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The role of gender in a smoking cessation intervention: a cluster randomized clinical trial

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Abstract

Background: The prevalence of smoking in Spain is high in both men and women. The aim of our study was to evaluate the role of gender in the effectiveness of a specific smoking cessation intervention conducted in Spain.

Methods: This study was a secondary analysis of a cluster randomized clinical trial in which the randomization unit was the Basic Care Unit (family physician and nurse who care for the same group of patients). The intervention consisted of a six-month period of implementing the recommendations of a Clinical Practice Guideline. A total of 2,937 current smokers at 82 Primary Care Centers in 13 different regions of Spain were included (2003-2005). The success rate was measured by a six-month continued abstinence rate at the one-year follow-up. A logistic mixed-effects regression model, taking Basic Care Units as random-effect parameter, was performed in order to analyze gender as a predictor of smoking cessation.

Results: At the one-year follow-up, the six-month continuous abstinence quit rate was 9.4% in men and 8.5% in women ($p = 0.400$). The logistic mixed-effects regression model showed that women did not have a higher odds of being an ex-smoker than men after the analysis was adjusted for confounders (OR adjusted = 0.9, 95% CI = 0.7-1.2).

Conclusions: Gender does not appear to be a predictor of smoking cessation at the one-year follow-up in individuals presenting at Primary Care Centers.

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Keywords: gender, smoking cessation, primary health care, clinical trials

Background

Smoking has devastating effects on health [1] and is the first avoidable cause of mortality in developed countries [2]. In Spain, there were 53,155 deaths attributable to tobacco use in 2006 (14.7% of all deaths occurred in individuals ≥ 35 years), 47,174 in men and 5,981 in women [3].

Over the last decade, global tobacco consumption has decreased progressively in Spain; however, tobacco consumption remains high. According to data from 2006, 21.5% of women and 31.6% of men older than 16 were current smokers in Spain [4]. Specifically, until the 1970s, the prevalence of smoking in women was lower than 5%. Tobacco consumption in women has since

increased, reaching peak levels around 1995 and 2001, and falling slightly in the following decade. In men, tobacco consumption began to decrease after the mid 1970s [5].

In light of this prevalence of smoking in both genders, it is necessary to implement specific intervention programs for smoking cessation in Primary Care Units. Until recently, tobacco control initiatives have not differentiated between the two gender groups; however, attitudes, perceptions and behaviors related to tobacco consumption patterns and cessation can differ between men and women [5-8]. Therefore, knowledge of the mechanisms by which gender influences abstinence could provide targets for intervention [9].

Interventions aimed at smoking cessation are sometimes based on models such as the Transtheoretical Change Model [10]. According to this model, smoking

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cessation is a process of movement through motivational stages of change, from no intention to quit to maintaining smoking cessation [11]. From the point of view of the Transtheoretical Change Model, many factors, such as attitude, social influence, self-efficacy, employment, age, marital status and gender, among others, could be key factors in determining behavior and change of stage.

The main purpose of this project was to evaluate gender as a predictor of smoking cessation in a smoking cessation intervention ("Intervención Sistemática sobre Tabaquismo en Atención Primaria de Salud- ISTAPS") using motivational interviews and the stages of change model [12]. Additionally, we assessed potential differences in the pattern of tobacco use by gender at baseline and at one year after inclusion in the study.

Methods

This article is based on the ISTAPS study.

ISTAPS study

The ISTAPS Study evaluated the effectiveness of a stepped smoking cessation intervention based on Prochaska and DiClemente's Transtheoretical Change Model [10]. This study was a cluster randomized clinical trial in which the randomization unit was the "Basic Care Unit" (BCU). A BCU comprises a family physician and a nurse who are in charge of the care for a given population of patients. Subjects were recruited from 82 Primary Health Care Centers in 13 regions of Spain.

The intervention consisted of a six-month period of structured and systematic recommendations implemented from a Clinical Practice Guideline based on the "cessation-induction trials" model proposed by Hughes et al [13], including: motivational counseling for smokers at the precontemplation/contemplation stage; brief intervention for smokers in preparation/action who did not want help; intensive intervention with drug therapy for smokers in preparation/action who wanted help; and reinforcing intervention in the maintenance stage. The guidelines that served as the basis of the intervention had been published recently [14]. The control group received usual care (standard care), including smoking cessation counseling offered in primary care to patients with diseases related to tobacco consumption. This is entirely free of charge, as the Spanish National Health Service (NHS) provides universal medical coverage and is financed essentially by general taxes. The usual care could also include drug therapies, although these treatments were not covered by the National Health Service.

