Eur Respir J 2011; 38: 1005–1011
DOI: 10.1183/09031936.00109610

Effect of a nicotine-free inhalator as part of a smoking-cessation programme

P. Caponnetto*, F. Cibella#, S. Mancuso*,¶, D. Campagna*,¶, G. Arcidiacono*,¶ and R. Polosa*,¶

ABSTRACT: Smoking-cessation drugs are inadequate at addressing the behavioural component of tobacco dependence. Nicotine-free inhalators are plastic devices that may provide a coping mechanism for conditioned smoking by replacing some of the rituals associated with smoking gestures. This study assessed the effect of using a nicotine-free inhalator to improve success in a cessation programme.

At baseline, 120 smokers attending a smoking-cessation programme were assessed for their sociodemographic factors, smoking history, depression, physical and behavioural dependence, and motivation. Participants were randomly assigned to two groups, nicotine-free inhalator group (PAIPO; Echos Srl, Milan, Italy) *versus* reference group.

For the whole sample, no significant difference was found in quit rates at 24 weeks between the PAIPO group and the reference group. However, the quit rate in the PAIPO group (66.7%) was more than three-fold higher than the reference group (19.2%) for those individuals with high Glover–Nilsson Smoking Behavioural Questionnaire (GN-SBQ) scores at baseline. The results of the logistic model analysis indicate that a high GN-SBQ score is a strong independent predictor for successful quitting at 24 weeks (OR 8.88; 95% CI 2.08–37.94) in the PAIPO group.

Nicotine-free inhalators may be beneficial when used in the context of smoking-cessation interventions, particularly for those smokers for whom handling and manipulation of their cigarettes plays an important part in the ritual of smoking.

KEYWORDS: Behavioural dependence, nicotine-free inhalator, smoking cessation

Tobacco smoking is a modern day epidemic that poses a substantial burden to health and related costs. With ~5 million tobacco-related deaths annually, tobacco smoking is the leading cause of preventable premature mortality in the world [1]. Tobacco smoke harms nearly every system in the human body thus causing a broad range of diseases, many of which are fatal [2–4]. The risk of serious disease diminishes rapidly after quitting and permanent abstinence is known to reduce the risk of lung cancer, heart disease, chronic lung disease, stroke and other cancers [5, 6]. Although evidence-based recommendations indicate that smoking-cessation programmes are useful in helping smokers to quit [7], smoking is a very difficult addiction to break. It has been shown that ~80% of smokers who attempt to quit on their own relapse within the first month of abstinence and only ~3–5% remain abstinent at 6 months [8]. There is little doubt that currently marketed smoking-cessation products increase the chance of committed smokers stopping smoking, but they reportedly lack high levels of efficacy, particularly in clinical practice [9]. Although this reflects the chronic relapsing nature of tobacco dependence, the need for more effective smoking-cessation interventions is unquestionable.

Smokers trying to quit have to cope not only with the pharmacological aspect of nicotine addiction but also with the psychological components (cognitive, social and behavioural) associated with tobacco dependence. Smoking is much more than the addictive effect of nicotine; the smoking habit is also the rituals that each smoker associates with their habit [10, 11]. For example, smoking gestures (*e.g.* the tactile sensations of the cigarette and other sensations associated with smoking gestures) can play an important part in tobacco addiction, as they are usually performed in a predictable, ritualistic manner that act to signal a mental context shift. When the smoker stops smoking the need for the ritual still exists and this is an important cause of relapse. Smoking-cessation products cannot

AFFILIATIONS
*Centro per la Prevenzione e Cura del Tabagismo (CPCT), Azienda Ospedaliero-Universitaria ''Policlinico-Vittorio Emanuele'', Università di Catania,
¶Institute of Internal Medicine and Clinical Immunology, S. Marta Hospital, Azienda Ospedaliero-Universitaria ''Policlinico-Vittorio Emanuele'', Università di Catania, Catania, and
#Istituto di Biomedicina e Immunologia Molecolare del Consiglio Nazionale delle Ricerche, Palermo, Italy.

CORRESPONDENCE
R. Polosa
Institute of Internal Medicine and Clinical Immunology,
S. Marta Hospital
Università di Catania
Via G. Clementi 36
95124 Catania
Italy
E-mail: polosa@unict.it

Received:
July 13 2010
Accepted after revision:
April 03 2011
First published online:
May 12 2011

European Respiratory Journal
Print ISSN 0903-1936
Online ISSN 1399-3003

A press release for this article is available from www.erj.ersjournals.com/site/misc/presspack.xhtml

replace the rituals associated with the act of smoking. Counselling for smoking cessation is intended to help smokers cope with this important aspect of their life by implementing personalised replacement rituals, but even counselling for smoking cessation lacks high levels of efficacy.

