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EFFECT OF A NICOTINE FREE INHALATOR AS PART OF A SMOKING CESSATION PROGRAM

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SUMMARY (word = 324)

Background: Currently-marketed smoking cessation drugs reportedly lack high levels of efficacy and 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 cues by replacing some of the rituals associated with smoking gestures. The present study assessed for the first time the effect of using a nicotine free inhalator to improve success in a standard smoking cessation program.

Method: At baseline, 120 healthy smokers attending a smoking cessation program (pharmacological treatment with high dose nicotine patch plus 300mg/day bupropion and counseling) were assessed for their sociodemographic factors, smoking history, subjective ratings of depression (by Beck Depression Inventory; BDI), physical dependence (by FTND), behavioural dependence (by Glover-Nilsson Smoking Behavioral Questionnaire; GN-SBQ) and motivation (by Mondor Motivational Questionnaire). Participants were randomly assigned into two groups (nicotine free inhalator - PAIPO group vs reference group) and asked to attend two further follow-up visits at week-4 and week-24 during which abstinence from cigarette smoking was subjectively and objectively reviewed.

Results: Of the 120 participants , 90 (75.0%) and 85 subjects (70.8%) completed the follow-up visit at week-4 and week-24 respectively. For the whole sample, no significant difference was found in quit rates between PAIPO (33.3%; week-24) and reference group (28.3%; week-24). However, the quit rate in PAIPO group (66.7%; week-24) was more than three-fold higher compared with the reference group (19.2%; week-24) for those individuals with high 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 week-24 (OR = 8.88; 95%CI = 2.08-37.94) in the PAIPO users.

Conclusion: 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 likely to have a strong behavioural component of their tobacco dependence.

INTRODUCTION

Tobacco smoking is a modern day epidemic that poses substantial health burden and costs. With approximately five 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 of 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 programs are useful in helping smokers to quit (7), smoking is a very difficult addiction to break. It has been shown that approximately 80% of smokers who attempt to quit on their own relapse within the first month of abstinence and only about 3% to 5% remain abstinent at 6 months (8). There is little doubt that currently-marketed smoking cessation products increase the chance of committed smokers to stop 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 pharmacologic aspect of nicotine addiction but also with the psychological components (cognitive, social and behavioural) associated with tobacco dependence. Smoking is much more than the addicting effect of nicotine; the smoking habit is also the rituals that each smoker associates with his/her 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 replace the rituals associated with the act of smoking. Counselling for smoking cessation is intended to helpsmokers in coping with this important aspect of their life by implementing personalized replacement rituals, but even counselling for smoking cessation lacks high levels of efficacy.

Nicotine free inhalators are plastic devices (Figure 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 remaining abstinent during their quit attempt and could be particularly useful when used in the context of smoking cessation interventions. As there is no formal demonstration supporting the efficacy of these devices in smoking cessation studies, it was assessed for the first time the effect of using a widely marketed nicotine free inhalator (Paipo; Echos Srl – Milano, Italy) as part of a smoking cessation program for smokers willing to quit. Paipo is safe for all smokers and non smokers. Its main ingredeient is simply a fiber sponge filter plug soaked in naturally extracted herbal aroma oil, encased in plastic cartrige container similar to a cigarette.

METHODS

Study Population

Regular smokers (≥20 cigarettes/day, for at least 10 yrs), consecutive first timer attendees who booked with the call-center of our smoking cessation clinic (Centro per la Prevenzione e Cura del Tabagismo – CPCT; Universitàdi Catania, Italy), were invited to participate in the study at time of their first consultation. Smokers with an exhaled breath carbon monoxide concentration (eCO) of ≥10 ppm were recruited. Subjects with a history of alcohol and illicit drug use, 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.

