

# BMJ Open Protocol for creating new warnings on cigarette packs and evaluating their efficacy in a randomised experimental setting

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## ABSTRACT

**Introduction** Tobacco smoking is one of the leading causes of preventable death. This is not inevitable as tobacco control tools have become more powerful and more effective. Among these, warnings on cigarette packs have proven to be somewhat effective. Our objective is to increase the efficacy of antismoking warnings by using innovative psychological approaches and to create an experimental setting for the evaluation of these new warnings based on behavioural indicators.

**Methods and analysis** First, we created new warnings based on three categories of motivational leverage and on harm reduction. New warnings with innovative texts and pictures were designed for each category and inserted on plain packs. We will then use standard indicators to compare their effect to that of control packs: plain pack without warning, plain pack with conventional warning and branded pack with conventional warning. Second, the novelty of our approach will consist in designing an experimental protocol that uses monetary incentives to evaluate the effect of warnings. Subjects will be able to 'sacrifice' part of their participation defrayal to purchase a good whose subjective value is related to one's attitude towards smoking. These monetarily incentivised measures are designed to assess smokers' immediate/mid-term intention to quit and non-smokers' aversion to smoking. In both cases, the monetary amounts individuals accept to sacrifice may be a more reliable measure than declarative responses, which may be distorted by several hypothetical biases. In the end, we should be able to robustly measure the impact of our new warnings between intervention and control groups by using both traditional indicators and our new monetarily incentivised measure.

**Ethics and dissemination** The ethics committee of the *Groupement des Hôpitaux de l'Institut Catholique de Lille* approved the research protocol on 5 July 2019 (CIER 2019-22). Results will be presented at scientific meetings and published.

## INTRODUCTION

One billion premature deaths attributable to tobacco are expected in this century, making smoking the most preventable cause of death worldwide.<sup>1</sup> The global economic burden of tobacco is estimated at €1330 billion in 2012,

## Strengths and limitations of this study

- In this research protocol, three different motivational leverages are used to build new warnings.
- Other warnings are also created to promote harm reduction of smoking.
- Behavioural responses measured with economic incentives are observed to test the efficacy of new warnings.
- Experiments are implemented in the French smoking context.
- No follow-up of participants after the experiment is planned.

leading to a loss of nearly 2% of global GDP.<sup>2</sup> Europe and France, even after the implementation of the main antismoking measures of the Framework Convention on Tobacco Control and despite their effectiveness,<sup>3</sup> still have high levels of smoking prevalence. Despite a decrease in recent years, 26.9% of French people still smoke,<sup>4</sup> twice as many as in Australia or the USA. In France, more than 70 000 preventable deaths are attributable to smoking each year,<sup>5</sup> for a social cost estimated at €120 billion in 2010.<sup>6</sup>

One of the most recent antismoking policies implemented in France is the compulsory plain (standardised) packaging that seeks to cancel out, or at least mitigate, the effects of one of the last communication and advertising tools available to the tobacco industry. Today, the French population, smokers and non-smokers alike, is less exposed to the marketing of the tobacco industry thanks to the plain packaging policy. In addition, it is informed, among other things, of smoking consequences and dangers (to oneself and to others) through textual and visual warnings displayed on all tobacco packs. Size (65% of both the external front and back surface of the pack) and positioning standards are set



by the European Union (EU) and warnings are grouped into three sets that shall be used in a given year and rotated on an annual basis according to Directive 2014/40/EU.

The efficacy of warnings on cigarette packs is well established,<sup>7,8</sup> especially when the visual and/or the text is enlarged.<sup>9,10</sup> As such, warnings are considered to be a useful, low-cost, population-wide tobacco control strategy. Nonetheless, some concerns have been raised regarding the validity of these evaluations given the difficulty of estimating the causal effect of this tool, taken in isolation of other tobacco control measures, on actual smoking behaviours.<sup>11</sup> Moreover, even if current warnings are already effective, and some conditions of effectiveness have already been highlighted (see among others<sup>12-14</sup>), one could wonder whether other types of warnings, based on different rationales than mainly social or physical threat or fear, could be even more effective. Indeed, the generalisation of warnings as a policy naturally calls for attempts to increase their effectiveness, and more general changes in their implementation.<sup>15</sup> Finally, since evaluation and identification of the impacts of public health interventions are difficult in the field, because of confounding factors for instance,<sup>16</sup> this protocol can provide new avenues for assessing public health policies and going beyond the limits of declarative methods.

