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# A randomized controlled trial to compare group motivational interviewing to very brief advice for the effectiveness of a workplace smoking cessation counseling intervention

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## ABSTRACT

**Background:** Studies show that smokers have a lower work performance due to time spent smoking, increased fatigue perception and are more absent from work due to smoking-related diseases. The workplace could represent an important location to promote smoking cessation.

**Methods:** This study is a multi-center, controlled trial for smoking cessation counseling at the participants' workplace, where 656 randomized participants received four sessions of group motivational interviewing or four sessions of very brief advice and were followed up for 52 weeks.

**Results:** The Continuous Quit Rate (CQR) was higher for the smoking cessation counseling group than for the very brief advice group during weeks 9 to 12 (17.5% vs. 3.6%) weeks 9 to 24 (13.4% vs. 3.4%) and weeks 9 to 52 (10.3% vs. 3.1%).

**Conclusions:** This study demonstrated that motivational interviewing is an efficacious smoking cessation approach for smokers at their workplace. The short-term and long-term cessation rate of the intervention of the smoking cessation counseling group exceeded that of very brief advice.

## KEYWORDS

Workplace; smoking cessation; smoking cessation counseling; tobacco addiction; motivational interviewing; reduced risk products

## Introduction

Every year, more than 8 million people die from tobacco use, approximately half of its users. More than 7 million of these deaths are caused by direct tobacco use, while around 1.2 million are nonsmokers exposed to secondhand smoke.<sup>1</sup>

The majority of adults spend one-third of their time at work. In these places, health empowerment programs can be delivered using different methodologies, the support of colleagues can be utilized in smoking cessation programs, no-smoking policies in the workplace can stimulate quitting, and smoking cessation interventions can be organized to fit workers' working schedules,<sup>2,3</sup> and for these reasons, the workplace could represent an important location for smoking cessation interventions for adult workers who smoke.

Medical and psychological attention for all smokers in their workplace can serve as a site for a "teachable moment" because it offers smokers the opportunity to initiate smoking cessation and improve their health. Several factors might influence the effectiveness of smoking cessation interventions delivered at the workplace, including the intensity of the intervention.

UK Nationals Department of Health and Public Health Guidance has indicated that providing Very Brief Advice (VBA) and referring smokers to evidence-based smoking cessation aids ensure the most effective method of quitting smoking. They recommend that every smoker should be given advice on quitting based on the Ask, Advise, Act (AAA).<sup>4</sup> A consulting technique considered effective in helping smokers quit is

motivational interviewing (MI) which, unlike the VBA, lasts longer and is more profound and intense and is described as a directive, client-centered counseling style used to elicit motivation to change by helping smokers explore and resolve ambivalence. This counseling approach has strong empirical support in individual interventions with emerging evidence that MI can be adapted to a group therapy format. Emphasis is placed on creating a collaborative relationship and affirming the client's autonomy regarding change.<sup>4,5</sup> In this study, these two approaches were chosen to evaluate whether using an approach that requires more effort and time without prescribing drugs could result in higher smoking cessation rates.

Cigarette smoke damages various parts of the human body, thus causing a wide range of diseases, many of them fatal,<sup>6,7</sup> and the risk of smoking-related diseases such as lung cancer, heart disease, stroke, chronic lung disease, and other cancers, decreases rapidly by quitting smoking.<sup>8,9</sup>

Three pharmacotherapies are licensed by the international smoking cessation guidelines: nicotine replacement therapy, bupropion and varenicline, though behavioral therapy combined with pharmacotherapy increases the smoking quit rate compared with pharmacotherapy alone.<sup>10</sup>

Studies show that smokers have a lower work performance due to time spent smoking, increased fatigue perception and are more absent from work due to smoking-related diseases.<sup>11–13</sup>

Troxel and Volpp<sup>14</sup> recently explored the evidence on the effectiveness of financial incentives for smoking cessation in obtaining smoking cessation at the workplace by examining the research considered in the meta-analysis conducted as part of a Cochrane review<sup>15</sup> of randomized trials of financial incentives for smoking cessation. These data showed that the relationships between the size and structure of incentive payments and smoking cessation rates remain major questions to be considered in future studies.