Nicotine-free inhalators are plastic devices (fig. 1) that are intended to provide a coping mechanism for conditioned smoking cues by replacing some of the rituals associated with smoking gestures (*e.g.* hand-to-mouth action of smoking). Therefore, nicotine-free inhalators may help smokers remain abstinent during their quit attempt and could be particularly useful when used in the context of smoking-cessation interventions. As there is no formal findings supporting the efficacy of these devices in smoking-cessation studies, we assessed, for the first time, the effect of using a widely marketed nicotine-free inhalator (PAIPO; Echos Srl, Milan, Italy) as part of a smoking-cessation programme for smokers willing to quit. PAIPO is safe for all smokers and nonsmokers. Its main ingredient is simply a fibrous, sponge-filter plug soaked in naturally extracted herbal oil, which is encased in a plastic cartridge container similar to a cigarette.

METHODS

Study population

Consecutive first time, regular smoker ($\geqslant$20 cigarettes per day for $\geqslant$10 yrs) attendees who booked with the call-centre of our smoking-cessation clinic (Centro per la Prevenzione e Cura del Tabagismo, Università di Catania, Catania, Italy) were invited to participate at the time of their first consultation. Smokers with an exhaled carbon monoxide (eCO) concentration of $\geqslant$10 ppm were recruited. Subjects with a history of alcohol and illicit drug use, or a diagnosis of major depression or other psychiatric conditions were not included. The study protocol was approved by the Catania University Hospital ''Vittorio Emanuele'' review board and all subjects gave written informed consent.

Study design and procedures

This 6-month prospective study was designed as a two-group randomised clinical trial to compare the effect of a nicotine-free inhalator (PAIPO) on quit rates at 4 and 24 weeks in smokers undergoing a smoking-cessation programme. Participants were randomly assigned in blocks of five to either the nicotine-free inhalator group (PAIPO) or to the reference group (control) using a form of adaptive randomisation designed to minimise imbalances in the distribution of prognostic factors (sex, depression, motivation, previous quit attempts and level of nicotine dependence) between study groups [12].

FIGURE 1. The PAIPO nicotine-free inhalator (Echos Srl, Milan, Italy). This plastic device resembles a cigarette and is intended to replace some of the rituals associated with smoking gestures, *e.g.* hand-to-mouth action of smoking, and handling and manipulation of cigarettes. The plastic device contains a sponge filter soaked in a natural oil enriched with extracts of different aromas. It comes in different flavours (mint, green tea, cinnamon and sweet tobacco) and it is sold without prescription in pharmacies. A pack of three inhalators retails at approximately €5.

The smoking-cessation intervention adopted at our clinical research unit has been described previously [13]. At baseline, sociodemographic factors together with a detailed smoking history (number of cigarettes smoked per day, pack-yrs, previous quit attempts and motivation score) were recorded. Scoring of the subjective ratings of depression was assessed with the Beck Depression Inventory [14]. Physical dependence and behavioural dependence were measured by the Fagerström Test for Nicotine Dependence (FTND) [15] and Glover–Nilsson Smoking Behavioural Questionnaire (GN-SBQ) [16], respectively. Level of motivation was assessed by the Mondor Motivational Questionnaire, a tool developed in 1994 at the Hopital Henri-Mondor (Paris, France). This motivational questionnaire is easy to complete, relatively brief and frequently featured on several smoking-cessation websites in Italy, but is poorly validated. This questionnaire (Appendix 1) evaluates the motivation of a smoker willing to make a quit attempt and consists of 15 items. It classifies motivation to quit according to four possibilities of success: 1) it is not the time to quit ($<$6), 2) discrete (6–12), 3) good (12–16), and 4) very good ($>$16). The GN-SBQ (Appendix 2) consists of 11 items and classifies behavioural dependence according to quartiles: mild ($<$12), moderate (12–22), strong (23–33) and very strong ($>$33). In addition, levels of eCO were measured using a portable device (Micro CO; Micro Medical Ltd, Rochester, UK). Participants were instructed on how to prepare to stop smoking and requested to set a ''quit date'' within the next 7 days. Participants were prescribed standard pharmacological treatment for nicotine dependence (high-dose nicotine patch plus bupropion 300 mg·day^{-1}) and were assigned to either to an ''active'' group or a reference group. Subjects assigned to the active group were given a free supply of PAIPO inhalators (sweet tobacco aroma) and instructed about their use. Study participants were then invited to book their first follow-up appointment within 3 days of the quit date.

Psychological support and counselling were offered throughout the smoking-cessation programme (on average three to six short visits within the first 4 weeks of the smoking-cessation programme) and telephone contact was maintained in order to encourage attendance. Abstinence from smoking was reviewed objectively throughout the study by measuring eCO levels at each follow-up visit. Participants attended follow-up visits at week 4 and week 24, during which abstinence from cigarette smoking was subjectively and objectively reviewed. The follow-up visits at weeks 4 and 24 were conducted by an independent physician who was unaware of the baseline characteristics and group allocation of the study participants.

