)
Gay, lesbian or bisexual	88 (24.5)	93 (25.8)
Hispanic	56 (15.6)	44 (12.2)
Race		
White	136 (37.9)	132 (36.7)
Black or African American	124 (34.5)	133 (36.9)
Asian	29 (8.1)	31 (8.6)
American Indian or Alaska Native	17 (4.7)	17 (4.7)
Native Hawaiian or other Pacific Islander	11 (3.1)	12 (3.3)
Other/multiracial	42 (11.7)	35 (9.7)
Education		
High school graduate or less	67 (18.7)	89 (24.7)
Some college	151 (42.1)	124 (34.4)
College graduate	114 (31.8)	122 (33.9)
Graduate degree	27 (7.5)	25 (6.9)
Household income, annual $		
0–24 999	154 (42.9)	170 (47.2)
25 000–49 999	88 (24.5)	89 (24.7)
50 000–74 999	53 (14.8)	35 (9.7)
75 000+	64 (17.8)	66 (18.3)
Low income, <200% of federal poverty level	197 (54.9)	216 (60.0)
Cigarettes smoked per day, mean (SD)	9.97 (12.2)	11.62 (16.9)
Smoking frequency		
Daily	273 (76.0)	281 (78.1)
Non-daily	86 (24.0)	79 (21.9)
E-cigarette use in the past 3 weeks	95 (26.5)	94 (26.2)
Other tobacco product use in the past 3 weeks	149 (41.5)	139 (38.6)
Primary trial outcome at baseline		
Intended to quit smoking in the next month, mean (SD)	2.36 (1.0)	2.37 (0.9)
Secondary trial outcomes at baseline		
Made quit attempt (for 24 hours) in the past 3 weeks*	96 (26.7)	91 (25.3)
Quit smoking for ≥7 days	8 (2.2)	6 (1.7)
Number of times forgoing/ butting out a cigarette in the past week, mean (SD)†	4.9 (4.6)	5.3 (4.8)
Thinking about the harms of smoking, mean (SD)	2.9 (1.1)	2.8 (1.0)
Thinking about quitting, mean (SD)	2.8 (1.3)	2.8 (1.2)
Thinking about the chemicals in cigarettes, mean (SD)	2.6 (1.3)	2.5 (1.2)

Participant characteristics and outcomes did not differ by trial arm at baseline (all P>0.05). Baseline surveys did not assess awareness of health effects (on or not on labels), awareness of chemicals (on or not on labels), thinking about the message, negative affect, perceived likelihood of harm from smoking and number of conversations about the label. For thinking about the harms of smoking, baseline surveys included two of the three items (thinking about harms to self and harms to others) but not the third item on thinking about health problems caused by smoking.

*Quit attempts in the past three weeks were assessed at enrolment.

†Summed score, ranging from 0 to 20, reflecting number of times forgoing a cigarette and number of times butting out a cigarette.

(359 smokers received control messages about littering and 360 received intervention messages about toxic chemicals in cigarette smoke) did not differ with respect to demographic characteristics and baseline values for primary and secondary outcomes (table 1). Participants attended and had their cigarette packs labelled at an average of 2.9 of 3 trial visits. Analyses of attrition showed that 98% of participants (n=704) completed the final visit and survey. Fifteen participants were lost to follow-up; no participant withdrew from the trial. Attrition did not differ by trial arm (P=0.79). Attrition also did not differ by demographic characteristics across trial arms except for income (P<0.05 for interaction); low-income smokers in the intervention arm and high-income smokers in the control arm were less likely to complete the visit 5 survey. No participant reported adverse events during the trial.

Motivating quitting

The intervention and control arms did not differ on the primary trial outcome, intentions to quit smoking, at the end of the trial (table 2). Smokers who received chemical messages had mean quit intentions of 2.6 (SD 1.0), and smokers who received litter messages had mean quit intentions of 2.6 (SD 1.1, P=0.56). In exploratory analyses, the effect of trial arm on quit intentions did not differ among the demographic subgroups we examined (P>0.38 for all interactions; eTable 2 in online supplementary 2); the effect of trial arm on quit intentions differed by smoking frequency but not after controlling for baseline quit intentions.