Information related to process of change, decisional balance, self-efficacy and quality of life was collected through telephone interviews. Information related to socio-demographics, lifestyles and pattern of tobacco

consumption was collected through personal interviews. Finally, clinical information was collected from the subjects' medical records. Informed consent to participate was obtained from all study subjects.

The follow-up period was two years from the start of the intervention. For this project, we have restricted our analysis to the first year of follow-up.

Definitive approval from the Clinical Ethics Committee of the IDIAP Jordi Gol has been granted for the ISTAPS project (P02/13).

Detailed information about the ISTAPS project has been published previously [12].

Study population

Our population was based on 2,937 subjects between 14 and 75 years of age from the ISTAPS study, recruited from 2003 to 2005. Subjects were individuals who presented at Primary Health Care Centers for any reason and answered "yes" to the question: "Do you smoke cigarettes?". Of 2,937 subjects, 2,827 with valid information were selected for the analysis.

Data collection

Baseline information on socio-demographics, lifestyles, tobacco use, stages of change, nicotine dependence (Fagerström test scores) [15], motivation to quit (Richmond test scores) [16], confidence in quitting, importance of quitting and readiness to quit as defined by Rollnick et al [17] was collected through personal questionnaires administered by the doctor or nurse in the Primary Care Center.

Age in years, age at smoking initiation, alcohol consumption, number of cigarettes per day, Fagerström and Richmond test scores, importance of quitting smoking, confidence in quitting smoking and readiness to quit smoking, measured using a scale from 0 (lowest) to 10 (highest), were analyzed as continuous variables. The measure of alcohol consumption was based on the standard unit of alcohol (1 unit = 10 gr). Alcohol consumption was measured as standard units of alcohol per week.

It is interesting to mention the Richmond test. This test is used very widely in Spain and was described by RL. Richmond in 1993. The test measures the smoker's motivation to quit smoking.

Social class was categorized according to the British Registrar General's Social Classification (2000) and codified into two categories (I-II: professionals, managerial and technical occupations/III-V: non-manual skilled and manual skilled occupations, partly skilled and unskilled occupations) [18]. Physical exercise (leisure time) was also classified into two categories, one for subjects who exercised at least once a week versus those who did not exercise at all. Categorical variables also included: group

allocation (control/intervention), smoker partner (yes/no), smoker friends (yes/no), stage of change (pre-contemplation: the individual has no intention to change behavior in the next six months; contemplation: the individual recognizes the benefits of changing and is considering taking action in the next six months; preparation: the individual has decided to make a change in the next 30 days; action: the individual is actively engaged in changing their behavior), number of previous smoking cessation attempts lasting at least 24 hours (from 0 to 5), reduction in the number of cigarettes consumed over last month (yes/no) and presence of tobacco related disease (yes/no). The maintenance and relapse stages were not considered since the study focused on active smokers. A few subjects were in the action stage at baseline because they gave up smoking between the recruitment day and the interview day.

Some study subjects (21% of men and 19.4% of women) received treatment during the study period. Treatment was defined as both drug therapy and supplemental treatments, such as anti-anxiety agents, candies, regular gums and books. Drug therapy included medications such as bupropion and nicotine substitutes (gums and patches) that were part of the intervention. Since the intervention is considered as an indivisible whole, the impact of treatment on the primary outcome cannot be known. The control group, which included brief advice for smokers, also used these drug therapies in some cases, but not in the same protocolized way as in the intervention group. For this reason, a greater use of pharmacological treatment in the intervention than the control group is normal and desirable. Thus, treatment could not be included as a separate variable because it was assessed basically as a part of the intervention or usual care.

The dichotomous outcome variable was selected, comparing those patients who had been ex-smokers for at least six months of continuous abstinence (self-reported) versus those who were current smokers at the end of study period (one year). Subjects who were former smokers for less than six months were considered smokers. Initially all subjects were asked to confirm their self-reported abstinence on the expired air carbon monoxide test. Smoking abstinence was considered to be confirmed at a carbon monoxide level lower than 10 ppm. Only 12% of former smokers could be confirmed biochemically.

Data analysis

Differences in socio-demographics, lifestyles and tobacco characteristics at baseline and at one-year follow-up were assessed in men versus women using the chi-square and Student's *t*-test or Mann-Whitney *U* as appropriate.

