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STUDY PROTOCOL

Cigarette pack design: visual attention and perceptions among Colombian smokers and non-smokers

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Background

Smoking causes 13% of all deaths among Colombian adults, and the prevalence of smoking among children is higher than in other middle-income countries. Unlike the UK, where smoking-related morbidity and mortality is projected to decrease over the next decade, this is set to increase in Colombia (Mathers & Loncar, 2006; Ministerio de Salud y Proteccion Social, 2013). To warn adults and children about the risks of smoking, the World Health Organisation (WHO) recommends that pictorial warnings cover at least 50% of the pack and that standardised packaging replaces branding. In countries where these measures have been implemented, there is evidence that they 1) make smoking less appealing, especially among young people, 2) increase warning noticeability, 3) prevent people from being misled about the health risks of smoking and 4) ultimately lead to smoking cessation. There is also evidence that pictorial health warning labels are the most cost-effective form of health communication about the health risks of smoking, capable of reaching all groups of smokers, including those from lower socio-economic backgrounds. New health warning labels, which were introduced in Colombia in July 2018, cover 30% of the pack. We have been asked by the Colombian Ministry of Health for 'local evidence' before larger warnings, or standardised packaging are introduced.

There is considerable interest in using eye-tracking as an objective measure of attention to tobacco warnings (Kaufman, Klein, Koblitz, & Price, 2018; Maynard, McClernon, Oliver, & Munafò, n.d.; Meernik et al., 2016). Our previous research found that while daily smokers avert their gaze from warnings (i.e. avoid warnings) (Maynard et al., 2014; Maynard, Munafò, & Leonards, 2013; Munafò, Roberts, Bauld, & Leonards, 2011), standardised tobacco packaging increases visual attention to health warning labels among non-smokers and non-daily smokers. The attention literature suggests that visual attention is a critical first step in stimulus processing and thus necessary before any higher order cognitive processes, such as covering up warnings (a type of self-reported avoidance), can occur (Noar et al., 2015; Stothart, Maynard, Lavis, & Munafò, 2016). This suggests that standardised packaging and larger warnings may be an effective method of increasing visual attention to warnings.

There has also been considerable literature using discrete choice methodologies to examine the trade-offs smokers make when considering the characteristics of different cigarette packs (Adkison, Bansal-Travers, Smith, O'Connor, & Hyland, 2014; Hammond, White, Anderson, Arnott, & Dockrell, 2014; Kotnowski, Fong, Gallopel-Morvan, Islam, & Hammond, 2016; Salloum et al., 2018). Discrete choice experiments (DCEs) have become a useful technique in health economics to address policy questions (de Bekker-Grob, Ryan, & Gerard, 2012), and they can be used to assess tobacco-control policies (Regmi, Kaphle, Timilsina, & Tuha, 2017), particularly in low- and middle-income countries (Mangham, Hanson, & McPake, 2009; Regmi et al., 2017). Moreover, DCE is a useful technique to understand the preference of consumers for products that are not traded in the market yet (Mangham et al., 2009). This methodology relies on Random Utility Theory (Kuhfeld, 2010; Mangham et al., 2009; Train, 2003) and is used to understand the choices from consumers to alternative products and it assumes that consumers will choose the alternative that offers the greatest value or utility, determined by the attributes associated with that alternative. Only one previous study using DCE has investigated the effect of health warning size and standardised packaging as potential attributes that can influence intention to try, judgment of product taste and judgment of product harm (Kotnowski et al., 2016). The study found that standardised packaging decreases demand and that health warning size was important in judging product harm.

In the present study we want to examine the impact of cigarettes pack attributes of branding (branded vs. standardised packaging) and health warning size (30%, 50% vs. 70%) on visual attention and on preferences to try and judgements of taste and of harm among Colombian smokers and non-smokers. We will conduct an eye-tracking experiment and a DCE. These experiments will provide important information on the potential impact of these tobacco control policies among Colombian smokers and non-smokers.

Study Objective and Hypotheses

To examine the impact of health warning size and branding on visual attention, we will conduct an eye-tracking experiment. We hypothesise that:

H1: increasing the size of the health warning label will increase visual attention toward it.

H2: the use of standardised packaging instead of branded packaging will increase visual attention toward the health warning label.

H3: there will be an interaction between the size of the health warning label and package design, such that visual attention to warnings will be greatest when the warning is largest and located on a standardised pack.

