

Smoking cessation after 12 months with multi-component therapy

Abstinencia a los 12 meses de un programa multicomponente para dejar de fumar

ANTÒNIA RAICH*,****; JOSE MARIA MARTÍNEZ-SÁNCHEZ**,***; EMILI MARQUILLES*; LÍDIA RUBIO*; MARCELA FU**; ESTEVE FERNÁNDEZ**,****

*Unidad de Tabaquismo (Smoking Cessation Unit), Althaia Xarxa Assistencial Universitària de Manresa FP. **Unidad de Control del Tabaquismo (Smoking Control Unit), Institut Català d'Oncologia (Catalonian Institute of Cancer) (ICO-IDIBELL). ***Unidad de Bioestadística (Biostatistics Unit), Departamento de Ciencias Básicas (Dept. of Basic Sciences), Universitat Internacional de Catalunya, Sant Cugat del Vallès. ****Departamento de Ciencias Clínicas (Dept. of Clinical Sciences), Campus de Bellvitge, Facultat de Medicina, Universitat de Barcelona.

Abstract

Smoking is one of the most important causes of morbidity and mortality in developed countries. One of the priorities of public health programmes is the reduction of its prevalence, which would involve millions of people quitting smoking, but cessation programs often have modest results, especially within certain population groups. The aim of this study was to analyze the variables determining the success of a multicomponent therapy programme for smoking cessation. We conducted the study in the Smoking Addiction Unit at the Hospital of Manresa, with 314 patients (91.4% of whom had medium or high-level dependency). We observed that higher educational level, not living with a smoker, following a multimodal programme for smoking cessation with psychological therapy, and pharmacological treatment are relevant factors for quitting smoking. Abstinence rates are not associated with other factors, such as sex, age, smoking behaviour characteristics or psychiatric history. The combination of pharmacological and psychological treatment increased success rates in multicomponent therapy. Psychological therapy only also obtained positive results, though somewhat more modest.

Key words: multimodal treatment, smoking cessation, mental disorders, heavy smokers.

Resumen

El tabaquismo es una de las causas de morbimortalidad más importantes en los países desarrollados. Uno de los objetivos prioritarios de los programas de salud pública es la disminución de su prevalencia lo que implica que millones de personas dejen de fumar, sin embargo los programas de cesación a menudo tienen resultados discretos, especialmente con algunos grupos de población. El objetivo de este estudio fue analizar la eficacia de un tratamiento de cesación tabáquica multicomponente realizado en una unidad de tabaquismo hospitalaria. Fue realizado en la Unidad de Tabaquismo del Hospital de Manresa, e incluyó 314 pacientes (91,4% presentaban un nivel de dependencia medio o alto). Se observó que el nivel de estudios, no convivir con fumadores, seguir la terapia multicomponente y utilizar tratamiento farmacológico son factores relevantes en el éxito al dejar de fumar. La tasa de abstinencia no se asocia con otras características como el sexo, la edad, las características del hábito tabáquico o el presentar antecedentes psiquiátricos. La combinación del tratamiento farmacológico y psicológico aumentó las tasas de éxito en la terapia multicomponente. La terapia psicológica única también obtuvo resultados positivos aunque más modestos.

Palabras clave: tratamiento multicomponente, deshabitación tabáquica, trastornos mentales, pacientes con alta dependencia.

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Address for correspondence:

Antònia Raich. Unidad de Tabaquismo. Althaia Xarxa Assistencial Universitària de Manresa FP. C/Dr. Llatjós, 6-8, edifici CSAM. 08243 Manresa. E-mail: araich@althaia.cat

Among the most challenging aspects involved in interventions with smokers are the chronicity of this addiction and the apparent limitations of programmes designed to help people quit smoking. In order to design interventions with maximal levels of efficiency, it is of the utmost importance to consider previous studies that can contribute data for analyzing the conditions and characteristics of efficacious treatments, the predictors of good results, the characteristics of participants and their success or failure in smoking cessation programmes.

