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

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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 relapse. Smoking-cessation products cannot 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.

Smoke 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

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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 (>20 cigarettes per day for >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 >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 using a widely marketed nicotine-free inhalator (PAIPO; Echos Srl, Milan, Italy) as part of a smoking-cessation programme for smokers willing to quit.

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 ≤10 ppm at the final follow-up visits were defined as quiters. Smokers who failed to meet these criteria (smoking abstinence and eCO of ≤10 ppm) were categorised as smoking-cessation failures (i.e. relapers). Continuing smokers and relapers were used as a smoking reference group for 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].

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 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.

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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 ≥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 test was used for nonparametric variables. Chi-squared for normally distributed variables, and the Mann–Whitney U-test was used to test between-group differences. Smokers setting a firm quit date were counted as 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).

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A logistic regression model was used to assess the relative risk differences in distribution at 4- and 24-week quit rates. In fact, among subjects with a high GN-SBQ (FTND ≥ 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 presented as median (interquartile range) 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.
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

### 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)       | 1/20 (50.0)         | 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       |

Data are presented as 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.

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.
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

| Question                                                                 | 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

| Question                                                                 | 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  |
| **Total**                                                                |     |    |

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

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

| Question                                                                 | 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, cercando 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 fermata dell’autobus, ad una festa, etc? | 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, etc. | 0 1 2 3 4 |
| 12. Alcuni stimoli ambientali le fanno pensare alla sigaretta (senza sentirne il bisogno)? | 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, cercando il numero corrispondente: 0=Per nulla; 1=Un po’; 2=Abbastanza; 3=Molto; 4=Moltoissimo.

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

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