## OBJECTIVES

This paper describes a research protocol designed to meet the following two objectives: (1) creating new warnings based on the recent advances in behavioural literature and testing their efficacy in terms of tobacco prevention compared with that of conventional regulatory warnings and (2) crafting a robust and innovative experimental situation based on financial incentives to evaluate the efficacy of warnings in general.

Regarding the first objective, our hypothesis is that warnings, as they are implemented today, may be suboptimal in terms of tobacco use prevention. Indeed, they may not use the full scope of the cognitive and psychological forces identified by behavioural science in the past decades. In other words, motivational leverage can be gained, in the spirit of nudges,<sup>17</sup> to prevent tobacco use. These motivational driving forces go beyond the conventionally used motivators, generally a mix of rational appeal (insisting on the negative health and socioeconomic consequences) and emotional awe (fear based on graphic representation of health consequences). We postulate that they can increase the efficacy of warnings on smokers while also remaining effective on non-smokers. Our proposal is that the use of *empowerment* mechanisms, aversion to *cognitive dissonance* and *commitment* may help increase the efficacy of warnings as they have been found to be robust and powerful drivers of behavioural changes.<sup>18-21</sup> In addition, we also propose to test warnings that advise practising smoking *harm reduction*, mainly by using Electronic Nicotine Delivery Systems (ENDS).<sup>22</sup> The new warnings we created thus fall into four grand categories. To test all

these warnings, we first intend to rely on widely used indicators. In previous studies, the impact of visual or textual (or both) warnings has often been evaluated with indicators such as attention, perceived effectiveness, attractiveness or recall.<sup>23</sup>

Our second main objective is to go a bit further in methodological terms, by setting up and testing a new measure of warning efficacy. Indeed, a rigorous assessment of the effect of warnings on tobacco packs is notoriously difficult and requires subtle methods.<sup>24</sup> For instance, when long-term behavioural indicators (smoking cessation for instance) are tested, the positive effect of warnings appears weaker or unreliable.<sup>15</sup> Three explanations for this are regularly offered up. The first is that, in a context in which tobacco control measures are simultaneously being implemented (increase in price and taxes, smoking bans in public places, limitation of advertising, etc), the effect of warnings is difficult to separate from other policies. The second is that warnings may be more effective in encouraging non-smokers to remain non-smokers than in convincing smokers to quit, even if the latter's motivation and intention to quit are increased.<sup>12,25</sup> The third one is a common problem in behavioural science: the answers to a questionnaire may have a hypothetical<sup>26</sup> or a social desirability bias (a tendency to conform to what is perceived as the experimentalist's expectations)<sup>27</sup>. The problem may be particularly acute in our case as warnings may affect the perceived social desirability of quitting without genuinely modifying the individual's intention in this regard. Studies using non-declarative methods such as eye-tracking, functional MRI or others partly avoid this bias as they rely on neurophysiological measures and not answers to hypothetical questions.<sup>28-30</sup> Yet, these studies typically correlate physiological measures and the individuals' answers. As such, they are calibrated on hypothetical variables rather than on 'true' behaviours. Our goal is to propose methods that provide incentive compatibility, which would complement typical survey methods as well as neuroscience measures. Relying on non-declarative methods from experimental economics, our goal is to contribute to overcoming these issues by designing a robust experimental framework to evaluate the impact of a wide range of warnings on both smokers and non-smokers.

Following recent studies that have examined the combined effect of the plain pack and the warnings,<sup>31-33</sup> we will seek to evaluate whether the efficacy of warnings is enhanced by the plain packaging. Indeed, it is possible that such a packaging, without the advertising communication of the brand, reinforces the efficacy of warnings. We hence aim to use the established combined effect of the plain pack and the regulatory warnings as an additional check for our new experimental methodology.