Study efficacy measures

Participants who self-reported giving up smoking and with an eCO concentration of $\leqslant$10 ppm at the final follow-up visits were defined as quitters. Smokers who failed to meet these criteria (smoking abstinence and eCO of $\leqslant$10 ppm) were categorised as smoking-cessation failures (*i.e.* relapsers). Continuing smokers and relapsers were used as a smoking reference group for

comparison of the study measures after smoking cessation between groups. Smokers setting a firm quit date were counted as lost to follow-up if, on attempting to determine and verify their quitter status, they could not be contacted. Success rates were defined as 24-week success rate (24WSR; calculated as the ratio between eCO minus verified 24-week quitters divided by the number of smokers setting a firm quit date) and the 4-week success rate (4WSR; calculated as the ratio between eCO minus verified 4-week quitters divided by the number of smokers setting a firm quit date) [17].

Statistical analyses

The sample size calculation for this study, based on the expected cessation rates from a previous smoking-cessation study [18], indicates that 63 subjects are required to have 80% power with two-sided 0.05 significance level test to detect a difference of $\geqslant$10% quit rate between study groups. Allowing for a conservative attrition rate of 40% at our institution, the target number of participants was increased to a total of 120.

In the primary analyses, 4WSR and 24WSR were computed by excluding the proportion of subjects lost to follow-up (per-protocol analysis). As secondary analyses and for comparison purposes, 4WSR and 24WSR were also computed by including all enrolled participants, assuming that all those individuals who were lost to follow-up were classified as smoking-cessation failures (intention-to-treat analysis).

One-way ANOVA was used to test between-group differences for normally distributed variables, and the Mann–Whitney U-test was used for nonparametric variables. Chi-squared statistics was used to calculate the significance of observed differences in distribution at 4- and 24-week quit rates.

A logistic regression model was used to assess the relative risk of PAIPO use in influencing the quit rate at 4 and 24 weeks. Odds ratios (OR) and 95% confidence intervals (CI) were calculated and adjusted for the following confounders: sex, age, FTND, Mondor, pack-yrs, instruction level and cigarettes smoked per day at enrolment. Continuous variables were dichotomised using the following cut-off levels: age 45.5 yrs (range 23–69 yrs); FTND 6; Mondor 12; 48 pack-yrs (highest quartile of its distribution); instruction level 13 yrs; and 20 cigarettes smoked per day at enrolment. $p<0.05$ was considered statistically significant.

The statistical analyses were conducted by an independent biostatistician who was unaware of the group allocation of the study participants.

RESULTS

A total of 120 smokers participated in the study (table 1). At enrolment, no significant difference was found between study groups for all the investigated variables. 70 (58.3%) subjects had a low degree of behavioural impact on smoking dependence (GN-SBQ $\leqslant$22) and 50 (41.7%) presented with a high degree of impact (GN-SBQ $>$22). At week 4, 13 (21.7%) out of 60 subjects were lost at follow-up in the PAIPO group and 17 (28.3%) out of 60 in the reference group (Chi-squared, $p=0.399$). At week 24, subjects who were lost at follow-up accounted for 16 (26.7%) out of 60 in PAIPO group and 19 (31.7%) out of 60 in reference group (Chi-squared, $p=0.547$). Consequently, out of 120 participants, 90 (75.0%) and 85 (70.8%) subjects completed the follow-up visit at week 4 and week 24, respectively.

Continuous variables are presented as mean$\pm$SD for normally distributed variables or as median (interquartile range) for nonparametric variables.

Quit rates at week 4 and 24 are shown in table 2. For the whole sample, no significant difference was found in quit rates between the PAIPO group and the reference group at any time. However, when study participants were evaluated separately on the basis of their GN-SBQ score at baseline, a significant difference was found in the frequency distribution of quit rates. In fact, among subjects with a high GN-SBQ (*i.e.* smokers with strong to very strong behavioural dependence) the quit

TABLE 1 Subjects' characteristics at enrolment

	Reference group	PAIPO group	p-value
Males/females n	40/20	40/20	#
Age yrs	48.6±10.8	45.7±11.6	0.154¶
Smoking history yrs	32.3±10.9	29.1±12.1	0.123¶
Number of cigarettes smoked per day at enrolment	23.5 (18.0–30.0)	25.0 (20.0–30.0)	0.395+
Pack-yrs	33.9 (25.3–47.5)	31.0 (22.5–48.7)	0.477+
Exhaled CO ppb	27.2±13.0	30.2±15.8	0.264¶
Age at initiation yrs	16.3±3.8	16.6±4.3	0.686¶
BDI	12.5±7.7	12.9±9.0	0.777¶
FTND	6.0 (4.5–7.0)	7.0 (6.0–8.0)	0.061+
Mondor	13.2±2.7	13.1±2.8	0.818¶
GN-SBQ	20.0 (15.0–32.5)	19.5 (15.0–33.0)	0.948+

Data are presented as mean±SD or median (interquartile range), unless otherwise stated. BDI: Beck Depression Inventory; FTND: Fagerström Test for Nicotine Dependence; Mondor: Mondor Motivational Questionnaire; GN-SBQ: Glover–Nilsson Smoking Behavioural Questionnaire. #: Chi-squared test; ¶: one-way ANOVA; +: Mann–Whitney U-test.

