

The impact of pictorial health warnings on tobacco products in smokers behaviours and knowledge: the first quasi-experimental field trial after the implementation of the tobacco law in Italy

Alice Mannocci¹, Daniele Mipatrini¹, Gianmarco Troiano², Federico Milazzo¹, Elisa Langiano³, Maria Ferrara³, Alberto Firenze⁴, Sandro Provenzano⁴, Maria Rosaria Gualano⁵, Maria Fiore⁶, Giovanni Boccia⁷, Gabriele Messina², Elisabetta De Vito³, Roberta Siliquini⁵, Paolo Villari¹ and Giuseppe La Torre²

¹Dipartimento di Sanità Pubblica e Malattie Infettive, Sapienza Università di Roma, Rome, Italy

²Dipartimento di Medicina Molecolare e dello Sviluppo, Università degli Studi di Siena, Siena, Italy

³Dipartimento di Scienze Umane Sociali e della Salute, Università degli Studi di Cassino e del Lazio Meridionale, Cassino, Italy

⁴Dipartimento di Scienze per la Promozione della Salute e Materno Infantile "G. D'Alessandro", Università degli Studi di Palermo, Palermo, Italy

⁵Dipartimento di Scienze della Sanità Pubblica e Pediatriche, Università degli Studi di Torino, Turin, Italy

⁶Dipartimento di Scienze Mediche, Chirurgiche e Tecnologie Avanzate "G.F. Ingrassia", Università degli Studi di Catania, Catania, Italy

⁷Dipartimento di Medicina Chirurgia ed Odontoiatria, "Scuola Medica Salernitana", Università degli Studi di Salerno, Salerno, Italy

Abstract

Background. The aim of the study was to evaluate in the Italian smokers, the effects of implementation of the law about Pictorial Health Warnings (PHWs) on tobacco products.

Methods. A quasi-experimental longitudinal design was conducted between 2016 and 2017. The data were collected before (pre-PHW/Wave 1) and after (post-PHW/Wave 2) the implementation of the law. The adopted questionnaire included impact of advertisement (Label Impact Index, LII), quitting behavior and knowledge of tobacco related diseases.

Results. 455 respondents completed both the Waves. 7.7% of smokers declared to have stopped smoking in Wave 2 and 29% of these declared the PHWs as one of the reasons to quit. The knowledge of tobacco related diseases was significantly ($p < 0.001$) increased from Wave 1 to Wave 2 (58% versus 72%), similarly the LII (mean = 26.9, SD = 16.7 and mean = 40.4, SD = 16.2).

Conclusion. Tobacco addiction is a problem that needs to be addressed from different angles. PHWs confirm their complementary role as a support for smokers along with other strategies such as text warnings and the tobacco quit line of the Istituto Superiore di Sanità (Italian National Institute of Health) reported on the packages. Nonetheless, over the years these measures have been not enough and policy makers should consider more strategies synergistically acting in the fight against tabagism.

Key words

- pictorial warnings
- health labels
- health warnings
- tobacco advertisement
- quasi-experimental study



INTRODUCTION

WHO has recommended the application of pictorial warnings on tobacco products since 2008 [1].

Pictorial Health Warnings (PHWs) constituted an important policy to inform adult smokers on the impact of smoking on health [2, 3], but at European level pictorial warnings have not been implemented in all countries in the same time [4].

The first European Tobacco Products Directive (TPD), which regulated aspects such as manufacture, sale and presentation of tobacco products, was approved in 2001. In 2009 the European Commission decided to review the TPD. The ordinary legislative process began immediately after this, on January 2013, finishing in October 2015, when the final act was signed [4, 5].

In April 2014 the European Parliament and of the Council approved a Directive on “the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products”. In particular the Articles 11, 12 and 13 of TPD on “Labelling of tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco”, “Labelling of smokeless tobacco products” and “Product presentation” underlined that the attractive, modern packages and trendy brand names attractive to young people and thus might increase smoking initiation. The Article 13, letters a), b) and c), invited to the Members States to introduce more stringent rules concerning the labelling and the outside packaging of tobacco products that delete the erroneous impression about its characteristics, health effects, risks or emissions; quit any possible suggestive references to the less harmfulness of some tobacco products than others; and remove references to taste, smell, any flavorings [6].