Our research project is thus at the intersection of three types of interventions in the modification of smoking behaviours: warnings, plain packaging and nudges. Our evaluations will be based on the recommendations concerning the frameworks for evaluation of tobacco

products labelling<sup>24</sup> and the literature on the indicators routinely tested on warnings.<sup>23</sup>

## DESIGNING AND TESTING NEW PICTORIAL AND TEXTUAL CIGARETTE PACK WARNINGS

### Generalities

The flourishing theoretical and empirical literature in behavioural sciences (cognitive and social psychology, experimental and behavioural economics, neuroscience, etc) is likely to be of interest for antismoking action. One central feature in the literature on behavioural change is the notion of *nudges*: these are defined by their early proponents<sup>17</sup> as seemingly irrelevant changes in the architecture of choice that induce people to behave more in accordance with their own long-term interest. They also differ from traditional interventions in the sense that they are non-coercive. The critical point regarding nudges is that they do not rely on the assumption that decisions result from a fully rational process. Thaler and Sunstein strongly emphasise that most daily decisions are not the result of a rational process that gathers all the relevant information, considers all possible costs and benefits and reaches a balanced judgement regarding the appropriate course of action—system 2 type decision—but rather result from a series of fast heuristics, impulsive cognitive shortcuts or routines—system 1 type decision—(see Kahneman's distinction<sup>34</sup> between system 1 and system 2). Because most decisions in daily life rely on system 1, they can be easily influenced by rationally irrelevant changes in the choice context. Thaler and Sunstein provide numerous examples where elements of a context that should have no influence on a system 2 decision generate considerable changes in behaviour. Nudges can be seen as manipulations of the imperfect system 1 processes to lead individuals to act more in line with what their system 2 would, or should, have decided. Instead of relying on appeals to rational action based on objective information, nudges use the same type of psychological motivations or impulses that in most circumstances lead to long-term 'irrational' conducts.

We intend to use this nudge approach to design new warnings. Conventional regulatory warnings often favour, implicitly or explicitly, an appeal to smokers' rationality (or system 2) by providing information about the objective dangers of smoking ('Smoking is bad for your health', 'Smoking can cause a painful death', 'Smokers die younger', etc.). Very often, this system 2 approach is reinforced with explicit graphical elements ('pictorial warning'), whose role is both to illustrate the hazard of smoking and generate emotions such as disgust or fear to sustain motivation towards a rational decision. Alternative approaches, relying on seemingly irrelevant elements (ie, neither on processes appealing to a fully rational decision, nor on processes appealing to a purely emotional one), are suggested elsewhere<sup>15</sup> but appear to be rarely taken. This is the purpose of this study, namely to design

nudge-like warnings and test them. Approaching written and pictorial warnings as nudges may be a fruitful way to increase the efficacy of warnings. To a certain extent, the mandatory plain pack can be seen as a first step in this direction as its central goal is to cancel out the marketing efforts to appeal to system 1 among smokers (or potential smokers).

### Creation and selection of textual and pictorial warnings

To design nudge-like warnings, we adapted mechanisms that have been found to be effective in other areas than smoking prevention (health related or not). Among the possible psychological leverages, robust positive influences have been shown for commitment mechanisms,<sup>21</sup> empowerment messages<sup>35 36</sup> and cognitive dissonance.<sup>37 38</sup>

Commitment can be defined as 'the pledging or binding of an individual to behavioural acts'.<sup>21</sup> In other words, people who act become committed to their action.<sup>39 40</sup> Such commitment will then affect subsequent attitudes and behaviours. Thus, performing an action increases the likelihood of performing further consistent actions. This link between individuals and their actions can be of the engagement/promise type but can also merely be the continuation of a chosen course of action. The typical effect expected in the case of smoking behaviour is that engaging in a small reduction of smoking may change the general course of the user's smoking habit. As highlighted by a meta-analysis conducted in the field of environmental research,<sup>41</sup> commitment appears to be an effective leverage to promote targeted behaviours.

