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Impact of the professional pharmaceutical care service for smoking cessation in community pharmacies. Study protocol and characteristics of researchers and patients

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KEYWORDS

Smoking cessation, community pharmacy, professional pharmaceutical care service

ABBREVIATIONS

BMI: body mass index
BP: blood pressure
CP: Community pharmacist
CREC: Clinical Research Ethics Committee
CSRI: Client Service Receipt Inventory
SPFA: professional pharmaceutical care service

ABSTRACT

Introduction: Smoking is a serious public health problem, 23% of Spanish adults aged over 15 smoke every day and 2.4% are occasional smokers. Community pharmacists (CP) are health professionals who are accessible and close to the population and can have an important role in smoking cessation. It is essential to conduct research studies that show the impact of CP intervention in smoking and help define an action protocol that can generally be implemented in any community pharmacy of our country.

Material and methods: The protocol was used in a prospective, placebo-controlled, non-randomized, 12-month follow-up study among smoking patients aged over 18 who came to the community pharmacy with a medical prescription to quit smoking, for a consultation to quit smoking or a patient identified as a smoker. The study was designed to be carried out in 100 pharmacies with pharmacists trained in the CESAR program (intervention group) who performed a structured intervention and in 100 pharmacies with untrained pharmacists (control pharmacies) who performed a habitual intervention. Each pharmacy had to enlist a total of 5 patients, which would involve a total of 1000 cases.

Results: 182 CPs participated in the study (intervention group: 102, control group: 80), most of whom practiced their profession in neighborhood pharmacies. The research involved 1,078 patients (intervention group: 800, control group: 278), with a homogeneous gender distribution and an average age of 49 years.

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INTRODUCTION

Smoking is a serious public health problem and, as a result, it is calculated that 23% of Spanish adults aged over 15 smoke every day and 2.4% are occasional smokers (1). It is currently considered the first preventable public health problem in developed countries. Each year, smoking kills more than 8 million people worldwide, around 7 million die from direct smoke and 1.2 from exposure to tobacco smoke (2). In Spain, more than 55,000 people are estimated to die each year due to smoking, as this is the first cause of premature death and preventable illness (3).

Health promotion is one of the most important activities of community pharmacies, and the professional pharmaceutical care service (SPFA) for smoking cessation is among these activities (4). Various studies have shown that, if this service were introduced in pharmacies with trained and skilled professionals (5), it would have at least the abstinence rates found in studies performed by other health professionals. Additionally, pharmacies are health establishments easily accessible by the general population due to their proximity and high number, which makes it possible, if the service is introduced on a large scale, to contribute to reduce the number of smokers in our country, with the resulting positive impact at the clinical, economic and human level.

As a result, the study *Impact of the pharmaceutical care service of smoking cessation in community pharmacies - A placebo-controlled, non-randomized, 12-month follow-up study* was designed, with the main aim of evaluating the impact of a smoking cessation SPFA (the *CESAR* program) in community pharmacies, as the cost of effectiveness and the cost of value of said service, to obtain a more robust evidence on the impact of CP interventions in smoking cessation.

The specific objective of this article is to describe the characteristics of participating CPs and the sample obtained in the study, as well as the protocol followed for its conduct.

MATERIAL AND METHODS

Study design

The protocol was executed in a prospective, placebo-controlled, non-randomized, 12-month follow-up study.

Area of development

The study was conducted in community pharmacies all over Spain. The invitation to participate in the study was emailed by SEFAC to all its member pharmacists and was voluntary.

The pharmacies that decided to participate were divided into two groups, control and intervention. In the intervention study, the participating pharmacists had been trained to the service in the *CESAR* program, while the pharmacists in the control group had not been trained and offered their patients the usual pharmaceutical care.

For each intervention pharmacy, a control pharmacy was selected with similar characteristics to that of the intervention pharmacy: type of pharmacy (urban, rural, tourist), pharmacy personnel (number of pharmacists and assistants), pharmacy characteristics (opening hours, size, proximity to the closest primary healthcare facility) and characteristics of the population receiving care (similar socio-demographic characteristics and level of education).