Linear regression models were used to assess the independent predictor variables on number of cigarettes consumed last month in men, importance, confidence and readiness to quit at the one-year follow-up in both genders, adjusted for baseline measurement. The standard errors were adjusted for the cluster effect of the BCU. Because significant variability among BCUs was found in the number of cigarettes consumed last month in women, a linear mixed-effects model was performed to assess the independent predictors on number of cigarettes consumed last month. These analyses were stratified by gender.

The initial individual variables considered were study group, age, social class, alcohol intake, physical exercise, number of cigarettes consumed last month, Fagerström test scores, Richmond test scores, smoker partner, smoking reduction over last month, importance of quitting smoking, confidence in quitting smoking, readiness to quit smoking and tobacco-related disease.

All subjects were included in the groups to which they were randomized and an intention-to-treat analysis was performed. Additionally, subjects lost to follow-up were considered unsuccessful in their attempt to quit smoking and therefore current smokers, which is the standard approach in smoking cessation intervention studies [19].

A logistic mixed-effects model was performed to assess gender as a predictor of continuous smoking abstinence, accounting for clustering at the level of BCU [20]. We used the binomial logit link with full maximum likelihood method of estimation via the adaptive Gaussian quadrature with fifty integration points.

We modeled individuals (level-1 units) as nested within BCUs (level-2 units).

Initially we examined whether there was significant variability among BCUs in the likelihood of smoking cessation fitting an unconditional model with no predictors at either level. As significant variation existed between BCUs, we built a conditional model adding level-1 individual fixed effects. We did not consider contextual variables at the BCU level.

The initial regression model was adjusted for gender, study group, age, social class, alcohol intake, physical exercise, age at smoking initiation, number of cigarettes consumed last month, Fagerström test scores, Richmond test scores, smoker partner, smoker friends, stage of change, number of previous smoking cessation attempts lasting at least 24 hours, reduction of number of cigarettes consumed over the last month, importance of quitting smoking, confidence in quitting smoking, readiness to quit smoking and tobacco-related disease. The method recommended by Raudenbush & Bryck (2002) [21] was followed to select a subset of covariates to include in the final regression model. The authors checked for confounders and multi-collinearity among the independent variables. Homogeneity of the group

effect over men and women was verified, and therefore this interaction was not included in the model.

The alternative models were compared using the partial likelihood ratio test and Akaike's information criterion (AIC) to determine which model provided the best fit for the data. All results were expressed with their 95% confidence intervals (CIs). Statistical significance was set at $p < 0.05$ (two-tailed).

Data were managed using the ACCESS databases, and statistical analysis was performed using the SPSS statistical package for Windows, version 13.0 (SPSS Inc., Chicago IL) and Stata/SE version 11.1 statistical package (Stata Corp).

Results

A flow chart of clusters and individual participants through each phase of the study is shown in figure 1.

Of the 2,827 subjects considered for this analysis, 50% were men and the mean age was 42.8 (Standard Deviation = 13.6).

At baseline, men were significantly older and consumed more alcohol than women. Men also started to smoke earlier, consumed more tobacco and had higher nicotine dependence than women. There were more men than women in the preparation and action stages, and men were more confident and prepared to quit than women (Table 1). When the analysis was stratified by study group (Table 2), differences were found between men and women in both groups at baseline. The difference in the Fagerström test scores was statistically significant in the control group ($p = 0.004$), and stage, confidence in quitting and readiness to quit were only statistically significant in the intervention group ($p = 0.010$, $p < 0.001$, and $p = 0.048$ respectively). The key changes between genders among current smokers interviewed one year after their inclusion in the study were differences in confidence in quitting, which were observed in the control group ($p = 0.044$) but not in the intervention group ($p = 0.206$).

The variables associated with number of cigarettes per day, importance, confidence and readiness to quit of smokers at the one-year follow-up showed differences between men and women (Table 3). The most important difference is that physical exercise reduces significantly the number of cigarettes consumed daily in women. Differences between men and women for the remaining predictor variables are of lesser magnitude. Baseline values for each variable considered are highly significant predictors.

The abstinence rate (point prevalence) at the one-year follow-up was 18.2% in the intervention group versus 13.8% in the control group ($p = 0.002$). By gender, the abstinence rate (point prevalence) was 17.2% for men and 15% for women ($p = 0.118$).