TABLE 2 Successful quit rates according to per-protocol and intention-to-treat analysis

	Reference group	PAIPO group	p-value
Successful quit rates at week 4			
Per-protocol analysis			
Overall sample	21/43 (48.8)	23/47 (48.9)	0.993
Low GN-SBQ ⩽22	12/23 (52.2)	7/27 (25.9)	0.057
High GN-SBQ >22	9/20 (45.0)	16/20 (80.0)	0.022
Intention-to-treat analysis			
Overall sample	21/60 (35.0)	23/60 (38.3)	0.705
Low GN-SBQ ⩽22	12/34 (35.3)	7/36 (19.4)	0.136
High GN-SBQ >22	9/26 (34.6)	16/24 (66.7)	0.024
Successful quit rates at week 24			
Per-protocol analysis			
Overall sample	17/41 (41.5)	20/44 (45.5)	0.711
Low GN-SBQ ⩽22	12/21 (57.1)	4/25 (16.0)	0.004
High GN-SBQ >22	5/20 (25.0)	16/19 (84.2)	0.0002
Intention-to treat analysis			
Overall sample	17/60 (28.3)	20/60 (33.3)	0.553
Low GN-SBQ ⩽22	12/34 (35.3)	4/36 (11.1)	0.016
High GN-SBQ >22	5/26 (19.2)	16/24 (66.7)	0.0007

Data are presented a n/N (%), unless otherwise stated. GN-SBQ: Glover–Nilsson Smoking Behavioural Questionnaire.

TABLE 3 Multiple logistic regression analysis for successful quitting at 24 weeks[#]

	OR (95% CI)	p-value
Low GN-SBQ class		
Sex, male *versus* female	0.92 (0.21–4.16)	0.923
Age, older *versus* younger	0.50 (0.12–2.11)	0.344
FTND, high *versus* low	0.28 (0.05–1.47)	0.131
Mondor, high *versus* low	12.70 (1.36–118.82)	0.026
Pack-yrs, high *versus* low	0.55 (0.08–4.06)	0.559
Instruction level, high *versus* low	1.62 (0.32–8.34)	0.564
Number of cigarettes smoked per day at enrolment, high *versus* low	1.13 (0.20–6.20)	0.892
PAIPO, use *versus* control group	0.34 (0.08–1.48)	0.150
High GN-SBQ class		
Sex, male *versus* female	1.43 (0.23–8.87)	0.700
Age, older *versus* younger	0.14 (0.02–1.03)	0.054
FTND, high *versus* low	1.22 (0.24–6.31)	0.814
Mondor, high *versus* low	3.56 (0.72–17.53)	0.119
Pack-yrs, high *versus* low	2.53 (0.25–25.36)	0.431
Instruction level, high *versus* low	0.67 (0.14–3.21)	0.615
Number of cigarettes smoked per day at enrolment, high *versus* low	1.86 (0.27–12.66)	0.525
PAIPO, use *versus* control group	8.45 (1.73–41.20)	0.008

Data were corrected for confounding variables (sex, Fagerström Test for Nicotine Dependence (FTND), Mondor Motivational Questionnaire, pack-yrs, instruction level and number of cigarettes smoked per day at enrolment). Continuous variables were dichotomised as discussed in the Methods section. GN-SBQ: Glover–Nilsson Smoking Behavioural Questionnaire, cut-off level=22. [#]: PAIPO *versus* control group; intention-to-treat analysis.

rate in the PAIPO group was significantly higher than in the reference group. This was already evident at week 4 and particularly evident at week 24, by both intention-to treat analysis and per-protocol analysis. In particular, the quit rate in the PAIPO group at week 24 was more than three-fold higher compared with the reference group for those individuals with high GN-SBQ scores.

However, among subjects with a low GN-SBQ, the quit rate in the PAIPO group was lower than in the reference group at week 4 and week 24, but it was statistically significant only at 24 weeks.