Empowerment messages were first put forth in feminist literature as a tool to lead women to take action and increase their degree of autonomy and self-determination.<sup>42</sup> The same effect is sought here with smokers. It is about making them aware that they can take control of their tobacco use, and even quit smoking altogether.

Cognitive dissonance<sup>38</sup> relates to the effect of inconsistent cognitions at the individual level. More precisely, the perception of the contradiction between, for instance, a behaviour and a belief, is assumed to generate a feeling of discomfort. People ought then to be motivated to reduce this discomfort by restoring consistency between these cognitions, notably by changing their behaviour. In the case of smoking, leading individuals to notice the inconsistency between the health consequences of smoking, or their intention to quit, and their current behaviour of smoking may increase their motivation.<sup>43</sup>

In addition to these three general approaches, and partly as an extra benchmark, we designed warnings that promote *harm reduction* not only in a manner of dealing with nicotine craving<sup>44 45</sup> but also in a way to substitute a mode of nicotine consumption with another, less harmful one. More specifically, we used warnings that stress the possibility of reducing the harm of smoking by using ENDS (so called 'electronic cigarettes'). This approach, which does not stem from the behavioural literature per se, is of importance in the public health literature,<sup>46</sup>





and the debate it generates would be enriched by some evidence of its efficacy.

For each of these approaches (commitment, empowerment, cognitive dissonance and harm reduction), the authors of this article produced text messages aimed at inviting smokers to quit (or non-smokers not to start). Collectively we selected five such messages for each approach, based on our expectation of their efficacy but also on achieving some heterogeneity in the type of messages. An independent graphic designer was then hired to produce corresponding pictorials: for each text message, she/he was asked to provide two pictorial warnings, respecting the European and French current regulation about the size and the location of the warnings affixed on the packets of cigarettes. In total, for every approach, we obtained 10 pictorial warnings, that is in total 40 new warnings (see online supplementary table A).

To select the most relevant pictorial warnings, we asked experts to rank them based on their expected efficacy. These experts, numbering about 50, are currently members of the scientific committees of 2 French institutes dedicated to public health and tobacco control policy: the French Monitoring Centre for Drugs and Drug Addiction (*Observatoire Français des Drogues et des Toxicomanies*) and Public Health France (*Santé Publique France*). Each of them had to choose between two pictures for each text message. That provided us with five pairs of message and image for each type. Probably in order to maintain participants' attention and for budgetary reasons, experimental studies in this field generally use 4–7 warnings,<sup>44 45 47</sup> so our study is comparable in this respect. Indeed, as we intend to test types of warnings and the relevance of motivational leverages rather than a specific warning, we chose to use a mean of the number of warnings used in a typical study.

For the two control conditions that involve regulatory warnings, we rely on existing warnings, but which we have reason to believe our subjects have not encountered. First, we only use former warnings (no longer in use today), possibly from other countries than France (eg, Belgium or other European countries but as close to France as possible in terms of culture), to prevent attenuation due to habituation. Second, to avoid any form of (anti-)selection, we also asked the same experts to rank these regulatory warnings.

## EXPERIMENTALLY TESTING THE EFFICACY OF WARNINGS: CONVENTIONAL INDICATORS AND A NEW INCENTIVE-COMPATIBLE METHOD

### Generalities

The general design will follow this sequence: (1) participants—divided into different treated and control groups—will be exposed to several images of cigarette packs; (2) they will answer questions that will provide 'traditional' indicators of efficacy (attention, credibility, memorisation and perceived effectiveness at not starting, reducing or quitting smoking); (3) their willingness to

pay (WTP) to purchase a good related to their attitude towards smoking will be elicited.

