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Intervention

Does the effect go up in smoke? A randomized controlled trial of pictorial warnings on cigarette packaging

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ABSTRACT

Objective: Placing a combination of a written warning and a graphic image on cigarette packaging (so called "pictorial warnings") is one of the WHO Framework Convention on Tobacco Control's most controversial recommendations. Our randomized controlled trial investigated if pictorial warnings lead to significantly higher motivation to quit, as compared to written warnings alone.

Methods: Four pictorial warnings were selected from the EU Commission's official image catalogue. Study arm 1 (44 adult smokers) viewed only the written warnings while study arm 2 (44 adult smokers) viewed the corresponding pictorial warnings. Self-affirmation was a second randomly manipulated factor, and nicotine dependence a quasi-experimental third factor. The main outcome measured was the motivation to quit, with fear intensity as one of the secondary outcomes.

Results: Pictorial warnings were associated with a significantly higher motivation to quit. A pictorial warning was also associated with higher fear intensity. The effect of warnings appears to be independent of nicotine dependence and self-affirmation.

Conclusions: Nationwide implementation of pictorial warnings may be effective in increasing heavy smokers' motivation to quit.

Practice implication: Due to the fact that perceived vulnerability, response and self-efficacy are not more strongly affected by pictorial warnings this effect may turn out to be short-term.

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1. Introduction

This randomized controlled trial is focusing on one of the WHO Framework Convention on Tobacco Control's (FCTC) most discussed recommendation: Article 11.1.b.V of the FCTC recommends the use of pictures to emphasize warnings on cigarette packaging [1]. Despite the fact that the FCTC was signed and ratified by more than 150 countries, only a few have made the effort to actually introduce and enforce the use of images [2,3]. Canada (2001), Brazil (2002), and Singapore (2004) were the first countries to make the combination of written warnings and graphic images on cigarette packaging (so called "pictorial warnings") a legal requirement [3–5]. The European Union has urged all EU member states to introduce and enforce similar measures (2003/641/EG). Therefore,

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the European Commission recently developed a collection of images to be printed on cigarette packaging in combination with the written warnings already in use and made this image catalogue available to the EU member states [3,6]. The discussion within and among EU nations regarding the introduction of these measures is still ongoing. Among the EU states actively involved in these discussions is the one with by far the largest number of smokers, namely Germany.

The concept of printing warnings on cigarette packaging appears to be enticingly smart; such warnings are cheap, appeal to a broad audience among smokers and non-smokers, and they restrict and counterbalance the advertising and brand label space of tobacco companies. Last but not least, they appeal to a smoker at an ideal point in time, i.e. the moment she/he feels the desire to smoke [7]. Thus, a smoker who consumes approximately one pack of cigarettes per day will be confronted with the warning images at least 7000–8000 times a year [5,8].

The pictorial and written warnings suggested by the EU represent classic fear appeals. From the many experimental studies into fear appeals, two main theoretical frameworks have been derived: The Protection Motivation Theory [9] and the Extended Parallel Process Model [10–12]. Both models define relevant components of effective

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fear appeals: the Extended Parallel Process Model (EPPM) states that an effective fear appeal causes a consecutive, cognitive response to fear reaction, awareness of one's own vulnerability, as well as of the severity of the presented threat, along with an estimation of response efficacy and feasible self efficacy. This model further asserts that this cognitive process results in an increase in the motivation to quit, which, in the ideal case, in turn leads to the actual cessation of smoking. In this way, the components of this model can, on the one hand, be seen as the cognitive consequences of a fear appeal. On the other hand, these constructs can, according to the two aforementioned theories, be interpreted as determinants of a consecutive motivation. Since the EPPM has more often been implemented in tobacco prevention programs than Protection Motivation Theory, we chose the former for our theoretical rationale [8,13]. Therefore our study includes the model's central constructs as outcome measures (fear intensity, vulnerability, severity, self and response efficacy). Another aspect discussed in the prevention research field examines the effect of health warnings dependent on an individual's self-perception. In order to reinforce their positive perception of themselves, those affected (e.g. patients, HIV-risk groups, alcohol consumers, drug consumers) could react defensively to such emotive and fear-inducing appeals by means of avoidance strategies, according to Steele's Theory of Self Affirmation [14]. Therefore, we took into account the role of the smokers' selfperception (via the construct of self-affirmation) in our study.

