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Quasi-experimentally examining the impact of introducing tobacco pictorial health warnings: Findings from the International Tobacco Control (ITC) 4C and Netherlands surveys in the Netherlands, Australia, Canada, United Kingdom, and the United States

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ABSTRACT

Background: Our study evaluated the short-term impact of introducing European Union's tobacco pictorial health warnings (PHWs).

Methods: Longitudinal data were collected at two time-points from adult smokers, participating in the International Tobacco Control (ITC) surveys, conducted in the Netherlands, Australia, Canada, the United Kingdom and the United States. In the Netherlands, textual health warnings (THWs) were replaced by PHWs between both time-points. Health warning policies did not change in the other countries. Data from continuing smokers were used (N = 3,487) and analyzed using Generalized Estimating Equations.

Results: Between both time-points, only Dutch smokers showed increases in noticing health warnings ($\beta = 0.712$, $p < 0.001$), self-reports of health warnings leading to a cognitive response such as thinking about smoking health-risks (SHRs) (OR = 1.834, $p < 0.001$), knowledge about SHRs ($\beta = 0.369$, $p < 0.001$), and avoiding health warnings (OR = 9.869, $p < 0.001$). However, Dutch smokers showed no changes in attitude towards smoking ($\beta = 0.035$, $p = 0.518$), intention to quit smoking (OR = 0.791, $p = 0.157$), self-efficacy to quit smoking ($\beta = -0.072$, $p = 0.286$), or reporting that health warnings helped them to resist having a cigarette (OR = 1.091, $p = 0.714$).

Conclusions: Results suggest that introducing the European PHWs was effective in provoking changes closely related to health warnings, but there was no direct impact on variables more closely related to smoking cessation.

1. Background

Health warnings on the packet of tobacco products are a health communication strategy to inform the public about the health risks of smoking (Hammond et al., 2006). Dutch tobacco control policy makers have been reluctant with using negative campaign messages about the health risks of smoking and preferred positive messages about quitting smoking (Willemsen, 2018). The Netherlands used textual health warnings (THWs; on 30 % of the front and 40 % of the back of the packet) since 2002, until in May 2016 all European member states were required to introduce pictorial health warnings (PHWs; on 65 % of both sides of the packet; accompanied with THWs on 50 % of both sides)

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Table 1
Health warning policy, year when introduced, sizes, fieldwork periods, and sample sizes per country.

	Health warning policy	Year introduced	Size – front	Size – back	Size – side(s)	Baseline Survey	Follow-up Survey
The Netherlands Baseline	THWs on front and back	2002	30 %	40 %	0 %	May 2013 - June 2013 N = 1,480	
The Netherlands Follow-up	PHWs on front and back. THWs on both sides.	2016	65 %	65 %	50 %		November 2016 - December 2016 N = 578
Australia Baseline & Follow-up	PHWs on front and back	2006	30 %	90 %	0 %	October 2008 - July 2009 N = 1372	July 2010 - June 2011 N = 833
Canada Baseline & Follow-up	PHWs on front and back	2001	50 %	50 %	0 %	October 2008 - July 2009 N = 1,511	July 2010 - June 2011 N = 985
United Kingdom Baseline & Follow-up	PHWs on back	2008	0 %	40 %	0 %	July 2010 - June 2011 N = 968	February 2013 - September 2013 N = 527
United States Baseline & Follow-up	THW on one side	1984	0 %	0 %	50 %	July 2010 - June 2011 N = 1252	August 2013 - March 2015 N = 579
Total						N = 6,583	N = 3,478

THWs, textual health warnings; PHWs, pictorial health warnings.

(European Union, 2015), as part of the Tobacco Products Directive (2014/40/EU) (European Union, 2014) (see Supplementary Table 1) (7). The new tobacco health warnings had to be fully implemented as of May 2017.

Previous pre-post studies from Australia (Borland et al., 2009), the United Kingdom (UK) (Nagelhout et al., 2016), Thailand (Yong et al., 2013) (all quasi-experimental), and Mauritius (Green et al., 2014) found that after introducing PHWs (accompanied with THWs), more smokers reported 1) noticing health warnings (salience; result was not found in the UK study), 2) avoiding health warnings, 3) having a cognitive response to health warnings (such as thinking about the health risks of smoking), and 4) health warnings stopped them from having a cigarette when they were about to have one (forgoing). Also, an Australian quasi-experimental study found that introducing PHWs increased smokers' knowledge about the health risks of smoking (Kennedy et al., 2012). According to the International Tobacco Control (ITC) conceptual model, which articulates how tobacco control policies exert their impact, salience, avoiding, cognitive response, forgoing, and knowledge can be considered as 'policy-specific variables', as they are most specifically related to the policy itself (Fong et al., 2006).