The last step intends to establish the relevance of incentivised mechanisms inspired by experimental economics in order to go beyond declarative or hypothetical measures. A major issue in testing the efficacy of messages on smoking behaviour is that—unless funding for large-scale randomised controlled trials is available—the researchers can only gather stated intentions or attitudes at a reasonable cost (in studies reviewed by Tajfel,<sup>19</sup> only one relies on an 'objective' behavioural measure: the number of cigarette filters returned by participants to the lab each week, which is prone to mismeasurement or falsification). It is well known that these suffer from possible biases such as the hypothetical bias<sup>26</sup> as well as, more relevantly here, the social desirability bias.<sup>27</sup> While the hypothetical bias may result in a simple overstatement of intention to quit, the social desirability bias may be more of a problem when the testing is conducted in the way it is routinely done in experimental economics. Indeed, experimental economics is based on the (perhaps wrongly overstated) idea that 'talk is cheap' and that any proper measure of behaviour should rely on a decision made by participants that has 'real' consequences for them. In addition to reducing the hypothetical bias, incentive compatibility is often thought to reduce noise (as it increases people's efforts to handle the tasks<sup>48</sup>). In our case, we intend to measure the WTP for products related to an intention of quitting (or for non-smokers to an aversion to smoking). Instead of questions to which subjects know the acceptable answers and for which they would bear no cost in abiding to the norm in their replies, they will state their monetary value for goods related to smoking prevention: a quitting method book for smokers and a donation to an antitobacco association for non-smokers. Note that, strictly speaking, the WTP for the quitting book does not measure smoking (or quitting) behaviour per se. Measuring actual behaviours would require to follow subjects over a long-term range, which would be very challenging in practice. Nevertheless, our indicator does measure the strength, immediately after exposure to the warnings, of the subject's intention to quit without being affected by the hypothetical biases that could characterise declarative answers.

Simply stated, the fact that participants will bear the costs of acquiring these goods may change (some aspects of) the measures of efficacy of treatments. To illustrate this point, if a participant is willing to pay more for a book that provides advice by a health-professional to quit smoking than another individual, she/he is likely to have a stronger 'genuine' willingness to quit. In other words, the monetary value a participant is willing to sacrifice for goods that will help her/him to quit smoking is assumed to be a good indicator of her/his true motivation. This method relies on aligning incentives (receiving the goods or getting some money *for real*) with actual behaviour and are often believed to lead to better experimental estimates.<sup>49</sup> We will use the typical Becker-DeGrot-Marschak

method,<sup>50</sup> with the use of interactive multiple pricing list,<sup>51</sup> which is known to simplify the task of valuing a commodity by transforming it into a series of plain and simple binary questions.

In sum, the experimental conditions will be the following:

- ▶ Control conditions
  - Plain packs with no warnings.
  - Plain packs with conventional regulatory warnings.
  - Branded packs with conventional regulatory warnings.
- ▶ Treatments
  - Plain packs with warnings based on cognitive dissonance.
  - Plain packs with warnings based on empowerment.
  - Plain packs with warnings based on engagement/commitment.
  - Plain packs with warnings based on harm reduction.

Each participant will be exposed, on a computer screen, to 10 images of cigarette packs falling under one of the 7 above-mentioned groups (3 control groups, 4 treatment groups). This implies that the design will be a between-subject design: participants in the experiment will be confronted to a single type of pack design/warning. This is driven by the need for psychological independence of the effects of the different interventions. The reason for exposing subjects to multiple images is twofold: first, it allows us to test *a type of nudge/intervention* rather than a single image/message; second, it reproduces more closely real-life smoking conditions where smokers (and non-smokers to a certain extent) are exposed to several warning messages. Another advantage is that it allows us to test several brands in the second control condition (usually, the package of the brand with the largest market share is used, but that may not trigger impulses or reactions for smokers of another brand).

The comparison between the three control conditions will work as a replication of recent work<sup>33</sup> on the independent effect of plain versus branded packages and hence serve as an independent validation of our methodology, especially the incentivised mechanism. We will use both the typical questionnaire measures used in this type of study and our own methodology based on financial incentives (WTP).

Our main focus is to compare nudge-like interventions to the two main control conditions with plain packs. The main hypothesis will be formulated in terms of the monetary values participants attribute to quitting tools or to the monetary gift to an antitobacco association: the null hypothesis is that these values are similarly distributed in the various treatments (plain pack with regulatory warnings against a given nudge treatment).

