

## Research Article

## Open Access

Antigona Carmen Trofor, Milena Adina Man\*, Corina Marginean, Filipeanu Dumitru, Letitia Trofor

# Smoking cessation for free: outcomes of a study of three Romanian clinics

DOI 10.1515/med-2016-0098

received October 3, 2016; accepted December 12, 2016

**Abstract:** In 2007, Romania implemented a national program for smoking cessation, providing medication and counseling, entirely for free. The present study focuses on the results of the program among participating smokers treated in three smoking cessation centers from three main cities of Romania: Iasi, Targu Mures and Cluj.

Telephone interviews of 832 subjects from three databases of the Romanian cessation clinics of Iasi, Cluj and Targu Mures cities were conducted. These interviews were based on a standard Romanian guideline follow-up questionnaire.

At 3 months follow up, abstinence was quite high (53.4%); at 12 months post quit date the study found 18.6% still abstinent subjects. More severely addicted smokers have quit with varenicline and the most difficult category of patients was represented by heavy smokers with respiratory co-morbidities. 61.5% of smokers and 97.2% of non-smokers were willing to receive relapse prevention counseling. Many subjects achieved a long duration partial abstinence (154 days  $\pm$  180 SD abstinence days).

This is the first study in Romanian smoking cessation centers to analyze the long term impact of fully reimbursed smoking cessation, covering three months phar-

macotherapy and counseling. Providing smoking cessation for free had a positive long term impact on program participants.

**Keywords:** Smoking cessation; Abstinence; Long term follow up; Addicted smokers

## 1 Introduction

There is enough available evidence to advocate for the higher effectiveness of free of charge smoking cessation. For example, both the groups of Doescher et al. and Kaper et al. demonstrated over 10 years ago a beneficial impact of medical insurance contributions on using medication to stop tobacco use and on smoking cessation success rates [1,2]. Harris and collaborators showed that medical systems completely covering the costs for tobacco dependence treatment ensure increased self-reported tobacco abstinence rate and duration, with a relatively low price, as compared to the partial or absent benefits of non-compensation [3].

Several studies have shown that different factors such as the type of cessation treatment as well as individual characteristics (age, gender, socio-economical level, length of smoking exposure, nicotine addiction) may influence the smoking cessation process both in terms of uptake and of short or long term abstinence rates [4, 5, 6]. Co-morbidities have been found to impact the cessation process and sometimes to cause discontinuation of the cessation treatment [7].

In 2007, when smoking prevalence in the general Romanian population was 30% [6], Romania implemented a national program (“Stop Smoking”), providing medication and counselling, entirely for free. At that time, the initiative was very welcomed by smokers, specialists in the field and policy makers, as pharmacological treatment and qualified aid to quit smoking were practically unavailable in a standardized manner and many low income individuals could not afford the treatment costs.

\*Corresponding author: **Milena Adina Man**, University of Medicine and Pharmacy “Iuliu Hatieganu” Cluj, Romania, Tel. +40-264-597453; Fax: +40-264-592933, E-mail: manmilena50@yahoo.com

**Antigona Carmen Trofor, Letitia Trofor**, University of Medicine and Pharmacy “Grigore T. Popa” Iasi, Romania

**Corina Marginean**, County Clinical Hospital Mures, Clinic of Pulmonary Diseases Tg. Mures, Romania

**Filipeanu Dumitru**, Technical University “Gh.Asachi” Iasi, Romania  
University of Medicine and Pharmacy “Grigore T. Popa” Iasi, Romania

Patients were directed to the tobacco treatment centers by a free phone advice line, being offered pharmacotherapy (varenicline, bupropion or nicotine patch) and 4-6 counseling sessions, for three months.

However, even if designed as a national and free of charge intervention, over the next six years, numerous difficulties were encountered such as high call volume the need for more full-time qualified personnel/auxiliary staff, insufficient centers available in small cities and rural areas, administrative deficiencies in providing cessation medication supplies and finally, progressively decreasing governmental funding. Program coordinators struggled annually to maintain the program, so by continuing efforts and introducing patients' co-payment, they succeeded program survival until 2014, by keeping governmental financial support at an acceptable level.

The present study focused on the results of the program among participating smokers treated in three smoking cessation centers from three big cities of Romania-Iasi, Targu Mures and Cluj. It had three objectives. First, to report the smoking cessation rate at the end of the program at 3 months after the enrolment in the program (T1) for different types of treatment. Second, to investigate the individual factors associated with smoking cessation among smokers who received different types of treatment. Third, the abstinence rate at 12 months after the quitting date (T2) was also assessed, giving special attention to the changes of the smoking status from T1 to T2.