There are a range of different types of smoking cessation interventions: brief advice from a health professional (the person is advised and encouraged to give up smoking), self-help courses and materials, the prescription of pharmacological treatments with or without follow-up, motivational interventions, and multicomponent therapy (Hays, Ebbert, & Sood 2009; Hays, Leischow, Lawrence, & Lee 2010; Stead & Lancaster 2012). The last in this list may be the most intensive of such interventions, since it combines psychological and pharmacological interventions of proven efficacy. The results of smoking cessation treatments currently available are modest: the most efficacious have achieved no more than 30-40% abstinence rates at the one-year follow-up (Ranney, Melvin, Lux, McClain, & Lohr, 2006) in general population.

Pharmacological treatment and smoking cessation advice have been widely analyzed in the scientific literature, and the majority of studies concur that they increase the likelihood of success in quitting smoking (PHS Guideline Update Panel, Liaisons, and Staff, 2008; Silagy, Lancaster, Stead, Mant, & Fowler, 2004; Wilkes, 2008). Various studies have shown that sociodemographic variables (sex, educational level, socioeconomic level) influence the results, as well as the characteristics of the smoking addiction and the person's health antecedents (Nerin, Novella, Beamonte, Gargallo, Jimenez-Muro, & Marqueta, 2007; Ramon & Bruguera, 2009). However, there is scarcely any research analyzing these aspects in multicomponent therapy, whose efficacy has indeed been studied, but not the influence on it of these variables (Bauld, Bell, McCullough, Richardson, & Greaves, 2010; Hays et al., 2009).

Addictive disorders are complex entities that affect human behaviour with physiological, psychological and sociological bases. The comprehensive approach involved in multicomponent therapy is that which has yielded the best outcomes in the medium and long term (PHS Guideline Update Panel, 2008; Alonso-Perez, Alonso-Cardenoso, Garcia-Gonzalez, Fraile-Cobos, Lobo-Llorente, & Secades-Villa, 2013; Stead & Lancaster 2005). Thus, the aim of the present study was to analyze the efficacy of a multicomponent smoking cessation treatment carried out in a hospital Smoking Addiction Unit and how its outcomes were influenced by the characteristics of participants and their addiction, social factors, different pharmacological treatments, and psychological therapy.

Method

Design and participants

Longitudinal study of 314 patients who attended the Smoking Addiction Unit at the Hospital de Manresa (Manresa, Spain) to try and quite smoking between January 2001 and December 2009. This unit takes in patients referred from other departments in the same hospital or from primary care services, where all have received brief interventions for smoking cessation, and more than 65% have received specific interventions that have failed (carried out by specialist nurses working in primary care, cardiology units, pulmonary units, etc.). Included in the study were all those patients treated in the unit that followed multicomponent therapy; inclusion was in accordance with order of registration on the waiting list, where they remained for an average of nine months. Exclusion criteria for the multicomponent treatment were: psychiatric illness in an acute phase or a psychotic disorder, reading and/or writing problems, and other disorders that would make it difficult to follow the therapy. The majority of the patients referred to this programme were from the central area of Catalonia (Manresa and the surrounding area).

Procedure

A one-year follow-up was carried out, counting from the point at which the patient gave up or should have given up smoking, which for the patients meant a mean of 14 months of therapy. A total of 90% of the patients received the multicomponent therapy in group format, while just 10% did so on an individual basis. The structure of the therapy was the same for the group and individual formats. In principle, all patients were assigned to the group mode, the individual format being employed only in exceptional cases (pregnant patients who could not wait for the start of group programme, or people with difficulties for following the group timetable). The therapy was implemented by the same professionals (a psychologist and a lung specialist) throughout the study. The multicomponent treatment programme brings together all those strategies that have shown themselves to be efficacious (Alonso-Perez et al., 2014; Fiore, Jaen, Baker, Bailey, Benowitz, & Curri, 2009): psychological treatments based on behavioural, cognitive, motivational and relapse prevention techniques combined with pharmacological treatment based on nicotine replacement (Becoña & Míguez, 2008; Ranney et al., 2006), bupropion and varenicline (Wu, Wilson, Dimoulas, & Mills, 2006; Tinich & Sadler 2007; Cahill, Stevens, & Lancaster 2014). Multicomponent therapy consists of three phases: a) "preparation", which involves psychoeducation about addiction, motivation to quit, changing habits, and monitoring of tobacco use with or without reduction in six weekly 75-minute sessions; b) "cessation", in which pharmacological treatment is introduced where applicable

and the therapists work on coping with the day the patient gives up (“D-Day”), withdrawal syndrome and craving, in four two-weekly 60-minute sessions; and c) “relapse prevention”, following the models of Marlatt, Curry and Gordon (1988) and Baer and Marlatt (1991), in 10 monthly 60-minute sessions.