In 2015, the European Commission implement a decision on “the technical specifications for the layout, design and shape of the combined health warnings for tobacco products for smoking” [7]. The key provisions of this TPD refers to the size and position of health warnings, to increase the sizes of pictorial and textual health warning labels, to information on smoking cessation and to present a colour photograph on smoking-related harm. The introduction of pictorial warnings is according to the Article 5 of the executive protocol compiled by the National Comprehensive Law on Tobacco Control presented published by WHO in 2004: “PHWs should be applied to cigarette packs” [8].

The recommendation on the health warnings and on the product presentation were present in tobacco packages across the whole EU in 2016. Several European Countries adopted the pictorial health warnings (PHWs) on tobacco products in 2016, including Italy [7, 9]. In particular, the Italian Minister of Health issued a decree for the introduction of the PHWs in May 2016 [6].

Hammond *et al.* published in 2007 a study on the impact of the pictorial warnings before and after the implementation of the warnings in UK [10]. In this study, the smokers reported greater levels of awareness, salience and considered the warning as a more effective deterrent. Heydari *et al.* conducted a similar study in the city of Tehran. The research was designed and conducted

in two phases before the implementation of pictorial health warning labels law on tobacco products and after nine months, and evaluated the effect of it on smokers' knowledge, attitude and pattern of smoking. Their study showed that 7.7% of smokers decreased their smoking rate [11]. The same conclusion was found by Gravelly *et al.* [12]: their study tested the effectiveness in terms of warning salience, cognitive, emotional, and behavioral responses to the warnings on adult smokeless tobacco users from the symbolic warning (pre-policy) to graphic health warning labels (post-policy).

A systematic review published in 2015 reported an evidence against the use of pictorial warnings on cigarette packages (PWCP), suggesting that the effects of PWCP on behavioral were quite modest [13]. Yong *et al.* reported the value of labelling which acts through the ability to stimulate thoughts about risks of smoking, which in turn increase one's health concerns, with a subsequent increase in the intention to quit, an important predictor of the increase in the likelihood of making an attempt to quit [14]. Bewer *et al.* performed a randomized clinical trial and found that the PHWs effectively increased intentions to quit, forgoing cigarettes, quit attempts, and successfully quitting smoking over 4 weeks [15]. Although the limited effect, according to international studies, its implementation is beneficial in any case [16-20].

In Italy two studies have explored the possible impact to the introduction of the PHW and the plain packaging in 2012 and 2013. They underlined that the perception of the pictorial warnings are more effective to communicate the health damages in the smokers and lead to the reduction of the tobacco consumption [3, 21].

Another crucial aspect to be taken into account is the need for reliable and validated measures in this kind of studies, as reported in Francis *et al.*, which stresses “Accurate measurement tools are vital to identify factors associated with cigarette pack pictorial warning perceived and actual effectiveness. Data from such studies is critical for building the evidence regarding the role of cigarette pack warnings in impacting smoking-related beliefs and behaviors” [22]. However, there are no studies that assess the impact before and after the introduction of the new law in Italy. The aim of our study was to evaluate the effects of the introduction of the PHWs on tobacco products on smokers in terms of tobacco related behaviors, knowledge and perception using a standardized tool in Italy.

MATERIALS AND METHODS

We conducted a longitudinal study organized as a quasi-experimental national survey. It was conducted in 2 phases before and after the implementation of the law on tobacco packaging. Wave 1 of the study was conducted six months before the implementation of the PHWs law (November 2015-April 2016: pre-PHW); Wave 2 was conducted 8-18 months (January 2017-November 2017: post-PHW) post-implementation.

Participants

We considered eligible for our study people belonging to the general population, smokers at the time of

the Wave 1 and adult (>18years). Only those who completed both the surveys (Wave 1 and 2) were considered for the final analysis.

The definition adopted to define the smokers was: “who had smoked more than 100 cigarettes in their lifetime” and “smoked at least once in the past 30 days at recruitment”.

The individuals involved in the study were contacted in the opportunistic places: University Campus, waiting rooms of hospitals and in front of supermarket area. An informed consent from participants was obtained before that they enter the research.