At the one-year follow-up, the six-month continuous abstinence rate was 11.3% and 6.3% in the intervention and control group respectively ($p < 0.001$). By gender, the rates were 9.4% for men and 8.5% for women ($p = 0.400$).

The logistic mixed-effects model showed that women had non-significant lower odds of being an ex-smoker than men after the analysis was adjusted for study group, age, alcohol intake, number of cigarettes per day, Fagerström test scores, Richmond test scores, confidence in quitting and readiness to quit smoking at baseline (adjusted OR = 0.9, 95% CI = 0.7-1.2). Statistically significant variability was found between BCUs (variance = 0.2, 95% CI = 0.1-0.7) (Table 4).

Discussion

This study focused on the role of gender as a potential predictor of smoking cessation after controlling for potential confounders such as age and amount smoked, among other variables.

This study, which was carried out in a large number of sites, was aimed primarily at assessing the role of gender rather than focusing on the effect of the intervention, as tobacco consumption in Spain is increasing among women.

Therefore, gender differences were considered in socio-demographic and lifestyle factors, as well as in the patterns of tobacco use. Almost all p values between genders in Table 1 were statistically significant. Part of this effect was due to the large sample size of our study; however, this effect was also partly due to the existence of a gender pattern in socio-demographic and socio-economic variables, as described in the Spanish National Health Survey conducted in 2006 [4].

Females had different habits than males in relation to tobacco consumption; for example, men started to smoke at a younger age, and their consumption of cigarettes per day was higher than in women, as has been reported in other studies [9,22,23]. Men also had greater nicotine dependence; as many studies have demonstrated, nicotine addiction is the main barrier to cessation [1,24]. Although women seem to be more conscious of their health, the six-month continuous abstinence rate was slightly higher in men than in women, as reported previously [25,26]. However, this difference observed between genders in our study was not statistically significant. In the univariate analysis, men were more confident and ready to quit smoking than women [9]. In this study, male smokers were older than female smokers, which reflects the actual situation in the Spanish population [4]. The difference observed in the levels of confidence and readiness to quit between genders could stem from the fact that men were older than women and that there is a clear tendency to quit