An Italian smoking cessation intervention at the workplace consisting of eight meetings, promoted by Luxottica in 2006, provided a total cessation of 6 months for 13% of the participants.<sup>16</sup>

Cigarette dependence in the workplace appears to be an important cause of accidents at work. In fact, a study conducted in northern Italy on 2,174 workers who smoked about 20 cigarettes a day, found an increase in the number of occupational injuries compared to places where the majority of workers were nonsmokers.<sup>17</sup>

In order to reduce the risk of developing smoking-related diseases, it is important to provide the correct information within the work context in relation to tobacco consumption and related risks for both smokers and nonsmokers. The so-called basic clinical intervention consists of “very brief counselling” lasting a few minutes aimed at helping the smoker make the decision to reduce or quit smoking accompanied by adequate medical and psychological support.<sup>18</sup> Through the implementation of these therapeutic strategies aimed at the general improvement of workers, it will be possible to increase the number of quitters within the workplace.<sup>19</sup> The use of brief counseling is generally structured in VBA or brief advice. VBA on smoking is a proven 30-second clinical intervention, which identifies smokers, advises them on the best method of quitting, and supports subsequent quit attempts. VBA comprises three elements: ASK, ADVISE, ACT and is designed to be used opportunistically with patients by healthcare professionals in almost all situations with a smoker<sup>4</sup>. The five A's approach (Ask, Advise, Assess, Assist, Arrange) or brief advice is a goal-directed way to more effectively address tobacco use with patients with the goal of meeting tobacco users' needs in terms of readiness to quit. Altogether, the 5 A's may take one to five minutes.<sup>20</sup>

By reducing the number of smokers in the workplace, risks such as: fire, accidents, damage to machines and equipment, interaction between cigarette smoke and other substances, exposure to smoke will be minimized.<sup>21</sup>

The purpose of the study is to observe whether a more structured and time-consuming counseling approach results in an increase in smoking cessation rates. The initial hypothesis was that the MI could double the cessation rates compared to VBA.

This study provided the opportunity to assess the effectiveness of MI and VBA smoking cessation counseling in the workplace with the intention of being able to involve part of the workers in a process of awareness and reduction of tobacco consumption.

## Materials and methods

### Study design

A multi-center, controlled trial for smoking cessation counseling at workplace participants was conducted in Italy and specifically in the most important cities of Sicily and Calabria, where 656 randomized participants received four sessions of group MI or four sessions of VBA for 52 weeks.

The project consisted of four study visits that included counseling plus assessment. Participants received two hours of MI or 30 second of VBA and then they completed the assessment procedures.

The study complied with the ethical principles of the Declaration of Helsinki. All participants provided written informed consent. This study was carried out by a cohort of workers within the framework of occupational health surveillance in accordance with the Italian Law (no. 81/2008).

### Study population

Eligible participants were men and women employed in Italian supermarkets, regular smokers ( $\geq 5$  cigs/day), had smoked cigarettes during the preceding month, had a concentration of Carbon Monoxide (CO) in expired air of  $>10$  ppm, aged between 18 and 65 years. All participants were screened using in-person visits during which medical and psychological history, physical examination, vital signs, and smoking history were obtained.