H4: the levels of attention to the health warning label will differ between smoking groups. Non-smokers will pay the most attention to the health warning labels followed by weekly smokers then daily smokers.

We will also explore the interaction effects between smoking status (daily-smoker, weekly-smoker, and non-smoker), health warning label size and package design.

To examine the impact of health warning size and branding on smokers' and non-smokers' interest in trying and perceptions of product taste and harm, we will conduct a DCE. We hypothesise that:

H5: compared to branded packs, participants will select standardised packs as those which they least prefer to try, would taste worse and are perceived as being more harmful.

H6: compared with packs with smaller warnings, participants will select packs with larger warnings as those which they least prefer to try, would taste worse and are perceived as being more harmful.

H7: there will be a positive interaction between branding and health warning size attributes, such that participants will select the standardised packs with the largest warnings as those which they least prefer to try, would taste worse and are perceived as being more harmful.

H8: there will be a difference in the preferences to try, judgment of taste and perception of harm between smokers and non-smokers.

We will also explore the interaction effect between smoking groups and the different attributes.

Study Design

First, we will examine visual attention to health warning labels using eye-tracking technology. We will use a human experimental laboratory mixed model design with health warning size (percentage of the cigarette pack covered by the health warning label: 30%-design 1 vs. 30%-design 2 vs. 50% vs. 70%) and branding (branded packaging vs. standardised packaging) as a within-subject factor; and smoking status (non-smoker vs. weekly smoker vs. daily smoker) as a between-subject factor.

Second, we will examine the impact of the attributes: health warning size (30% vs. 70%), branding (branded packaging vs. standardised packaging) and brand name (Lucky Strike Red vs. Marlboro) on smokers' and non-smokers' interest in trying and perceptions of product taste and harm through a DCE.

Study Site

Laboratory, Laboratorio Interfacultades de Investigación en Comunicación Cultura y Cognición (LIICCC), Universidad Nacional de Colombia.

Participants and Recruitment

Study participants (n = 156) will be non-smokers, weekly smokers and daily smokers recruited via Facebook advertisements, email and Twitter. We will also advertise the study through fliers in strategic places and manual distribution. We will contact the University Radio to advertise our study. Potential participants will be asked to attend an experimental session at the laboratory.

Prior to participating in the study, participants will be categorised into non-smokers, weekly smokers, and daily smokers via an online screening form, as per the inclusion/exclusion criteria defined below. We will recruit approximately equal numbers of males and females into these three groups. Participants will be reimbursed $ 25.000 COP (Equivalent to 6 Pound Sterling) on completion of the study or, if applicable, with course credits.

Inclusion criteria

- Age (18 – 40).
- Has Spanish as a first language or, in the view of the experimenter, is fluent to a near-equivalent standard.
- Either a non-smoker, weekly smoker or a daily smoker;
    - If a daily smoker, smokes at least 5 cigarettes a day and within one hour of waking;
    - If a weekly smoker, smokes at least one cigarette a week, but not every day;
    - If a non-smoker, has smoked fewer than 100 cigarettes in their lifetime;

Exclusion criteria

- Inability to track eyes (e.g. failure of calibration with the eye tracker);
- Another factor which, in the view of the experimenter, renders the participant unsuitable for the study.

Sample size determination

Our participants will be Colombian non-smokers (n = 52), weekly smokers (n = 52) and daily smokers (n = 52); giving us 80% power and type 1 error (alpha)=5% with two-sided tests to detect the following effects in the DCE: Brand=0.25; Branding=0.30; Warning Size=-0.25: the interaction between Brand*Branding=0.68 and the interaction Branding*Warning Size=0.40. According to the literature (de Bekker-Grob, Donkers, Jonker, & Stolk, 2015), less than 155 participants might be insufficient to detect any real differences for the interaction parameters. We will recruit 156 participants in order to allow equal numbers of males and females in each group.

In a previous eye-tracking experiment, we showed that daily smokers preferentially attend to branding, as compared with health warning labels, on branded packs (mean difference = -3.8 fixations, SD = 10.1), while weekly smokers attend both approximately equally (mean difference = 0.7, SD = 6.8) and non-smokers preferentially attend the warning (mean difference = 2.8 fixations, SD = 5.4) (Maynard et al., 2013). In order to detect the effect of a manipulation that increases weekly smokers' attention to warnings to a level equivalent to non-smokers (i.e., mean difference = 0.7, SD = 8.5), but does not impact daily smokers' attention to warnings (mean difference = -3.8, SD = 8.5) we will require 75 participants (25 per group) to achieve 80% power at an alpha level of 5%. As more participants are required for the DCE, 156 participants will complete both tasks.