Study Design and Procedures

This 6-month prospective study was designed as a two-group randomized clinical trial to compare the effect of a nicotine free inhalator (Paipo; Echos Srl – Milano, Italy) on quit rates at 4 and 24 weeks in smokers undergoing a smoking cessation program; participants were randomly assigned in blocks of five to either a nicotine free inhalator group (Paipo; Echos Srl – Milano, Italy) or to a reference group (control) also using a form of adaptive randomization designed to minimize imbalances in the distribution of prognostic factors (gender, 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 daily smoked cigarettes, years of smoking, pack/yrs, previous quit attempts, motivation score) were annotated. Scoring of the subjective ratings of depression was assessed with the Beck Depression Inventory (BDI) (14). Physical dependence and behavioural dependence were measured by Fagerstrom Test for Nicotine Dependence (FTND) (15) and Glover-Nilsson Smoking Behavioral Questionnaire (GN-SBQ) (16), respectively. Level of motivation was assessed by Mondor Motivational Questionnaire, a tool developed in 1994 at the Hospital Henri-Mondor in Paris. This motivational questionnaire is easy, relatively brief, and frequently featured in several smoking cessation websites in Italy, but it is poorly validated. This questionnaire (Annex 1) evaluated the motivation of a smoker willing to make a quit attempt and consists of 15-items and had classified motivation to quit according to four possibilities of success: it isnt't the time to quit (<6), discrete (6-12), good (12-16), very-good (>16). The GN-SBQ (Annex 2) consists of 11-items and had classified behavioural dependence according to quartiles: mild (<12), moderate (12-22), strong (23-33), and very strong (>33). In addition, levels of carbon monoxide in expired breath (eCO) using a portable device (Micro CO, Micro Medical Ltd, Rochester, UK) were measured. Participants were instructed on how to prepare to stop smoking and 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 300mg/day) and they were assigned to either to an active group or to 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 from the "quit date".

Psychological support and counselling were offered throughout the smoking cessation programme (typically, 3 to 6 brief visits within the first 4 weeks of the smoking cessation programme) as well as telephone contacts to encourage attendance. Abstinence from smoking was reviewed objectively throughout the study by measuring the levels of eCO at each follow-up visit. Participants attended two further follow-up visits at Week 4 and Week 24, during which abstinence from cigarette smoking was subjectively and objectively reviewed. Week 4 and 24 follow-up visits 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 with an eCO concentration of ≤10 ppm at the final follow-up visits will be defined as quitters. Those smokers who failed to meet these criteria (smoking abstinence and eCO of ≤10 ppm) will be categorized 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. A smokers setting a firm quit date is counted as "lost to follow-up" if, on attempting to determine and verify his/her quitter status, he/she cannot be contacted. Success rates were defined as 24-week success rate - 24WSR (calculated as the ratio between number of eCO-verified 24-week quitters over the number of smokers setting a firm quit date) and the 4-week success rate - 4WSR (calculated as the ratio between number of eCO-verified 4-week quitters over 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 at least 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 are classified as smoking cessation failures (intention-to-treat analysis).

One-way analysis of variance (ANOVA) was used to test between-group differences for normally distributed variables, and Mann-Whitney U-test was used for nonparametric variables. χ^2 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: gender, age, FTND, MONDOR, No. of pack/yrs, instruction level, cigarettes/day smoked at enrolment. Continuous variables were dichotomized using the following cut-off levels: age 45.5 yrs (range 23-69), FTND 6; MONDOR 12; No. of pack/yr 48 (highest quartile of its distribution); instruction level 13 yrs; cigarettes/day at enrolment 20. A p level <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. Seventy subjects (58.3%) had a low degree of behavioural impact on smoking dependence (GN-SBQ≤22) and 50 (41.7%) presented a high degree (GN-SBQ>22). At 4-week, 13/60 subjects

(21.7%) were lost at follow-up in PAIPO group and 17/60 (28.3%) in reference group (p=0.399, χ^2). At 24-week, subjects who were lost at follow-up accounted for 16/60 (26.7%) in PAIPO group and 19/60 (31.7%) in reference group (p=0.547, χ^2). Consequently, out of 120 participants , 90 (75.0%) and 85 subjects (70.8%) completed the follow-up visit at 4-week and 24-week respectively.

Table 1 - Subjects' characteristics at enrolment

	Reference group	Paipo group	p value
Gender (M/F, No.)	40/20	40/20	-[†]
Age (yrs, mean±SD)	48.6±10.8	45.7±11.6	0.154[#]
Smoke years (mean±SD)	32.3±10.9	29.1±12.1	0.123[#]
Cigarette/day at enrolment (No., median and IQ)	23.5 (18.0-30.0)	25.0 (20.0-30.0)	0.395[§]
No. of pack/yr (median and IQ)	33.9 (25.3-47.5)	31.0 (22.5-48.7)	0.477[§]
Exhaled CO (ppb, mean±SD)	27.2±13.0	30.2±15.8	0.264[#]
Age at initiation (yrs, mean±SD)	16.3±3.8	16.6±4.3	0.686[#]
BDI (mean±SD)	12.5±7.7	12.9±9.0	0.777[#]
FTND (median and IQ)	6.0 (4.5-7.0)	7.0 (6.0-8.0)	0.061[§]
MONDOR (mean±SD)	13.2±2.7	13.1±2.8	0.818[#]
GN-SBQ (median and IQ)	20.0 (15.0-32.5)	19.5 (15.0-33.0)	0.948[§]

[†]χ^2 test[#]one-way ANOVA
[§]Mann-Whitney U-test
Continuous variables are presented as means ± standard deviations (SD) for normally distributed variables or as medians and interquartile ranges (IQ) for nonparametric variables.