Although these theoretical models exist, up until now they have barely been investigated regarding explaining the possible effects of warnings on cigarette packaging: a systematic review published by the German Cancer Research Center in May 2009 as well as our own investigations show that some population-based surveys seem to support the positive impact of warnings on cigarette packaging in general [5]. But, most studies investigate only written warnings [15–17] or only pictorial warnings [18,19], respectively. Only few studies compare the effects of a combination of pictorial and written warnings by for example comparing their effects in different countries or for various survey years [20–23]. To date, especially randomized controlled trials regarding this topic are rare.

Typical methodological limitations of survey data were criticized and it was suggested to carry out additional experimental studies [4,24]. The German Cancer Research Center's review of literature shows that so far only two randomized controlled trials comparing the impact of both types of warning exist. Neither of these studies investigates the impact on the "motivation to quit" which is a central and crucial variable. Peters and colleagues studied affective reactions [25] whereas Thrasher et al. [26] took a closer look on the impact of warnings on the price of cigarette packs in a very special context (in an auction). Therefore our study aims at filling the gap in research that exists with regard to randomized controlled trials.

It focuses on the following research questions:

- Do pictorial warnings on cigarette packaging lead to a stronger motivation to guit than written warning information?
- Are factors preceding the motivation to quit (fear intensity, vulnerability, severity, self and response efficacy) more strongly influenced by pictorial warnings than by those containing only text?
- Does previous self-affirmation play a significant role for these primary and secondary outcomes by reducing defensive reactions?
- Do these warnings have the same effects on addicted smokers as they do on non-addicted smokers?

By addressing these questions, this classical randomized controlled trial aims to meet current demand for effectual evaluation of this prevention method before it is implemented on millions of packs of cigarettes worldwide [27].

2. Methods

2.1. Eligibility criteria for participants

Ninety-five students were recruited from October 22nd to 23rd, 2007 in front of the central canteen and the cafeteria of Mannheim University, Germany. Participants were admitted to this convenience sample if they fulfilled the following criteria: at the time of the study (1) current smoker (according to their own rating), (2) aged between 18 and 30, (3) student and (4) fully informed and consented to participating in the study. On returning the questionnaire each student received one Euro and a bar of chocolate as a symbolic thank-you.

2.2. The study intervention

2.2.1. Manipulation of the factor "pictorial versus written warning"

The stimulus material consisted of four selected fear appeals in the form of solely written warning information ("written warning", study arm 1), or a combination of the same written warnings with pictorial warning information ("pictorial warning", study arm 2). Four motifs were selected from the official EU Commission's image catalogue [28], all of which clearly represented fear appeals. Based on the method suggested by Petersen and Lieder [8], a graphic programme (Adobe Photoshop CS2) was used to position the written or pictorial warnings on color images of authentic cigarette packages (Fig. 1).

2.2.2. Manipulation of self-affirmation

Before the participants were confronted with the abovementioned stimulus material, they were asked to complete a questionnaire for the purpose of gathering information as to their personal qualities and values (social skills, relations with family and friends, etc.). The principal investigator of the study (A.F.) claimed that this questionnaire was a pretest for a study to be conducted by a colleague. The questionnaire's real purpose was however to manipulate participants' self-affirmation.

Based on Sherman's approach [29], participants were asked to sort a list of values by what was most important to them. This list was based on Harbers' Sources of Validation Scale [30] and the item list of the Sources of Self-Esteem from Schütz [31]. As part of the





Fig. 1. Example of a selected pictorial and written warning. *Note*: translation: "smoking can cause a slow and painful death." For legal reasons, in this publication the brand and logo from cigarettes packages were concealed and replaced with the name "Brand". However, in order to design the experiment as realistically as possible, for the experiment pictorial warnings on authentic cigarette packages were kept. Four of Germany's most popular cigarette brands were used for this purpose.