Withdrawal of participants

Participants will be informed that they are able to withdraw from the study at any time. Full reimbursement will be provided to participants who experience an adverse event during the experiment. For all other withdrawals (i.e., that are not due to an adverse event), participants will be reimbursed an amount commensurate with the amount of time they have spent in the study (i.e., 50% reimbursement if they have completed half of the study). Full details of ethics approval are provided below.

Randomisation

In the eye-tracking task, stimuli will be shown in a pseudo-randomised order. There will be six blocks, with eight cigarette packs presented in each block. Within each of the eight blocks each health warning label size (30%-design 1, 30%-design 2, 50% and 70%) will be presented twice, once on a branded pack and once on a standardised pack. In addition, within each block, each of the six health warning labels will be presented at least once and these will be presented in a randomised order.

Participants will complete a recall phase after each block (to maintain attention). We will show four stimuli: two of these four stimuli will be two shown in the previous block and two will be novel warnings selected at random from the stimuli not shown in the previous block.

For the DCE, participants will choose the cigarette packet that they would rather to try, they think that taste better and would be less harmful. The presentation of the packets within each choice set will be also randomised. The choices sets will be presented twice: once giving the option to choose none of the alternatives and other one forcing the participant to choose one of the alternatives. Therefore, a total of 72 choice sets (12 choices sets * 3 questions * 2 forced/none option) will be shown in a randomised order across the participants.

Materials

Cigarette pack stimuli

The stimuli used for the health warning labels will be the six 2018 Colombia health warning labels including the six following topics: smoking can cause death, smoking can cause pancreatic cancer, second-hand smoking, smoking can cause heart damage, smoking can increase anxiety and risk for the unborn child. These health warning labels will be adapted for the different sizes following a similar procedure used in studies in Canada (Health Canada, 2008). Health warnings in Colombia have the pictorial warning and text-warning side-by-side. As this is not possible for the 50% and 70% warnings without distorting the images, we will edit

these, so the pictorial is on the top, with the text underneath and cropped so together they fill 30%, 50% or 70% of the pack. For the eye-tracking study, we will also include an additional 30% condition where the text and pictorial are side-by-side, which will allow us to compare current practice with our warnings. For the DCE we will use just the new 30% design and 70% warnings.

For the eye-tracking task, cigarette packets will be six of the most popular Colombian tobacco brands, based on market share data (Dinero, 2017; S.A.S, 2017). These brands are: Marlboro, Lucky Strike Red, Lucky Strike Green, Chesterfield White, Chesterfield Blue, Rothman Blue and Rothman Grey. As with the warnings, the brands will need to be adapted so that they are three different sizes (covering 70%, 50% or 30%) of the pack.

Standardised packets will be designed specifically for the purpose of this study by the researchers following the guidelines for the World Health Organisation and Gov.uk (Tobacco Policy Team, Healthier Lives Division, Public and International Health Directorate - 10800, 2016; World Health Organization, 2016) and again will be 70%, 50% or 30% in size.

Therefore, for the eye-tracking experiment, each of the six warnings will be adapted to four different sizes (30%-design 1, 30% design 2, 50% and 70%) and presented alongside branded and standardised packs, with six different brands. We will therefore design a total of 288 stimuli for this experiment. See the Appendix section for stimuli examples.

For the DCE we will show a single health warning, (smoking can cause death). We have chosen this warning as in a previous (currently unpublished) study we have found that it is the most effective. To avoid the effect of perceived price influencing participant's responses, all packs will be presented as having a constant price of $50000. The attributes that we consider for DCE are:

1. *Cigarette Brand (two levels).* We will only use the two most popular cigarette brands: Marlboro and Lucky Strike Green.
2. *Branding (two levels).* The standardised packaging and the branded packaging.
3. *Health Warning Label Size (two levels).* The health warning will be adapted for the two different sizes (30% and 70%).

Therefore, as a combination of the different attributes, a total of eight stimuli will be necessary for the DCE. These stimuli will be retrieved from the 288 stimuli designed for the eye-tracking experiment. See the Appendix for stimuli examples.