Evaluating the impact of PHWs should, however, preferably also be done for outcome variables belonging to socio-cognitive models of health behavior, and that have been conceptually and empirically linked to behavioral outcome variables such as quitting (Francis et al., 2017). According to the ITC conceptual model, these 'psychosocial mediators' include attitude towards smoking, intention to quit smoking, and self-efficacy to quit smoking; outcome variables distally related to the policy, as they may be affected by multiple factors, not just policies (Fong et al., 2006). No previous studies have examined the impact of introducing PHWs on attitude towards smoking. Attitude towards quitting was studied in a study from Thailand which found that smokers had a more positive attitude towards quitting after introducing PHWs (Silpasuwan et al., 2008). Self-efficacy was only studied experimentally (Noar et al., 2016), but to our knowledge there are no studies that examined the impact of introducing the PHWs in a country. Intention to quit smoking was examined by one study from Mexico that revealed that intention did not change directly after introducing PHWs (Thrasher et al., 2012).

It is also important to consider whether the impact of PHWs varies as a function of education, since low educated individuals are more likely to smoke (Brown et al., 2014; Benson et al., 2015). Moreover, they generally have less knowledge about the health risks of smoking than more highly educated smokers (Cummings et al., 2004; Yang et al., 2010; Siahpush et al., 2006; Sansone et al., 2012; Klesges et al., 1988; Brownson et al., 1992; Driezen et al., 2016). It is important to test whether health communication policies such as PHWs are effective among these individuals, and whether educational differences can be reduced through tobacco control policies. Observational studies examining the implementation of PHWs in France, the UK (Nagelhout et al., 2016), and Brazil (Thrasher et al., 2010; Bittencourt et al., 2013) found inconsistent results on educational differences in the impact of PHWs on salience, cognitive response, and forgoing. For instance, previous studies found equal (Nagelhout et al., 2016) or more impact on cognitive responses among low educated smokers (Thrasher et al., 2010; Bittencourt et al., 2013). The PHWs from these countries differed from the PHWs from the current study as they covered 1.0 % of either the front or the back of the packet (Thrasher et al., 2010; Bittencourt et al., 2013) or were on one side of the packet (Nagelhout et al., 2016).

The present study was designed to evaluate the impact of introducing the European PHWs, using a rigorous, quasi-experimental design, comparing pre-post differences in the Netherlands to countries where there was no change in health warning policy. The current study was designed to answer the following research questions (RQs): 1) Was introducing PHWs in the Netherlands associated with changes in policy-specific variables among continuing smokers? 2) Was introducing PHWs in the Netherlands associated with changes in psychosocial mediators among continuing smokers? 3) Were these changes larger in the Netherlands than in the control countries, which had unchanged health warning policies? 4) Did the changes in the Netherlands differ according to smokers' level of education?

2. Materials and methods

2.1. Data collection and sample

We used the evaluation framework from the International Tobacco Control Policy Evaluation Project (ITC Project). The ITC Project's methodology (Thompson et al., 2006) and conceptual framework (Fong et al., 2006) have been described elsewhere. For this study, four high-income countries, with different health warning policies, were used as control countries for the Netherlands: Australia, Canada, the UK, and the United States (US). The survey protocols and all materials, including the survey questionnaires, were cleared for ethics by Human Research Ethics, Cancer Council Victoria, Australia; Office of Research Ethics, University of Waterloo, Canada and the Netherlands; Research Ethics Office, King's College London, UK; and Office of Research Subject