Data collection

Data were collected through a face-to-face interview for the first Wave, and a telephone-administered questionnaire for the second-round interview. The average time to complete the interview was 20 min. The collected socio-demographic characteristics were: gender, age, educational level (graduated versus not graduated), civil status (married/cohabitant versus single/divorced), sons (yes/no), socio-economic status (SES) (low, medium or high, based on a combination of homeownership, number of travels in the last years, educational level and type of works).

The followed smoking related variables were considered:

- number of smoked cigarettes per day;
- number of quit attempts (0, 1, 2 or more than 2);
- age of starting to smoke;
- smoking dependence using Fagerström scale [23];
- smoking dependence using Fagerström score divided in groups: >4 translated into high dependency [23, 24].

In order to compare the impact of the health warnings, we adopted the Label Impact Index (LII) [25] Germany (2007). LII is an international validated tool evaluating four dimensions related to the perception of labeling: SALIENCE; HARM; QUITTING; FORGO.

The knowledge was investigated showing to each participant a list of twenty diseases. Participants were asked to identify tobacco related illnesses and the answer was defined as dichotomous variable (correct/wrong). The list of diseases was created on the basis of the scientific evidence [26]. The Knowledge Score (KS) was computed adding the correct answers (1 = correct; 0 = wrong): the KS ranged from 0 to 20.

In the Wave 2 two questions were included to establish a change in smoking habits:

- the smokers have stopped to smoke after the implementation of the law (yes/no);
- the smokers who stopped attribute their choice to the PHWs (yes/no).

Research ethics approval was obtained from the Teaching Hospital Umberto I, Sapienza University of Rome.

Sample size

Sample size calculation was done with a 95% confidence interval (95% CI) and a precision of 5%. The percentage of Italian adults smokers who have quit is around 18% [27]; the hypothesis was that the propor-

tion in the population post implementation would have been 5% more (23%). The calculated sample size was represented by at least 491 smokers. The target sample size was increased to 40% in order to contain non-response bias.

Statistical analysis

The statistical analysis was carried out using IBM-SPSS version 19 software for Windows Release (IBM Corp. released in 2010 IBM SPSS Statistics for Windows, Version 19; IBM Corporation, Armonk, NY, USA).

Categorical data were described as absolute frequencies and percentages. Continuous data were presented as means and SD.

The dichotomous nicotine dependence was compared between groups using the χ^2 test.

To compare the LII pre-PHW and post-PHW the t-student test for paired samples was applied. The Mann-Whitney test was applied to assess the difference between current smokers versus ex-smokers in the Wave 2.

The Komogorov-Smirnov's test was adopted to control the assumption of normality distribution before using some parametric test.

The statistical significance was set at a p-value <0.05.

Ethics approval

The study was reviewed and approved by the Research Ethics Committee of the Teaching Hospital Umberto I, Sapienza University of Rome (Prot. N. 279/16 RIF.CE: 4024).

RESULTS

Characteristics of studied sample and of the lost to follow-up participants

Eight hundred-fifty smokers were invited to participate but the response rate in Wave 1 was 93% (N = 788 enrolled).

Sixty-two persons refused to participate: 48% (of the refusals) were females and the mean age was 35.6, SD = 14.6.

The flow chart of the quasi-experimental study design is shown in *Figure 1*.

Among the participants in Wave 1, 58% (N = 455) were then surveyed also in the Wave 2.

The characteristics and the comparisons of the lost participants to Wave 2 (N=333) and the sample that completed the study are shown in *Table 1*.

No significant differences were found between the two groups for the following characteristics: gender, age group, age to starting to smoke and nicotine dependence classes (all p >0.05). There was a significant difference in occupational level: the percentage of the students was lower in the sample that competed the entire study (Waves 1+2) compared to the sample that completed only the Wave 1 (p = 0.045).

Impact of pictorial warnings on smoking habits

Thirty-five smokers (7.7%, Group A) declared that have quit to smoke after May 2017 (post-PHW), 20 smokers declared that have quit to smoke before May 2017 (pre-PHW, Group B) (4.4%) and 22 did not specify the date (5%, Group C) (*Figure 1*). Ten of those