Study population

Inclusion criteria

Smokers aged over 18 who come to the community pharmacy in any of the following situations:

- Patient with a medical prescription to stop smoking.
- Patient who requests a consultation to stop smoking.
- Patient identified as a smoker without consultation.

It was a proactive intervention, as it was not just conducted on smoking patients who requested the service.

Exclusion criteria

- Subjects with cognitive deterioration and/or severe/unstable metal illness.
- Subjects in treatment for drug addiction.
- Pregnant or breastfeeding women.

Sample size

The study was designed to be conducted in 100 pharmacies with pharmacists trained in the *CESAR* program (intervention group) and in 100 pharmacies with un-trained pharmacists (control group). Each pharmacy had to enlist a total of 5 patients, which would involve a total of 1000 cases.

Ethics committee

The study received a favorable evaluation by the Ethics Committee for Clinical Trials (CEIC) of the San Juan de Dios Foundation of Barcelona in June 2016.

Intervention group

The intervention according to the *CESAR* program consists in a pharmaceutical approach to the smoking patient in an agreed manner and according to a protocol. The intervention consists in the following stages:

Patient recruitment

When the patient comes to the pharmacy with a medical prescription to quit smoking, he/she asks for advice or is identified after a few pharmaceutical actions (e.g., taking blood pressure, [BP]), dispensing medication in the pharmaceutical indication...). In the study it was confirmed that the inclusion criteria were met and the patient was invited to participate. If the patient accepted, we proceeded to obtain the written informed consent to participation and the baseline assessments were conducted. Once done, an appointment was offered for the first interview.

First interview

It consists in that pharmacist intervention with that specific patient who is determined to quit smoking and has met the previous requirements. In the first study visit, we had to check the sociodemographic data, history of smoking, personal history and we indicated whether to start treatment and which.

Follow-up visits

These visits are scheduled in the protocol and the patient is provided with an appointment schedule for each. The reason for these appointments is to ask the patient about their condition to be able to reinforce and help them with their problems, they are asked about any side effects of the medication, adherence to the treatment... (in the case that treatment is provided or corresponds to the period of treatment). This is the time for the patients to express any concerns and they are helped to solve them. The study was scheduled to have visits on days 7, 15, 30, 60, 90 and 180 after the first visit.

Last visit

Conducted at 12 months.

Control group

The control CP provided a habitual intervention on smoking in their professional practice. Patients were recruited and it was verified that they complied with the inclusion criteria and signed the informed consent form. To guarantee strictness in the investigation and to improve the control group by comparison, the CP filled out a sheet that described their usual approach.

Both the control group and the intervention group at baseline, after 6 months and 12 months scheduled the patients for the assessment interviews, in which the following data were collected:

Baseline

- Weight, BP and co-oximetry.
- Sociodemographic data: gender, age, occupation, civil status, education, cohabitation, chronic illnesses.
- Degree of motivation to quit smoking (Richmond test).
- Degree of nicotine addiction (Fagerström test).
- Years smoked.
- Cigarette consumption/day.
- Cumulative cigarette consumption (No. of cigarettes per day x years as a smoker/20).

Baseline, 6 and 12 months

- BP.
- Weight.
- Co-oximetry.
- Quality of life: measured in the EuroQol-5D questionnaire (6). Generic health-related quality of life instrument.
- Relapse and number of cigarettes/day.
- Adherence to the pharmacological treatment (if any) according to the pharmacy register of withdrawn medications mentioned in the pharmacotherapeutic history of the pharmacy.
- Use of direct and indirect services: CSRI, questionnaire on the use of health services and of direct and indirect costs.