With respect to motivators of quitting, intervention messages led to more negative affect (P<0.001) and more conversations about the messages (P=0.04). Forgoing a cigarette in the past week was more common in the chemical message arm than litter message arm (mean (SD)=6.6 (5.6) vs 5.6 (5.1) times, P=0.02; table 2). Trial arms did not differ on quit attempts or quitting, outcomes the trial was not powered to detect.

Increasing understanding

Exposure to chemical messages led to greater awareness of the chemicals (28% vs 15%, P<0.001) and health effects (60% vs 52%, P=0.02) mentioned in the intervention messages than did the litter messages. Trial arms did not differ with respect to awareness of chemicals and health effects *not* in the intervention messages. Exposure to chemical messages also led to more thinking about the chemicals in cigarettes (P=0.002) and about

Table 2 Trial outcomes at visit 5, intent-to-treat analysis

	Control messages (n=359)		Chemical messages (n=360)			
	n	Mean (SD)	n	Mean (SD)	Difference (95% CI)	P values
Primary outcome						
Quit intentions*	359	2.6 (1.1)	360	2.6 (1.0)	0.05 (–0.11 to 0.20)	0.56
Secondary outcomes						
Negative affect†‡	351	2.0 (1.0)	350	2.4 (1.1)	0.34 (0.18 to 0.49)	<0.001
Thinking about						
The chemicals in cigarettes†	359	2.5 (1.3)	360	2.8 (1.2)	0.30 (0.11 to 0.48)	0.002
The harms of smoking†	359	2.8 (1.1)	360	3.0 (1.0)	0.17 (0.02 to 0.33)	0.03
The message†‡	351	2.6 (1.1)	353	2.7 (1.1)	0.01 (–0.15 to 0.17)	0.88
Quitting†	359	3.1 (1.4)	360	3.1 (1.2)	0.03 (–0.16 to 0.22)	0.75
Perceived likelihood of harm from smoking†	359	3.1 (0.9)	360	3.2 (0.9)	0.03 (–0.09 to 0.16)	0.62
Number of conversations about label in the past week	359	1.9 (3.3)	360	2.5 (4.2)	0.57 (0.02 to 1.12)	0.04
Number of times forgoing/butting out a cigarette in past week	359	5.6 (5.1)	360	6.6 (5.6)	0.94 (0.15 to 1.73)	0.02
		%		%	% Difference (95% CI)	
Awareness of						
Chemicals in intervention messages§	359	15.0	360	28.1	13.01 (7.08 to 18.95)	<0.001
Health effects in intervention messages§	359	51.8	360	60.3	8.47 (1.24 to 15.70)	0.02
Chemicals not in intervention messages§	359	16.2	360	13.6	–2.54 (–7.75 to 2.66)	0.34
Health effects not in intervention messages§	359	48.2	360	43.9	–4.30 (–11.58 to 2.98)	0.25
Made quit attempt (for 24 hours) in the past 3 weeks	359	41.8	360	41.4	–0.39 (–7.60 to 6.81)	0.92
Quit smoking for ≥7 days	359	7.0	360	5.8	–1.13 (–4.71 to 2.45)	0.54

Outcomes were assessed by survey at the final trial visit.
*Response scale for quit intentions ranged from 1 to 4, with 4 indicating highest intentions.
†Response scale for negative affect, thinking about the chemicals in cigarettes, thinking about the harms of smoking, thinking about the message, thinking about quitting and perceived likelihood of harm from smoking ranged from 1 to 5, with 5 indicating higher quantity or stronger endorsement.
‡Negative affect and thinking about the message were not assessed until week 3 follow-up, resulting in a smaller n for these analyses.
§Had heard of at least half of the chemicals being in cigarette smoke or their health effects, in a 2-to-4-item index.

the harms of smoking (P=0.03). Trial arms did not differ on thinking about the message, thinking about quitting or perceived likelihood of harm.