Eye-tracking experiment

Participants will view four blocks with eight cigarette packet stimuli (see Randomisation section for details). Each image will be presented individually on screen for 10,000 ms. Between trials, a gaze-contingent fixation dot (drift correction) will be presented, where the trial will start only once the participant has fixated the dot and the researcher has confirmed it. In case of any miscalibration the researcher will be able to recalibrate the system and continue the experiment. Fixation dots will be presented randomly in one of two locations on the screen, either to the left or right of the centre of the screen, such that the location of the first saccade on the package and first saccade latency can be meaningfully analysed. Both set-up of the eye-tracker and the task itself will last approximately 13 minutes.

After each block, participants will complete a recall phase, where they will be required to determine whether the images presented to them were shown in the previous block by pressing

one of two buttons on a keyboard. Participants will have to recall the image as a whole, that is, the health warning accompanied with the brand on the packaging (see the Randomisation section for details). This recall phase will ensure that participants actively attend the images presented in the test phase.

The experiment will be design through the software Experiment Builder from SR Research Ltd.

Discrete choice experiment

To design the DCE we followed recommendations from previous literature (Burgess & Street, 2005; Mangham et al., 2009; Street, Burgess, & Louviere, 2005). To design the choice sets we considered a complete factorial design, so all the possible combinations of attributes levels would be shown through the different options in the choice sets. We also considered an optimal design which allows the estimation of the main effects and two-factors interactions: branding $_x$ health warning size and branding $_x$ brand name, previously considered by other similar DCE (Kotnowski et al., 2016). Being k the number of attributes equal to three, the optimal design in this context is the one that includes all choice sets with $\frac{k+1}{2} = 2$ attributes different (because k is odd) (Street et al., 2005).

The DCE will include 12 choice sets with two cigarette packets in each set as is shown in Table 1. This design is 100% efficient for estimating the main effects and the two-factor interactions. Each set will be presented three times for each outcome variable: purchase intentions, taste perceptions and harm perceptions, resulting in a total of 36 choice sets. Moreover, we will show these 36 choices sets twice, once without giving the option "none" to force participants to choose one the two cigarette packs and another one giving the participant the option to choose "none". Therefore, the DCE includes a total of 72 choice sets. See the Appendix to see examples of the choice sets.

Table 1. Discrete Choice Experiment Design

Choice set	Stimulus 1	Stimulus 2
1	Marlboro, plain, 30%	Marlboro, branded, 70%
2	Marlboro, plain, 70%	Marlboro, branded, 30%
3	Lucky Strike Green, plain, 30%	Lucky Strike Green, branded, 70%
4	Lucky Strike Green, plain, 70%	Lucky Strike Green, branded, 30%
5	Marlboro, plain, 30%	Lucky Strike Green, plain, 70%
6	Marlboro, plain, 70%	Lucky Strike Green, plain, 30%
7	Lucky Strike Green, branded, 70%	Marlboro, branded, 30%
8	Lucky Strike Green, branded, 30%	Marlboro, branded, 70%
9	Marlboro, plain, 30%	Lucky Strike Green, branded, 30%
10	Marlboro, plain, 70%	Lucky Strike Green, branded, 70%

11	Lucky Strike Green, plain, 30%	Marlboro, branded, 30%
12	Lucky Strike Green, plain, 70%	Marlboro, branded, 70%

These 12 choice sets will be presented three times for each outcome variable: purchase intentions, taste perceptions and harm perceptions. Moreover the 36 choice sets will be presented twice: once with the option "none" and another one without this option.

Measures

Eye-tracking outcome measures

The primary outcome measure will be Number of fixations. Number of fixations = number of fixations towards health warning labels – number of fixations to the branding.

Secondary eye-tracking outcome measures will be:

- Number of saccades = number of saccades towards health warning labels – number of saccades to the branding.
- Duration of fixations = duration of saccades towards health warning labels – duration of saccades to the branding.
- A time-course of attention to the health warnings and to the branding over the stimulus presentation time.

Discrete choice experiment

The outcome measures for the DCE will be the same as previous research (Kotnowski et al., 2016):

Purchase intentions

To understand the effect of these attributes on the intention to try, we will ask: "¿Cuál de estos productos le gustaría probar? (Which one of these brands would you rather try?).