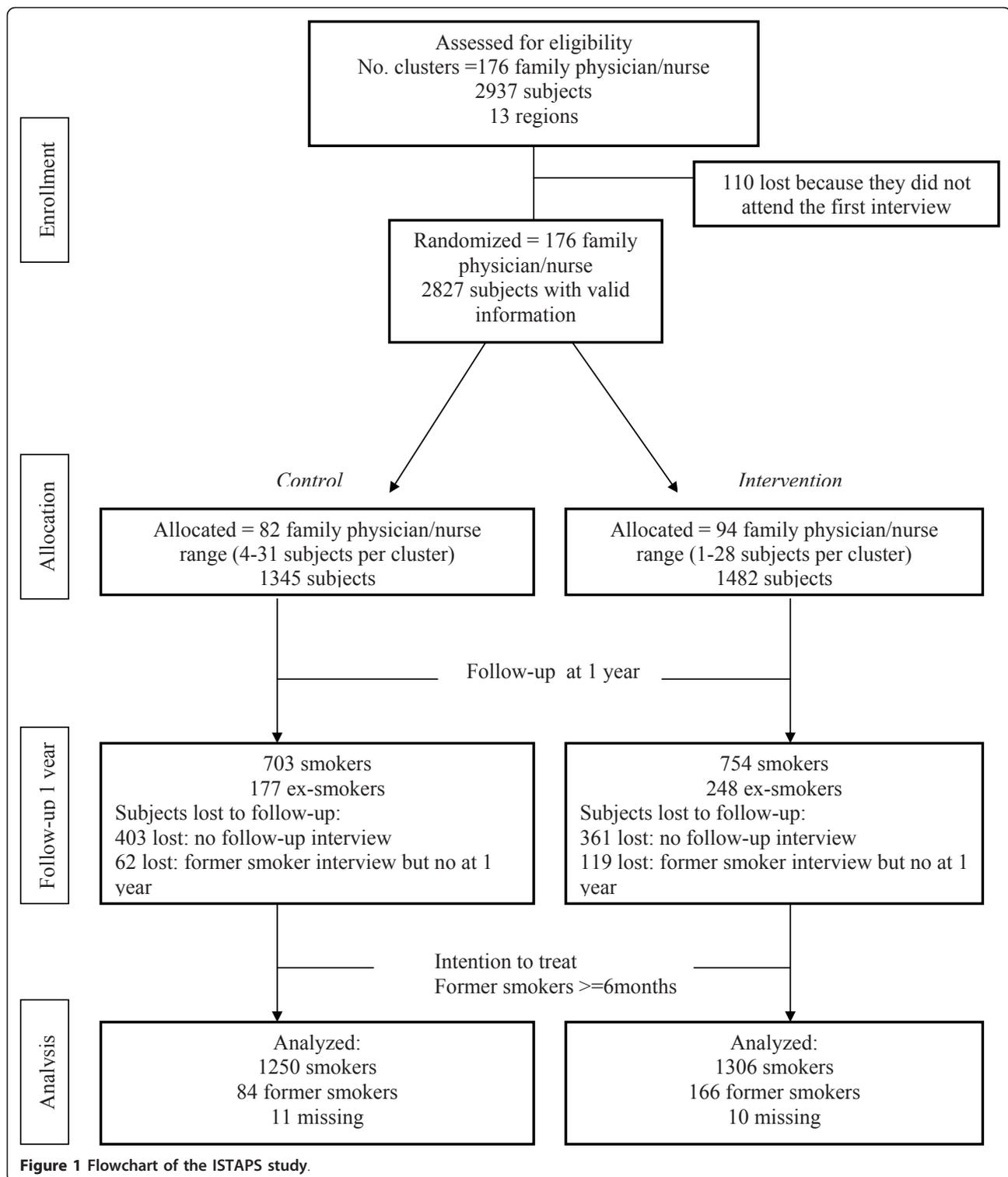


Figure 1 Flowchart of the ISTAPS study.

smoking in older age groups, as reported by a study conducted in Britain [27].

The existing evidence regarding gender and smoking cessation interventions has so far been diverse. Studies by Bohadana et al., Pogun et al. and others authors

show that the male gender, among other factors, is usually considered to be a predictor of a successful outcome in smoking cessation [25,28-30]. Women seem to resort to smoking to confront difficult situations that cause anxiety or depression. Furthermore, women who

Table 1 Distribution of socio-demographic information, lifestyle information and tobacco consumption characteristics according to gender at baseline.

	Total	Men (%)	Women (%)	p-value
Sample size (n)	2827	1413 (50)	1414 (50)	
group				
control	1345	699 (47.3)	676 (47.8)	
intervention	1482	744 (52.7)	738 (52.2)	0.806
age (years), mean (SD)	42.8 (13.6)	45.9 (14.5)	39.7 (11.8)	<0.001
social class				
I-II	491	236 (17.4)	255 (20.1)	
III-V	2131	1120 (82.6)	1011 (79.9)	0.073
alcohol intake*, mean (SD)	6.0 (10.3)	9.2 (12.7)	2.8 (5.9)	<0.001
physical exercise				
never	1569	760 (54.3)	809 (57.9)	
≥ 1 per week	1228	639 (45.7)	589 (42.1)	0.059
age at smoking initiation, mean (SD)	16.7 (4.5)	16.0 (3.9)	17.5 (5.0)	<0.001
n° cig/day, mean (SD)	20.4 (10.8)	22.1 (11.5)	18.7 (9.8)	<0.001
Fagerström test scores, mean (SD)	4.5 (2.5)	4.6 (2.5)	4.3 (2.5)	0.002
Richmond test scores, mean (SD)	6.3 (2.7)	6.3 (2.7)	6.2 (2.7)	0.191
smoker partner				
yes	1183	499 (41.2)	684 (59.6)	
no	1174	711 (58.8)	463 (40.4)	<0.001
smoker friends				
yes	2477	1242 (89.7)	1235 (89.4)	
no	288	142 (10.3)	146 (10.6)	0.788
stage				
pre-contemplation	643	326 (23.4)	317 (22.9)	
contemplation	1455	688 (49.5)	767 (55.4)	
preparation	554	302 (21.7)	252 (18.2)	
action	123	75 (5.4)	48 (3.5)	0.002
No. of previous attempts to quit lasting ≥ 24 hrs				
0	812	356 (25.6)	456 (32.8)	
1	511	254 (18.2)	257 (18.5)	
2	403	186 (13.4)	217 (15.6)	
3	298	153 (11.0)	145 (10.4)	
4	170	87 (6.3)	83 (6.0)	
5	588	356 (25.5)	232 (16.7)	<0.001
reduction no. cig over last month				
yes	1453	722 (52.2)	731 (53.2)	
no	1303	660 (47.8)	643 (46.8)	0.614
importance of quitting smoking (rank 0-10), mean (SD)	7.8 (2.6)	7.8 (2.6)	7.9 (2.5)	0.169
confidence in quitting smoking (rank 0-10), mean (SD)	4.9 (3.1)	5.1 (3.1)	4.6 (3.2)	<0.001
readiness to quit smoking (rank 0-10), mean (SD)	5.1 (3.1)	5.4 (3.1)	4.8 (3.1)	<0.001
tobacco-related disease				
yes	1171	692 (52.0)	479 (36.2)	
no	1481	638 (48.0)	843 (63.8)	<0.001