Protection, Roswell Park Comprehensive Cancer Center, US. Table 1 describes health warning policy, year when introduced, and size for each country. A prerequisite for choosing the time-points was that in the control countries there was no change in health warning policy, and that the baseline time-point did not just follow a change in health warning policy. To ensure that the time between measurements was similar for the Netherlands and control countries, we chose to use the 2013 Dutch baseline time-point and the 2016 follow-up time-point. Only current continuing smokers were included because exposure to health warnings is reduced once smokers quit smoking. Moreover, ex-smokers were not asked questions on avoiding, intention, and self-efficacy, as these were not applicable. The number of respondents smoking at baseline and at follow-up ranged between 527 (UK) and 985 (Canada), with a total of 3487 continuing smokers. Table 1 shows fieldwork periods and sample sizes per country. In the Netherlands, computer-assisted web interviews were conducted, while the control countries used computer-assisted telephone interviews. An ITC study found that web- and telephone interviewing were comparable on key demographic and smoking-related variables (Nagelhout et al., 2010).

To ensure a representative sample, Dutch respondents were recruited from a probability-based database (Nagelhout et al., 2010), while respondents from control countries were selected via random-digit dialing. Through tailored replenishment samples in the Netherlands (Zethof et al., 2016) and sampling weights in all countries, we tried to ensure representativeness by compensating for attrition effects (Zethof et al., 2016; International Tobacco Control Policy Evaluation Survey, 2011). Only smokers aged 18 years and older were included in this study. Respondents were eligible as smokers if they had smoked at least 100 cigarettes in their lifetime, and if they reported smoking at least monthly (Hyland et al., 2006). To determine smoking frequency, respondents were asked whether they smoked at least once a day, at least once a week, or at least once a month.

2.2. Measurements

Table 2 elaborates on the current study's outcome variables. Composite measures were used for cognitive response ($\alpha = 0.72$), knowledge ($\alpha = 0.53$), and self-efficacy ($\alpha = 0.59$). The responses to the cognitive response-questions were combined by computing a composite binary variable of (0) no cognitive response versus (1) cognitive response (Nagelhout et al., 2016).

2.3. Control variables

Time invariant control variables were age, country and gender. Four time-varying control variables were applied in this study. First, we controlled for time-in-sample effects (Driezen and Thompson, 2011), i.e. the number of surveys in which the respondent participated. Second, we controlled for the level of addiction to tobacco, by including the Heaviness of Smoking Index (HSI). This is a combined measure of the time before smoking the first cigarette of the day (5 min or less, 6 – 30 min, 31 – 60 min, 61 + minutes), and the number of cigarettes smoked per day (0–10, 11–20, 21–30, 31 +). HSI values range between 0 and 6, with higher values indicating stronger addiction to tobacco (Heatherton et al., 1989). Third, we controlled for intention to quit smoking. Finally, in the analyses for RQs 1 through 3, we controlled for the respondents' educational level. In each country education was classified into 3 ordinal categories, although the actual classification points varied across countries because of differences in educational systems, similar to previous ITC studies (Nagelhout et al., 2010; Hyland et al., 2006).

2.4. Analyses

Analyses were performed with SPSS 23.0. All statistical estimates and tests presented were weighted by gender and age. Generalized estimating equations (GEE) analyses were conducted to examine time, country and educational differences. To test whether introducing PHWs in the Netherlands was associated with changes in policy-specific (RQ1), and psychosocial mediators (RQ2), GEE analyses were conducted on the Dutch sample. To examine whether the changes were greater in the Netherlands than in the control countries (RQ3), GEE analyses were conducted, with interactions between country (with dummy variables of the interactions of the Netherlands vs. each control-country separately) and time-point. To test whether the changes in the Netherlands differed according to level of education of the smoker (RQ4), separate GEE analyses, with interactions between time-point and educational level, were conducted on the Dutch sample.

Table 2
Outcome variables.