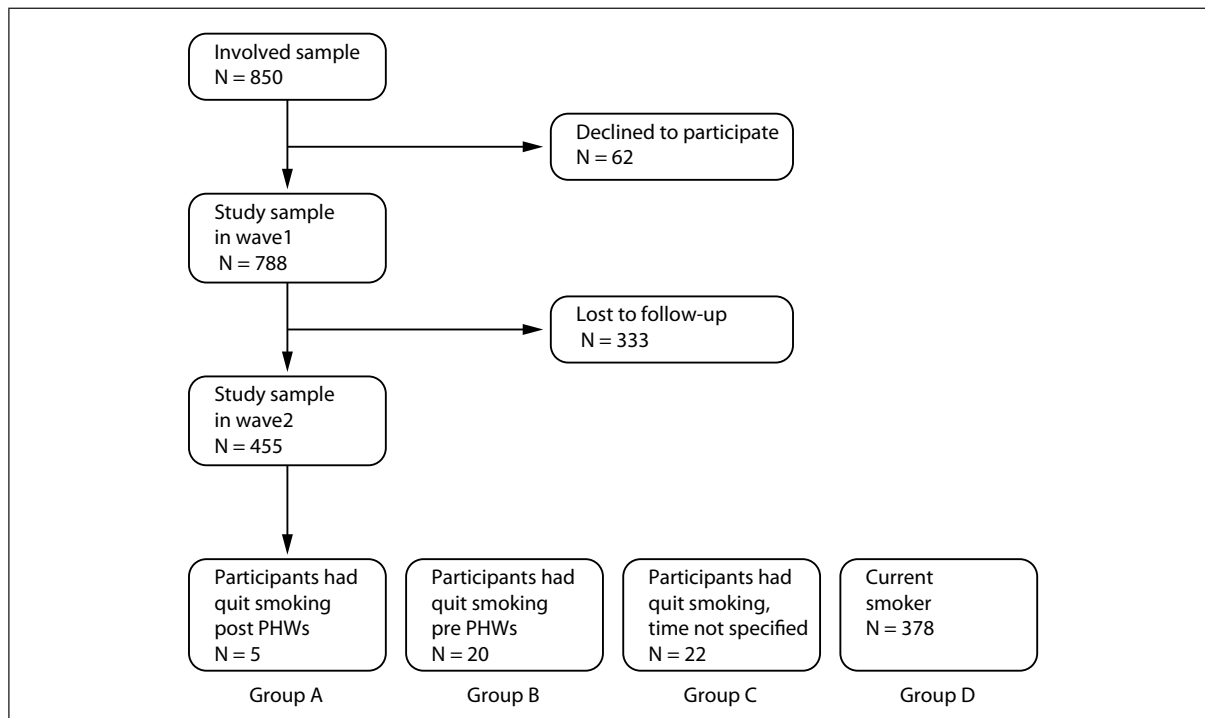


Figure 1
Flow diagram of the participants included in the study.
PHW: pictorial health warnings.

Table 1
Demographic characteristics and smoking habits of the studied sample (participants enrolled in waves 1 and 2) and the sample lost to the follow-up

Variables		Participants in wave1 and lost in the wave2		Participants in the waves 1 and 2		p
		N = 33		N = 455		
		N	%	N	%	
Gender	male	167	50	198	44	0.083
	female	166	49	254	56	
Age	<25 yrs	120	45	148	38	0.121
	25-35 yrs	90	34	140	36	
	>35 yrs	56	21	104	26	
Occupational level	student	152	50	172	43	0.045
	employed	114	38	186	48	
	unemployed	27	9	23	6	
	pensioners	10	3	12	3	
Age of starting to smoke	<14 yrs	60	18	71	16	0.333
	14-17 yrs	212	65	285	64	
	>17yrs	54	17	91	20	
Nicotine dependence (Fagerström test)	no	141	50	200	55	0.248
	moderate	96	34	125	34	
	strong	35	13	31	9	
	very strong	9	3	7	2	

who quitted post-PHW declared that pictorial warnings have supported them to quit (29%). Nobody reported having stopped exclusively thanks to the PHWs.

The univariate analysis (Table 2) that assessed the characteristics associated to the group A versus the one of current smokers (group D) did not report significant differences by: gender ($p = 0.255$), age group ($p = 0.873$), civil status (0.768), number of smoked cigarettes ($p = 0.876$), nicotine dependence level ($p = 0.246$), number of quit attempts ($p=0.555$) and age of starting to smoke (0.157) (data not showed). Occupational level was not analyzed because the assumption of the χ^2 test was not satisfied: two cells (25.0%) have expected count less than 5 and the minimum expected count is 0.89.