Data analysis

All participants record the data collected on the www.investigacionsefac.org platform and the intervention group recorded the visits in the *SEFAC eXPERT* platform (comprehensive SPFA management platform, developed by the Spanish Society for Clinical, Family and Community Pharmacy, SEFAC). The analysis of data obtained was performed using the STATA v16.1 statistical software package. The comparability between groups at baseline was assessed using the chi-square test or Fisher's exact test for the categorical data and using the Student's t-test for the continuous variables. To evaluate the effectiveness of the CESAR intervention, linear and logistic multivariate models were used for the continuous and dichotomous variables, respectively.

RESULTS

Pharmacists' sociodemographic characteristics

In the study, whose phases are shown in **Figure 1**, participated a total of 182 CP nationwide) 102 of who belonged to the intervention group and 80 to the control group **(Figure 2)**. Most participants were female (68.1%).

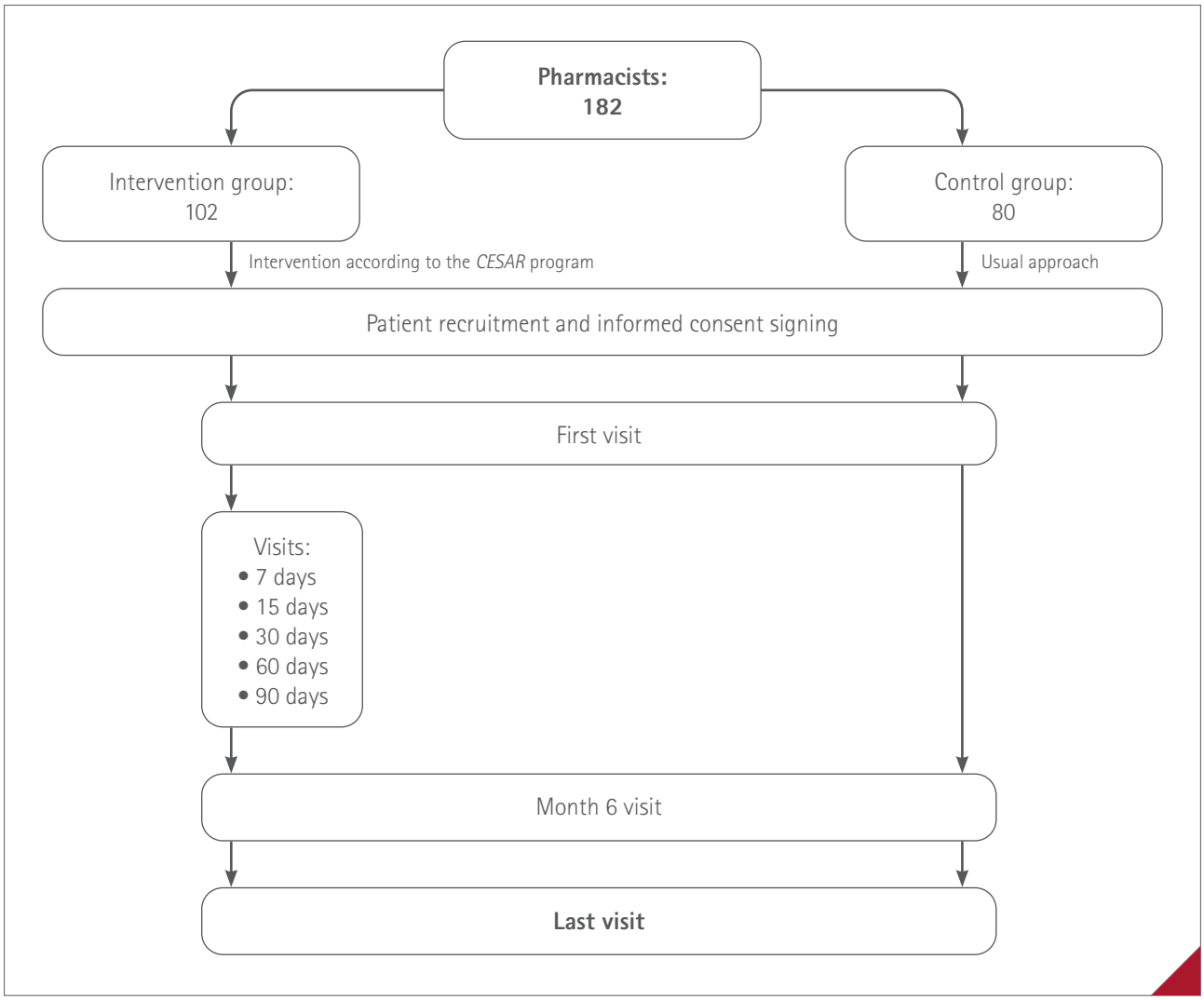

Figure 1 CPs participating in the study and visits conducted in each of the groups

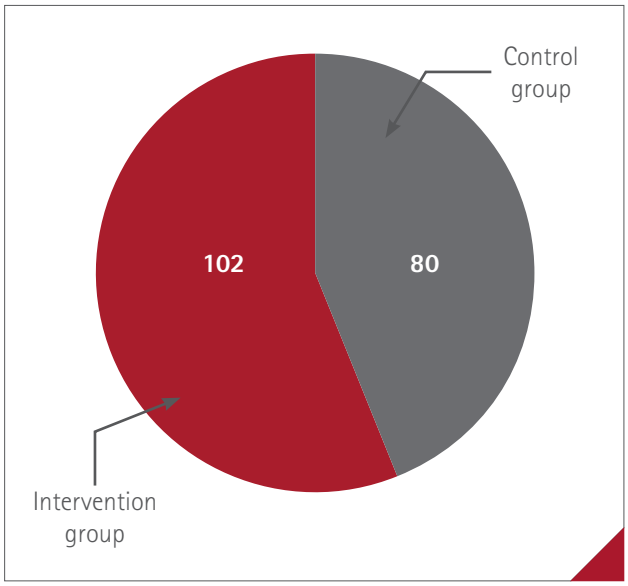

Figure 2 CPs participating in the control group and in the intervention group

In the type of CP who participated in the study (owner, substitute or associate) statistically significant differences were found, as the proportion of owners was higher in the control group (63.8%), while the intervention group had a higher proportion of assistants (50%). As for the type of participating pharmacy (tourist, city, neighborhood, near a health center or a shopping center), the majority were neighborhood pharmacies (75% in the control group and 66.7% in the intervention group). There were no significant differences between the groups p=0.158.

