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General

# Impact of a soft tip nicotine-free harmless cigarette as part of a smoking cessation program with psychological support and varenicline: an integrated workplace smoking cessation intervention

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Cigarette consumption in the general population has shown a sustained decline over the past 20 years, but despite this, it is essential to monitor consumption among smokers at their workplace. There is an association between cigarette addiction and work-related stressors, with high prevalence rates for smokers, at least double those of other adults. This two-group randomized clinical trial compared the 12-week combined effect of psychological support and varenicline associated with the use or not of a nicotine-free inhaler with a soft mouthpiece (QuitGo™) on the 4 to 24-week cessation rate in enrolled smokers to a smoking cessation program promoted by our research group. The results of the logistic model analysis showed that the likelihood of quitting successfully at week 24 was significantly higher in the QuitGO™ group than in the control group for participants with high behavioral dependence as assessed by Glover-Nilsson Smoking Behavioral Questionnaire-GN-SBQ (OR = 8.55; CI at 95% = 1.75-43.20). The data presented suggest that the soft tip nicotine-free harmless cigarette may be helpful for smokers and those with work-related stress symptoms who recognize the need to have a gesture in the traditional cigarette smoking ritual.

## INTRODUCTION

Although studies on cessation paths for smokers in their workplaces are increasing,[1,2] the effects of the grouping of lifestyle factors (mainly unhealthy diet, lack of physical activity, alcohol consumption) with smoking, therefore, need further research.[3]

To date, therefore, there is a strong association between smoking and risky lifestyles in the workplace.

These findings are potentially helpful for directing intervention efforts regarding smoking cessation in professional settings,[3] bearing in mind, however, some crucial caveats: the cessation process itself produces withdrawal symptoms, which include a variety of disorders (depressed mood, anxiety, nervousness, restlessness, irritability, fatigue, and sleepiness); these are most pronounced in the days immediately following cessation and generally return to baseline levels within one month of continued abstinence.[4]

The treatment of cigarette addiction, shorter and more pragmatic than the more durable and complex treatments of other addictions, is based on the essential components of this approach. It consists of an integrated intervention consisting of individual or group assessment, counseling (psycho-behavioral intervention), use of self-help information material, and possible pharmacotherapy (essentially nicotine replacement therapy, varenicline, and bupropion), which closely accompanies the individual path and also supports group treatment, as an integral part or is carried out externally as a parallel and coordinated intervention.[5,6]

While the other tools are more defined and consolidated, the psycho-behavioral intervention component, which will be dealt with more in this article, needs more definition and investigation.

## THEORETICAL BACKGROUND

Many studies report a positive association between smoking and psychological distress, with smoking rates increasing with disease severity linked to stressors.[7,8] The association between smoking and stress in the workplace can also be bidirectional: to alleviate the effects of stress, one could start smoking, but it has been observed that this behavior does not lead to improvements but deterioration.[9] Individuals experiencing work-related stress and smokers have more significant nicotine withdrawal symptoms.[10,11] Although smokers with high levels of stress have similar levels of motivation to quit smoking or even higher than those of smokers in the general population[12,13] and they try to quit with similar rates,[14] the chances of successful abstinence at

one month are 30-50% lower for those with high levels of stress.[14]

These brief introductory notes immediately suggest that there may be a strong association between cigarette consumption and workplace stress.

Since 1997, the Luxembourg Declaration on Workplace Health Promotion in the European Union has advocated systematic prevention interventions that involve both the environment and the individual.[15,16] In practice, however, it has been found that the concrete organizational health management strategies implemented by companies have focused on two continuously interacting factors:[17]

a) the set of personal resources made available by workers regarding values, beliefs, attitudes, health practices followed by employees.

b) the set of support, instrumental and psychosocial, that the work organization makes available to them.

The action of these two factors tends to materialize as a dynamic of continuous exchange:[18] the more the personal resources (and the efforts produced by the workers) are recognized as balanced and supported by the organization of work, the more the health of workers becomes a strategic objective of the organization, tending to reduce levels of work stress. This premise is fundamental if we reflect on the fact that most of the specialist literature on health in the workplace insists on the incidence of health costs borne by organizations as a result of bad habits of workers and related individual risk factors (nutrition, obesity, lack of physical activity, drug abuse, alcohol, and smoking),[19] often ignoring the impact of work organization models and related managerial practices.

At this point, a question emerges: what have managerial practices produced with the strategies to reduce tobacco consumption in the workplace, in the hypothesis that this habit is strictly correlated to work stress?