The therapy involved no direct financial cost for the patients, except for the pharmacological treatment, for which they had to pay. All the patients received the same psychological therapy and assignment to one type of pharmacological treatment or another was in line with clinical criteria, taking into account at each moment the treatment that could most benefit the patient in accordance with availability, previous experience, personal health antecedents and pharmacological interactions with other treatments he or she might be undergoing at that time. Some patients decided not to take up the treatment, and this group also includes those who did not receive treatment because they dropped out of the programme before beginning it (n=69).

Those patients that did not take up the treatment for whatever reason remained in the study, and were contacted by telephone or personally for the purpose of obtaining the necessary follow-up data. The distribution of the patients across the different treatment modes and retention up to the 12-month follow-up are shown in detail in Figure 1.

Information on sociodemographic variables, health antecedents and smoking characteristics were obtained at the first visit (which was always individual) based on the patient interview and the data from the person’s clinical records. Information on how the patient was developing and the drugs used was recorded in the first, third, sixth and twelfth month after “D-Day”. All patients were contacted

in person at the hospital or by telephone for the follow-up (months 1, 3, 6 and 12) and all the relevant information recorded. All the patients who claimed to remain abstinent were given an appointment to take a carbon monoxide test.

Instruments

The objective measure of abstinence used was level of carbon monoxide (CO) in expired air, or co-oximetry (abstinent if CO≤6ppm) (Middleton & Morice, 2000). The instrument employed for this purpose was a co-oximeter (Bedfont Pico Smokerlyzer®).

For the data analysis, the following variables were taken into account: sex, age, educational level, living with other smokers or not, occupation, number of cigarettes smoked per day, years smoked, level of dependence according to Fagerström Test (low dependence ≤4; medium=5; high ≥6), psychiatric antecedents (yes/no), multicomponent therapy (yes/no), pharmacological treatment (yes/no), and drug used for smoking cessation.

Statistical analysis

The categorical variables are shown as absolute value and relative frequency. The continuous variables are shown with the mean and standard deviation. We calculated the accumulated incidence of abstinence, both global and according to multicomponent programme, at 1, 3, 6 and 12 months, together with its 95% confidence interval. The variables associated with relapse at 12 months were examined using bivariate and multivariate logistic regression models. In the multivariate logistic regression model we introduced the covariables found to be significant in the bivariate analysis, or with evidence of their association. We used a stepwise exclusion strategy controlled by the researcher. The