ISTAPS study.

SD: Standard Deviation

* measure: standard unit of alcohol per week (1 unit = 10 gr) (no drinkers included)

are concerned about post-cessation weight gain are less motivated to quit smoking [31,32]. These factors may contribute to the observation that women have poorer smoking cessation outcomes. Another reason that could

explain why women are not as successful in smoking cessation is the poorer effect of nicotine replacement therapies in women. A number of studies show that more men than women quit smoking after using

Table 2 Differences between genders in control and intervention groups at baseline and at one-year follow-up.

Baseline (restricted to individuals from whom information is available at one year)								
	Control n (%) = 703 (48.2)				Intervention n (%) = 754 (51.8)			
	total	men	women	p-value	total	men	women	p-value
no. cig/day, mean (SD)	20.2 (10.6)	22.1 (11.6)	18.7 (9.4)	<0.001	20.7 (10.5)	22.1 (10.9)	19.5 (10.0)	0.001
Fagerström test scores, mean (SD)	4.5 (2.5)	4.8 (2.6)	4.3 (2.5)	0.004	4.7 (2.5)	4.6 (2.5)	4.7 (2.5)	0.609
Richmond test scores, mean (SD)	6.0 (2.7)	6.1 (2.7)	5.9 (2.8)	0.198	6.2 (2.8)	6.2 (2.8)	6.3 (2.7)	0.755
stage								
pre-contemplation	176	73 (3.3)	103 (27.3)		178	92 (27.6)	86 (21.0)	
contemplation	376	166 (53.0)	210 (55.7)		397	156 (46.8)	241 (58.9)	
preparation	121	64 (20.4)	57 (15.1)		139	69 (0.7)	70 (17.1)	
action	17	10 (3.2)	7 (1.9)	0.151	28	16 (4.8)	12 (2.9)	0.010
reduction no. cig over last month								
yes	365	174 (55.1)	191 (50.1)		370	153 (47.2)	217 (53.8)	
no	332	142 (44.9)	190 (49.9)	0.194	357	171 (52.8)	186 (46.2)	0.076
importance of quitting smoking, mean (SD)	7.7 (2.6)	7.6 (2.5)	7.8 (2.6)	0.181	7.7 (2.6)	7.6 (2.8)	7.9 (2.5)	0.195
confidence in quitting smoking, mean (SD)	4.4 (3.1)	4.5 (3.0)	4.3 (3.1)	0.474	4.8 (3.1)	5.2 (3.0)	4.4 (3.1)	<0.001
readiness to quit smoking, mean (SD)	4.6 (3.0)	4.8 (2.9)	4.5 (3.1)	0.146	4.9 (3.1)	5.2 (3.2)	4.7 (3.0)	0.048
One-year follow-up								
	Control n (%) = 703 (48.2)				Intervention n (%) = 754 (51.8)			
	total	men	women	p-value	total	men	women	p-value
no. cig/day, mean (SD)	16.9 (9.9)	18.3 (11.2)	15.8 (8.5)	0.009	15.9 (9.5)	17.0 (10.5)	15.1 (8.6)	0.013
Fagerström test scores, mean (SD)	-	-	-		-	-	-	
Richmond test scores, mean (SD)	-	-	-		-	-	-	
stage								
pre-contemplation	226	97 (30.7)	129 (33.8)		219	97 (28.8)	122 (29.3)	
contemplation	252	112 (35.4)	140 (36.6)		307	129 (38.3)	178 (42.8)	
preparation	220	107 (33.9)	113 (29.6)	0.454	227	111 (32.9)	116 (27.9)	0.283
reduction no. cig over last month								
yes	348	157 (49.7)	191 (50.5)		382	168 (50.3)	214 (51.8)	
no	346	159 (50.3)	187 (49.5)	0.824	365	166 (49.7)	199 (48.2)	0.680
importance of quitting smoking, mean (SD)	8.0 (2.5)	8.0 (2.4)	8.1 (2.5)	0.524	8.0 (2.4)	7.9 (2.4)	8.0 (2.4)	0.749
confidence in quitting smoking, mean (SD)	4.3 (3.1)	4.5 (3.0)	4.1 (3.1)	0.044	4.2 (2.9)	4.4 (2.9)	4.1 (2.9)	0.206
readiness to quit smoking, mean (SD)	4.3 (2.9)	4.7 (2.9)	4.0 (3.0)	0.002	4.4 (2.9)	4.8 (3.0)	4.1 (2.8)	0.001