Table 2

Comparison of Label Impact Index and Knowledge Score before and after the implementation of the law

Variables	Pre-PHWs	Post-PHWs	p
	Mean (SD)	Mean (SD)	
LII (0-100)	26.9 (16.7)	40.4 (16.2)	<0.001
KS (0-20)	11.6 (2.5)	14.6 (1.8)	<0.001

PHW: pictorial health warnings; LII: Label Impact Index; KS: Knowledge Score.

LII of health warnings

Considering only the current smokers in Waves 1 and 2 ($N = 378$, group D), the mean values of the LII standardized score increased significant from pre-PHW to post-PHW ($p < 0.001$ with mean = 26.9, $SD=16.7$ to mean = 40.4, $SD = 16.2$).

Considering the group of ex-smokers in Wave 2 ($N = 35$) the mean value LII pre-PHW was 14.8 with $SD = 4.5$ (the mean value of LII post-PHW was not computable because the LII was designed only for current smokers).

Knowledge Score on tobacco related diseases

433 respondents completed the section about knowledge (response rate 96%). A significant difference was found: the KS was significantly increased from Wave 1 to Wave 2: mean = 11.6 $SD = 2.5$ and mean = 14.6 $SD = 1.8$ respectively, with $p < 0.001$. The distributions of answers are shown in Figure 2.

The major increments of tobacco related knowledge were registered in the followed health aspects: gangrene (from 11.6% to 68.2%); risk of blindness (from 12.2% to 60.6%); premature labor (from 24% to 70.9%); erectile dysfunction (from 42.9 to 87.2).

The KS at Wave 2 between Group A versus Group D has shown not significant difference ($p = 0.656$): mean = 14.4, $SD = 1.9$ (median = 14, interquartile range = 3) versus mean = 14.6 $SD = 1.8$ (median = 15, interquartile range = 2.5) respectively.

DISCUSSION

This paper presents the methodology for and results of the first before and after assessment of PHWs on tobacco products in Italy. To the best of our knowledge, there are no similar assessments for Italy. Also this study present a measure standardized to assess the effectiveness of PHWs and it could provide a model for Italian Country to monitoring the effectiveness of tobacco labeling.