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experimental requirements (self-affirmation), participants wrote a short text explaining why the value they had indicated as most significant was so important to them. The subjects in the control group (no-affirmation) were asked to describe in a text why the value they had chosen as being the most insignificant for them could be important to an average Mannheim University student. A 2 (self-affirmation vs. no-affirmation) \times 2 (pictorial warning vs. written warning) factorial design emerged as a result of this approach.

2.2.3. Operationalization of the quasi-experimental factor "level of nicotine dependence"

Both studies regarding the EPPM and those regarding the effect of self-affirmation examine if nicotine dependence could play an important role as a moderator variable [18,32]. A further aspect is the discovery that people at risk often react defensively to threatening health messages. To consider this claim, data on the level of nicotine dependence was obtained from the German version of the Fagerström-test for nicotine dependence [33]. Smokers with a FTND sum score of \geq 5 were classified as "addicted smokers" [33].

2.2.4. Motivation to quit

Motivation to quit was assessed with four items. Participants were asked to express to what extent the warnings induced them to: (1) consider ceasing their cigarette consumption", (2) consider reducing their cigarette consumption, (3) think about the health risks associated with smoking', or (4) refrain from smoking a cigarette at the moment. Cronbach's alpha showed consistency between the four items (α = .91), we combined the four indicators into a sum score.

2.2.5. Fear intensity, vulnerability, level of threat and self and response efficacy

In accordance with the method of Kees and colleagues [4], data regarding fear intensity was gathered by means of four items covering how afraid, worried, uncomfortable or disgusted participants felt after having seen each warning. In accordance with Gierl and Koncz [6] participants were also asked to evaluate their own feelings of vulnerability, as well as the level of threat they felt presented with, and the self and response efficacy. Response options ranged from 1 = "not at all" to 7 = "completely". Cronbach's alpha showed consistency between these four items ($\alpha =$.86).

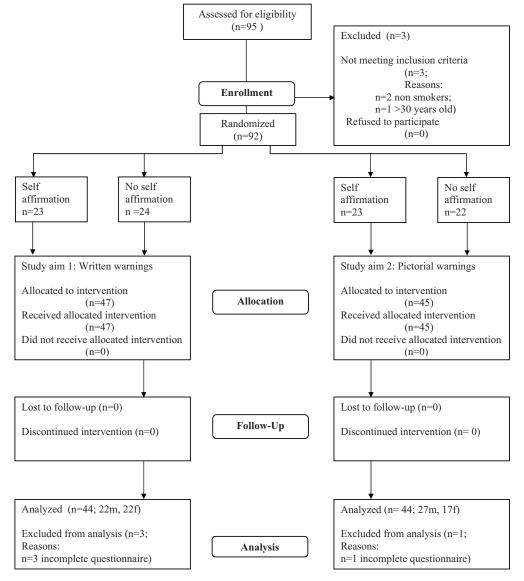


Fig. 2. CONSORT flow diagram of all participants and their allocation. *Note*: two participants were excluded later from the analysis because they reported that they were smokers during the recruitment interview but marked themselves as non-smokers in the study questionnaire.

Table 1Effects of pictorial and written warnings, nicotine dependence and self affirmation on cigarette packages on the motivation to quit.

	Mean	F	р
Warning (W)			
Pictorial warning	18.59	17.668	< 0.001
Written warning	12.41		
Nicotine dependence (ND)			
Addicted smoker	14.34	1.322	0.254
Non addicted smoker	16.66		
Self affirmation (SA)			
Yes	16.57	1.988	0.279
No	14.52		
$ND \times W$	-	1.673	0.200
$ND \times SA$	-	1.377	0.244
$W \times SA$	_	0.090	0.765
$ND \times W \times SA$	-	0.096	0.329
Total $R^2 = 0.255$	15.50		

Note: $2 \times 2 \times 2$ factorial analysis of variance (ANOVA). The scale ranged from 4 to 28, with higher values representing higher levels of motivation induced by the warnings. All variables had 1 degree of freedom. Significance level p < 0.05.