Supermarket workers were chosen for two reasons, first there was the interest of a company in the sector called Eurospin. This company is highly sensitive to the implementation of health promotion procedures, secondly the supermarket workers represent an extremely heterogeneous group in terms of age, gender, and level of education and therefore potentially comparable to the general population

## Assessments

After the successful completion of the screening procedures, baseline data were collected. The Fagerström Test for Cigarette Dependence (FTCD) was administered.<sup>22</sup> This test is a six-item measure that scores between 0 and 10, with higher scores reflecting greater nicotine dependence.<sup>22</sup> A Nicotine Use Inventory (NUI) was administered at workplace visits in order to assess self-reported smoking or any other use of nicotine or tobacco products since the previous contact as well as the previous 30 days. An exhaled CO measurement along with reports of changes in the motivation to quit was taken at baseline and at each visit in order to confirm the smoking status and the motivation to quit smoking. A CO value of  $\leq 10$  parts per million (ppm) was established to confirm the smoking abstinence status.

### Interventions: study procedures

Participants were randomly assigned to one of the two treatment groups (intensive group MI or VBA counseling). Randomization was completed centrally by using a computer-generated list and sites used an electronic system to assign participants to the treatment.

The interventions were provided in a private location of the supermarket. Participants were asked to quit smoking completely on their target quit date, which was set at eight days following their baseline study visit.

The first group received two hours sessions of an intensive group smoking cessation counseling in a dedicated room outside the workplace. The smoking cessation counseling followed the US Public Health Service guidelines,<sup>20</sup> and was provided, at the baseline visit and at each visit during the following 52 weeks, with two clinical psychologists, experts in MI for smoking cessation.<sup>23</sup>

In MI group, counseling was used to elicit motivation to change by helping clients explore and resolve ambivalence. Emphasis was placed on creating a collaborative relationship and affirming the client's autonomy regarding change. Therapists evoked motivation for change by drawing on client's goals and values rather than by imposing motivation onto the client.<sup>5</sup>

VBA consisted in three steps: Ask: confirm smoking status; Advise: on the harm of smoking,

benefits of quitting or reducing smoking; Act: for participants who do not want to quit smoking, researchers advised that the offer of support remains in case they wish to take it up again; for participants who wanted to quit smoking, the researchers suggested booking a visit to the local smoking cessation center;<sup>4</sup> all participants received a smoking information pamphlet.

The second group received VBA<sup>24</sup> at the baseline visit and at each visit during the following 52 weeks. The VBA was provided by two physicians trained in VBA intervention for smoking cessation. All participants attended a total of four visits: baseline, week 12, week 24, and week 52.

### Study endpoints

*Primary endpoint:* success rates at week 24 in the MI group versus VBA group. As recommended by the Russell standard<sup>25</sup> success rates were defined as the Continuous Quit Rate (CQR) since the last visit. Subjects were classified as responders if they were able to abstain from cigarette smoking during this period with end-expiratory exhaled CO measurements  $\leq 10$  ppm. CQR was obtained through reports of cigarette use by means of the NUI confirmed by a measurement of an expiratory exhaled CO concentration of  $\leq 10$  ppm at week 24.

*Secondary endpoint:* success rates at week 12 in the MI group versus VBA group. Success rates were defined as CQR for weeks 9–12 of treatment. Subjects were classified as quitters if they were able to completely abstain from cigarette smoking (not even a puff) from the previous month (from week 9 to week 12) with CO  $\leq 10$  ppm. This measure was obtained through reports of cigarette use by means of the NUI during the last four weeks confirmed by a measurement of an end-expiratory exhaled CO concentration that was  $\leq 10$  ppm at each study visit.

Success rates at week 52 in the MI counseling group versus VBA group. Success rates were defined as the CQR throughout the last two visits (week: 12 and 24). Subjects were classified as quitters if they were able to abstain from cigarette smoking during this period with CO  $\leq 10$  ppm. This measure was obtained through reports of cigarette use by means of the NUI during the last

two study visits (week: 12 and 24) confirmed by a measurement of an CO  $\leq 10$  ppm at each study visit.

Point-prevalence abstinence was defined as self-reported abstinence in the past 30 days (no-smoking traditional cigarettes, not even a puff), CO of 10 ppm or less.

Reduction in daily cigarette consumption by 50% or higher was also assessed.