Monetary incentives are critical to the quality of data in our case. We intend to pay subjects on average €15 for an experimental session of under an hour, to be completed with a show-up fee of €3. Depending on their own choices, they could get the full amount in cash or partly in cash plus the goods they may have

purchased. This level of payment is standard in experimental economics.

### Setting and recruitment

The experiment will take place during the fourth quarter of 2020 at the experimental economics lab of the Anthropo-Lab (*Institut Catholique de Lille*), which has 30 individual and physically separated booths that allow subjects to make decisions in typical experiments. The lab follows the three methodological rules of experimental economics: subjects are paid based on performance or decision, experimentalists never deceive subjects and the context of the experiments is usually ‘neutral’.<sup>52</sup> The lab has a pool of 3000 subjects who are regularly invited by electronic message to take part in experiments through the ORSEE system.<sup>53</sup> The subject pool is mainly composed of students or former students, so the median age is presumably around 20.

Complementary recruitment will be carried out to limit the sample bias in terms of education and social status (particularly to enrol older smokers): leaflets inviting smokers to join the Anthropo-Lab subject pool will be distributed at strategic locations (tobacco shops, bar terraces and entrances of office buildings where smokers gather on breaks). In total, we expect about 1000 participants (150 in each control/treatment group; see power calculation below). Information on the type of experimentation is given to participants at reception. Subjects must provide written consent or leave the experiment.

### Randomisation

As choice of sessions (time of the day, day of the week) may correlate to certain individual variables, the randomisation of conditions (attribution of a control/treatment group) will be done at the individual level, within a session. The experimental platform (based on O-Tree<sup>54</sup>) will randomly assign each subject to a condition.

### Power calculation

Our main statistical test will be to compare the WTP elicited by subjects between treatments. Assuming this WTP follows a lognormal distribution, as it cannot be negative, with an average of €2.3 and a SD of €1.6 (these parameters roughly correspond to former experiments run with similar procedures to estimate the value of minor consumption products<sup>55 56</sup>), we estimate statistical power by running simulations on 999 occurrences of two randomly drawn samples of  $n$  WTP, rounded to our experimental precision (€0.10) and truncated to €8 (which is the commercial value of the book that participants are offered to buy). The first simulated sample corresponds to the control condition, with an expectation of €2.3 and the second sample has an expected value of €2.3 plus some effect. Then, we calculate the frequency with which a non-parametric Wilcoxon rank-sum test yields a statistically significant difference at a threshold of  $p < 0.05$ . The results are provided in [table 1](#).

**Table 1** Statistical power analyses

Effect size in $\epsilon$ (Cohen's d)	Simulated frequency with which a significant diff. is observed			
	n=75	n=100	n=150	n=200
0.4 (0.25)	0.50	0.60	0.79	0.89
0.6 (0.375)	0.79	0.92	0.98	>0.99
0.8 (0.5)	0.97	>0.99	>0.99	>0.99

Assuming a small effect (Cohen's  $d=0.25$ ), our targeted sample size for each group (150) gives a probability of a type II error in a binary comparison of treatments of around 0.20, which is generally considered as satisfactory.

### Summary of the experimental protocol

In a nutshell, our protocol can be summarised by a simple table, such as [table 2](#).

### Collected variables

During the experiment, we will collect data on:

- ▶ Individual characteristics
  - Gender.
  - Age.
  - Socio-professional status.
  - Smoking status, and for smokers: age of first smoked cigarette, number of cigarettes smoked over the last 7 days, light versus heavy smoker, Fagerström test for cigarette dependence.<sup>57</sup>
  - Time and risk preferences.<sup>58</sup>
- ▶ Classical measures of the efficacy of warnings
  - Attention.
  - Recall.
  - Intention.
  - Perceived effectiveness (not starting smoking, cutting down or quitting smoking).
- ▶ Monetarily incentivised value of the antismoking goods
  - WTP for the quitting book or for a monetary gift to an antitobacco organisation.

