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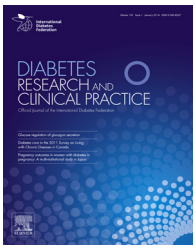

Continued smoking abstinence in diabetic patients in primary care: A cluster randomized controlled multicenter study

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SUMMARY

Aims: To assess the effectiveness of an intensive smoking cessation intervention based on the transtheoretical model of change (TTM) in diabetic smokers attending primary care.
Methods: A cluster randomized controlled clinical trial was designed in which the unit of randomization (intervention *vs.* usual care) was the primary care team. An intensive, individualized intervention using motivational interview and therapies and medications adapted to the patient's stage of change was delivered. The duration of the study was 1 year.
Results: A total of 722 people with diabetes who were smokers (345 in the intervention group and 377 in the control group) completed the study. After 1 year, continued abstinence was recorded in 90 (26.1%) patients in the intervention group and in 67 (17.8%) controls ($p = 0.007$). In patients with smoking abstinence, there was a higher percentage in the precontemplation and contemplation stages at baseline in the intervention group than in controls (21.2% *vs.* 13.7%, $p = 0.024$). When the precontemplation stage was taken as reference (OR = 1.0), preparation/action stage at baseline showed a protective effect, decreasing 3.41 times odds of continuing smoking (OR = 0.293 95% CI 0.179–0.479,

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$p < 0.001$). Contemplation stage at baseline also showed a protective effect, decreasing the odds of continuing smoking (OR = 0.518, 95% CI 0.318–0.845, $p = 0.008$).

Conclusions: An intensive intervention adapted to the individual stage of change delivered in primary care was feasible and effective, with a smoking cessation rate of 26.1% after 1 year.

1. Introduction

Many studies have reported the unfavourable effects of smoking in patients with diabetes, with an increased risk for micro and macrovascular complications, such as diabetic nephropathy, retinopathy and neuropathy especially in type 1 diabetic patients, and coronary heart disease, stroke and peripheral vascular disease, most pronounced in patients with type 2 diabetes [1–5]. Both the International Diabetes Federation [6] and the American Diabetes Association [7,8] have strongly recommended that people with diabetes not to smoke because of the increased risk of diabetes complications. The development of type 2 diabetes is another possible consequence of cigarette smoking, besides the well-known increased risk for cardiovascular disease [8].

Routine components of diabetes care include smoking cessation counselling [7,9]. Quitting smoking is an effective kidney-protective intervention in early nephropathy of type 2 diabetes [10,11]. Also, in smokers with newly diagnosed type 2 diabetes, smoking cessation was associated with amelioration of metabolic parameters and reduced blood pressure and albuminuria at 1 year [12]. However, systematic interventions to help diabetic patients stop smoking are difficult since many are not motivated to quit [13]. Also, the number of studies assessing the effectiveness of diabetic-specific smoking cessation programs is low [14–16], particularly in primary care [17,18], despite diabetic patients visiting their family physicians periodically for routine check-ups. According to the World Health Organization [19], the optimal level of service delivery should be based on a diabetes team comprised of a physician and a professional educator in the primary care setting. Although primary care is the ideal place for the implementation of smoking cessation programs in diabetic smokers, the provision of tobacco intervention services remains below desirable levels [20].

The transtheoretical model of change (TTM), originally proposed by Prochaska and DiClemente [21], describes a series of successive stages (precontemplation, contemplation, preparation, action and maintenance). This model has been the basis for developing effective interventions to promote health behaviour changes, including smoking cessation. Different studies have shown that TTM-based interventions increase quitting rate [22–24], particularly in prepared and motivated people [25] but evidence remains inconclusive [26]. The experience with the use of the TTM model in diabetic smokers is very limited [27]. It has been reported that the majority of individuals with diabetes who smoke are in the precontemplation stage of change and providing advice is important in moving smokers towards change [28]. Also, an intervention developed from the TTM was significantly better than usual treatment in helping individuals with type 1 and type 2 diabetes move into action stages of critical diabetes self-care behaviours, including readiness for self-monitoring of blood glucose, healthy eating, and/or smoking cessation [29].

However, as far as we are aware, the effectiveness of an intensive smoking cessation intervention based on the TTM in diabetic patients in the primary care setting has not been previously examined. Therefore, a cluster randomized trial in smoking cessation with intensive advice according to the TTM Stages of Change Model and motivational interview techniques was designed. The main objective of the study was to assess the effectiveness of this intervention in diabetic patients in primary care. The impact of the intervention on the evolution of TTM stages and tobacco consumption were secondary objectives of the study.