The results of the logistic model analysis (table 3) show that the probability of successful quitting at week 24 was significantly higher in the PAIPO group than in the control group for participants with high GN-SBQ scores (OR 8.45, 95% CI 1.73–41.20). Moreover, in the class with the higher GN-SBQ an unfavourable effect of older age for successful quitting was found at the limit of statistical significance. Of note, success rates at week 24 in participants with low GN-SBQ scores appeared to be markedly (OR 12.70, 95% CI 1.36–118.82) dependent on their level of motivation.

Many participants in the PAIPO group were enthusiastic about using the inhalator. They reported finding themselves placing the PAIPO in their mouth and sucking to get relief from stress, irritability or frustration (fig. 2). They also reported that placing the inhalator in their mouth was useful to distract

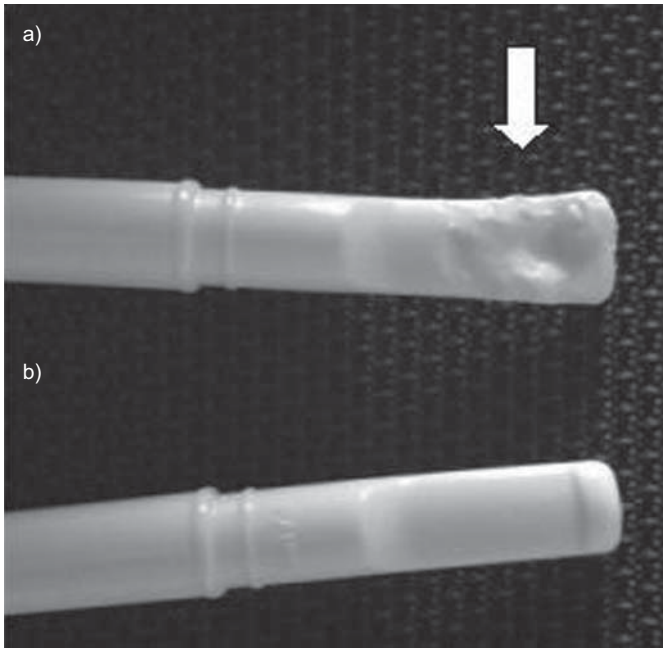

FIGURE 2. a) A PAIPO nicotine-free inhalator mouthpiece after use. Note the bite marks on the mouthpiece (arrow), a clear sign that the inhalator was being used to get relief from stress, irritability or frustration. b) A brand new, unused PAIPO for comparative purposes.

them from smoking urges. Although this study was not designed to specifically address safety, no adverse effects were reported by the participants using PAIPO.

DISCUSSION

This is the first study to investigate the effect of adding a nicotine-free inhalator (PAIPO) into a smoking-cessation programme. For the whole sample, no significant difference in quit rates were observed between participants using the device and the reference group. However, nicotine-free inhalators may be specifically beneficial for those smokers for whom handling and manipulation of their cigarettes play an important part of the ritual of smoking. When study participants were re-evaluated on the basis of their behavioural patterns, the quit rate in the PAIPO group at 24 weeks was more than three-fold higher compared with the reference group for those smokers with strong to very strong behavioural dependence assessed by GN-SBQ scores. Conversely, low quit rates were observed in the PAIPO group with low GN-SBQ scores. The data presented suggest that nicotine-free inhalators may be beneficial for smokers for whom handling and manipulation of their cigarettes play an important part of the ritual of smoking. Most PAIPO users reported that placing the inhalator in their mouth was useful to get relief from withdrawal symptoms (mainly stress and irritability) and to distract them from smoking urges. This is not surprising considering the strong interaction between the physical and behavioural dependence of smoking. Moreover, no adverse effects were reported by the participants in the PAIPO group.

Because of its design, there are a number of limitations that must be considered when interpreting the findings of this study. Due to the inclusion criteria, some characteristics of the sample limit generalisation of the findings; all participants were regular smokers with an elevated level of nicotine dependence, their subjective ratings of depression were low, and all participants were adults with a mean age of 45.7 yrs (PAIPO group) and 48.6 yrs (reference group). In addition, exclusion of patients with a history of alcohol and illicit drug use, a diagnosis of major depression or other psychiatric conditions may decrease the generalisability of the study results. Finally, the lack of study controls is also an important limitation, but given the nature of the intervention it was difficult to conceptualise an adequate control for this type of study. Nonetheless, our study indicates that adding a nicotine-free inhalator into a smoking-cessation programme is an inexpensive strategy that can be quite effective for some smokers.

The high quit rate in this study (33.3% in the PAIPO group and 28.3% in the reference group at week 24) reflects the notion that a combined smoking-cessation programme of pharmacotherapy and counselling provides the most favourable level of cessation [8]. In addition, retention at the final 24-week visit was satisfactory, subjects who were lost to follow-up accounted for 26.7% in PAIPO group and 31.7% in reference group. This is in agreement with the notion that drop-outs from smoking-cessation trials are common, with attrition rates of ~20–50% being reported [19–21].