Quit rates at 4-week and 24-week are shown in **Table 2**. For the whole sample, no significant difference was found in quit rates between PAIPO and reference group at any time. However, when study participants were separately evaluated on the basis of their GN-SBQ score at baseline, a significant difference was found in frequency distribution of quit rates: in fact, among subjects with high GN-SBQ (i.e. smokers with strong to very strong behavioural dependence) the quit rate in the PAIPO group was significantly higher than in the reference group. This was evident already at 4-week and particularly at 24-week, by both intention-to treat analysis and per-protocol analysis. In particular, the quit rate in PAIPO group at 24-week was more than three-fold higher compared with the reference group for those individuals with high GN-SBQ scores.

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

Table 2 - "Per-protocol" and "Intention-to-treat" successful quit rates

A – Successful quit rates at week-4

	Reference group	PAIPO group	p value
Per-protocol analysis (No., %)			
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 (No., %)			
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

B – Successful quit rates at week-24

	Reference group	PAIPO group	p value
Per-protocol analysis (No., %)			
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 (No., %)			
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

The results of the logistic model analysis (**Table 3)** showed 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 24-week 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 (Figure 2). They also reported that placing the inhalator in their mouth was useful to distract them from smoking urges. Although this study was not designed to specifically address safety, no adverse effects were reported by the participants using PAIPO.

Table 3 - Multiple logistic regression analysis for successful quitting at 24 weeks (Paipo vs Control group, intention-to-treat analysis)

A - Low GN-SBQ class

	OR	95% CI	P value
Gender (male vs female)	0.92	0.21-4.16	0.923
Age (older subjects vs younger)	0.50	0.12-2.11	0.344
FTND (high vs low)	0.28	0.05-1.47	0.131
MONDOR (high vs low)	12.70	1.36-118.82	0.026
No. of pack/yr (high vs low)	0.55	0.08-4.06	0.559
Instruction level (high vs low)	1.62	0.32-8.34	0.564
No. cigarettes/day at enrolment (high vs low)	1.13	0.20-6.20	0.892
PAIPO use vs control group	0.34	0.08-1.48	0.150

B - High GN-SBQ class

	OR	95% CI	P value

Gender (male vs female)	1.43	0.23-8.87	0.700
Age (older subjects vs younger)	0.14	0.02-1.03	0.054
FTND (high vs low)	1.22	0.24-6.31	0.814
MONDOR (high vs low)	3.56	0.72-17.53	0.119
No. of pack/yr (high vs low)	2.53	0.25-25.36	0.431
Instruction level (high vs low)	0.67	0.14-3.21	0.615
No. cigarettes/day at enrolment (high vs low)	1.86	0.27-12.66	0.525
PAIPO use vs control group	8.45	1.73-41.20	0.008

GN-SBQ (cut-off level at 22).
Data are expressed as odds ratio (OR) and 95% confidence interval (95%CI). and corrected for confounding variables (gender, FTND, MONDOR, No. of pack/yrs, instruction level, and No. of cigarettes/day smoked at enrolment). Continuous variables were dichotomized as in Methods section

DISCUSSION

This is the first study to investigate the effect of adding a nicotine free inhalator (PAIPO) into a smoking cessation program. 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-week was more than three-fold higher compared with the reference group for those smokers with strong to very strong behavioural dependence 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 those 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 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. By inclusion criteria, some characteristics of the sample limit generalization of the findings; all participants were regular smokers with a rather elevated level of nicotine dependence; their subjective ratings of depression were low; participants were all adults with a mean age of 45,7 years (PAIPO group) and 48,6 years (reference group). Also,

exclusion of patients with history of alcohol and illicit drug use, a diagnosis of major depression, or other psychiatric conditions may decrease the generalizability of the study results. Lastly, the lack of study controls is also an important limitations, but given the nature of the intervention it was difficult to conceptualize an adequate control for this type of study. Nonetheless, the present study indicates that adding a nicotine free inhalator into a smoking cessation program is an inexpensive strategy that can be quite effective for some smokers.