	Question and answer options
Policy-specific	
Salience	In the last month, how often have you noticed the warning labels on cigarette packages or on roll-your-own-packs? – (1) Never, (2) Rarely, (3) Sometimes, (4) Often, (5)Very Often, and Don't know
Avoiding	In the last 30 days, have you made any effort to avoid looking at or thinking about the warning labels – such as covering them up, keeping them out of sight, using a cigarette case, avoiding certain warnings, or any other means? – (0) No, (1) Yes, and Don't know
Cognitive response	1. To what extent, if at all, do the warning labels on cigarette packs make you more likely to quit smoking? – (0) Not at all, (1) A little, (1) Somewhat, (1) A lot, and Don't know 2. To what extent, if at all, do the warning labels make you think about the health risks of smoking? – (0) Not at all, (1) A little, (1) Somewhat, (1) A lot, and Don't know 3. In the past 6 months, have warning labels on cigarette packages led you to think about quitting?" – (0) Not at all, (1) A little, (1) Somewhat, (1) A lot, and Don't know
Forgoing	In the last 30 days, have the warning labels stopped you from having a cigarette when you were about to smoke one? – (1) Never, (2) Once, (3) A few times, (4) Many times, and Don't know
Knowledge	Based on what you know or believe, does smoking cause… 1. Impotence in male smokers – (0) No, (1) Yes (correct answer), and (0) Don't know 2. Blindness – (0) No, (1) Yes (correct answer), and (0) Don't know 3. Stroke – (0) No, (1) Yes (correct answer), and (0) Don't know
Psychosocial mediator	
Attitude	What is your overall opinion of smoking (1) Very negative, (2) Negative, (3) Not positive and not negative, (4) Positive, (5) Very positive, and Don't know
Intention	Are you planning to quit smoking? – (0) Not planning to quit, (1) Within the next month, (1) Within the next six months, (1) Sometime in the future, beyond six months, and Don't know
Self-efficacy	1. If you decided to give up smoking completely in the next 6 months, how sure are you that you would succeed? – (1) Not at all sure, (2) Slightly sure, (3) Moderately sure, (4) Very sure, (5) Extremely sure, and Don't know 2. How easy or hard would it be for you to quit smoking if you wanted to? – (1) Extremely difficult, (2) Very difficult, (3) Moderately difficult, (4) Slightly difficult, (5) Not at all difficult, and Don't know

Respondents with missing data were excluded for the analysis of that particular variable. The normal distribution and identity link were used for continuous outcome variables, whereas the binominal distribution and the logit link were used for dichotomous outcome variables. The unstructured correlation structure was applied (Ballinger, 2004). GEE analyses were adjusted for control variables. An alpha level of < 0.01 was chosen due to the relatively large number of comparisons (Lang and Secic, 2006).

3. Results

3.1. Sample

Of the 6583 smokers interviewed at baseline, 3487 smokers were interviewed at follow-up and were still smoking (Table 1). Attrition ranged from 26.8 % (Canada) to 49.3 % (the Netherlands) ($\chi^2 = 114.47$, $p < 0.001$). The percentage of respondents lost to follow-up because they had quit smoking ranged from 11.4 % (Australia) to 8.0 % (Canada) ($\chi^2 = 9.471$, $p = 0.050$), with the Netherlands having 11.0 % who had quit. Continuing smokers differed at baseline from smokers who stopped smoking or who were lost to follow-up: continuing smokers were older ($t = 9.41$, $p < 0.001$), heavier smokers ($t = 8.06$, $p < 0.001$), participated in more surveys ($t = 7.47$, $p < 0.001$), reported less often that health warnings made them resist having a cigarette when they were about to smoke one ($\chi^2 = 8.20$, $p = 0.004$), had lower self-efficacy ($t = 7.28$, $p < 0.001$), and intended to quit smoking less often ($\chi^2 = 23.61$, $p < 0.001$). Table 3 shows the sample characteristics at baseline for continuing smokers from Australia, Canada, the Netherlands, the UK, and the US. Smokers from these countries differed significantly in all sample characteristics except for gender. Ninety-four percent of the Dutch sample were daily smokers. Therefore, it is likely that the included smokers were exposed to the new tobacco health warnings because they smoke frequently.

3.2. GEE analyses

3.2.1. Outcome variables in the Netherlands

Between time-points, there was an increase in salience ($\beta = 0.712$, $p < 0.001$), avoiding (OR = 9.869, $p < 0.001$), and cognitive response (OR = 1.834, $p < 0.001$). However, no change was found in forgoing (OR = 1.092, $p = 0.714$) (RQ1; Table 4). Table 5 shows that between time-points there were no changes in attitude ($\beta = -0.035$, $p = 0.518$), self-efficacy ($\beta = -0.072$, $p = 0.286$), or intention (OR = 0.791, $p = 0.157$) (RQ2).