### Statistical analysis

A sample size of 328 subjects per group (656 participants in total) was chosen to have 80% power to detect a difference between MI with VBA. The Kolmogorov-Smirnov test checked normality. Outcomes were described as the mean and standard deviation or as frequency and percentage. T-Test and Chi-square were used correspondingly to evaluate the means and frequencies.

The efficacy of the treatment was carried out by Chi-square, between the two groups and at weeks 12, 24, and 52 comparing: continuous abstinence rates, 30 days point-prevalence,  $\geq 50\%$  reduction rates. Instead, FTCD and VAS scores were compared by Spearman's correlation coefficient.

Test used for the Odd Ratio is the Maximum-Likelihood Ratio Chi-Square.

Statistical significance was set at  $p < .05$  (two-tailed). Statistical analysis was performed by GraphPad Prims 8 (California, USA).

### Results

The flow of participants through the study appears in [Figure 1](#). Of the 813 volunteers screened, 656 (80.6%) were enrolled and randomized to one of the two groups: intensive motivational interview smoking cessation counseling group ( $n = 328$ ) or VBA group ( $n = 328$ ). Screen failures were due to participants who declined to participate ( $n = 157$  participants). The remaining 656 volunteers were included in the final analyses.

Overall study completion rates at week 52 were 78.7% (258 participants) in the intensive motivational interview smoking cessation counseling group and 70.7% (232 participants) in the