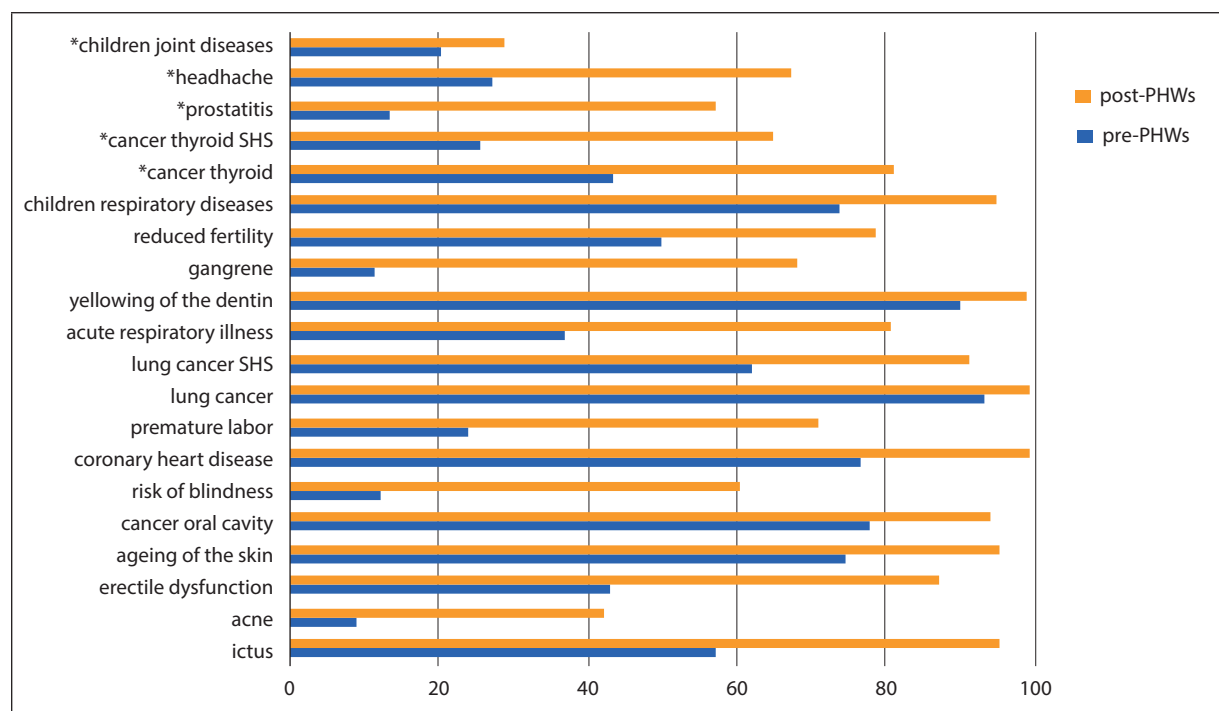


Figure 2

Distribution of the tobacco-related diseases pre-PHWs and post-PHWs implementation.

PHW: pictorial health warnings; *not tobacco-related disease; SHS: second-hand tobacco smoke exposure.

The results reported in the research underline significant increases of knowledge of health tobacco risk after the PHWs introduction in a short period (8-18 months). These results are in accordance with other studies conducted in different and same income Countries [28-36]. In fact, the knowledge about some pathologies (considered "tobacco related") significantly increased. The awareness about gangrene, blindness, premature labour and erectile dysfunction registered the higher increase before and after the law on PHWs. This datum suggested the possible progress from stage of pre-contemplation into contemplation according to the trans-theoretical approach model [37, 38]. These findings underlined the power of the graphic warnings in the communication of health messages and prevention compared to the textual ones and agreed with the scientific literature [34, 39-42]. On the other hand, it must also take into consideration that evidence concludes that the effectiveness of PHWs peaks shortly after implementation, like in this study, and that salience is the first dimension to suffer erosion thereafter [33].

It should be noticed that studies assessing the impact of plain packaging on behavioral outcomes are limited, and current evidence suggests that plain packaging may increase quit attempts and calls to quit-lines, as well as reduce smoking consumption and prevalence [43]. Concerning the smoking cessation, this research has shown that the implementation of PHWs could have a positive but limited impact: only 2% of the sample declared to have stopped smoking thanks to the graphical messages. However, if these results are extended to general population, it will be a considerable result. This modest impact is confirmed by other scientific studies [13, 36, 44]

In literature are available many studies that present combination and evolution of policies with PHWs that increase the smoking cessation. An interesting way to increase its efficacy is suggested by Saha *et al.*, that is to increase the coverage: health warning has to be mandatorily displayed in the cigarette packet and the graphic picture and text warning should cover 60% and 25% of the package, respectively [45]. In compliance with this, India decided that the new graphic health warnings should cover 85% of the principal display area on all tobacco products packages on both sides from 1 April 2016 [46].

In this direction the recent literature underlines that the ways to decrease the influence of cigarette packaging on tobacco consumption could include warnings and plain packaging [41, 47-49]. Warnings on packs can both counteract appealing pack design elements and communicate health messages to consumers. Compared to text-only warnings, pictorial warnings on cigarette packs attract more attention, evoke more negative affect and attitudes towards the product, and more effectively limit the initiation and promote intentions to quit [41].

The world's first legislation mandating plain packaging of tobacco products was implemented in Australia on 1 December 2012. An Australian study conducted by Dunlop *et al.* found a considerable positive response to plain packaging among Australian adolescents and

young adults, including quitting-related behaviours and thoughts, behavioural and emotional indicators of social denormalisation and high levels of support for the policy [49].

The systematic review of Stead *et al.* suggests that standardized packaging will reduce the appeal of packaging and of smoking in general; that it will go some way to reduce consumer misperceptions regarding product harm based upon package design; and will help make the legally required on-pack health warnings more salient [47]. These effects are confirmed by the review of Smith *et al.*: their study reported that plain packaging represents one potential policy measure that can be deployed as part of a suite of comprehensive public health strategies to reduce morbidity and mortality caused by tobacco use [48].