Taste perceptions

To understand the effect of these attributes on the taste related perceptions, we will ask: "¿Cuál de estos productos piensa que sabe mejor?" (Which one of these brands do you think would taste better?).

Harm perceptions

To understand the effect of these attributes on the harm related perceptions, we will ask: "¿Cuál de estos productos le parece menos dañino?" (Which one to these brands do you think would be less harmful?).

Questionnaires

Smoking dependence

A breath CO measurement will be taken for all participants. Spanish translations of The Fagerström Test for Nicotine Dependence (FTND) (Heatherton, Kozlowski, Frecker, & Fagerstrom, 1991), the brief Questionnaire of Smoking Urges (QSUBrief) (Cox, Tiffany, & Christen, 2001) and the Quitting Smoking Contemplation Ladder will be administered to smokers.

Procedures

The present experimental procedure is based on previous eye-tracking studies we have conducted investigating the impact of standardised packaging on visual attention to health warning labels (Maynard et al., 2014, 2013).

Potential participants will first complete an online screening questionnaire via Qualtrics to confirm they are eligible to participate in the study, according to the eligibility criteria. Eligible participants will be invited via email to attend a testing session. On arrival at the testing session, participants will reread the information sheet and be given the opportunity to ask questions, after which they will read and sign the consent form. Ineligible participants at this stage will be thanked and debriefed but provided with no financial reimbursement. Then participant's level of CO will be measured using a Pico Co Smokerlyzer. Weekly and daily smokers will also complete the FTND, the QSU-Brief, and the Quitting Smoking Contemplation Ladder via an online form using Qualtrics.

All participants will be sat a standard distance from the computer screen and eye makeup will be removed if necessary. After a nine-point calibration and validation of the eye-tracker, with a validation value of < 0.5, participants will complete the main eye-tracking phase using an Eyelink 1000 eye tracker. Participants for whom eye-tracking is not possible (after approximately 10 minutes of attempting to achieve accurate calibration), will not continue with the rest of the experiment and will be thanked, debriefed and reimbursed for their time.

After finishing the eye-tracking experiment, participants will be asked to complete the DCE. First, participants will be informed about the instructions of the DCE and will be presented with a trial choice set that will not form part of the DCE. Participants will be asked to choose between different options of cigarette packets and, if applicable, the option "none". To prevent the preference from participants to buy single cigarettes (as is common practice in Colombia), the instructions will indicate that they need to consider that that option is no longer available in the market.

The entire experiment is expected to last between 30 and 45 minutes. Following completion of these tasks, participants will be debriefed and given the opportunity to ask questions. Participants will be reimbursed for their time and expenses or, if applicable, with course credits.

Statistical Plan

For the eye-tracking experiment, the principal analysis will be a 4 (health warning size: 30%-design 1 vs. 30%-design 2 vs. 50% vs. 70%) x 3 (smoking status: non-smoker vs. weekly smoker vs. daily smoker) mixed model MANOVA of the outcome variables: number of fixations, number of saccades and duration of fixations.

To examine how visual attention to the health warnings changes over the course of the 10 second viewing time, a time-course analysis will be conducted (Maynard et al., 2014). For each participant, each 10,000 ms trial will be divided into 10 ms time bins for branding and health

warnings. A value of 1 will be assigned to a bin if a saccade falls on the respective area within that interval. An average per participant will be taken for each health warning type. Time bins where participants are fixating the area outside of the cigarette pack, where they are making the actual saccadic eye movement, or blink, will be excluded. Analyses will compare whether curves are different between health warning conditions and between participant groups

For the DCEs, we will conduct two multinomial logit models. One for those choice sets including the option "none" and another one for the choice sets without including this option. These two multinomial logit models will be similar and will analyse the effect of each attribute: brand (Marlboro vs. Lucky Strike Red), branding (standardised vs. branded) and health warning size (30% vs. 70%) on intentions to try, perceptions of products taste and perceptions of product harm. Results will be analysed on the following utility function:

U = (βbrand * Xi brand) + (βBranding * Xi branding) + (βhealthwarningsize * Xi healthwarningsize) + ε

The model will be extended for the two attribute interactions: brand*branding and health warning size*branding. The model will be also adjusted to smoking status (smoker, non-smoker), sex (male, female) and age (as a continuous variable). We will also consider the possible interactions between smoking status and each attribute.