2.2.6. Randomization

The allocation to the 2×2 factorial design mentioned earlier was achieved by means of a computer generated block randomization list.

2.3. Statistical analyses

Univariate analyses of variance (ANOVA) were calculated, with inclusion of the "level of nicotine dependence" as a third (quasi-experimental) factor. In addition to the primary outcome measure, additional ANOVAs for secondary outcome measures were calculated. Two sided test were used throughout, with a significance level set at p < 0.05. All statistical tests were performed with the SPSS for Windows, version 17.0 statistical software package.

Table 2Means and standard deviations of experimental and quasi-experimental factors on the motivation to quit.

	Nicotine dependence	
	Addicted	Non addicted
	Mean/SD	Mean/SD
Pictorial warning		
Self-affirmation		
Yes	19.80 ± 3.99	$19.33 \pm 6,79$
No	17.60 ± 6.55	17.67 ± 7.60
Written warning		
Self-affirmation		
Yes	13.10 ± 6.01	13.50 ± 8.41
No	9.00 ± 4.28	15.40 ± 7.37

Note: The scale for motivation to quit ranged from 4 to 28, with higher values representing higher motivation.

3. Results

Eighty-eight out of ninety-five volunteers fulfilled the inclusion criteria and delivered complete questionnaires (Fig. 2). The collective consisted of 39 males and 49 females aged between 18 and 30 (Mean age 22.0 ± 2.40). All of the participants were students from various faculties (business administration, economics, social sciences, law, humanities and economic education). The CONSORT flow diagram indicates that all $2 \times 44 = 88$ participants were randomly assigned for the successful allocation (study arm 1: n = 22 male, age mean 22.32 ± 2.19 , n = 22 female, age mean 21.95 ± 2.89 ; study arm 2: n = 27 male, age mean 21.81 ± 2.30 , n = 17 female, age mean 21.94 ± 2.30 ; see Fig. 2).

The main result of this study is that pictorial warnings on cigarette packaging lead to a significantly higher motivation to quit than solely written warnings (18.59 \pm 6.31 vs. 12.41 \pm 6.75; effect size (Cohen's *d*) 0.95; p < .001). Details of the effects of the experimental and quasi-experimental factors on the motivation to quit are shown in Table 1.

Having seen warnings that combined text and pictures, participants' positive answers were located >6 points over those

Table 3Effects of pictorial and written warnings, nicotine dependence and self affirmation on cigarette packages on secondary outcome measures.

	Fear intensity		Vulnerability		Severity of threat		Response efficacy		Self-efficacy	
	F	р	F	р	F	р	F	р	F	p
Warning (W)	20.5	< 0.001	0.5	0.490	7.1	0.009	2.9	0.091	0.0	0.942
Nicotine dependence (ND)	0.8	0.362	0.3	0.596	0.9	0.351	0.0	0.997	30.4	< 0.001
Self-affirmation (SA)	0.5	0.471	0.0	0.929	0.4	0.535	0.3	0.607	0.5	0.492
$ND \times W$	2.5	0.115	0.3	0.589	0.0	0.956	0.9	0.352	0.6	0.814
$ND \times SA$	7.3	0.008	0.1	0.721	1.9	0.168	0.1	0.795	0.5	0.464
$W \times SA$	0.3	0.573	0.5	0.499	3.4	0.052	3.0	0.089	1.7	0.199
$ND \times W \times SA$	7.4	0.393	0.2	0.665	0.8	0.367	0.1	0.822	0.2	0.682

Note: $2 \times 2 \times 2$ factorial analyses of variance (ANOVAs). All variables had 1 degree of freedom. Significance level p < 0.05.

Table 4Correlation matrix of primary and secondary outcome measures.

	Motivation to quit $ au_{ m b}/p$	Fear intensity $ au_{ m b}/p$	Vulnerability $ au_{ m b}/p$	Severity of threat $ au_{ m b}/p$	Response efficacy $ au_{ m b}/p$
Fear intensity	0.573***				
Vulnerability	0.182 [*]	0.275***			
Severity of threat	0.245***	0.363***	0.336***		
Response efficacy	0.228**	0.059	0.005	0.056	
Self efficacy	0.103	0.139	0.302***	0.292***	-0.056

Kendall's $\tau_{\rm b}$ and p-values with p < 0.05.