3.2.2. Differences between the Netherlands and control countries

GEE analyses showed significant interactions between country and time-point for salience ($p < 0.001$), avoiding ($p < 0.001$), knowledge ($p < 0.001$) (Table 4), cognitive response ($p = 0.002$) (Table 4), attitude ($p < 0.001$), self-efficacy ($p < 0.001$), and intention ($p < 0.001$) (Table 5), but not for forgoing ($p = 0.109$) (Table 4). The outcome variables showing a significant interaction between country and time-point from Table 4 only show increases among smokers from the Netherlands, whereas a decrease or no change was found in the control countries (RQ3).

3.2.3. Educational differences in the Netherlands

In the Netherlands, the interaction between time-point and education was significant for avoiding ($p < 0.001$), cognitive response ($p < 0.001$), and for knowledge ($p < 0.001$) (not presented in tables). In the Netherlands, the increase in avoiding was especially pronounced among highly educated (OR = 18.488, $p < 0.001$) compared to moderately (OR = 7.962, $p < 0.001$) and low educated smokers (OR = 6.280, $p = 0.010$) (RQ4; not presented in tables).

The increase in cognitive response was only significant among highly educated smokers (OR = 3.646, $p < 0.001$) compared to moderately (OR = 1.275, $p = 0.291$) and low educated smokers (OR = 1.575, $p = 0.186$). The increase in knowledge was slightly greater among low educated smokers ($\beta = 0.406$, $p = 0.004$) compared to moderately ($\beta = 0.350$, $p = 0.001$) and highly educated smokers ($\beta = 0.325$, $p = 0.006$) (not presented in tables).

Table 3
Sample characteristics at baseline, and participation time of all continuing smokers according to country[a].

	NL (n = 637)	AU (n = 809)	CA (n = 964)	UK (n = 519)	US (n = 586)	
Age group[b]						$\chi^2 = 93.264$
18–24 years (%)	6.8	6.1	2.4	4.7	4.2	$p < 0.001$
25–39 years (%)	17.3	28.3	24.1	26.8	26.0	
40–54 years (%)	33.1	39.6	44.6	38.1	35.2	
55+ (%)	42.8	26.1	29.0	30.4	34.7	
Educational level						$\chi^2 = 177.33$
Low (%)	30.2	60.8	42.7	55.8	48.5	$p < 0.001$
Moderate (%)	44.8	26.2	36.8	25.2	41.7	
High (%)	25.0	13.0	20.5	19.0	19.8	
Gender						$\chi^2 = 1.917$
Male (%)	51.7	53.5	51.9	50.6	54.1	$p = 0.751$
Female (%)	48.3	46.5	48.1	49.4	45.9	
Level of addiction[b]						$\chi^2 = 35.219$
0–1 (%)	23.0	21.9	21.3	18.7	15.2	$p < 0.001$
2–4 (%)	67.4	64.2	66.8	74.4	74.7	
5–6 (%)	9.6	13.9	11.9	6.9	10.1	
Number of surveys participated						$F = 19.820$
Mean (SD)	4.2 (2.2)	4.0 (2.2)	3.7 (2.2)	4.7 (2.0)	3.8 (2.3)	$p < 0.001$
Range	1-7	1-7	1-7	2-8	1-8	
Smoking frequency						$\chi^2 = 35.09$
Daily (%)	93.6	92.9	94.4	96.5	92.6	$p < 0.001$
Weekly (%)	4.7	6.2	5.0	3.3	4.2	
Monthly (%)	1.7	0.9	0.6	0.2	3.2	

[a]Estimates were weighted by gender and age.
[b]Variable is used as a continuous variable in the GEE analyses.
NL, the Netherlands; AU, Australia; CA, Canada; UK, United Kingdom; US, United States.

Table 4
GEE analyses predicting policy-specific variables, pooled across countries and separately for each country, and interactions of country by time-point[a].