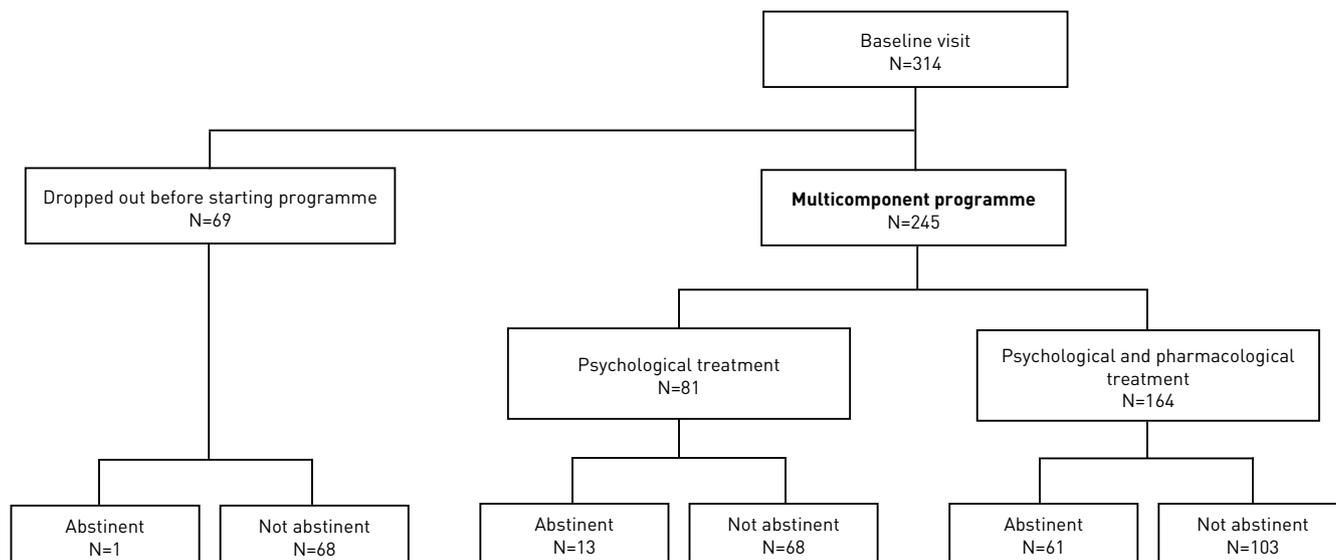


Figure 1. Patient flow

raw and adjusted odds ratios (OR) and the 95% confidence intervals (CI 95%) were calculated. Statistical significance level was bilateral 5% ($p < 0.05$).

The programs used in the statistical analysis were IBM® SPSS® Statistics for Windows v.22 (IBM Corporation, Armonk, New York, USA) and Stata® v.10 (StataCorp LP, College Station, Texas, USA).

Results

Mean age of the patients was 48.5 years; 61.8% were men, 61.9% had only elementary education and 32.6% were skilled workers or professionals. As regards smoking characteristics, 50.3% lived with other smokers, 34.4% had been smoking for 35 years or more, 48.2% smoked 21 or more cigarettes per day, and 68.8% had high nicotine dependence (score ≥ 6) according to the Fagerström Test. Furthermore, 57.1% of the patients had made two or more previous attempts to quit smoking, 85% had been referred to the programme from other hospital departments where they were being treated for illnesses associated with smoking, and 58% had psychiatric antecedents (Table 1).

Of the total 314 patients, we included all those who during the studied period put their names down on the waiting list and came to the first appointment when called; of these, 69 dropped out of the programme before the first session of multicomponent therapy and the remaining 245 began the multicomponent therapy (Figure 1). Of these 245 patients, 81 did not receive the pharmacological treatment, on their own or the doctors' decision ($n=29$) or because they gave up the therapy before completing the first phase ($n=52$).

Abstinence for the whole sample was 50.3% at the one-month follow-up, 38.5% at three months, 29.0% at six months and 23.9% at 12 months. Patients who received psychological and pharmacological treatment obtained the highest abstinence rates at all the follow-up points, showing an abstinence rate at 12 months of 37.2%, followed by those who

received psychological therapy only, with a rate of 16%, and those who received no type of treatment (1.4%) (Table 2).

In the bivariate analysis, sex, age, years smoked, dependence (score on Fagerström Test) and psychiatric antecedents, did not appear as relapse risk factors. A trend towards significance was observed, with higher relapse rate, among younger patients (OR 0.98) and those who had been smoking for 20 years or less (OR 1.96). Having at least

Table 1.
Baseline characteristics of participants ($n=314$)

	n(%)
Mean age [standard deviation]	48,5±[12,1]
Sex	
Man	194 (61,8)
Woman	120 (38,2)
Educational level	
Primary	192 (61,9)
Secondary	63 (20,3)
University	55 (17,7)
Living with smokers	
No	156 (49,7)
Yes	158 (50,3)
Years smoked	
≤ 20	68 (21,7)
21-35	138 (43,9)
> 35	108 (34,4)
Fagerström Test	
< 4 Low	27 (8,6)
4-5 Medium	71 (22,6)
≥ 6 High	216 (68,8)
Psychiatric antecedents	
No	132 (42,0)
Yes	182 (58,0)
Multicomponent programme	
Neither psychological nor pharmacological treatment	69 (22,0)
Psychological treatment	81 (25,8)
Psychological and pharmacological treatment	164 (52,2)
Nicotine replacement therapy	84 (51,2)
Bupropion	30 (18,3)
Varenicline	50 (30,5)