The results of the logistic model analyses indicate that a high GN-SBQ score is an important predictor of successful quitting in PAIPO users, thus emphasising a role for patient stratification based on their level of behavioural dependence. An unfavourable effect of older age for successful quitting was found at the limit of statistical significance in the class with the higher GN-SBQ, suggesting that, with regular repetitions of rituals associated with cigarette smoking over the years, the influence of behavioural dependence could become more prominent than physical dependence. Initial motivation levels to stop smoking can predict success with smoking cessation [22, 23]. It was also shown that success rates in participants with low GN-SBQ scores appeared to be markedly dependent on their level of motivation. This indicates that initial levels of motivation to stop smoking may not predict success in participants with high GN-SBQ scores and that methods for enhancing motivation (*e.g.* motivational interviewing) could be less effective in smokers with strong to very strong behavioural dependence.

In the present study, it was observed that quit rates were quite low in the PAIPO group with low GN-SBQ scores. The reason for this finding is not clear, but could be related to psychological/behavioural maladaptations occurring during quitting. The PAIPO device might not have helped in coping with some of the psychological/behavioural aspects of tobacco dependence in the low GN-SBQ group, thus failing to meet the expectations of these smokers undergoing the smoking-cessation programme. Experience by itself this failure would constitute an additional stressor, and its associated decrease in self-efficacy should produce an increased negative effect [24]. This is likely to be the cause for an additional sense of failure and more stress. Smokers in these stressful situations react by adopting the best coping strategy know to them, *i.e* lighting a cigarette. Therefore, in smokers with low GN-SBQ scores, the nicotine-free inhalator could cause a paradoxical effect, with the device triggering relapse in order to compensate for the additional frustration/stress. In addition, the purpose of the study may convey to participants the message (*i.e.* the nicotine-free inhalator may help you stay quit during your attempt) that there is an easy remedy for tobacco addiction, which could generate false expectations in the smokers' mind. This, unintentionally, would produce a boomerang effect that undermines motivation to stay a quitter in some participants (particularly those with low GN-SBQ scores) who would then quickly relapse. This interpretation is speculative and warrants specifically designed investigation but, if proven, smokers with low GN-SBQ scores should not be given the device.

This study adds to the body of knowledge on the effectiveness of multidimensional approach for smoking cessation and behavioural change. In particular, this is the first study to demonstrate that nicotine-free inhalators may be beneficial when used in the context of smoking-cessation interventions, particularly for those smokers for whom handling and manipulation of their cigarettes play an important part of the ritual of smoking and are likely to be a strong behavioural component of their tobacco dependence. However, in smokers with no significant behavioural component, the device is likely to produce a negative effect. Therefore, stratification of smokers according to their level of behavioural dependence by GN-SBQ may be necessary to take maximum advantage from the use of these devices in smoking-cessation studies.

APPENDIX

Appendix 1: Mondor Motivational Questionnaire

The English and the Italian versions of the Mondor Motivational Questionnaire are shown in tables 4 and 5.

The following questionnaire evaluates the motivation of a person who sees their doctor about giving up.

TABLE 4 English version

	Yes	No
1. I decided to give up spontaneously	2	0
2. I have already given up for more than a week	1	0
3. I don't have any problems at work at the moment	1	0
4. I don't have any family problems at the moment	1	0
5. I want to free myself from my addiction	2	0
6. I do sport or I intend to do sport	1	0
7. I want to be in better physical shape	1	0
8. I want to look after my physical appearance	1	0
9. I am pregnant/my partner is pregnant	1	0
10. I have small children	2	0
11. I am in a good mood at the moment	2	0
12. I usually finish what I start	1	0
13. I am usually calm and relaxed	1	0
14. My weight is usually stable	1	0
15. I want to improve my quality of life	2	0
Total		

Possibilities of success: it is not the time to quit (<6), discrete (6–12), good (12–16), very good (>16).

TABLE 5 Italian version

	Yes	No
1. Ho deciso di presentarmi spontaneamente	2	0
2. Ho già smesso almeno una volta per una settimana	1	0
3. Attualmente non ho problemi sul lavoro	1	0
4. Attualmente non ho problemi sul piano familiare	1	0
5. Mi sento schiavo del fumo e mi voglio liberare	2	0
6. Pratico/ho intenzione di praticare sport	1	0
7. Voglio raggiungere una forma fisica migliore	1	0
8. Voglio curare di più il mio aspetto fisico	1	0
9. Sono incinta/mia moglie è incinta	1	0
10. Ho bambini piccoli	2	0
11. Attualmente sono di buonumore	2	0
12. Di solito porto a termine ciò che intraprendo	1	0
13. Sono di temperamento calmo e disteso	1	0
14. Il mio peso è abitualmente stabile	1	0
15. Voglio migliorare la qualità della mia vita	2	0
Totale		

Possibilità di successo: Non è il momento migliore (<6), discrete (6–12), buone (12–16), ottime (>16).