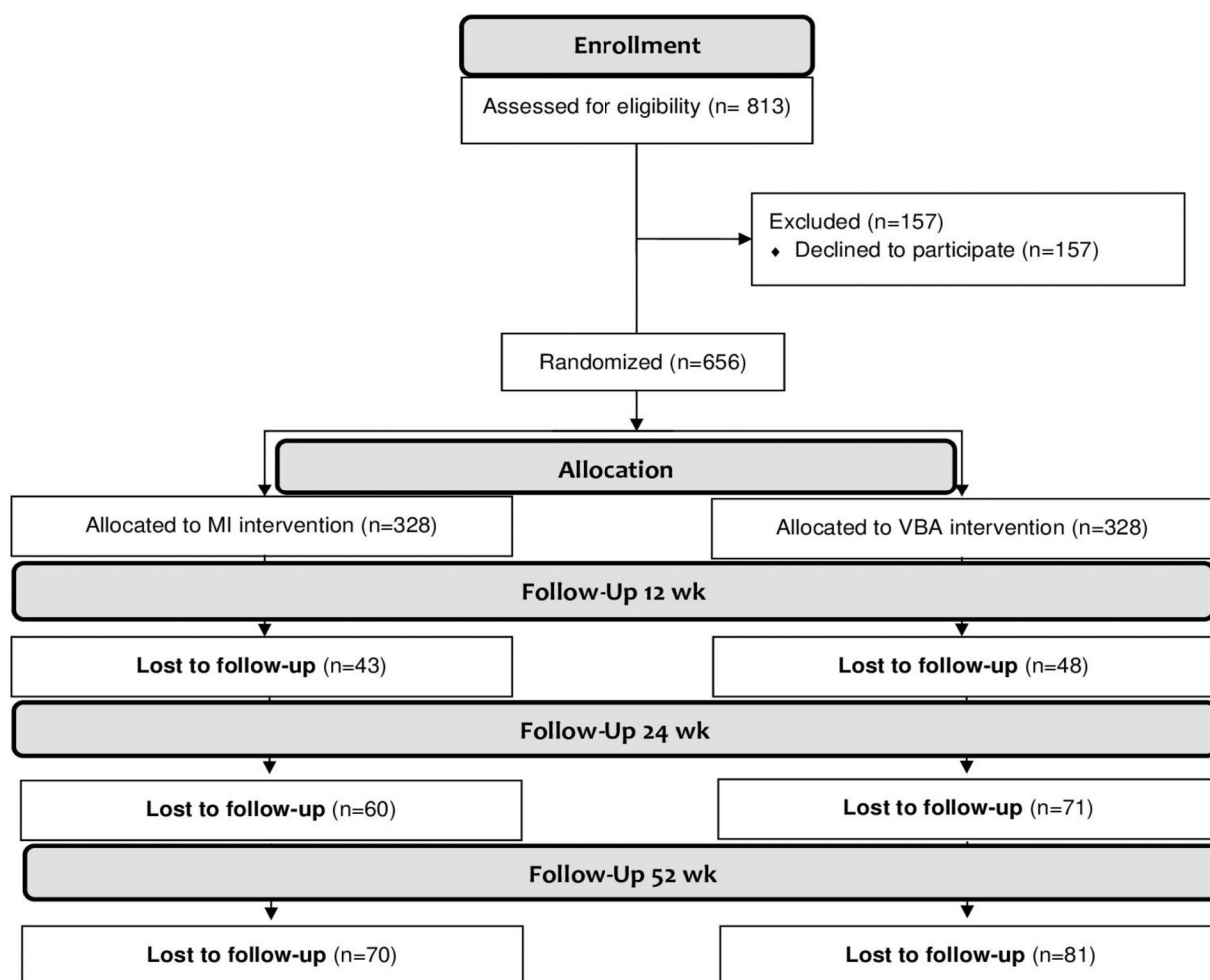


**Figure 1.** Flow-chart of participant disposition.

VBA group. More participants in the VBA group failed to complete the study procedures. There were no differences in socio-demographic variables or baseline characteristics between the two groups. The demographic and smoking history characteristics of all randomized participants are shown in Table 1. On average, participants were young adults, predominantly men, who had smoked about 16 cigarettes daily for an FTCD score of around 4.5 indicating a moderated level of cigarette dependence.

### **Efficacy**

The primary, co-primary, and secondary continuous smoking abstinence outcomes at the end of the treatment and during the follow-up appear in Figure 2. The intensive motivational interview smoking cessation counseling group had higher

continuous abstinence rates than the VBA group at all time points. The CO-confirmed CQR for the intensive motivational interview smoking cessation counseling group and VBA group, during the treatment phase, are shown in Figure 2. The CQR was higher for the intensive motivational interview smoking cessation counseling group than the VBA group during weeks 9–12 (17.5% vs. 3.6%;  $p \leq .001$ ), weeks 9–24 (13.4% vs. 3.4%;  $p \leq .001$ ) and weeks 9–52 (10.3% vs. 3.1%;  $p \leq .001$ ).

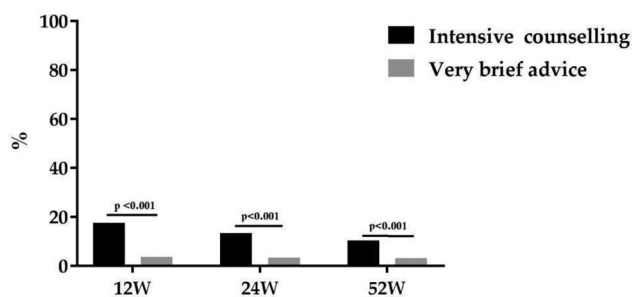
Unexpectedly, 30 days point-prevalence smoking abstinence increased over the course of the study (Figure 3) for the intensive motivational interview smoking cessation counseling group, from the 25.9% at week 24 to the 35.4% at week 52. The difference in 30 days point-prevalence abstinence remained significant at all follow-ups through the end of the 12-week session and 52-week follow-up ( $p \leq .001$ ).