The high quit rate in this study (33,3% in PAIPO group and 28,3% in reference group at 24-week) reflects the notion that combined smoking-cessation program with pharmacoterapies and counseling, provides the most favourable level of cessation (8). In addition, retention at the final 24-week visit was satisfactory, subject who were lost to follow up accounting 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 about 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 emphasizing 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 levels of motivation 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/behavioral maladaptations occurring during quitting. The PAIPO device might not have helped with coping with some of the psychological/behavioral aspects of tobacco dependence in the low GN-SBQ group, thus failing to meet the expectations of these smokers undergoing the smoking cessation program. This failure experience by itself would constitute an additional stressor, and its associated decrease in self-efficacy should produce increased negative affect (24). This is likely to be the cause for an additional sense of failure and more stress. Smokers in these stressful situation react by adopting the best coping strategy know to them; i.e lighting up a cigarette. Therefore, in smokers with low GN-SBQ scores, the nicotine free inhalator could cause a paradoxical effect, the device triggering relapse in order to compensate for the additional frustration/stress. Besides, 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 quit in some

participants (particularly those with low GN-SBQ scores) who would then quickly relapse. This interpretation is speculative and warrants specifically designed study, 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 likely to have a strong behavioural component of their tobacco dependence. On the other hand, in smokers with no significant behavioral component, the device is likely to produce a negative effect. Therefore, stratification of smokers according to their level of behavioral dependence by GN-SBQ may be necessary to take maximum advantage from the use of these devices in smoking cessation studies.

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LEGEND TO FIGURES

Figure 1: The “PAIPO” nicotine free inhalator (Echos Srl – Milano, Italy). This plastic device resembling a cigarette is intended to replace some of the rituals associated with smoking gestures (e.g. hand-to-mouth action of smoking; handling and manipulation of cigarettes). The plastic device contains a sponge filter soaked in a natural oil enriched with extracts of different aroma. Hence, it comes in different flavours (mint, green tea, cinnamon, sweet tobacco) and it is sold without prescription in pharmacies (a pack of three inhalators is retailed at about 5 Euros) .

Figure 1

Figure 2: The PAIPO nicotine free inhalator (detail of the mouthpiece) after use. Please note the several bite marks on the mouthpiece (white arrow), a clear sign that the inhalator was being used to get relief from stress, irritability or frustration. A brand new PAIPO is illustrated here (lower part of the figure) for comparative purposes.

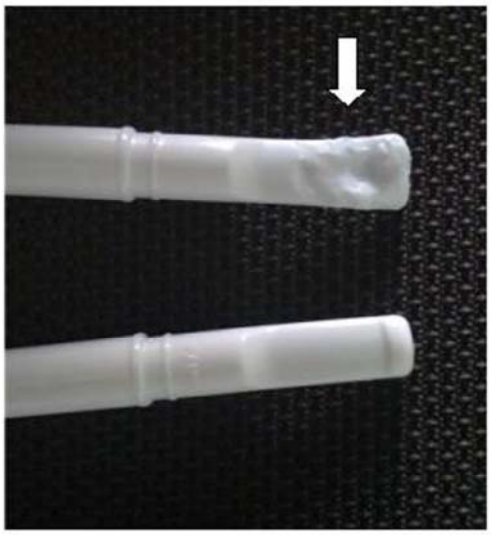

Figure 2

Annex 1: Mondor Motivational Questionnaire

Annex 2: Glover-Nilsson Smoking Behavioral Questionnaire (GN-SBQ)

Annex 1

Mondor Motivational Questionnaire (English Version)

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

	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 dont have any problems at work at the moment	1	0
4. I donthave 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 physicla 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 momen	2	0
12. I usually finish what I start	1	0
13. I am usually calm and relaxed	1	0
14. My wieght is usually stable	1	0
15. I want to improve my quality of life	2	0
Total		

Possibilities of success

it isnt't the time to quit (<6), discrete (6-12), good (12-16), very-good (>16).

Questionario Motivazionale di Mondor (Italian Version)

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

	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).

Annex 2

Glover-Nilsson Smoking Behavioral Questionnaire (GN-SBQ), (English Version)

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**

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, eg, favorite 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 partof 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 behavioral dependence, and the lower numerical response indicated a lower behavioral dependence.	
Scoring for Behavioral Dependence <12 Mild 12-22 Moderate 23-33 Strong >33 Very Strong	

Questionario Glover Nilsson sulla Dipendenza Comportamentale dal Fumo (GN-SBQ), (Italian Version)

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

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 <12Leggera 12-22Moderata 23-33Forte >33 Molto forte	