	Salience β (95 % CI)	Avoiding OR (95 % CI)	Cognitive response OR (95 % CI)	Forgoing OR (95 % CI)	Knowledge β (95 % CI)
All countries	**N = 4583**	**N = 4,559**	**N = 4,605**	**N = 4,063**	**N = 4,603**
Follow-up vs. baseline	−0.110 (-0.166 to -0.055)**	1.207 (1.052; 1.384)*	1.069 (0.974–1.174)	0.926 (0.800–1.073)	0.032 (-0.003 to 0.067)
Interactions (separate analyses)					
Country × wave	p < 0.001	p < 0.001	p = 0.002	p = 0.109	p < 0.001
The Netherlands	**n = 676**	**n = 662**	**n = 694**	**n = 677**	**n = 694**
Follow-up vs. baseline	0.712 (0.528 to 0.895)**	9.869 (5.404–17.992)**	1.834 (1.336–2.518)**	1.092 (0.682–1.747)	0.369 (0.231 to 0.507)**
Australia	**n = 1,223**	**n = 1,222**	**n = 1,223**	**n = 1,222**	**n = 1,223**
Follow-up vs. baseline	−0.337 (-0.444 to -0.229)**	0.781 (0.615 to 0.991)	0.819 (0.684 to 0.982)	0.694 (0.528 to 0.911)*	−0.008 (-0.078 to 0.062)
Canada	**n = 1,370**	**n = 1,366**	**n = 1,366**	**n = 1,366**	**n = 1,370**
Follow-up vs. baseline	−0.072 (-0.178 to 0.033)	1.300 (0.982–1.722)	1.120 (0.950–1.321)	1.249 (0.935–1.669)	0.053 (-0.003 to 0.109)
UK	**n = 728**	**n = 723**	**n = 729**	**n = 729**	**n = 728**
Follow-up vs. baseline	−0.413 (-0.539 to -0.288)**	0.973 (0.721–1.312)	1.023 (0.776–1.349)	0.883 (0.611–1.277)	−0.075 (-0.162 to 0.011)
US	**n = 586**	**n = 586**	**n = 588**	**n = 586**	**n = 588**
Follow-up vs. baseline	−0.093 (-0.211 to 0.025)	1.091 (0.684–1.739)	1.065 (0.846–1.341)	0.705 (0.479–1.037)	0.035 (-0.059 to 0.129)

*p < 0.01; **p < 0.001.
[a]All models were adjusted for age, educational level, gender, HSI, intention, and participation time. The pooled analyses were also adjusted for country. All estimates were weighted by gender and age.
GEE, Generalised Estimating Equations; HSI, Heaviness of Smoking Index.

Table 5
GEE analyses predicting psychosocial mediators separately for each country and pooled across countries with interaction of country by time-point[a].

	Attitude β (95 % CI)	Self-efficacy β (95 % CI)	Intention OR (95 % CI)
All countries	**N = 4,538**	**N = 4,588**	**N = 4,605**
Follow-up vs. baseline	0.028 (-0.008 to 0.063)	−0.083 (-0.118 to -0.048)**	1.137 (1.032–1.251)*
Interactions (separate analyses)			
Country × wave	p < 0.001	p < 0.001	p < 0.001
The Netherlands	**n = 684**	**n = 683**	**n = 694**
Follow-up vs. baseline	−0.035 (-0.142 to 0.072)	−0.072 (-0.205 to 0.060)	0.791 (0.572–1.094)
Australia	**n = 1,209**	**n = 1,222**	**n = 1,223**
Follow-up vs. baseline	0.142 (0.075 to 0.209)**	−0.034 (-0.100 to 0.032)	1.727 (1.432–2.083)**
Canada	**n = 1,349**	**n = 1,369**	**n = 1,371**
Follow-up vs. baseline	0.060 (-0.006 to 0.126)	0.003 (-0.058 to 0.064)	1.134 (0.965–1.354)
United Kingdom	**n = 715**	**n = 729**	**n = 729**
Follow-up vs. baseline	−0.080 (-0.169 to 0.008)	−0.262 (-0.351 to -0.173)**	1.090 (0.872–1.363)
United States	**n = 581**	**n = 585**	**n = 588**
Follow-up vs. baseline	−0.101 (-0.197 to -0.005)	−0.219 (-0.310 to -0.127)**	0.617 (0.477 to 0.799)**

*p < 0.01; **p < 0.001.
[a]All models were adjusted for age, educational level, gender, HSI, intention, and participation time. The pooled analyses were also adjusted for country. All estimates were weighted by gender and age.
GEE, Generalised Estimating Equations; HSI, Heaviness of Smoking Index.