**Table 1.** Demographic and baseline characteristics of participants.

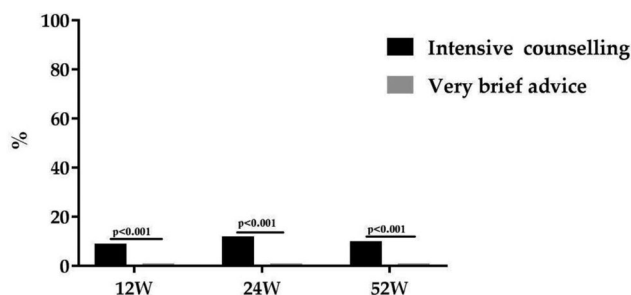
| Variable                                                     | Intensive group smoking cessation counseling | VBA            | <i>p</i> Value |
|--------------------------------------------------------------|----------------------------------------------|----------------|----------------|
| <i>Gender n (%)</i>                                          |                                              |                |                |
| Male                                                         | 207 (63%)                                    | 203 (62%)      | n.s.*          |
| Female                                                       | 121 (37%)                                    | 125 (38%)      | n.s.*          |
| Age Mean $\pm$ SD <sup>§</sup>                               | 33.5 $\pm$ 7.5                               | 34.3 $\pm$ 8.2 | n.s.*          |
| <i>Education n (%)</i>                                       |                                              |                |                |
| Primary school                                               | 2 (0.6%)                                     | 4 (1.2%)       | n.s.*          |
| Secondary school                                             | 86 (26.2%)                                   | 84 (25.6%)     | n.s.*          |
| Diploma                                                      | 222 (67.7%)                                  | 217 (66.2%)    | n.s.*          |
| University                                                   | 18 (5.5%)                                    | 23 (7%)        | n.s.*          |
| <i>Marital Status n (%)</i>                                  |                                              |                |                |
| Single                                                       | 169 (51.5%)                                  | 167 (50.9%)    | n.s.*          |
| Married                                                      | 150 (45.7%)                                  | 151 (46.0%)    | n.s.*          |
| Divorced                                                     | 9 (2.7%)                                     | 10 (3.1%)      | n.s.*          |
| <i>Sons n (%)</i>                                            |                                              |                |                |
| Yes                                                          | 152 (46.3%)                                  | 156 (47.6%)    | n.s.*          |
| No                                                           | 176 (53.7%)                                  | 172 (52.4%)    | n.s.*          |
| <i>Smoking Behavior Mean <math>\pm</math> SD<sup>§</sup></i> |                                              |                |                |
| Current smoking rate (cigs/day)                              | 16.2 $\pm$ 8.1                               | 16.5 $\pm$ 8.2 | n.s.*          |
| Baseline CO (ppm)                                            | 15.3 $\pm$ 6.2                               | 15.9 $\pm$ 6.4 | n.s.*          |
| FTCD total score                                             | 4.4 $\pm$ 2.5                                | 4.6 $\pm$ 2.2  | n.s.*          |
| Motivation to quit assessed by VAS                           | 6.1 $\pm$ 3.1                                | 6.4 $\pm$ 3.4  | n.s.*          |

n.s.\*=not significant. § = Standard Deviation.

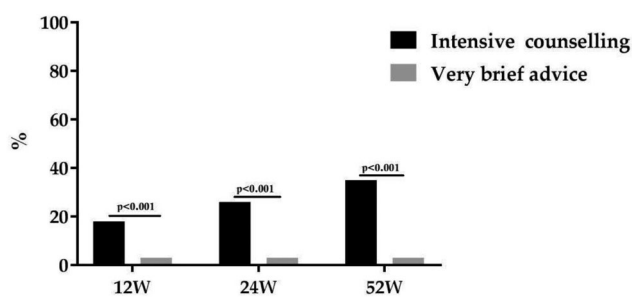
### Continuous Abstinence Rates

**Figure 2.** CO-confirmed CQR results in intensive counselling (MI) and VBA group.

### $\geq 50\%$ Reduction Rates

**Figure 4.** Reduction rates ( $\geq 50\%$ ) in intensive counselling (MI) and VBA group.

### 30 Days Point Prevalence

**Figure 3.** Results of 30 days point-prevalence smoking abstinence in intensive counselling (MI) and VBA group.

Sustained smoking reduction in daily cigarette consumption by 50% or more was higher for the intensive motivational interview smoking cessation counseling group than the VBA group at week 12 (8.5% vs. 1.5%;  $p \leq .001$ ), at week 24 (12.5% vs. 1.2%;  $p \leq .001$ ), and at week 52 (10.9% vs. 1.2%;  $p \leq .001$ ). A sustained 50% reduction in