Only smokers. ISTAPS study.

SD: Standard Deviation

nicotine replacement therapies (NRT), indicating that NRTs are less effective in female smokers [33]. However, it has been reported that women and men benefited equally from treatment with Bupropion [34]. It should be emphasized that NRTs or bupropion cannot be assessed for individual effectiveness on smoking cessation in our study, since these treatments were considered to be a part of the intervention.

However, in a group of studies, no gender differences were found in the abstinence rates [22,35]. When gender was adjusted for potential confounders, no gender differences in smoking cessation were found as we have observed in our study [23,36]. Using evidence from studies that vary in design, sample characteristics, and intensity of the interventions studied, researchers to date have not found consistent gender-specific

differences in the effectiveness of intervention programs for tobacco cessation.

Other studies have reported that females are more likely to have achieved a six-month abstinence [35], perhaps because the higher percentage of female smokers responding to follow-up [37]. Nevertheless, many studies have not reported cessation results by gender [36].

There is limited information related to importance, confidence and readiness to quit smoking and gender differences in the literature. Specifically, there is no literature regarding the predictors that could increase the importance of quitting, self-confidence in quitting and readiness to quit at one-year follow-up. Some gender differences were observed in these variables at one-year follow-up in our study, but further research is warranted to support these results.

Table 3 Independent predictors of no. cig/day, importance of quitting, confidence in quitting and readiness to quit at one-year follow-up.

	Men one-year follow-up			
	N°cig/day	importance of quitting	Confidence in quitting	Readiness to quit
	Coefficient (robust SE [†])			
no. cig/day	0.5 (0.05)***			
Fagerström test scores	0.7 (0.19)***		-0.3 (0.05)***	-0.2 (0.05)**
Richmond test scores		0.2 (0.05)***		
importance of quitting		0.2 (0.04)***		
confidence in quitting			0.3 (0.04)***	0.2 (0.05)**
readiness to quit	-0.4 (0.12)***	-0.1 (0.04)*		0.1 (0.05)**

	Women one-year follow-up			
	N°cig/day [‡]	Importance of quitting	Confidence in quitting	Readiness to quit
	Coefficient (SE)	Coefficient (robust SE [†])	Coefficient (robust SE [†])	Coefficient (robust SE [†])
physical exercise > = 1 per week [ref.never]	-1.8 (0.49)***			
no. cig/day	0.4 (0.03)***			
Fagerström test scores	0.4 (0.13)***		-0.2 (0.04)***	-0.2 (0.04)***
Richmond test scores		0.1 (0.04)***		
Importance of quitting		0.3 (0.04)***		
confidence in quitting	-0.2 (0.10)*	-0.1 (0.03)***	0.3 (0.04)***	
readiness to quit	-0.2 (0.10)*			0.2 (0.04)***

Linear regression model. ISTAPS study

SE: standard error

Predictors variables were measured at baseline

Final models were adjusted only for significant variables.

* p ≤ 0.05 ** p ≤ 0.01 *** p ≤ 0.001

[†] The standard errors were adjusted for the cluster effect of the Basic Care Unit

[‡] Linear mixed-effects model

Table 4 Predictors of smoking cessation (ex-smokers versus smokers).