Table 2.
Abstinence (global and according to multicomponent programme) at 1, 3, 6 and 12 months

	n	1 month ^a	3 months ^a	6 months ^a	12 months ^a
Global	314	50,3 [44,6-56,0]	38,5 [33,1-44,2]	29,0 [24,0-34,3]	23,9 [19,3-29,0]
According to multicomponent programme					
Neither psychological nor pharmacological treatment	69	2,9 [0,4-10,1]	1,4 [0,04 -7,8]	1,4 [0,04 -7,8]	1,4 [0,04 -7,8]
Psychological treatment	81	27,2 [17,9-38,2]	23,5 [14,8-24,2]	16,0 [8,8-25,9]	16,0 [8,8-25,9]
Psychological and pharmacological treatment	164	81,7 [74,9-87,3]	61,6 [53,7-69,1]	47,0 [39,1-54,9]	37,2 [29,8-45,1]
Nicotine replacement therapy	84	83,3 [73,6-90,6]	61,9 [50,7-72,3]	50,0 [38,9-61,1]	44,0 [33,2-55,3]
Bupropion	30	83,3 [65,3-94,4]	70,0 [50,6-85,3]	50,0 [31,3-68,7]	36,7 [19,9-53,9]
Varenicline	50	78,0 [64,0-88,5]	56,0 [41,3-70,0]	40,0 [26,4-54,8]	26,0 [14,6-40,3]

^a % [95% Confidence Interval]

Table 3.
Risk factors for relapse at 12 months. Bivariate analysis.

	Abstinence ^a n=75	Relapses ^a n=239	Raw OR (95% CI)	p value
Mean age [standard deviation]	50,7±[12,0]	47,8±[12,0]	0,98 (0,96-1,00)	0,068
Sex				
Man	51 (26,3)	143 (73,7)	1 ^b	
Woman	24 (20,0)	96 (80,0)	1,43 (0,82-2,47)	0,205
Educational level				
Primary	35 (18,2)	157 (81,8)	1 ^b	
Secondary	23 (36,5)	40 (63,5)	0,39 (0,21-0,73)	0,003
University	16 (29,1)	39 (70,9)	0,54 (0,27-1,08)	0,082
Living with smokers				
No	47 (30,1)	109 (69,9)	1 ^b	
Yes	28 (17,7)	130 (82,3)	2,00 (1,18-3,41)	0,011
Years smoked				
> 35	32 (29,6)	76 (70,4)	1 ^b	
21-35	31 (22,5)	107 (77,5)	1,45 (0,82-2,58)	0,202
<= 20	12 (17,6)	56 (82,4)	1,96 (0,93-4,15)	0,077
Fagerström Test				
<4 Low	7 (25,9)	20 (74,1)	1 ^b	
4-5 Medium	24 (33,8)	47 (66,2)	0,68 (0,25-1,85)	0,455
<= 6 High	44 (20,4)	172 (79,6)	1,37 (0,54-3,44)	0,505
Psychiatric antecedents				
No	36 (27,3)	96 (72,7)	1 ^b	
Yes	39 (21,4)	143 (78,6)	1,38 (0,82-2,32)	0,231
Multicomponent programme				
Neither psychological nor pharmacological treatment	1 (1,4)	68 (98,6)	1 ^b	
Psychological treatment	13 (16,0)	68 (84,0)	0,08 (0,01-0,60)	0,015
Psychological and pharmacological treatment	61 (37,2)	103 (62,8)	0,02 (0,003-0,18)	< 0,001
Nicotine replacement therapy	37 (44,0)	47 (56,0)	1 ^b	
Bupropion	11 (36,7)	19 (63,3)	1,36 (0,58-3,21)	0,483
Varenicline	13 (26,0)	37 (74,0)	2,24 (1,04-4,81)	0,039

^a Number of individuals (% of row). ^b Reference category
OR: Odds Ratio; 95% CI: 95% Confidence Interval .

secondary education, not living with smokers, and receiving multicomponent therapy with psychological treatment alone or in conjunction with pharmacological treatment emerged as predictors of success ($p < 0.05$). As regards pharmacological treatments, nicotine replacement therapy is found to be the best predictor of success, with significant differences compared to varenicline, though not compared to bupropion (Table 3).