Additionally, statistically significant differences were identified between groups in the size of the town of reference and the number of pharmacists owners, associates and pharmacy technicians/assistants. In the control group pharmacies, it was more frequent to have a higher number of owners; conversely, the number of associates and assistants was higher than in the pharmacies of the intervention group.

The sociodemographic characteristics of the participating CPs are shown in Table 1.

Table 1 Sociodemographic characteristics of the CPs participating in the study

Variable	Control group (n=80)	*CESAR* group (n=102)	p-value*
Gender n (%)			0.424
Male	23 (28.8)	35 (34.4)	
Female	57 (71.13)	67 (65.7)	
Role, n (%)			
Pharmacist owner	51 (63.8)	41 (40.2)	Ref.
Substitute pharmacist	4 (5.0)	10 (9.8)	0.071
Associate pharmacist	25 (31.3)	51 (50.0)	0.004
Type of pharmacy, n (%)			0.158
Tourist pharmacy	7 (8.8)	4 (3.9)	Ref.
City pharmacy	6 (7.5)	9 (8.8)	0.239
Neighborhood pharmacy	60 (75.0)	68 (66.7)	0.293
Pharmacy near a health center	7 (8.8)	20 (19.6)	0.035
Pharmacy in a shopping center	0 (0.0)	1 (1.0)	
Size of a town pharmacy (inhabitants), n (%)			
<10,000	32 (40.0)	31 (30.4)	Ref.
10,000-50,000	15 (18.8)	33 (32.4)	0.041
50,000-500,000	18 (22.5)	31 (30.40)	0.139
>500,000	15 (18.8)	7 (6.9)	0.162
Number of pharmacists owners, n (%)			0.033
1	60 (75.0)	89 (87.3)	
>1	20 (25.0)	13 (12.7)	
Number of associate pharmacists, average (SD)	1.4 (1.2)	2.3 (1.8)	0.000
Number of technical assistants, average (SD)	1.9 (1.0)	2.5 (2.4)	0.020

* p-value according to logistic regression models.
The statistically significant differences were marked with a **red** square.