the number of cig/day at week 12, 24, and 52 from baseline (reducers) was defined as a sustained self-reported 50% reduction in the number of cig/day compared to baseline for the 30 days period prior to weeks 12, 24, and 52 of study visits (CO levels were measured to verify smoking status and confirm a reduction compared to baseline). Smoking reduction data from baseline visit at weeks 12, 24, and 52 are shown in Figure 4.

Reduction in cigarette dependence, as assessed by FTCD, was significantly lower for the intensive motivational interview smoking cessation counseling group than the VBA group. Smokers' FTCD reduction data from baseline visits at weeks 12, 24, and 52 are shown in Figure 5.

Increasing in motivation to quit as assessed by a Visual Analogic Scale (VAS) was significantly higher for the intensive motivational interview smoking cessation counseling group than the

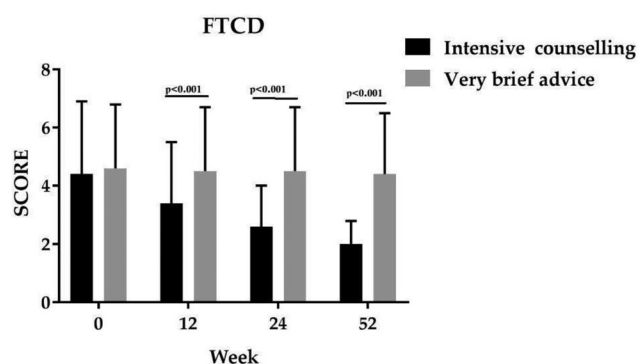


**Figure 5.** Smokers FTCD data in intensive counseling (MI) and VBA group.

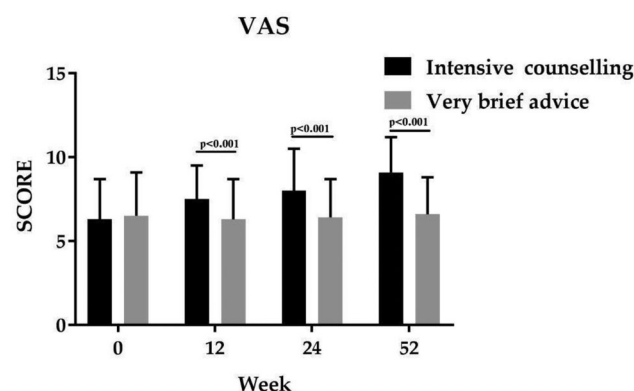


**Figure 6.** Smokers' motivation to quit data in intensive counseling (MI) and VBA group.

VBA group. Smokers' motivation to quit data from baseline visits at weeks 12, 24, and 52 are shown in Figure 6.

Overall odd ratio in favor to intensive counseling is 2.34 with an interval of confidence at 95% (1.87–2.64).

## Discussion

This pragmatic and randomized controlled smoking cessation study, conducted within a work environment, demonstrated that the use of the motivational interview with the smoking cessation counseling group is an approach that supported effective smoking cessation in the workplace. The motivational smoking cessation counseling group tripled the tobacco CQR after 12 weeks of treatment compared to the VBA group. The CQR was higher for motivational interview smoking cessation counseling group than the VBA group during weeks 9–12 (17.5%

vs. 3.6%) weeks 9–24 (13.4% vs. 3.4%), and weeks 9–52 (10.3% vs. 3.1%).