Il presente questionario valuta il grado di motivazione di una persona che si rivolge al medico per smettere di fumare.

Appendix 2: Glover-Nilsson Smoking Behavioural Questionnaire (GN-SBQ)

The English and Italian versions of the Glover–Nilsson Smoking Behavioural Questionnaire are shown in tables 6 and 7.

TABLE 6 English version

How much do you value the following (Specific to Questions 1-2).	
1. My cigarette habit is very important to me.	0 1 2 3 4
2. I handle and manipulate my cigarette as part of the ritual of smoking.	0 1 2 3 4
Please indicate your choice by circling the number that best reflects your choice.	
(Specific to Questions 3-11).	
0=Never; 1=Seldom; 2=Sometimes; 3=Often; 4=Always	
3. Do you place something in your mouth to distract you from smoking?	0 1 2 3 4
4. Do you reward yourself with a cigarette after accomplishing a task?	0 1 2 3 4
5. If you find yourself without cigarettes, will you have difficulties in concentrating before attempting a task?	0 1 2 3 4
6. If you are not allowed to smoke in certain places, do you then play with your cigarette pack or a cigarette?	0 1 2 3 4
7. Do certain environmental cues trigger your smoking, *e.g.* favourite chair, sofa, room, car, or drinking alcohol?	0 1 2 3 4
8. Do you find yourself lighting up a cigarette routinely (without craving)?	0 1 2 3 4
9. Do you find yourself placing an unlit cigarette or other objects (pen, toothpick, chewing gum, *etc.*) in your mouth and sucking to get relief from stress, tension or frustration, *etc.*?	0 1 2 3 4
10. Does part of your enjoyment of smoking come from the steps (ritual) you take when lighting up?	0 1 2 3 4
11. When you are alone in a restaurant, bus terminal, party, *etc.,* do you feel safe, secure, or more confident if you are holding a cigarette?	0 1 2 3 4
TOTAL	
A high numerical response indicated a high behavioural dependence, and the lower numerical response indicated a lower behavioural dependence.	
Scoring for Behavioural Dependence	
<12 Mild	
12–22 Moderate	
23–33 Strong	
>33 Very strong	

Please indicate your choice by circling the number that best reflects your choice: 0=not at all; 1=somewhat; 2=moderately so; 3=very much so; 4=extremely so.

TABLE 7 Italian version

Indicare la propria considerazione riguardo le seguenti affermazioni (Domande 1-2).	
1. Fumare è molto importante per me	0 1 2 3 4
2. Tenere in mano la sigaretta è parte del rito del fumo	0 1 2 3 4
Scegliere tra le seguenti opzioni quella che meglio rispecchia le proprie abitudini, cerchiando il numero corrispondente (Domande 3-11).	
0=Mai; 1=Raramente; 2=Alcune volte; 3=Spesso; 4=Sempre	
3. Tiene qualcosa in bocca per evitare di fumare?	0 1 2 3 4
4. Fuma una sigaretta come ricompensa per aver assolto a un compito?	0 1 2 3 4
5. Se è rimasto senza sigarette, trova difficoltà a concentrarsi?	0 1 2 3 4
6. Se si trova in posti in cui non è consentito fumare, tiene in mano un pacchetto di sigarette o una sigaretta?	0 1 2 3 4
7. Alcuni stimoli ambientali le fanno pensare alla sigaretta? Ad es. Un divano o una sedia comodi, una stanza, l'auto, o l'assunzione di alcol	0 1 2 3 4
8. Si è mai reso conto di accendere una sigaretta per abitudine (senza sentirne il bisogno)?	0 1 2 3 4
9. Spesso tiene in bocca una sigaretta spenta o altri oggetti (penna, stuzzicadenti, chewing gum, *etc.*) per scaricare stress, tensione o frustrazione?	0 1 2 3 4
10. Parte del piacere del fumo per lei deriva dai momenti (rituale) in cui accende la sigaretta?	0 1 2 3 4
11. Quando si trova solo in un ristorante, alla fermata dell'autobus, ad una festa, *etc.*, sente più rassicurato o a suo agio fumando una sigaretta?	0 1 2 3 4
TOTALE	
Un punteggio alto è indicatore di alta dipendenza comportamentale, un basso punteggio è indicatore di bassa dipendenza comportamentale	
Punteggio della Dipendenza Comportamentale	
<12 Leggera	
12–22 Moderata	
23–33 Forte	
>33 Molto forte	

Scegliere tra le seguenti opzioni quella che meglio rispecchia le proprie abitudini, cerchiando il numero corrispondente: 0=Per nulla; 1=Un po'; 2=Abbastanza; 3=Molto; 4=Moltissimo.