In the multivariate analysis, the factors found to protect against relapse were having a secondary or university education, not living with smokers, and receiving some type of smoking cessation treatment, be it psychological only or psychological plus pharmacological (Table 4).

Table 4.
Risk factors for relapse at 12 months.
Multivariate analysis.

	Adjusted OR (95% CI)	p value
Age	0,98 (0,96-1,01)	0,169
Sex		
Man	1 ^a	
Woman	1,36 (0,69-2,66)	0,371
Educational level		
Primary	1 ^a	
Secondary	0,36 (0,18-0,73)	0,005
University	0,41 (0,19-0,89)	0,024
Living with smokers		
No	1 ^a	
Yes	2,03 (1,12-3,68)	0,020
Multicomponent programme		
Neither psychological nor pharmacological treatment	1 ^a	
Psychological treatment	0,06 (0,01-0,51)	0,010
Psychological and pharmacological treatment	0,02 (0,003-0,17)	<0,001

^a OR: Odds Ratio; 95% CI: 95% Confidence Interval.

Discussion

As a result of a multicomponent smoking cessation programme, 1 in 4 smokers with high levels of dependence remained abstinent at the 12-month follow-up. These results are independent of sex, age, psychiatric antecedents or smoker characteristics. On the other hand, social factors such as educational level or living/not living with other smokers did indeed influence the results of this type of therapy. Furthermore, receiving multicomponent therapy with or without pharmacological treatment clearly increases the likelihood of success, though patients who also receive pharmacological treatment achieve better abstinence rates.

The results obtained in this study raise a number of points for discussion. Some of the findings are at odds with those of previous research. Thus, for example, the abstinence rates are somewhat lower than might be expected for a high-intensity therapy, while aspects such as participant's sex or psychiatric antecedents, which in the majority of studies affect the success of the treatment (Fernández, García, Schiaffino, Borràs, Nebot, & Segura, 2001; Nerín et al., 2007; Perkins & Scott, 2008; Piper et al., 2010) do not yield differences in this respect in our study.

These low abstinence rates compared to those of other studies (Becona & Vazquez, 1998; Nerín et al., 2007) may be due to the fact that the sample is not from the general population; indeed, it is highly selective: the study took place in a hospital smoking cessation unit, with participants who had failed in previous attempts to quit smoking, with high levels of nicotine dependence and who had been referred from other hospital departments because they presented smoking addiction-related pathologies. Some authors refer to such people as recalcitrant smokers (Wilson, Wakefield, Owen, & Roberts, 1992). Moreover, the results were analyzed on an "intent-to-treat" basis, which makes it difficult to compare this study with previous ones that exclude those patients who gave up after the first visit. We found no differences between men and women at any of the follow-ups or at the end of the treatment. Although some previous studies refer to sex differences (Bjornson et al., 1995) in success rates for smoking cessation, more recent studies with populations in phase IV of smoking dependence report no such differences (Villalbí, Rodríguez-Sanz, Villegas, Borrell, 2009; Wilson et al., 1992). The absence of sex differences in our study may be attributable to this, or to the intensive intervention involved in multicomponent therapy. Although some studies have found a higher incidence of relapse in women (Heatherton, Kozlowsky, Frecker, & Fagerström, 1991), others report a substantial improvement in women's results when psychological therapy is added to pharmacological treatment (Nerín & Jané, 2007) – but this is an aspect requiring further research.

Educational level is associated with success of the therapy, as various studies have shown (Fernández et al., 2001; Piper et al., 2010), and the fact of receiving multicomponent therapy

does not reduce the weight of this variable. In the univariate analysis we observed that it is only significant to have secondary education, and that having a university education does not attain statistical significance, even though this aspect does emerge as significant in the multivariate analysis. This is probably due to the fact that in the subgroup with university education there is a higher proportion of young people, in whom we already saw a greater tendency for relapse; therefore, when we adjust for age, having a university education also shows up as significant. Thus, educational level is significant as a predictor of success in multicomponent therapy. Bearing in mind that various studies have shown how people with higher levels of education respond better to psychological therapy of whatever kind (Haustein, 2004; Piper et al., 2010; Siahpush, McNeill, Borland, & Fong, 2006), all of this would be in support of the hypothesis that psychological aspects play a relevant role in attempts to quit smoking (Likura, 2010).