DISCUSSION

Government agencies regularly require disclosures about potential product harms, but the impact of such disclosures on the public is poorly understood.[6] In our randomised trial with adult smokers, chemical messages on cigarette packs did not increase motivation to quit smoking as measured by quit intentions. This is in contrast to pictorial cigarette pack warnings, which increase quit intentions, quit attempts and successful quitting.[12] One explanation for the difference is that pictorial warnings caused large increases in negative affect as well as thinking and talking about the messages, whereas chemical messages had only a modest impact on these outcomes (table 3).[12] Affective reactions bring meaning and importance to facts.[48–51] Facts presented plainly, as in our messages, may not adequately trigger the kinds of emotional, cognitive and interpersonal responses necessary to motivate smokers to quit. Other potential explanations are that text-based chemical messages are not as vivid as pictorial warnings, and the placement of chemical messages on the side of the pack may reduce their impact. Pictorial warnings,[12] and the chemical messages in our trial, increased forgoing a cigarette, perhaps reflecting a brief and transitory behavioural impact of the messages that might influence future cessation based on prior research about micro-indicators of quitting.[36 52 53]

Table 3 Impact of chemical messages and pictorial warnings

	Effect size for chemical messages (d)	Effect size for pictorial warnings (d)[12]
Negative affect	Medium (0.31)	Large (0.54)
Thinking about the harms of smoking	Small (0.15)	Small (0.18)
Thinking about the message	Small (0.01)	Large (0.61)
Perceived likelihood of harm from smoking	Small (0.04)	Small (0.00)
Number of conversations about label in the past week	Small (0.15)	Medium (0.26)
Quit intentions	Small (0.04)	Small (0.18)

Cohen's d of <0.20 is a small effect, 0.20–0.50 is a medium effect and >0.50 is a large effect.[64]

Chemical messages in our trial were, however, successful in informing smokers about chemicals in cigarette smoke. Although the chemical messages in our trial did not increase perceived likelihood of harm from smoking, neither do pictorial warnings.[10 12 54] Awareness increased for the chemicals and health effects mentioned in the chemical messages—and awareness did not change for other chemicals and health effects *not* mentioned. Chemical messages also increased thinking about chemicals in cigarette smoke and the harms of smoking. These findings are important given that US smokers have low awareness of the many chemicals in cigarette smoke.[5 16] Chemical messages may fill gaps in knowledge and increase understanding about these toxic chemicals, new information that the public is interested in receiving.[16 55] Another way to inform smokers about the many risks associated with smoking is a media campaign about chemicals in cigarette smoke.[56] Government media campaigns face fewer legal constraints than messages required on cigarette packs. Campaigns can also communicate about chemicals in

more active and vivid ways that are potentially more impactful, as the USA is doing as part of *The Real Cost* campaign that targets at-risk youth.[57 58]

In the likely event of a cigarette company lawsuit challenging any government-required chemical messages on packs, the US government would have to demonstrate that it acted within its legal authority. The Tobacco Control Act permits the US FDA Center for Tobacco Products to require cigarette packs to have chemical messages that would protect public health, benefit public health or 'increase consumer awareness of the health consequences of the use of tobacco products'.[13] In our trial, chemical messages increased awareness of chemicals in cigarette smoke and of the harms of smoking. Thus, our findings would support government action to require chemical messages on cigarette packs.