## 2 Methods

### 2.1 Sampling procedure

The study is part of a national program which received the approval and funding of the Romanian Ministry of Health. It was implemented in smoking cessation centers from three hospitals; the patients who were enrolled were coming on a voluntary basis to the hospitals in order to receive smoking cessation support and were agreeing that they accept the medical procedures offered by the smoking cessation centers accessed by them, in respect to the national program protocol participation.

Data collection was performed in two phases. First, an analysis of the databases that included smokers who participated in the "Stop smoking" program between 2007 and 2010 in three tobacco treatment centers in Romania (Clinic of Pulmonary Diseases Iasi, Clinic of Pulmonary Diseases Cluj and Clinic of Pulmonary Diseases Targu Mures) was conducted. These databases contained infor-

mation about demographics, medical history, smoking characteristics, abstinence rate at the end of the program (3 months after the enrolment of the participants) and cessation therapy and program compliance. Second, all program participants were contacted by telephone for a long term telephone follow-up (LTFU) at 12 months after the quitting date (as recorded in patients' files) in order to assess long term abstinence rate. Follow-up was conducted as a short telephone interview done by volunteer pulmonologists or psychiatrists in training. It used a standard follow-up questionnaire, based on recommendations in the Romanian Smoking Cessation Guideline (GREFA) [8,9], which investigated present smoking status, abstinence duration, difficulties to staying abstinent and willingness to receive relapse prevention counseling.

### 2.2 Statistical analysis

The prevalence of several individual characteristics and smoking and cessation profiles at 3 months and 12 months follow-up were assessed.

Pearson bivariate correlation analyses were used to highlight interrelations between abstinence rate at three months and several individual and smoking related characteristics such as: gender, presence of respiratory co-morbidities, presence of cardiovascular co-morbidities, number of cigarette packs/years, nicotine dependence score, quit attempts, and the presence of severe withdrawal syndrome. The Pearson bivariate correlation analyses were performed separately for each treatment regimen (nicotine patch, bupropion, or varenicline).

Data were analyzed using the SPSS 17 statistical program (SPSS Inc.). A statistically significant threshold was considered at  $p < 0.05$ .

## 3 Results

### 3.1 Sample characteristics and abstinence rate at three months follow-up

The study included 832 smokers who participated in the smoking cessation program. The overall abstinence rate at three months follow-up was 53.4%, while 28.6% were still smokers and 18% were registered as unrated.

The sample characteristics and their smoking profile by treatment regimen are described in Table 1.

**Table 1:** Individual characteristics, smoking and cessation profile, by treatment regimen at three months follow-up

Variable	Nicotine patch	Bupropion	Varenicline
Number of patients	130	489	213
Age(years) (mean)	43.65±12.2SD	43.09±12.5SD	44.9±12.45SD
Female gender (%)	42.3	48.3	36.2
Cigarettes/day (average) in the last 12 months	23.91±11.1SD	20.14±7.8SD	23.4±7.9SD
Nicotine dependence score (≥7)(%)	42.1	29.9	55.9
Packs-years (average)	24.7±16.6SD	27.2±11.01SD	21.6±10.12SD
Co-morbidities (n)	65	206	57
≥1quit attempt (%)	23.1	13.3	51.2
Withdrawal syndrome (%)	14.6	27.4	17.4
Exhaled air carbon monoxide level (ppm)-Initial status (average)	14.9±4.2SD	16.08±4.7SD	15.33±2.5SD
Exhaled air carbon monoxide level (ppm)-Final status (average)	0.12±0.7SD	0.04±0.2SD	0.24±0.7SD
End of treatment abstinence (%)	10.8	15.5	30.5

### 3.2 Factors associated with smoking cessation at three months

The results of Pearson bivariate correlation analyses show that among subjects treated with nicotine patch, no statistical significant correlations were found with individual and smoking characteristics.

Among subjects receiving bupropion, fewer quitters were found among those with respiratory co-morbidities ( $r=-0.76$ ,  $p=0.02$ ), with a high nicotine dependence score ( $r=-0.82$ ,  $p=0.019$ ) and with  $\geq 2$  quit attempts ( $r=-0.13$ ,  $p\leq 0.001$ ) or with a severe withdrawal syndrome ( $r=-0.29$ ,  $p\leq 0.001$ ), respectively.