We will also calculate the attribute importance following the same method as Kotnowski et al. (2016).

Ethical Considerations and Informed Consent

Ethics approval has been obtained from the Ethics Committee at the Universidad Nacional de Colombia (B.VIE-FCH-09-2019). Participants will access the information sheet electronically, explaining the nature, purpose, and risks of the study to the participant. There will be no time restriction on how long participants take to respond, with the exception that participants who respond after data collection is completed will not be able to participate. Therefore, participants will be given sufficient time to read the information sheet and consider any implications, and to raise any questions with the investigators (email addresses will be provided) prior to making a decision to participate. Participants will be informed that they are free to withdraw at any time.

Safety

We do not anticipate that there will be any risks associated with participating in this experiment. Insurance will be provided by the Universidad Nacional de Colombia.

Data Management

All aspects of the Data Protection Act will be adhered to. Consent forms will be retained by the Departamento de Psicologia at the Universidad Nacional de Colombia for a period of 10 years after study completion. In the event that a participant revokes authorisation to collect or use personal health information, the investigator retains the ability to use all information collected prior to the revocation of participant authorisation

Anonymised study data

All study data will be anonymised using a unique numeric identifier. Study data will be stored on an encrypted drive after completion. Only study personnel will have access to these data. At the end of the study, electronic study data (including finalised data sheet) will be transferred to a designated University of Bristol Research Data Storage Facility for long-term archiving. Study data will be kept for a minimum of 15 years. At the appropriate time the data sheet will be locked and made open using the University of Bristol Research Data Repository.

Screening documents and participant contact details

Participant email addresses will be stored on a secure server in a password protected datasheet. Email addresses will be kept for one year after study completion, or until data are made open (whichever comes first), after which this datasheet will be destroyed. No other identifiable information from participants will be collected.

Revoked data

If a participant decides that they do not want their data used after their participation they have the right to request that the data are withdrawn. They can request this up to one year after study completion or until the data are made open (whichever comes first).

Quality Control and Quality Assurance

The investigators will be responsible for data quality. After approximately 10% of data collection has been completed, the study will undergo an in-house quality assessment. During this monitoring process, all study documents will be assessed as well as the investigators laboratory management and participant engagement and corrected where necessary.

Publication Policy

The findings from this research study may be published in an appropriate scientific journal (and made available open access), and/or presented at an appropriate meeting. Study data will be collected and held by the study investigators. The data will be made available for sharing via a University of Bristol online data repository.

Once the data have been analysed, we may write a summary of the research for the Colombian Ministry of Health in Spanish and create an infographic of our results which can be distributed widely. This will mean that the Ministry can cite our work soon after data collection is complete.

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Funding Source

This study is supported by a University of Bristol. A University of Bristol Global Challenges Research Funding Pump-Priming grant awarded to Dr Olivia Maynard.

Conflicts of Interest

There are no conflicts of interest.

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Appendix

Figure 1. Stimili examples for the Eye-tracking Experiment qith difference health warning size (70%, 50%, 30% version 2 and 30% version 1) and different branding (branded and satarised branding).

Figure 2. Choice set example for the Discrete Choice Experiment without the "none" option for taste perceptions.

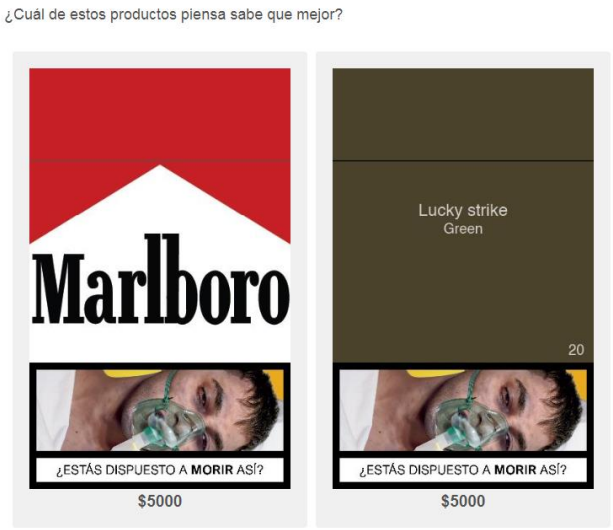

Figure 3. Choice set example for the Discrete Choice Experiment with the "none" option for harmful perceptions.