The government would also have to demonstrate that requiring chemical messages does not violate First Amendment constraints on regulating commercial speech.[14] Courts could make the government establish that the chemical messages plausibly advance a legitimate interest.[59] The increase in awareness in our trial shows that requiring such messages would advance the government interest of informing smokers. In addition, courts could make the government demonstrate that the chemical messages are 'factual and uncontroversial'.[59] The messages in our trial are both factual and uncontroversial, as confirmed by scientists with expertise in toxic chemicals and their health consequences, as well as by legal scholars with expertise in public health and the First Amendment. An intriguing possibility is that pairing pictorial health warnings with chemicals messages on cigarette packs could act synergistically to better inform and motivate smokers beyond what either do on their own. However, it is also possible that putting both chemical messages and pictorial health warnings on packs could detract from the effectiveness of pictorial warnings. Future studies should assess their joint impact.

Trial strengths include a large sample of diverse smokers who received carefully developed messages on their cigarette packs for 3 weeks. Other strengths include random assignment and control messages matched for size, colour, word length and location on the pack, allowing us to isolate the effects of the chemical message content. The generalisability of these findings to youth and non-smokers has yet to be established given that our trial enrolled only adult smokers, although our developmental findings were promising for these groups. Similarly, it will be helpful to replicate the findings in other locales with different tobacco control policies and norms surrounding smoking and outside the context of a clinical trial. Studies of the impact of chemical messages over the course of months or years could offer new insights on how to counter the waning impact of tobacco warnings over time,[37 60–62] which necessitates regular implementation of novel messages.

CONCLUSIONS

Our findings suggest that chemical messages on the side of cigarette packs could advance the US government interest of informing smokers, supporting their implementation. However, in our trial, chemical messages did not increase quit intentions and therefore do not appear to motivate quitting smoking. The extent to which pictorial warnings and chemical messages work in a complementary manner to reinforce one another is an important area for future study.[63]

Acknowledgements The authors thank the staff at Ewald & Wasserman Research Consultants LLC, Trent Johnson, MPH, and Jessica Pepper, PhD, for their assistance with the trial; and Micah Berman, JD, and Eric Lindblom, JD, for their feedback on the manuscript. They received no compensation for their contributions beyond that received in the normal course of their employment.

What this paper adds

- The US Tobacco Control Act allows cigarette packs to have messages about toxic chemicals in cigarette smoke. Data do not yet show whether such messages help people understand how smoking puts their health at risk or motivates them to quit smoking.
- Chemical messages on the side of cigarette packs did not lead to higher intentions to quit in a randomised clinical trial with 719 adult smokers in California, USA.
- However, chemical messages informed smokers of chemicals in cigarette smoke and harms of smoking.

Contributors NTB had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: NTB, MHB, JRM, MGH, SMN, SAB, JCM and KMR. Acquisition, analysis or interpretation of data: NTB, MJ, DZ, HP and MHB. Drafting of the manuscript: NTB, MJ, JRM and MGH. Critical revision of the manuscript for important intellectual content: all authors. Statistical analysis: NTB, MJ, DZ and MHB. Obtained funding: NTB, MGH, SMN and KMR. Administrative, technical or material support: NTB, MJ, JRM, MGH, HP, SAB, JCM and KMR. Study supervision: NTB and JRM.

Funding Research reported in this publication was supported by grant number P50CA180907 from the National Cancer Institute and FDA Center for Tobacco Products (CTP). T32CA057726 from the National Cancer Institute of the National Institutes of Health supported MGH's time writing the paper.

Disclaimer The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH or the Food and Drug Administration. The funding institutions had no role in the design and conduct of the study; collection, management, analysis and interpretation of the data; preparation, review or approval of the manuscript; and decision to submit the manuscript for publication.

Competing interests None of the authors have received funding from tobacco product manufacturers. NTB and KMR have served as paid expert consultants in litigation against tobacco companies. The other authors declare no conflicts of interest.

Patient consent Obtained.

Ethics approval The University of North Carolina institutional review board approved the trial procedures.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement Due to our university's requirements on grant-funded research, we can share the study data with a signed data use agreement. Investigators wishing to access the data may contact the first or last author of the paper.

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