4. Discussion

This study examined whether introducing PHWs as a health communication strategy, as required by the European Union, was associated with changes among Dutch smokers in policy-specific variables (RQ1). We found that Dutch smokers increasingly noticed health warnings, avoided health warnings, reported having a cognitive response, and gained knowledge about the health risks of smoking. These findings were expected, as these outcome variables are policy-specific to health warnings (Fong et al., 2006), and previous pre-post studies observed similar results after introducing PHWs (Borland et al., 2009; Nagelhout et al., 2016; Yong et al., 2013; Green et al., 2014; Kennedy et al., 2013; Noar et al., 2016b). One quasi-experimental study found no impact on salience, but that study evaluated PHWs on one side of the packet (Nagelhout et al., 2016). The current study found no change among Dutch smokers in forgoing, contrary to similar other studies (Borland et al., 2009; Nagelhout et al., 2016; Yong et al., 2013; Green et al., 2014). The latter studies were conducted in countries with, in general, larger and more graphic PHWs and might, therefore, have been more effective in helping them to resist having a cigarette. Another explanation is that there could be a differential composition of the smoking population (e.g. educational differences) between countries.

This study was also designed to examine whether introducing PHWs in the Netherlands was associated with changes among Dutch smokers in psychosocial mediators (RQ2). We found no changes among Dutch smokers in self-efficacy, attitude, or intention. This in contrast to a study from Thailand which found that smokers' had a more positive attitude towards quitting after introducing PHWs (Silpasuwan et al., 2008). The finding regarding self-efficacy is in line with a meta-analysis of experimental studies that found no strengthened effect of PHWs on self-efficacy (Noar et al., 2016a). In addition, the finding regarding intention to quit smoking was in line with a study from Mexico which showed that smokers' intention did not change directly after introducing PHWs (Thrasher et al., 2012). These psychosocial mediators are influenced by many factors, and the impact of PHWs might not be strong enough to directly change them (Fong et al., 2006). Another explanation is that we only used data from continuing smokers who had lower self-efficacy and intended to quit smoking less often compared to smokers who were lost to follow-up. This may have led to an underestimation of the effects regarding these outcome measures because those smokers may have been more strongly influenced by the PHWs.

The third RQ was whether the changes in the Netherlands were larger than in the control countries. The policy-specific variables in which we observed an increase among Dutch smokers, remained

unchanged or decreased in the control countries. This implies that the changes in the Netherlands may be associated with introducing PHWs. In the control countries, salience decreased (Australia and the UK) or remained unchanged (Canada and the U.S.) implying that warnings become less effective over time. The increase in intention to quit smoking among smokers from Australia may be explained by strong increases in the costs of tobacco product between baseline and follow-up surveys.

The fourth RQ was whether the changes in the Netherlands differed according to level of education. This study's findings imply that low educated smokers benefitted more in terms of gaining knowledge about the smoking health risks. Low educated smokers have a lower health literacy than those more highly educated (Van der Heide et al., 2013) and, therefore, might benefit more from larger and more graphic health warnings. However, it was mainly highly educated smokers who went a step further by thinking about quitting or about the health risks of smoking, as they reported more often having had such a cognitive response. Low educated smokers may require more than just gaining knowledge about health risks of smoking, as they, in particular, need to be supported and motivated to quit smoking (Hiscock et al., 2012). This study's findings also imply that mainly high educated smokers showed an increase in avoidance of health warnings, in contrast to previous research that found that mainly low and moderate educated smokers showed an increase in avoiding after introducing PHWs on one side of the packet (Nagelhout et al., 2015). We also found that cognitive response mainly increased among high educated smokers, whereas previous studies found equal impact (Nagelhout et al., 2015) or more impact on low educated smokers (Thrasher et al., 2010; Bittencourt et al., 2013). The PHWs from these countries differed from the PHWs from the current study as they were on one side of the packet (Nagelhout et al., 2015), or covered 1.0 % of either the front or the back of the packet (Thrasher et al., 2010; Bittencourt et al., 2013). The inconsistences in the findings on these educational differences indicates a need for further research on this topic.

4.1. Strengths and limitations

A major strength of this study is the use of a pre-post quasi-experimental research design, a relatively powerful design. Smokers from the four control countries showed no change in any of the outcome variables that changed among continuing Dutch smokers. Therefore, it is a likely interpretation that the changes in outcome variables were due to introducing PHWs. However, it is still hard to infer causality between introducing PHWs and changes in outcome variables; we could not control for alternative explanations and there was no randomization.