### Data management

The data are fully anonymous as the collection is made through a computer interface that does not compile

names/identification for subjects. The data will nevertheless be stored on an encrypted computer and password protected as is required by French and European law.

### DATA ANALYSIS

#### Main analysis

Our main analysis will be provided by a mere comparison of WTP in treatments. Given the randomisation procedure we use, subsamples should be statistically similar. As a consequence, we will simply test (with the multiple testing correction required) whether we observe differences in the distribution of the WTP. Our preferred test is the Wilcoxon rank-sum test, which is appropriate for between-subject design and is non-parametric.

#### Secondary analysis

We will test the correlations between our incentivised measures and the usual declarative answers (intention/cognitive tasks) to check their reliability.

#### Sensitivity analysis

Standard econometrics (OLS, Tobit) will be used to check the robustness of possible differences across treatments when sociodemographic variables are taken into account as control variables. This is aimed at testing the robustness of our results with respect to possible sampling variation.

### DISCUSSION

Two main issues seem worthy to be discussed. The first one has to do with the methodology we propose to introduce and test; the second relates to the nudge approach itself.

Economists as well as researchers in neuroscience or psychology tend to dismiss declarative data and rely almost exclusively on 'revealed' preferences, that is, ones that are appraised through actual behaviour. Although their mistrust of declarative data is probably exaggerated, the use of incentive-compatible methods developed by experimental economists in a tobacco control experiment may renew the field in the sense that it may help uncover the circumstances under which typical questionnaire answers are correlated with certain behaviours. Yet,

**Table 2** Experimental protocol

Treatment	Pack (nb. submitted to participants)	Type of warnings	Expected nb. of subj. including expected 25%–30% smokers
1	Plain (1)	None	150
2	Plain (5)	Regulatory	150
3	Branded (5)	Regulatory	150
4	Plain (5)	Cognitive dissonance	150
5	Plain (5)	Empowerment	150
6	Plain (5)	Engagement/commitment	150
7	Plain (5)	Harm reduction	150



one of the limits of our current approach is that we do not have, *in fine*, any way to test the *long-term validity* of the effects we observe. To do so, we plan to conduct future research based on a long-term follow-up. This is beyond the scope of this project for now, but we see it as a first stepping stone towards this more ambitious type of validation. Indeed, before engaging in such a long-term study, establishing the difference and congruence between incentivised and non-incentivised measures seems critical.

The nudge approach has two main advantages: it is not coercive and its implementation is almost costless. Yet, its effect is generally considered to be weak in the health field.<sup>59</sup> We believe our study will help to reach some resolution on this, as most of the time, the efficacy of nudges is measured in comparison to an absence of intervention (and not alternative, eg, rational, interventions). In this protocol, we do test nudge-like interventions against more conventional (regulatory) warnings, but also against the absence of warnings. In any case, we believe that this will clarify the intensity of the effects. Also, it seems worthwhile to test other types of psychological leverage than the ones used in standard regulatory warnings from a mere (expected) cost/(expected) benefit analysis. Warnings leading to marginally stronger effects on smoking deterrence would still have a huge global impact if they were generalised.

## ETHICS AND DISSEMINATION

As dictated by French law on biomedical research, all participants can withdraw from the study at any time and without any justification. The research protocol was approved by the ethics committee (*Comité Interne d'Éthique de la Recherche*) of the *Groupement des Hôpitaux de l'Institut Catholique de Lille* on 5 July 2019. A consent form in French is available on request. Results will be presented at scientific meetings. The authors commit to publish all the results of this study in medical, health economics or other scientific journals. The data will be the property of the University of Lille and the Catholic Institute of Lille. These institutions will define the standards of data sharing and data storage.

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**Contributors** All authors substantially contributed to the conception and the design of the research. The first version of the manuscript was drafted by FLL, AD and AP. CBL and AP conceived the warning based on psychological leverage and harm reduction. FLL and AD designed the experimental framework, which was discussed and approved by the other authors. CBL, SM, NV and FLL applied for funding and conceived and drafted the literature reviews. All authors drafted the data analysis section and revised the work critically for important intellectual content and gave final approval for the submitted version.

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