^{**} Kendall's $\tau_{\rm b}$ and p-values with p < 0.01.

Kendall's $\tau_{\rm b}$ and p-values with p < 0.001.

given by the control group (Table 2). Therefore our main hypothesis can be (preliminarily) confirmed. This effect was significant and stable: it was present independently of a previous self-affirmation. Furthermore, it did not depend on the severity of dependency. Interaction effects could also not be identified (Table 2).

Furthermore, pictures induced a higher level of instantaneous fear in participants. Pictorial warnings also caused participants to perceive smoking as a health risk more often (severity). However, pictorial warnings did not cause more smokers to perceive their consumption as a personal risk (vulnerability). In addition, the method of presentation influenced neither the perception that quitting would reduce the health risk, nor the belief that quitting could be achievable (self- and response-efficacy; Table 3).

Supplementary correlation analyses revealed the highest associations between motivation to quit and fear intensity (Kendall's τ_b/p value: +.573/p < .001) and motivation to quit and threat (Kendall's τ_b/p value: +.245/p = .001). The correlations between the main outcome and other secondary outcomes were weaker (Table 4).

4. Discussion and conclusion

4.1. Discussion

4.1.1. Comparison with findings of other studies

On the one hand, our findings are consistent with some findings of former studies on this topic, but on the other hand, they reveal general questions about the effect of pictorial warnings.

The fact that pictorial warnings produce a stronger motivation to guit and more intense levels of fear was also demonstrated by Gierl and Koncz [6], Hammond et al. [21], Hammond et al. [19], Kees et al. [4] and Thrasher et al. [22] with the exception of Petersen and Lieder [8]. Recent survey data from Australia suggest that pictorial warnings have a higher impact on adolescents' knowledge, beliefs and smoking behaviors than written warnings

The manipulation of the participants' self-affirmation in our study did not have any effect. Dillard and colleagues [16] also analyzed the manipulation of participants' self-affirmation as a method of reducing defensive reactions to pictorial warnings on cigarette packets. They were also unable to show that manipulation of smokers' self-affirmation leads to a more realistic estimation of personal health risks. The self-affirmation did not lead to any differences in the appraisal or acceptance of the warnings [16]. In contrast to this, Harris et al. [18] were able to demonstrate that self-affirmation can lead to a participant's intention to reduce his/her cigarette consumption, as well as to a better perception of the threat represented by the warning.

4.1.2. Limitations and strengths

The limitations of this study deal above all with the possible defensive reaction of the target subjects: the lack of a manipulation check for the self-affirmation, the stability of the effects, as well as the extent to which the results can be generalized.

Possible defensive reaction of the target subjects. Studies on attentional bias in current addiction research suggest that alcoholand nicotine-dependent patients consciously or unconsciously avoid being confronted by frightening pictures [18,34]. We are currently conducting an experiment in which the smoker performs a visual dot probe task presenting pictures of packages with either a written, a pictorial warning or a neutral picture. In this eye tracking experiment, compared to non-smokers, the group of light smokers diverted their attention away from pictorial warnings and focused on cigarette packages displaying neutral pictures [35]. Other indicators for such a reaction are using a private cigarette

case or covering the warning labels with humorous cardboard cases [19,21]. In order to be able to find out if such possible avoidance reactions went so far that some participants did not look at the warnings at all, they were asked at the end of the experiment to describe both the wording and the image in as much detail as possible. Sixty-six of the participants (77%) were able to recall all four warning labels word-by-word, and 18 (20%) could recall exactly at least three of the warnings. All participants were able to recall at least one of the warnings (average number of remembered warnings: 3.69). This result was consistent with the findings of a recent study [36].

Lack of a manipulation check for self-affirmation. The manipulation of self-affirmation did not have an effect in our study. Even though it would have been useful to conduct a manipulation check to ascertain whether the manipulation was successful in increasing self-affirmation in general, we refrained from doing so to avoid distrustful reactions.