Patients' sociodemographic and clinical characteristics

A total of 1,078 patients were added to the study, 800 assigned to the intervention group and 278 to the control group **(Figure 3).** The proportion of men and women between groups was similar (intervention group: 57% women / 43% men, control group: 55.8% women / 44.2% men) and the average age was around 49 years. Most patients were married, lived together, had high school or college education and were working. The average body mass index (BMI) was 26 kg/m^2 and the most frequent illnesses they suffered from were arterial hypertension, dyslipidemia, and respiratory illnesses.

Statistically significant differences were found between the control group and the intervention group participants at the study level, with a higher percentage of people with higher studies in the first (34.9% vs. 25.9% p=0.046). Differences were also observed in the number of illnesses

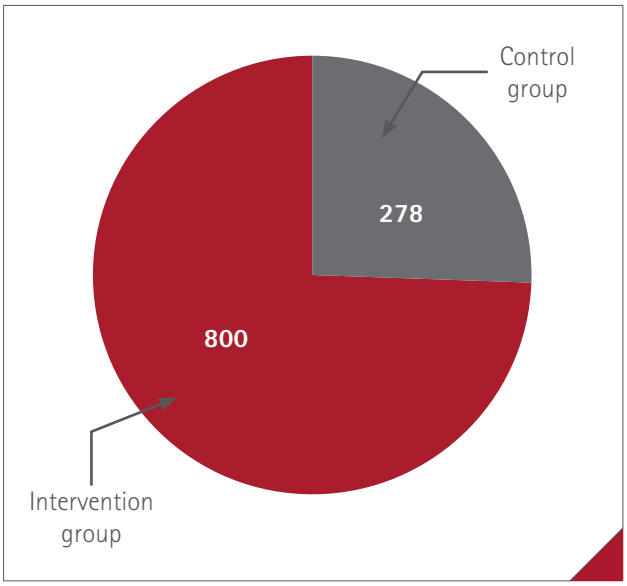

Figure 3 Smoking patients in the control group and in the intervention group

(p=0.018), higher in the control group (1.3 vs. 1.03), the presence of arterial hypertension was also significantly (p=0.007) more frequent (19.1% vs. 12.5%) in this group. The health-related quality of life at baseline was significantly (p=0.013) higher in the intervention group (0.84 vs. 0.81) (in the EuroQol 5D the measurement result is between 0 and 1, where 0 is death and 1 the best possible state of health).

Table 2 shows the sociodemographic and clinical characteristics of the patients included in the study.

Table 2 Sociodemographic and clinical data of the patients included in the study at baseline