In 2003, the ILO Safework placed the attitudes and regulatory policies implemented internationally concerning smoke-free workplaces at the center of attention in its report.[20] Also, in the same year, Smedslund and colleagues published a meta-analytical study of controlled trials of smoking cessation practices in the workplace conducted in the 1990s compared to similar studies conducted in the previous decade.[21] The meta-analysis concluded that the effectiveness of the applied smoking reduction interventions did not extend beyond 12 months, attributing this effect to methodological limits of the proposed procedures.

In 2005, a study conducted by Kouvonen and colleagues on 46 thousand workers operating in ten municipalities and 21 Finnish hospitals aimed to verify the correlation between levels of smoking intensity and quality/balance of effort/reward promoted by the organization of work in their smoking harm prevention policies.[22] The study, conducted based on the job strain model and the effort-reward imbalance model approaches,[23,24] arrives at the critical conclusion that greater smoking intensity was associated with a more significant imbalance between effort-reward, among smokers; in no longer smokers, the same imbalance raised the likelihood that they would return to smoking. The high work tension and the consequent increase in work-related stress, therefore, affect both the probability of relapse into addiction and increasing smoking intensity, circumstances that lead to emphasizing the importance of the environmental context in the effectiveness of reduction strategies of smoking in the workplace.

That perceived stress in the workplace is an essential factor in increasing-reducing smoking intensity is further demonstrated by a study conducted in 2016 in 41 countries containing more than 217,000 participants.[25] Research conducted in Japan in the same period confirmed that smoking reduction policies in the workplace are positively correlated with a general reduction in public health expenses and burdens and increased company productivity and organizational performance.[26]

In conclusion, it is well established that adult smoking rates have remained relatively stable in recent years.[27] Unfortunately, around 80% of smokers do not immediately quit.[28,29] Active cessation induction interventions that promote smoking cessation efforts among unmotivated smokers could profoundly impact public health even if efficacy is low.

Stress is positively associated with continued smoking and negatively associated with quitting.[30] Predictably, smokers who reported higher levels of negative mood and stress-related symptoms were less likely to quit than smokers with fewer stress-related disorders.[9]

As previously advocated, however, corporate smoking reduction practices within the workplace must necessarily consider three aspects contributing to structuring a wide-ranging strategy. The methods aimed at reducing smoking intensity must be conceived within an organizational culture[31] structured based on two major pillars: a climate of health and safety in which the efforts required of the workers with insured rewards; a recognition of the value and importance of personal resources such as self-efficacy, resilience, quality, and density of social support, elements that act as "mediators" between health promotion practices and work organization tools.

## METHODS

Regular smokers of traditional cigarettes (⩾10 cigarettes/day, for at least 1yrs) treated at their workplace (a medicine factory in Catania) were involved in the study. Participants with an exhaled breath carbon monoxide concentration (eCO) of ⩾10 ppm were considered eligible for participation.

This study included a two-group randomized clinical trial to compare the effect of a nicotine-free inhaler with a soft mouthpiece (QuitGo™) on quit rates at 4 and 24 weeks in smokers enrolled in a smoking cessation program; smokers were randomized to receive or not a soft tip inhaler (Figure 1).

Pharmacologic therapies were prescribed over 12 weeks according to manufacturer guidelines. Participants were prescribed varenicline at 1mg twice daily. Psychological support was delivered at each visit.

At the first visit, social and demographic factors and accurate smoking history were annotated. Scoring of the self-evaluation of depression was assessed by the Beck Depression Inventory (BDI).[32] Physical dependence and behavioral cigarette dependence were measured by Fagerström Test for Cigarette Dependence (FTCD)[33] and Glover-Nilsson Smoking Behavioral Questionnaire (GN-SBQ),[34] respectively.

Participants were advised to quit smoking and were asked to set a quit date within the next seven days. Smokers were prescribed varenicline 2 mg/day for 12 weeks, and they were assigned to either an active or a control group. Smokers of the active group received a free supply of a soft tip nicotine-free (mint aroma) QuitGO™ and instructed about its usage. Smokers were then invited to book their follow-up appointment within one week from the quit date. Over the weeks, support has been offered for smoking participants, characterized by psychological support and telephone contacts through WhatsApp to encourage participants' motivation. The levels of eCO were carried out at each visit with the function of checking the objective smoking abstinence.

During the follow-ups of weeks 4 and 24, the participants were followed by an independent researcher. This choice was made to avoid possible contamination with respect to the knowledge of the study participants' basic characteristics and group allocation.

Subjects who reported quitting smoking and had eCO <10 levels were referred to as quitters. Those who did not meet these criteria were considered to be failures or relapsers.