	Unadjusted OR (CI 95%)	Adjusted OR (CI 95%)	p-value
<i>Fixed effects</i>			
gender			
men	1	1	
women	0.9 (0.7-1.2)	0.9 (0.7-1.2)	0.696
group			
control	1	1	
intervention	1.9 (1.4-2.6)	1.7 (1.2-2.4)	0.001
age (years)	1.0 (1.0-1.0)	1.0 (1.0-1.0)	0.011
alcohol intake	0.9 (0.9-1.0)	0.9 (0.9-1.0)	0.003
no. cig/day	1.0 (1.0-1.0)	1.0 (1.0-1.0)	0.003
Fagerström test scores	0.9 (0.9-1.0)	0.9 (0.8-0.9)	<0.001
Richmond test scores	1.2 (1.1-1.2)	1.1 (1.0-1.2)	0.002
confidence in quitting smoking	1.1 (1.1-1.2)	1.1 (1.0-1.1)	0.091
readiness to quit smoking	1.2 (1.1-1.2)	1.1 (1.0-1.1)	0.207
<i>Random effects parameter</i>			
Variance (BCU) (2 level)	<i>Estimate (95%CI)</i> 0.2 (0.1-0.7)		

Logistic mixed-effects model. ISTAPS study.

Final model were adjusted for significant and/or confounder variables

Likelihood ratio test vs logistic regression p = 0.0137

Study strengths and limitations

In this study, which included several important factors associated with smoking cessation, the effect of gender was adjusted for confounding factors. Moreover, our study took into account the design effect in the calculation of the sample size, as well as the clustering of individuals within BCUs in the analysis.

Another strength of the study is the large number of participants. Furthermore, the study has great external validity since it was undertaken in several regions of Spain. All of the procedures were standardized, and all participating sites were coordinated by the same coordinating center. In addition, the professionals of both study groups received training before beginning the study. E-mails were sent each week, and meetings were held periodically to ensure continuity and quality of the study procedures.

Also, this study is one of the few to analyze gender when transtheoretical measures are included as predictor variables [9].

Some limitations of this study should be noted in interpreting the findings. One of the limitations was the recall bias related to dates. Patients may not have correctly remembered dates that were used in data collection, such as when they quit smoking. However, recall bias is normal in studies that use self-reported data.

The fact that patients were asked if they wanted to participate in the study could have had a therapeutic effect that improved their willingness to quit smoking. However, this therapeutic effect is present in both the control and the intervention groups, and in both genders.

There were only two time points of data collection, with a one-year interval [24]. Therefore, we do not have complete information about process or attitudes in the middle of the study period.

An important limitation in this study is the percentage of subjects lost to follow-up. Because the percentages of subjects lost to follow-up are similar in both groups (32.4% in the intervention group and 34.6% in the control group) and a penalizing data input method was used (subjects lost to follow-up were considered to be smokers), we do not believe this to represent a bias for estimating the relative effect of the intervention. However, this does result in a bias for estimating the absolute effect of both the intervention and the standard care administered in the control group. Indeed, if the analysis was performed only with subjects who were followed, the point abstinence rate at one year would be 24.5% in the intervention group and 20.1% in the control group. The actual abstinence rate is believed to lie somewhere between that value and the more conservative one which was reported in the Results section above. Additionally, we believe that this percentage of

dropouts may result from the complexity of the study, which was conducted at 82 healthcare centers in several regions of Spain and was incorporated to the routine of the visits. According to the CONSORT guidelines, all cases should be assessed as originally allocated to their study group under an intention-to-treat approach, and data for missing subjects should be input using the most suitable method, especially when there is a similar percentage of dropouts in both groups. In any case, no input method is free of bias.

One of the theoretical foundations for the study was the stages of change model. It is unclear how much time is needed to change a particular behavior, since not many differences were found in the stages of change between the baseline interview and the one-year interview.

Conclusions

We can conclude that gender does not appear to be a predictor of smoking cessation in individuals presenting at Primary Care Centers in Spain when the effect is adjusted for potential confounders. Further educational and public health campaigns are needed to encourage the use of pharmacological and non-pharmacological interventions in both genders. The study of characteristics associated with tobacco abstinence is important for assisting health care providers in tailoring interventions and for improving the quality of clinical services provided [37].

This study serves as a basis for the intervention used today in many Spanish Primary Care Centers, and some of the assessments proposed have been included in the clinical practice.

Conflict of interest

The authors declare that they have no competing interests.

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DP took responsibility for the cleanup and maintenance of the database as well as processing the manuscript. CC, CF, TC, MT, LC and CM participated in the design of the study and helped to draft the manuscript. TR performed part of the statistical analysis. All authors read and approved the manuscript.

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