SUPPORT STATEMENT
We thank Echos Srl (Milan, Italy) for the generous free supplies of PAIPO.

STATEMENT OF INTEREST
A statement of interest for the study itself can be found at www.erj.ersjournals.com/site/misc/statements.xhtml

ACKNOWLEDGEMENTS
We thank Echos Srl (Milan Italy) for the generous free supplies of PAIPO.

REFERENCES
1 World Health Organization. Tobacco or Health: a Global Status Report. Part I: a global overview. Geneva, World Health Organization, 1997; pp. 1–32.
2 Doll R, Peto R, Boreham J, *et al.* Mortality in relation to smoking: 50 years' observations on male British doctors. *BMJ* 2004; 328: 1519–1528.
3 Prescott E, Osler M, Hein HO, *et al.* Life expectancy in Danish females and males related to smoking habits: smoking may affect women more. *J Epid Comm Health* 1998; 52: 1311–1312.
4 Garfinkel L. Selection, follow-up and analysis in the American Cancer Society prospective studies, *In:* Garfinkel L, Ochs O, Mushinksi M, eds. Selection, Follow-up and Analysis in Prospective Studies: a Workshop. NCI Monograph 67. NIH Publications No. 85-2713. Bethesda, National Cancer Institute, 1985; pp. 49–52.
5 US Department of Health and Human Services. The health benefits of smoking cessation. DHHS Publication No. (CDC) 90-8516. Washington, US Dept of Health and Human Services, Public Health Service, Centers for Disease Control, Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 1990.
6 Lightwood JM, Glantz SA. Short-term economic and health benefits of smoking cessation. *Circulation* 1997; 96: 1089–1096.
7 Fiore MC, Jaen CR, Baker TB, *et al.* Clinical Practice Guideline. Treating Tobacco Use and Dependence: 2008 Update. Washington, US Dept of Health and Human Services, Public Health Service, 2008.
8 Hughes JR, Keely J, Naud S. Shape of the relapse curve and long-term abstinence among untreated smokers. *Addiction* 2004; 99: 29–38.
9 Casella G, Caponnetto P, Polosa R. Therapeutic advances in the treatment of nicotine addiction: present and future. *Ther Adv Chronic Dis* 2010; 1: 95–106.
10 Laurier E, McKie L, Goodwin N. Daily and life course contexts of smoking. *Soc Health Illness* 2000; 22: 289–309.
11 Jarvis MJ. ABC of smoking cessation. Why people smoke. *BMJ* 2004; 328: 277–279.
12 Taves DR. Minimization: a new method of assigning patients to treatment and control groups. *Clin Pharmacol Ther* 1974; 15: 443–453.
13 Piccillo G, Caponnetto P, Barton S, *et al.* Changes in airway hyperresponsiveness following smoking cessation: comparisons between Mch and AMP. *Respir Med* 2008; 102: 256–265.
14 Beck A, Ward C, Mendelson M, *et al.,* eds. Manual for the Beck Depression Inventory. New York, Harcourt Brace Jovanovich, 1987.
15 Fagerström KO, Schneider NG. Measuring nicotine dependence: a review of the Fagerström Tolerance Questionnaire. *J Behav Med* 1989; 12: 159–182.
16 Glover ED, Nilsson F, Westin A, *et al.* Developmental history of the Glover–Nilsson Smoking Behavioural Questionnaire. *Am J Health Behav* 2005; 29: 443–455.
17 West R, Hajek P, Stead L, *et al.* Outcome criteria in smoking cessation trials: proposal for a common standard. *Addiction* 2005; 100: 299–303.
18 Polosa R, Russo C, Di Maria A, *et al.* Feasibility of using E-mail counseling as part of a smoking cessation program. *Respir Care* 2009; 54: 1033–1039.
19 Cahill K, Stead LF, Lancaster T. Nicotine receptor partial agonists for smoking cessation. *Cochrane Database Syst Rev* 2007; 1: CD006103.
20 Lancaster T, Stead LF. Individual behavioural counseling for smoking cessation. *Cochrane Database Syst Rev* 2002; 3: CD001292.
21 Silagy C, Lancaster T, Stead L, *et al.* Nicotine replacement therapy for smoking cessation. *Cochrane Database Syst Rev* 2004; 3: CD000146.
22 Caponnetto P, Polosa R. Common predictors of smoking cessation in clinical practice. *Respir Med* 2008; 102: 1182–1192.
23 Boardman T, Catley D, Mayo MS, *et al.* Self-efficacy and motivation to quit during participation in a smoking cessation program. *Int J Behav Med* 2005; 12: 266–272.
24 Chassin L, Presson CC, Sherman SJ, *et al.* Long-term psychological sequelae of smoking cessation and relapse. *Health Psychol* 2002; 21: 438–443.