Occupational or professional level was also analyzed, though it only yielded significant differences in the first and sixth months, and not at the 12-month follow-up. Educational level is stable in adults, while the occupation variable can show considerable instability over the course of life (Belleudi et al., 2006), which would explain why the former yields greater significance and more robust results than the latter, as the previously-cited studies have also shown (Fernández et al., 2006; Yanez, Leiva, Gorreto, Estela, Tejera, & Torrent, 2013).

Level of dependence presented differences in the results, as observed in previous studies (Baer & Marlatt, 1991; Fernández et al., 1998), though these differences were only significant at the one-month and three-month follow-ups. This is probably due to the effect of the pharmacological treatment. The Fagerström Test is a good indicator of the smoker's level of physical dependence, but it is not reliable for measuring psychological dependence (Nerín et al., 2007). People with high levels of physical dependence are those that most benefit from pharmacological treatment (De Leon, Diaz, Bevona, Gurpegui, Jurado, Gonzalez-Pinto, 2003). However, in the medium and long term after the pharmacological treatment is finished, what could be determining relapse is not so much the physical dependence level as the degree of psychological dependence and the capacity for developing relapse prevention strategies (Hajek, Stead, West, Jarvis, Hartmann-Boyce, & Lancaster, 2013; Siahpush et al., 2006).

The majority of studies to date with psychiatric patients (Killen et al., 2008) have found them to have more difficulty giving up smoking and to present higher relapse rates. In our study, however, no such differences were appreciated. Various factors could explain this: first of all, the broad concept of psychiatric antecedents we employed, considering a patient to fall into this category if they had at any time in their life received a psychiatric diagnosis and been treated, and this covers a wide range of levels of severity. Secondly,

the fact that patients with schizophrenia or severe psychotic disorders were directly excluded. Though perhaps the most relevant factor is the environment in which the treatment programme took place, since the smoking cessation unit is part of the hospital's mental health department in which patients receive psychiatric follow-up. We believe that this may have led to greater adherence to the treatment and the sessions, as well as better monitoring and adjustment of the psychiatric treatment according to patients' progress towards giving up the habit, facilitated by the coordination between the professionals at the smoking cessation unit and the mental health department. Previous studies in similar environments, indeed, have found higher rates of smoking cessation in these types of patient (Cepeda-Benito et al., 2004; Fagerström & Aubin, 2009). Finally, it is reasonable to think that the intensive treatment involved in multicomponent therapy improves the results of these patients, as some authors have already suggested (Brown et al., 2001; Himelhoch & Daumit, 2003).

In the present study, multicomponent therapy with or without pharmacological treatment improves abstinence rates at the 12-month follow-up. If we focus on the 81 patients that opted for psychological treatment only, we can observe a substantial smoking cessation rate that reveals the effect of psychological therapy even without its reinforcement with pharmacological treatment, as also shown in several previous studies (Killen et al., 2008). Given that the data were analyzed on an "intent-to-treat" basis, the group of 81 participants that received the therapy without pharmacological treatment includes patients who dropped out during the first phase of the treatment, so that we may actually be underestimating the results yielded by psychological therapy without pharmacological treatment. Focusing on the differences between abstinence at one month and at twelve months, it can be seen that the "psychological treatment only" group lost 11% of patients to relapse, while the psychological plus pharmacological treatment group lost 44%. This leads us to think that those who achieve abstinence in the first month without pharmacological treatment are keener to maintain their abstinence than those who achieve it with the help of pharmacological treatment, though it would be necessary to carry out more studies with experimental design to be able to confirm this hypothesis.

As regards pharmacological treatments, it was found that all of them play an important role in all phases of the process (Hajek, Stead, West, Jarvis, Hartmann-Boyce, & Lancaster, 2013; Tinich & Sadler, 2007). The results suggest that pharmacological treatment increases the likelihood of success in quitting smoking in the first three months, and that once a period of abstinence has been attained, the probability of maintaining abstinence in the medium and long term increases substantially (PHS Guideline Update Panel 2008). A study with experimental design in patients with characteristics similar to those in our study showed that

following psychological therapy after the third smoking-free month is effective for the maintenance of abstinence (Hajek et al., 2013). Likewise, various reviews have shown how group therapy, cognitive-behavioural therapy and interventions with intensive follow-up are more efficacious in the long term (Bauld et al., 2010; Hall, Humfleet, Muñoz, Reus, Robbins, Prochaska, 2009).