In smokers treated with varenicline, there were statistically significant increased quit rates in more severely addicted smokers ( $r=0.23$ ,  $p\leq 0.001$ ), and in patients with  $\geq 2$  quit attempts ( $r=0.30$ ,  $p\leq 0.001$ ). Also, significantly more women than men have stopped smoking with varenicline ( $r=0.113$ ,  $p=0.001$ ). On the contrary, significantly fewer smokers with respiratory disorders ( $r=-0.10$ ,  $p=0.003$ ) and fewer heavy smokers ( $r=-0.23$ ,  $p\leq 0.001$ ) became abstinent under varenicline.

### 3.3 Abstinence rate at 12 months follow-up

The results show that at 12 months post quit date, 39.3% of the participants were still smokers, 18.6% were still abstinent and 42.1% were unrated patients. Even if at 3 months follow-up the smoking status could not be rated (no exhaled CO validation) in 18% of subjects, at 12 months follow-up 46.7% of these patients could be contacted and

it was found that 40% of the people from the unrated group were continuing smokers, while 6.7% declared themselves non-smokers. A further 53.3% subjects could not be contacted and rated at 12 months follow-up.

Among patients evaluated at 3 months follow-up as non-smokers, 35.4% declared themselves as relapsing smokers, 28.6% declared themselves as no-smokers, while 36% could not be rated at 12 months follow-up. Among smokers at 3 months follow-up, they had the following status at 12 months: 46.2% continued to be smokers, 7.6% were no-smokers, while 46.2% could not be rated.

Table 2 provides an overall summary of the characteristics and smoking status of the participants at 12 months follow-up.

## 4 Discussions

Tobacco use is detrimental to health and all health professionals have the duty to intervene and initiate tobacco cessation [10]. Successful pharmacotherapy and counseling of patients to stop smoking is the most cost-efficient approach to prevent death and disease due to tobacco smoking. Discount or free of charge cessation medication (compensated in advance) has been proved to increase both the number of medical prescriptions and the abstinence rates [11]. It seems when compensated, patients have a higher probability to receive treatment and to try to quit and to refrain from smoking [2]. It is in the interest of insurance companies, medical services, governmental departments and pharmaceutical companies to collabo-

**Table 2:** Characteristics and smoking status at 12 months follow-up

Characteristics	Smokers	Non-smokers	Unrated
Number of patients	327	155	350
Age *(years) (mean)	42.09±11.8SD	45.5±11.48SD	44.07±13.3SD
Female gender (%)	38.3	16.6	45.1
Cigarettes/day (average) in the last 12 months*	23.6±9.03SD	22.6±7.3SD	21.6±9.3SD
Nicotine dependence score (≥7)*(%)	41.4	53.4	28.7
Packs-years *(average)	23.8±15.41SD	27.2±16.3SD	27.1±17.9SD
Co-morbidities* (n)	117	51	160
≥1quit attempt *(%)	26.3	38.1	17.1
Withdrawal syndrome history *(%)	19	24.5	25.7
Expired air carbon monoxide level* (ppm) - Initial status (average)	15.82±3.9SD	15.7±4.2SD	15.8±4.8SD
Expired air carbon monoxide level ** (ppm) - Final status (average)	0.14±0.5SD	0.06±0.2SD	0.09±0.5SD
End of treatment abstinence**(%)	33.6	11.6	31.4
Maximum abstinence duration (mean) evaluated at 12 months follow up	154 days ±180.1SD	0	0
Willingness for relapse prevention counselling (%) evaluated at 12 months follow up	61.5	97.2	0

(\* = at enrollment, \*\* = at 3 months after enrollment)

rate, in order to ensure compensation of tobacco dependence interventions and to inform smokers about the existence of such a strategy [10].

Smoking cessation expertise is rather recent in Romania, as tobacco treatment units were created in 2000, at first only in 3 big cities (Bucuresti, Iasi, Timisoara). Until 2007, free counseling was offered by trained specialists, but the only pharmacotherapy available was bupropion and its cost had to be entirely supported by the patient. Because of this, very little data about smoking cessation outcomes in this period are available. However, due to lack of any medication compensation and to previous low accessibility of centers, such data refer mainly to bupropion or counseling cessation results in small groups of patients and other data come from European projects developed by Romanian NGO “Aer Pur” [12]. For example, in the cessation centre of the Clinic of Pulmonary Diseases Iasi, bupropion abstinence rate was 28%, at 6 months post quit date [13].