Variable	Control group N=278	%m	*CESAR* group N=800	%m	p-value*
Gender, n (%)		0		0	0,718
Female	155 (55.8)		456 (57.0)		
Male	123 (44.2)		344 (43.0)		
Age, average (SD)	49.7 (12.3)	0	48.4 (11.8)	0 %	0.116
Civil status, n (%)		1.8		2.5 %	
Married or living together	168 (60.4)		510 (63.8)		Ref.
Separated or divorced	29 (10.4)		108 (13.5)		0.393
Unmarried	69 (24.8)		133 (16.6)		0.011
Widowed	7 (2.5)		29 (3.6)		0.465
Living together, n (%)		1.1		2.5	0.374
Lives with a partner	230 (82.7)		671 (83.9)		
Lives alone	45 (16.2)		109 (13.6)		
Level of education, n (%)		1.8		3.8	
No education	5 (1.8)		11 (1.4)		0.462
High school	43 (15.5)		115 (14.4)		0.346
Primary school	37 (13.3)		125 (15.6)		Ref.
Secondary school	91 (32.7)		312 (39.0)		0.976
College	97 (34.9)		207 (25.9)		0.043
Employment status, n (%)		0		1.0	
Househusband/wife	26 (9.4)		73 (9.1)		Ref.
Unemployed receiving benefits	16 (5.8)		52 (6.5)		0.687
Unemployed not receiving benefits	8 (2.9)		21 (2.6)		0.889
Employed on sick leave	10 (3.6)		23 (2.9)		0.658
Working	172 (61.9)		510 (63.8)		0.816
Student	4 (1.4)		14 (1.8)		0.720
Temporarily unable to work	2 (0.7)		5 (0.6)		0.894
Retired	40 (14.4)		94 (11.8)		0.552
BMI (kg/m^2), average (SD)	26.1 (4.5)	3.6	26.2 (4.7)	8.6	0.868
Number of illnesses	1.3 (1.7)	0	1.03 (1.5)	0	0.018

%m: percentage of subjects who do not have the variable information registered.
*p-value according to the logistic regression models performed according to the allocated database.
The statistically significant differences are marked with a **red** square.

Table 2 ***(Continued)*** Sociodemographic and clinical data of the patients included in the study at baseline

Variable	Control group N=278	%m	*CESAR* group N=800	%m	p-value*
Comorbidities, n (%)		0		0	
HBP	53 (19.1)		100 (12.5)		0.007
Cholesterol	48 (17.3)		106 (13.3)		0.100
Diabetes	22 (7.9)		40 (5.0)		0.075
Neoplasms	5 (1.8)		13 (1.6)		0.846
Kidney disease	3 (1.1)		7 (0.9)		0.760
Liver disease	1 (0.4)		7 (0.9)		0.404
Neurological disorder	7 (2.5)		20 (2.5)		0.987
Endocrine disorder	14 (5.0)		41 (5.1)		0.954
Dermatological disorder	4 (1.1)		28 (3.5)		0.091
Mild mental disorders or chronic stable mental disorder	23 (8.3)		54 (6.8)		0.396
Musculoskeletal disorder	21 (7.6)		54 (6.8)		0.650
Respiratory disorder	29 (10.4)		85 (10.6)		0.928
Heart disease	14 (5.0)		28 (3.5)		0.257
Sleep disorders	22 (7.9)		43 (5.4)		0.128
Digestive disorders	19 (6.8)		45 (5.6)		0.463
Ophthalmic diseases	9 (3.2)		19 (2.4)		0.438
Dental diseases	10 (3.6)		15 (1.9)		0.106
Alcohol and other drugs	2 (0.7)		7 (0.9)		0.806
Drug and food allergies or other allergies	51 (18.4)		110 (13.8)		0.065
EQ-5D-3L, average (SD)	0.81 (0.20)	0.7	0.84 (0.18)	0.4	0.013

%m: percentage of subjects who do not have the variable information registered.
*p-value according to the logistic regression models performed according to the allocated database.
The statistically significant differences are marked with a **red** square.

DISCUSSION

This non-randomized, placebo-controlled study on the impact of CP intervention in smoking cessation is the first with these characteristics conducted in our country and one of the most complete on the international level, as it not only assesses the effectiveness of this intervention, but it will also allow us to discover its impact on the quality of life of patients, and if it is a cost-effective service.

One of the most important characteristics is the sample size obtained, both pharmacists (182) and patients (1,078). Table 3 shows the samples sizes (smaller) used in other published studies conducted in community pharmacies.

Another different aspect was the fact that patient recruitment was proactive, as the service was offered not only to the subjects who requested it, but also to all those who the pharmacist identified as smokers and who had come to the pharmacy with a medical prescription to quit smoking.