The study results are comparable to those of previous trials that had similar protocols<sup>26,27</sup> but lower than those of another recent study that used financial incentives in order to obtain higher cessation rates among their participants.<sup>28</sup>

There is currently little evidence of intensive counseling versus very brief counseling for smoking cessation in the workplace, therefore this study can be considered the first large randomized controlled trial on the effectiveness of motivational interview counseling group and on smoking cessation in the workplace. However, there are discrepancies between these results and those in the literature showing how Brief Advice, Cognitive Behavioral Therapy (CBT) or Motivational interventions are widely comparable in term of efficacy.<sup>29</sup> However, the quit rate of 3% in Brief Advice, which is lower than other studies conducted on volunteers interested in smoking cessation, can be explained by the use of its shorter version, that is the VBA.

In the motivational interview intensive counseling group of our study, the point-prevalence tobacco cigarettes abstinence rate and the motivation to quit increased during the motivational treatment, while the cigarettes dependence decreased. This mechanism could be related to the peer influence and motivational effects deriving from the positive role model associated to the observation of other colleagues who quit smoking thanks to the smoking cessation intervention<sup>30–36</sup> and to the spontaneous use of Reduced Risk Products (RRP) such as electronic cigarettes and heated tobacco products, which are popular and emerging tools for smoking cessation and tobacco harm reduction that could have influenced the study results. In fact, 130 participants of the intensive motivational interview smoking cessation counseling group (39%) versus 12 participants of the VBA group (3.6%) used RRP during their quit attempts and none of the participants used smoking cessation medication such as varenicline, bupropion or nicotine replacement therapy for their quit attempts.

No incentive was provided along the study for both groups. The low number of drop outs can be associated with the setting within which the

study was carried out, as being in the same workplace has probably affected a process of greater involvement and has increased the motivation to attend the smoking cessation group sessions.

This study has also limitations. It was conducted in Italian supermarkets and therefore the characteristics of other workplaces were not considered. Only volunteers who were potentially motivated to quit were included among the participants and other aspects were able to influence smoking cessation rates such as previous quit attempts, but unfortunately this information was not taken at the baseline visit; last but not least, the findings reported by Italian urban residents may not be valid for other population samples, as they must take into account specific socio-cultural conditions (e.g., the Italian “coffee puff-break” is still considered the norm despite the antismoking legislation in Italy). Further trials are warranted to assess the benefits of this approach. Moreover, it would be useful to assess the effects of an extended motivational treatment period in an effort to reduce the relapse rate after successful smoking cessation at the end of the conventional 52-week intervention period.

## Conclusions

The promising quit rate showed at weeks 12 (17.5%), 24 (13.4%), and 52 (10.3%) for the smoking cessation counseling group reinforce the idea that it is important to promote dedicated smoking cessation treatments in the workplace. Promoting the well-being of physical and mental health in the workplace is a challenge to improve the health empowerment. It is possible to promote the well-being of a population that would generally have difficulty going to a smoking cessation clinic or any other kind of clinic for reasons related to their young age or working hours. Promoting well-being within a workplace could reverse the negative process that began when, during adolescence, smokers started to smoke because one of their peers smoked too. In the same way, if one of their colleagues quit smoking, and then another and another, and this happens with extreme naturalness without medicalizations and hospital visits, it could be easy to feel the pro-health peer-pressure that motivated them to

attempt to quit. This mechanism could easily be generalized to other lifestyles that can be directly addressed in the workplace such as alcohol-related disorders, eating disorders, distress, anxiety or the emerging digital addiction.

## Disclosure statement

No potential conflict of interest was reported by the author(s).

## Author contributions

Conceptualization, P.C. and V.R.; methodology, P.C. and V.R.; software, C.L.; validation, P.C., M.M. and V.R.; formal analysis, C.L.; investigation, P.C.; resources, D.F.; data curation, M.M.; writing – original draft preparation, P.C.; writing – review and editing, M.M.; visualization, V.R.; supervision, R.P.; project administration, D.F.

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