Prior to 2007, most Romanian studies were based on results from reimbursed smoking cessation centers; despite this, there is a small amount of Romanian literature in this field. In the Clinic of Pulmonary Diseases Iasi, such end of treatment abstinence rate ranged from 38.3% to 50.7% [14].

The study presented here was performed in three smoking cessation centers in Romania. It shows that the overall abstinence rate at three months was 53.4 % and this was due mainly to the fact that pharmacotherapy and counseling have been offered for free.

Despite such fruitful abstinence outcomes at three months (T1), at 12 months follow up (T2), an abstinence rate of only 18.6% was found. Post-treatment abstinence should be a strong predictor for abstinence at the 12 months follow-up. One possible explanation of the observed versus estimated difference between the T1 and T2 abstinence rates is that program funding covered only 3 months treatment phase.

Looking for comparison with similar data in the field, a wide range of results can be found, varying from 12 months abstinence of 14% in a Swedish study [15] to 34% in a study performed in Australia. [16]. As well, in an intensive 8 days residential smoking cessation program, a significantly higher 6 months abstinence rate for residential patients compared to outpatients (52% vs. 27%) was found [17].

Abstinence rate at three months follow up by treatment regimen appears highest in the Varenicline group. Nevertheless, as due to different market costs of cessation therapies

(varenicline cost was three times higher than both costs of nicotine patch and of bupropion), and to the program regulatory request that all 3 medications had to fit the same budget equal shares; thus, unequal amounts of varenicline, bupropion and nicotine gum were provided to the centers. This represents a weak point of the program, but without jeopardizing scientific research criteria for smoking cessation validation, as they are described by literature in the field. [18]

Also, the individual characteristics described a random cessation pattern: more women, more heavy smokers, and more frequent previous withdrawal syndrome were described among subjects in the Bupropion group, while the highest nicotine dependence scores and most numerous cases of previous quit failures were seen in the Varenicline group. In the nicotine patch group, there were 50% of subjects with co-morbidities, but no other specific features. There was a similar age average between the treatment regimens.

Special emphasis should be placed on the positive impact generated by the reimbursed program, as was observed during the telephone investigation. This was suggested by the great number of respondents at the 12 months follow-up, even in the still smoker and unrated groups and by considerable willingness for relapse prevention counseling, in the majority of interviewed participants. As well, even if relapsed to smoking, many subjects achieved a long duration of partial abstinence (154 days  $\pm$  180 SD abstinence days), as revealed by the “longest stop smoking period” at 12 months follow-up.

There are multiple unexplored facets of the problem under discussion. For instance one could be validated at three months follow-up as non-smoker, but could relapse to smoking until long term evaluation. As 12 months follow-up was conducted by telephone interview, there was no possibility to objectively check self declared smoking status by exhaled air CO validation. In return, some smokers who did not manage to quit by the end of the 3 months treatment program were found to be non-smokers at 12 months. Thus, there is a possibility that, by 12 months, patients have succeeded in stopping smoking by their own will, based on program's long term impact. We may name this an educational “post-effect”, as besides free medication, they also received several counseling sessions during clinic visits.

## 5 Conclusions

This is the first study in our smoking cessation centers to analyze long term impact of fully reimbursed smoking cessation, covering three months pharmacotherapy and counseling. By analyzing data coming from a smoking cessation database in three Romanian centers from respiratory disease clinics of the medicine universities of Iasi, Cluj and Targu Mures, we have found 18.6% abstinent among respondents to a telephone contact visit, 12 months post quit date. Providing smoking cessation for free had a positive long term impact on program participants, even if there was no intermediary contact between the 3 months and the 12 months follow-up. Thus, for the majority of respondents declared willing to receive relapse prevention counseling, a total of 154 days  $\pm$  180 SD abstinence days was recorded among still smokers and some of the smokers at three months follow-up continued to quit even after program's end, probably due to an educational “post-effect” of the program.

Further research could be useful for cessation practitioners worldwide and for designing a standardized reimbursement approach to ease implementation of such programs at national level.