We observed a clear advantage of nicotine replacement therapy compared to varenicline. Given that this was a descriptive study, it should be borne in mind that there may be bias in relation to the selection of pharmacological options, since they were not assigned randomly; hence, we cannot draw the kinds of causal conclusions that could be drawn from a study with experimental design. These differences may be due to the fact that greater efficacy of varenicline for reducing symptoms of craving (Stapleton et al., 2008) would hinder the learning of coping strategies for craving on the part of these patients. This is why after the end of the pharmacological treatment we see a higher relapse rate. Since we are talking about patients with serious difficulties for quitting smoking, there may be an influence of poor ability to apply relapse-prevention strategies. If this were indeed the case, nicotine replacement therapy would emerge as the most appropriate pharmacological treatment for multicomponent therapy interventions with these types of patients, while varenicline would be more suitable for patients who had not previously tried and failed to quit, who would not be followed-up after the pharmacological treatment, or who did not receive psychological treatment, though this hypothesis would need to be tested with specially designed studies.

It would be useful to analyze therapy adherence according to the characteristics of participants who completed the treatment, since this would provide information on predictors of adherence to multicomponent therapy and would help in the consideration of possible aspects to improve with a view to increasing it.

The main limitation of the present study concerns the time dimension. The fact of the sample being recruited over a long period (9 years) means that socio-cultural variables (e.g., legislative changes with regard to the prohibition of smoking in public spaces, changes in society's perception of the risks involved in smoking) could be having an effect that we have not controlled for. Thus, it may be that the 2005 legislation restricting smoking in public had some influence on people's motivation to give up smoking. On the other hand, though, the fact that the smokers in our sample had homogeneous characteristics (high level of dependence, many with previous pathologies, several attempts to quit) brings some correctional elements, so that this aspect does not influence the results as much as it would in a study with the general population. Another limitation is not having a record of the exact date of relapse, as this prevents us from knowing whether a patient starts smoking again and

therefore drops out of the programme, or first drops out of the programme which in turn leads to smoking relapse.

An advantageous aspect of the study is the fact of its using co-oximetry to confirm abstinence, as it gives much greater validity to the results than if we had only the patient-reported information.

The restricted geographical context of the study may seem like a limitation, given that the whole sample is concentrated in the same smoking cessation unit, which attends to a population with particular socio-cultural characteristics and served by a specific health-service structure, and this could limit the generalization potential of the results. Nevertheless, the population is a heterogeneous one in terms of socio-cultural characteristics, since both rural and urban regions are represented: Manresa is a city of over 70,000 inhabitants, situated within the third ring of the Barcelona metropolitan area and with an urban culture, while other parts of the sample are drawn from regions of central Catalonia with primarily rural socio-economic environments.

The fact of being a clinical study carried out in a real and natural context, that it seeks the most appropriate treatment according to the patient's characteristics and that the data analysis is carried out on an intent-to-treat basis are relevant aspects of the present study, enabling it to provide information that complements the results obtained in clinical trials conducted in ideal conditions (Brown et al., 2001; Garrison & Dugan, 2009; Tinich et al., 2007). In sum, we believe that this study permits as to contribute data on the effectiveness of multicomponent therapy in the clinical context, with heavy smokers and in a real environment.

The results obtained in the present study show how multicomponent therapy facilitates smoking cessation at one, three, six and twelve months. Socio-environmental characteristics such as higher educational level and not living with smokers predicted success in quitting smoking through multicomponent therapy, but this was not the case for other variables, such as sex, smoker characteristics and personal psychiatric antecedents. The combination of pharmacological and psychological treatment increased success rates in the multicomponent therapy, and psychological therapy alone also yielded positive results, though they were more limited in this case. In the light of these results, which require confirmation through experimental studies with better control of other possible determinants of dropout and success, we might consider a more generalized application of this type of therapy, especially with heavy or recalcitrant smokers.

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Conflicts of interests

The authors declare that there are no conflicts of interests.

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