This may also have affected the large size of sample obtained.

Table 4 shows how patients were recruited, following different criteria, in individual studies conducted in community pharmacies.

The intervention delivered in this study was structured and intensive. In a Cochrane revision (5), the authors conclude that probably the more intensive care provided in community pharmacies helps people quit smoking more than less intensive interventions (Table 5).

Table 3 CPs and patients participating in different studies on smoking cessation conducted in community pharmacies

Study	No. of smokers included	Participating CPs
Training pharmacists and pharmacy assistants in the stage-of-change model of smoking cessation: a randomised controlled trial in Scotland. Sinclair et al. (7) (1998)	492: • 224 intervention group • 268 control group	• 40 pharmacists • 54 technicians
A randomized controlled trial of a smoking cessation intervention based in community pharmacies. Maguire TA et al. (8) (2001)	484: • 265 intervention group • 219 control group	• 124 pharmacists
Deshabituación tabáquica desde la farmacia comunitaria. Barbero et al. (9) (2007)	77	Unspecified (2 pharmacies participated)
Effectiveness of a pharmacist-delivered smoking cessation program in the State of Qatar: a randomized controlled trial. El Hajj MS et al. (10) (2017)	314: • 167 intervention group • 147 control group	• 16 pharmacists

Table 4 Types of target population selected in smoking cessation studies in community pharmacies

Study	Target population	No. of smokers included
Training pharmacists and pharmacy assistants in the stage-of-change model of smoking cessation: a randomised controlled trial in Scotland. Sinclair et al. (7) (1998)	Subjects who come to the CP asking for advice or a product to help them quit smoking	492
A randomized controlled trial of a smoking cessation intervention based in community pharmacies. Maguire TA et al. (8) (2001)	Subjects who come to the CP and express their wish to stop smoking	484
Deshabituación tabáquica desde la farmacia comunitaria. Barbero et al. (9) (2007)	Subjects who freely request to participate in the smoking cessation program advertised on posters in participating pharmacies	77
Randomized trial assessing the effectiveness of a pharmacist-delivered program for smoking cessation. Dent el al. (11) (2009)	Subjects motivated to quit smoking	101
A mixed methods feasibility study of nicotine-assisted smoking reduction programmes delivered by community pharmacists – The RedPharm study. Farley et al. (12) (2017)	Subjects who did not want to quit smoking in the next 4 weeks, but who wanted to reduce smoking	68

Table 5 Results of intervention in studies conducted by CPs in smoking cessation at 6 months

Study	Type of Intervention	% cessation at 6 months
Training pharmacists and pharmacy assistants in the stage-of-change model of smoking cessation: a randomised controlled trial in Scotland. Sinclair et al. (7) (1998)	Brief (initial advice and follow-up at the months 1, 4 and 9)	11,6
A randomized controlled trial of a smoking cessation intervention based in community pharmacies. Maguire TA et al. (8) (2001)	Structured (weekly structured advice for 4 weeks and later every month as necessary)	14,3
Randomized trial assessing the effectiveness of a pharmacist-delivered program for smoking cessation. Dent el al. (11) (2009)	Intervention group: 3 face-to-face sessions with the CP	28
	Control group: standard 5-10 minute telephone session with the CP	11,8
Effectiveness of a pharmacist-delivered smoking cessation program in the State of Qatar: a randomized controlled trial El Hajj MS et al. (10) (2017)	Structured (with 4 sessions in total, 2 to 4 weeks apart)	12,6

Among the limitations of the study is the fact that participants are not randomized participants into control and intervention groups, which could skew the results obtained by not ensuring homogeneity between both groups. Other limitations of the study is the wide difference between the size of the intervention group (800 smokers) and of the control group (278 smokers), which makes them difficult to compare. Another factor that could affect the results is that the pharmacies were self selected, as the pharmacies in the intervention group could be more motivated and make their intervention more numerous and intense, with a higher success rate as a result.

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