Continuing smokers and relapsers were put in a smoking reference group to compare the study measures after smoking cessation between groups. Success rates were defined as 24-week success rate - 24WSR (calculated as the ratio between a number of eCO-verified 24-week quitters over the number of smokers setting a quit date) and the 4-week success rate - 4WSR (calculated as the ratio between the number of eCO-verified 4-week quitters over the number of smokers setting a quit date).[35,36]

The sample size calculation for this study, based on the expected cessation rates from a previous smoking cessation study,[37] indicates that 63 subjects are required to have 80% power with a 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 calculated by including all enrolled participants - assuming that all those individuals who will be 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. $\chi 2$ statistics were 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 touch base QuitGO™ 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, FTCD, N. 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), FTCD 6; No. of pack/yr 48 (highest quartile of its distribution); instruction level 13 yrs; cigarettes/day at enrolment 10. A p


**Figure 1.**

level<0.05 was considered statistically significant. The statistical analysis was conducted by an independent biostatistician who was unaware of the group allocation of the study participants.

The study complied with the ethical principles of the Declaration of Helsinki. All participants provided written informed consent. The study was conducted in agreement with the ethical norms set by the Italian National Psychological Association. A cohort of workers carried out this study within the framework of occupational health surveillance following the Italian Law (no. 81/2008).

## RESULTS

120 smokers of traditional cigarettes who experience work-related stress assessed by the Karasek Job Content Questionnaire (JCQ) were enrolled in the study (Table 1). No significant difference was found between study groups for all the variables under investigation at the first visit. Sixty-nine subjects had a low degree of behavioral cigarette dependence (GN-SBQ ⩽22), and 51 presented a high level (GN-SBQ >22). At 4-week, 12/60 participants (20%) were lost at follow-up in QuitGO™ group and 16/60 (26.6%) in control group (p=0.366, $\chi 2$). A 24-week, smokers who were lost at follow-up accounted for 15/60 (25%) in the QuitGO™ group and 18/60 (30%) in the reference group (p=0.501, $\chi 2$). Subsequently, out of 120 participants, 92 (76.6%) and 87 participants (72.5%) completed the 4-week and 24-week visits, respectively.

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

**Table 1. Smokers' characteristics at baseline.**

| | QuitGO™ group | Reference group | p-value |
|---|---|---|---|
| Gender (M/F, No.) | 39/21 | 40/20 | -† |
| Age (yrs, mean±SD) | 46.1±10.7 | 46.7±9.4 | 0.123# |
| Smokeyears (mean±SD) | 28.9±11.7 | 29.3±7.9 | 0.151# |
| Cigarette/day at enrolment (No., median and IQ) | 26.3 (20.0-30.0) | 24.5 (18.0-30.0) | 0.295§ |
| No. of pack/yr (median and IQ) | 37.8 (25.5-48.7) | 34.3 (25.1-47.5) | 0.367§ |
| Exhaled CO (ppb, mean±SD) | 30.4±15.8 | 28.3±12.4 | 0.234# |
| Age at initiation (yrs, mean±SD) | 17.4±5 | 16±5 | 0.626# |
| BDI (mean±SD) | 22.8±4.3 | 22.5±3 | 0.677# |
| FTCD (median and IQ) | 7.0 (6.0-8.0) | 6.5 (4.5-7.0) | 0.051§ |
| GN-SBQ (median and IQ) | 20.0 (15.0-33.0) | 20.0 (15.0-32.0) | 0.848§ |

† $\chi$ 2test; #one-way ANOVA; §Mann-Whitney U-test

**Table 2. Smoking cessation quit rates at week-4 and week-24.**

| | No QuitGO™ | | QuitGO™ | | | |
|---|---|---|---|---|---|---|
| **Per-protocol analysis (No., %)** | **week-4** | **week-24** | **week-4** | **week-24** | **p-value week-4** | **p-value week-24** |
| Overall sample | 22/44 (50%) | 17/42 (41.5%) | 24/48 (50%) | 20/45 (45.5%) | 0.991 | 0.701 |
| Low GN-SBQ (≤22) | 13/24 (54.1%) | 12/22 (54.5%) | 8/28 (28.5%) | 4/26 (15.3%) | 0.056 | 0.002 |
| High GN-SBQ (>22) | 9/20 (45.9%) | 5/20 (25.0%) | 16/20 (81.5%) | 16/19 (84.2%) | 0.021 | 0.0001 |
| **Intention-to-treat analysis (No., %)** | | | | | | |
| Overall sample | 22/60 (36.6%) | 17/60 (28.3%) | 24/60 (40%) | 20/60 (33.3%) | 0.703 | 0.503 |
| Low GN-SBQ (≤22) | 13/34 (38.2%) | 12/34 (35.2%) | 8/35 (22.8%) | 4/35 (11.4%) | 0.133 | 0.016 |
| High GN-SBQ (>22) | 9/26 (34.6%) | 5/26 (19.2%) | 16/25 (64%) | 16/25 (64%) | 0.019 | 0.001 |