Stability of effects. So far studies such as this one have not investigated how long the effects observed persist after the subject is confronted with the warning information, a fact which has recently been criticized by McQueen and Klein [37]. Our participants were also confronted with the stimulus material only once, for a short period of time. This objection, however, applies only to studies such as the present one but not necessarily to a nationwide introduction of pictorial warnings. Instead of a single exposure, smokers would be exposed to such warnings several times a day. Although some scientists argue that such a constant actualization of the effects could result in reactance effects in some smokers (see below), several studies on the topic have failed to reveal a meaningful occurrence of such undesirable effects in either adults or adolescents [6,20,21]. In addition to this, the motivation to guit should not be equated with the actual cessation of consumption [32,38].

Extent to which the results can be generalized. The question regarding the extent to which the reactions of adult student smokers can be generalized to apply to smokers from other societal groups can also only be answered by further studies. Two studies published in German indicate analogue effects in school students and adolescents [6,8].

The EPPM suggests a hierarchical stepwise cognitive process. Therefore, the correlations between the primary and secondary outcomes are in line with that theoretical framework. However, these correlations might represent a statistical artifact since the secondary outcomes were rated after motivation to quit. Conversely, secondary outcomes might have been affected by these prior ratings (so called order bias [39]). In order to prevent the occurrence of order bias for at least the main outcome, motivation to guit was assessed first in the questionnaire.

Where possible, we used previously field-tested instruments. A pretest with n = 15 participants was carried out before the main study. To our knowledge this study with 88 included smokers is together with the study of Peters et al. [25] - the largest randomized study of this current, much-discussed prevention strategy. A post hoc power analysis yielded a beta value of .9924. A sample size of n = 19 per study arm would have been sufficient to observe any significant effects with pictorial warning labels. Furthermore, this is the only study that differentiates between two types of smokers. Furthermore, instead of randomly designed messages, officially designed warnings intended for use by the EU-Commission were used, positioned on cigarette packaging in the original design and size.

4.2. Conclusion

Pictorial warning labels have the primary desired effect. They produce a stronger motivation to quit than the use of written

warnings alone. Moreover, pictorial warnings induce more intensive levels of fear and severity of the threat. On the other hand, other central components of the corresponding EPPM, such as the perceived vulnerability, response and self-efficacy were not more strongly influenced by pictorial warning than they were by written warnings. Additionally, the effect of warnings appears to be independent of the level of nicotine dependence and self-affirmation. Thus, several central theses of two relevant theories (EPPM and the Theory of Self-Affirmation) could not be replicated and their predictive value for behavioral change in this context called into question.

Furthermore, if the level of nicotine dependence is accepted as a proxy of personal relevance, it could also be assumed that pictorial warnings would result in more defensive reactions among those to whom the threat is most relevant (here also for the strongly addicted smokers). This is associated not only with fundamental studies from the field of experimental social psychology (e.g. on a self-serving bias [40]) but also with current studies regarding the defensive processing of personally relevant information [18,29]. However, in our study a significant effect was neither shown for the factor "self-affirmation", nor for the factor "nicotine dependence". This is also the case for the interaction effect ND \times SA (Table 1). Only an interaction effect with fear intensity was detected (Table 2). Further analyses showed that the remembrance of the four warnings presented was also independent from the nicotine dependence (Fisher's exact test: p = .647).

4.3. Practice implications

Pictorial warnings lead to participants expressing more motivation to quit as well as a higher level of fear than they do after seeing written warnings. But, quitting smoking is difficult and more than simply a motivation to quit is needed. The effects on motivation to quit are, for example, not reflected by the findings on measures of perceived threat and perceived coping. This is a notable finding that is in contrast with social cognitive theories, which assert that most behavior is planned. The differences found in motivation might be an impulsive rather than planned response.

Conflict of interest

All authors disclose any actual or potential conflict of interest including any financial, personal or other relationships with other people or organizations that could inappropriately influence, or be perceived to influence, the work.

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