Others approaches and combinations of policies are implemented to reduce the tobacco epidemic were reported by Bhutan, where a strong political commitment, strict legislations, and the influence of religious leaders in anti-tobacco propaganda led to a great success [50]. Another example comes from Finland's plan to be tobacco free, which included making the country smoker free by imposing ban on even milder products such as e-cigarettes and snuff, increasing the product price and cost for the vendors selling the products enormously, not allowing residents to smoke in private cars in the presence of minors aged 15 years or less and other stringent enforcements [51]. Also Australia represent another example of a successful country in tobacco control applying synergic strategies [52]. In the last ten years this Country implemented along with plain packaging, complete ban on point-of-sale tobacco product displays, reduction in duty free tobacco allowance, harmonization of the taxation of roll-your-own tobacco, reduction in the duty free allowance from 250 cigarettes to 25 cigarettes, 12.5% excise increase about every year [53].

Strengths and limitations

The major strength of the study is the originality of the collected data since available information on the issue from Italy is limited. Secondly the before-after design: the longitudinal study design permitted to assess the possible change on tobacco habits in the same subject.

Several limitations should be cited and explained:

- i) the relatively small sample size, thus the main result is based on a limited number of smokers;
- ii) the lack of consideration of non-smokers (i.e., never and ex-smokers) in the study population so we have not studied its potential unfavourable effect on smoking initiation or relapse among non-smokers;
- iii) the self-reported nature of data: in the group of smokers who quitted after the adoption of the PHWs, this information was not validated by the measurement of biomarkers (e.g., CO or cotinine levels) or by 6-month (or 1-year) abstinence;
- iv) the two different methods used to collect the same data (face to face for the first Wave and telephone for the second one);
- v) the percentage of the participants lost to the fol-

low-up (Wave 2) was high (42%), and a significant different professional level was present in the lost group compared to the remaining one. This aspect could introduce a bias and an external validity;

vi) 5% of the smokers who declared to quit smoking did not precisely report the period: they didn't remember the month but only the year or they were confused. This aspect could have an impact on the analysis for the PHW;

vii) the selection of participants was performed without random methods: a possible effect of the selection bias could have determined a reduction of external validity of the study;

viii) the time window of the investigation consider the effect after different period 8-18 months and, also, the effectiveness of PWLs should be peaks shortly after implementation;

ix) finally, it is not possible to estimate the influence of PWHs on the decision to quit smoking: in the study nobody declared to have quit smoking exclusively thanks to the PHWs. In order to determine the single impact of PHWs on cessation, further studies based on strong methodological designs should be conducted, preferably with longer follow-up periods and a small proportion of individuals lost to follow-up. Moreover, as another ecological study has suggested, it would be interesting to develop scales, based in the original Tobacco Control Scale (TCS), for larger settings in order to be able to compare the results of these processes [54].

CONCLUSIONS

The present study represents a first step in order to assess the effectiveness of the PHWs policy and more research is recommended especially with a longer follow-up. Nevertheless the reported limitations, this study showed that also in Italy the PHWs could support smokers who want to quit and could increase significantly the knowledge on the tobacco related diseases independently by the tobacco habit. The PHWs despite the not so high effectiveness to quit, are a no-cost intervention that should be encouraged and diffused.

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If considered alone, it does not lead to strong resolution of tobacco addiction. Since 10 years the smoking prevalence in Italy has not changed at all (according to the National survey on smoking in Italy 2018 by "The Observatory on drugs alcohol and tobacco").

Therefore, in order to significantly reduce the prevalence of smoking epidemic, the policy makers have to develop and combine different strategies in order to amplify the power of each intervention to combat it.

In the last twenty years Italy approved several anti-smoking policies: bans on smoking in public buildings (restaurant, coffee, stations, schools), institutional telephone quit line, smoking ban in cars with minors and pictorial warnings, but much is still to be done following the Australian example such as increase the price, bans on point-of-sale tobacco image, more antismoking education in school and including antismoking medications in healthcare basket benefits.

Authors' contributions

Conceptualization: AM, DM and GLT; Methodology: AM, DM; Formal Analysis: AM; Investigation: AM; Data Collection: AM, DM, GT, EL, MF, AF, SP, MRG, MF, GB, GM and EDV; Data Entry: AM, FM; Writing – Original Draft Preparation: AM and GT; Writing – Review & Editing: GLT, RS and PV; Supervision: GLT; Project Administration: AM.

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Conflicts of interest statement

The authors declare no conflict of interest.

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