in quit rates between the QuitGO™ group and the reference group at any time. However, when smokers were separately evaluated based on their GN-SBQ score at baseline, a significant difference was found in the frequency distribution of smoking cessation quit rates: in smokers with high GN-SBQ (i.e., people with substantially high strong psycho-behavioral dependence), the quit rate in the QuitGO™ group was significantly higher than in the control group. The results of the logistic model analysis showed that the probability of successful quitting at week 24 was significantly higher in the QuitGO™ group than in the control group for participants with high GN-SBQ scores (OR = 8.55; 95%CI = 1.75-43.20).

The majority of smokers in the QuitGO™ group were satisfied with using this tool, principally for its anti-stress action. About 80% of participants declared that placing the QuitGO™ in their mouth was useful to distract them from cigarettes craving.

## DISCUSSION

This is the first study to investigate the effect of adding a soft tip nicotine-free harmless cigarette as part of a psychologically supported and varenicline quit workplace smoking program in smokers with work-related stress symptoms. No significant difference in smoking cessation rates was observed between smokers using the device and the reference group for the overall sample. This study made it possible to observe some positive effects related to the use of the investigated products, considered to be at zero risks, which significantly reduces tobacco dependence, especially for those related to behavioral aspects.

The results of the logistic model analysis showed that the likelihood of successfully quitting at week 24 was significantly higher in the QuitGO™ group than in the control group for participants with high GN-SBQ scores. The data presented suggest that QuitGO™ may be helpful for those smokers, such as those with work-related stress symptoms,

who recognize the need to have a gesture in the traditional cigarette smoking ritual, especially in contexts where smoking is impossible because it is prohibited, as the workplace.

The literature confirms the results of another study.[35] Other inhalers allowed the smokers to cope with the need to compensate for "craving" used in a traditional cigarette smoking cessation program.

The novelty of this study, conducted at a workplace, compared to the previous ones, focuses its attention on a sample of participants who have symptoms of work-related stress that typically have a higher percentage of smoking relapse, which is made up of scarce internal resources, understood as problem-solving skills, social skills and other types of skills related to the ability to manage frustration or other emotions.[38]

## CONCLUSIONS

An important fact that emerged from this research is that smokers who have used QuitGO™ were satisfied with its product. It allows the smoker to avoid the constant need to respect the typical gestures of those who smoke traditional cigarettes. These data will enable us to understand how important it is for a smoker to appreciate the need for gestures without necessarily having the satisfaction given by nicotine.[39] A suggestion for future studies will be to broaden the study sample by observing multiple workplaces and different professional figures.

### CONFLICTS OF INTEREST

RP has received lecture fees and research funding from Pfizer, Inc., GlaxoSmithKline plc, CV Therapeutics, NeuroSearch A/S, Sandoz, MSD, Boehringer Ingelheim, Novartis, Duska Therapeutics, and Forest Laboratories. He has also served as a consultant for Pfizer, Inc., Global Health Alliance for treatment of tobacco dependence, CV Therapeutics, NeuroSearch A/S, Boehringer Ingelheim, Duska Therapeutics, Forest Laboratories, ECITA (Electronic Cigarette Industry Trade Association, in the United Kingdom), Health Diplomat (consulting company that delivers solutions to global health problems with special emphasis on harm minimization), and Pharmacielo. RP was awarded an Investigator-Initiated Study award program established by Philip Morris International in 2017, but subsequently resigned from the role of Principal Investigator in 2018, before the trial began. Lecture fees from a number of European EC industry and trade associations (including Fédération Interprofessionnelle de la VAPE in France and Federazione Italiana Esercenti Svapo Elettronico in Italy) were directly donated to vaper advocacy no-profit organizations. RP is the Founder of the Center of Excellence for the acceleration of Harm Reduction at the University of Catania (CoEHAR), which has received a grant from Foundation for a Smoke Free World to develop and carry out eight research projects. RP is also currently involved in the following pro bono activities: scientific advisor for LIAF, Lega Italiana Anti Fumo (Italian acronym for Italian Anti Smoking League) and Chair of the European Technical Committee for standardization on Requirements and test methods for emissions of electronic cigarettes (CEN/TC 437; WG4). PC is paid by the University of Catania as an external part-time researcher and adjunct professor of clinical, addiction, and general psychology. He has been affiliated to the CoEHAR since December 2019 in a pro bono role. He is coauthor of a protocol paper supported by an Investigator-Initiated Study award program established by Philip Morris International in 2017. The other authors have no conflict of interests to declare.

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