There are further limitations that should be taken into account when interpreting the results. First, continuing smokers differed at baseline from smokers who stopped smoking or who were lost to follow-up. For instance, they had higher self-efficacy, intended to quit smoking more often, and more often reported that health warnings made them resist having a cigarette when they were about to smoke one. These smokers may have been more strongly influenced by the PHWs, and excluding them may have led to an underestimation of the effect regarding these outcome measures. Therefore, our results are possibly not fully generalizable to the population of smokers. Second, due to little overlap between countries regarding knowledge items, we could only use a few health risks of smoking as communicated by the PHWs (European Union, 2015). Third, the PHWs may not have been fully implemented in the Netherlands at follow-up (November – December 2016), as packets without PHWs could be sold until May 2017 (European Union, 2015). This might have led to an underestimation of its impact, and indicates the need to examine the impact of PHWs also on the long term. Fourth, we examined changes in self-reported responses, and did not assess the impact on quit attempts. We did not examine direct effects on quitting because quit attempts may be influenced by multiple factors (e.g. other tobacco control policies such as tobacco tax increases) besides PHWs, especially during the 3-year follow-up, that we could not control for in our analyses. Moreover, we only examined changes among continuing smokers. A limitation is that the same problem could apply to the psychosocial mediators that we included in our study. Fifth, there were differences between the Netherlands and control countries in the timing of and time between measurements, and changes in tobacco control policies, potentially influencing results.

4.2. Implications

Results from this study suggest that policy makers from countries that have not yet introduced PHWs as a health communication strategy should introduce larger and more graphic health warnings if they want to elicit an increase in smokers noticing health warnings, in provoking cognitive response, and being knowledgeable about the health risks of smoking. There may then also be an increase in avoiding health warnings, as found in the current study and in previous research (Borland et al., 2009; Nagelhout et al., 2016; Yong et al., 2013; Green et al., 2014). Avoiding PHWs may be related to increased quitting in the long-term (Thrasher et al., 2016). Introducing PHWs thus seems to have activated smokers to think about quitting and the health risks of smoking and to avoid health warnings. However, our findings of no apparent effects of PHWs on psychosocial mediators points to the need for a comprehensive range of policy measures to support smoking cessation in the Netherlands where smoking prevalence is still 22 % in 2018 (Trimbos Institute, 2018). Future longitudinal research by the same research group will use path analyses to examine how policy-specific variables and psychosocial mediators are interrelated and how they affect quit attempts and smoking cessation on the long term. This study was one of the first aiming to investigate educational differences in the impact of introducing PHWs, but findings remain ambiguous. To obtain better insight into educational differences, future studies on the impact of PHWs should continue to investigate this aspect.

5. Conclusion

This study found that introducing, the by the European Union required, PHWs on 65 % of the front and the back of the packet of tobacco products was associated with smokers increasingly noticing health warnings, avoiding health warnings, showing a cognitive response to health warnings, and being knowledgeable about the health risks of smoking. However, six months after introducing PHWs, no impact was found on attitude towards smoking, self-efficacy to quit smoking, or intention to quit smoking. The impact of introducing this health communication strategy on avoiding and cognitive response was strongest on high educated smokers, whereas the impact on knowledge about the health risks of smoking was strongest among low educated smokers.

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Contributors

DJvM drafted the manuscript with substantial contributions from GN. DJvM performed the statistical analyses. All authors contributed to the interpretation of the analyses and to writing the manuscript. All authors critically read, revised, and approved the final manuscript.

Availability of data

Data from the ITC Policy Evaluation Project are available to approved researchers 2 years after the date of issuance of cleaned data sets by the ITC Data Management Centre. Researchers interested in using ITC data are required to apply for approval by submitting an International Tobacco Control Data Repository (ITCDR) request application and subsequently to sign an ITCDR Data Usage Agreement. To avoid any real, potential, or perceived conflict of interest between researchers using ITC data and tobacco-related entities, no ITCDR data will be provided directly or indirectly to any researcher, institution, or consultant that is in current receipt of any grant monies or in-kind contribution from any tobacco manufacturer, distributor, or other tobacco-related entity. The criteria for data usage approval and the contents of the Data Usage Agreement are described online (http://www.itcproject.org).

Declaration of Competing Interest

GTF has served as an expert witness on behalf of governments in litigation involving the tobacco industry.

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.drugalcdep.2019.107818.

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