**Conflict of interest:** The authors have no conflict of interest.

## References

- [1] Doescher M.P., Whinston M.A., Gop A., Cummings D., Huntington J., Saver B.G., Pilot study of enhanced tobacco cessation services coverage for low income smokers. *Nicotine Tob. Res.*, 2002, 4, suppl.1, S 19- 24
- [2] Kaper J, Wagena E.J., Willemsen M.C., van Schayck C.P., Reimbursement for smoking cessation treatment may double the abstinence rate: results of a randomized trial. *Addiction* 2005; 100(7), 1012-1020
- [3] Harris J.R., Schauffler H.H., Milstein A., Powers P., Hopkins D.P., Expanding health insurance coverage for smoking cessation treatments: experience of the Pacific Business Group on Health. *Am. J. Health Promot.* 2001, 15(5), 350-356
- [4] Khati I., Menvielle G., Chollet A., Younès N., Metadieu B., Melchior M., What distinguishes successful from unsuccessful tobacco smoking cessation? Data from a study of young adults (TEMPO). *Prev. Med. Rep.* 2015, 2, 679-685
- [5] Stead L.F., Koilpillai P., Fanshawe T.R., Lancaster T., Combined pharmacotherapy and behavioural interventions for smoking cessation. *Cochrane Database Syst. Rev.*, 2016, Mar 24, 3:CD008286, doi:10.1002/14651858. CD008286.pub3



- [6] Trofor A., Mihaltan F., Mihaicuta S., Lotrean L., Smoking cessation and prevention for young people- Romanian expertise, *Pneumologia*, 2009, 58(1), 72-78
- [7] Trofor A., Miron R., Ciobanu M., Barnea E., Esanu V., Efficacy and safety of Varenicline in a smokers population with high prevalence of co-morbidities, presented at the XX-th ERS Congress in Barcelona, Spain, 20 Sep 2010, E-communication session-E2060
- [8] Trofor A., Mihaltan F., Mihaicuta S. Pop M., Todea D., Ghid de renuntare la fumat si asistenta de specialitate a fumatorului (GREFA), 2008, 1-st Ed., Tehnopres Publishing House, Iasi, 2008
- [9] Trofor A., Mihaltan F., Mihaicuta S. Pop M., Todea D., Notiuni elementare de tabacologie- supliment al ghidului GREFA, 1-st Ed., Tehnopres Publishing House, Iasi, 2008
- [10] Behrakis P., Bilir N., Clancy L., Dautzenberg B., Demin A., Giljam H., Trofor A., European Smoking Cessation Guidelines of ENSP, ISBN: 978-2-9600708-1-1, www.ensp.org, Brussels, 2012
- [11] Hughes J.R., Wadland W.C., Fenwick J.W., Lewis J., Bickel W.K., Effect of cost on the self administration and efficacy of nicotine gum: a preliminary study, *Prev. Med.*, 1991, 20 (4), 486-496
- [12] Trofor A., Mihaicuta S., Man M.A., Miron R., Esanu V., Trofor L., Approaching tobacco dependence in youngsters: impact of an interactive smoking cessation program in a population of Romanian adolescents. *J. Clin. Exp. Invest.*, 2010, 1(3), 150-155
- [13] Trofor A., Mihaescu T., Esanu V., Grigoras C., Smoking cessation with bupropion-is it succesful enough? presented at the XV-th ERS Annual Congress Copenhagen, Denmark, 2005, poster 247s
- [14] Trofor A., Esanu V., Sandu M., Miron R., Mihaescu T., Bordeianu I., Does reimbursement increase smoking cessation rate? – Outcomes of “stop smoking” national program in a smoking cessation center, presented at the XVIII-th ERS Congress in Berlin, Germany, 5 Oct 2008, E-communication session - E433
- [15] Nohler E., Öhrvik J., Tegelberg A., Tillgren P., Helgason A.R., Long-term follow-up of a high-and a low-intensity smoking cessation intervention in a dental setting – a randomized trial, *BMC Public Health*, 2013, 13, 592-603
- [16] Richmond L.R., Makinson J.R., Kehoe L., Giugni A., Webster I.W., One year evaluation of three smoking cessation interventions administered by general practitioners, *Addictive Behaviors*, 2003,18, 187-193
- [17] Hays J.T., Croghan I.T., Schroeder D.R., Burke V.R. Ebbert J.O., McFadden D.D., Hurt R.D., Residential Treatment Compared With Outpatient Treatment for Tobacco Use and Dependence, *Mayo Clinic Proc.*, 2011, 86 (3), 203-209
- [18] Hughes J.R., Keely J.P., Niaura R.S., Ossip-Klein D.J., Richmond R.L., Swan G.E., Measures of Abstinence in clinical trials: issues and recommendations, *Nicotine Tob. Res.* 2003, 5(1), 13-25