2. Materials and methods

2.1. Study design

The design and characteristics of the intensive advice in diabetic patients in primary care (ITADI) study have been previously reported [30]. ITADI was a cluster randomized, controlled and multicenter clinical trial, in which the primary health care team was the unit of randomization. A total of 43 primary care teams from the province of Barcelona that provided health coverage to urban, semirural and rural populations participated in the study, the primary objective of which was to assess the effectiveness of an intensive intervention to achieve continued smoking abstinence in patients with diabetes. Secondary objectives included assessment of the effectiveness of the intervention in the evolution of TTM stages and tobacco consumption. The time frame was 12 months after initiation of the study. The study protocol was approved by the Ethics Committee of the Primary Health Care Institute Jordi Gol. Written informed consent was obtained from all participants. The trial was registered in Clinical Trials.gov (identifier NCT00954967).

2.2. Study population

Eligible patients were type 1 and type 2 diabetic smokers of both genders, aged 14 or older that received routine diabetes care by the participating primary care teams, provided that an affirmative response was obtained to one or more of the following three questions: *Do you currently smoke?*, *Have you smoked more than 100 cigarettes in your lifetime?*, *Have you smoked any tobacco product in the last 7 days?*. Patients with communication difficulties (cognitive deterioration, language barrier); patients with terminal diseases, psychiatric diseases or with addictions to other substances; patients that were already in the process of quitting; patients who lived for more than 6

months outside the territory assigned to the primary care team; and those who refused to participate were excluded. Patients were sequentially enrolled at consultations in the routine daily practice during the recruitment period from September 2009 to September 2011.

2.3. Study procedures

The phases of the study have been described elsewhere [30]. Briefly, after presenting the project to all potential primary care teams, general practitioners and nurses who wanted to collaborate signed a commitment form. Centres were then assigned to the intervention or the control (non-intervention, usual care) groups using a centralized, computerized randomization system (ratio 1:1). The professionals in the intervention group received a full day specific training program that consisted of a motivational interview workshop and a pharmacological treatment workshop to quit smoking. Both workshops were focused on diabetic smokers and were taught by trained experts. They also were trained in the dynamics of the follow-up visits according to the Prochaska and DiClemente TTM and in how to use the electronic data collection systems. Professionals in the control group attended a practical training session that covered the methodology of the study and the electronic data collection system.

Patients were recruited as they visited the primary care team or alternatively were selected by simple random sampling from a list of diabetic smokers at each centre. Selected patients were scheduled for an appointment by a telephone call, in which the patient's eligibility was assessed, the characteristics of the study were explained, and patients were invited to take part in the study. Those who agreed signed the consent form and were initially classified into the precontemplation, contemplation and preparation/action stages. Primary care teams in the intervention group delivered an intensive, individualized intervention using the motivational interview, and used therapies and medications adapted according to the stage of change of the patient. The number of intervention visits varied according to the stage of the patient (five for precontemplation, seven for contemplation and eight for preparation/action). Patients could move forward and backward in their stage over the course of the study, so that intervention visits were adapted to these changes [30]. Patients in the intervention group and controls underwent a final assessment at the end of the study (12 months).

2.4. Data collection

For the purpose of the present report the following data were collected: age, sex, diabetes mellitus-related variables, age at initiation of smoking, number of cigarettes smoked in the last 2 weeks, nicotine dependence (Fagerström test), motivation to quit (Richmond test), phase of the patient according to the TTM at baseline and at the end of the study, number of visits, total time (in minutes) spent on the intervention, mean time spent on intervention visit per patient, and continued abstinence (yes, no). At the end of the study, continued abstinence was defined as at least 6 months without smoking and a carbon monoxide (CO) breath level of <6 ppm measured by a cooximeter in standard conditions.

2.5. Sample size calculation and statistical analysis

The sample size was calculated by multiplying the size of a randomized simple design by the design effect. In the simple randomization design, considering an alpha error of 0.05, a beta error of 0.20 in a bilateral contrast, and given that 15% of people with diabetes are smokers [31], 124 subjects were needed in each study group in order to determine a difference in continued abstinence greater or equal than 12% between study groups. This took into consideration the fact that smoking cessation in the general population is 5% with minimum advice [32] and 20% with intensive advice [33]. A continued abstinence of 5% was assumed for the control group, and a potential loss of follow-up of 20% was estimated. Using an intraclass correlation coefficient of 0.05 [13,34,35] and based on an average of 25 diabetic smokers per primary care team, the design effect was 2.2. Therefore, 546 diabetic smokers and 22 primary care teams were needed. Also, each professional had to recruit five patients, a number that was considered feasible for physicians in routine clinical practice. The sample size was calculated using the Granmo 5.2 program for Windows.

A per-protocol analysis was used. Categorical variables are expressed as frequencies and percentages and continuous variables as mean and standard deviation (SD) or median and first–third quartiles (Q1–Q3) (25th–75th percentile), as appropriate. Group comparisons (intervention *vs.* controls) were made using the Student's *t* test or the Mann–Whitney *U* test for continuous variables and the chi-square (χ^2) test for categorical variables. A multilevel mixed-effects logistic regression with random effect estimates for primary care team clusters was performed to assess the effect of intervention on smoking abstinence adjusted by TTM stage at inclusion in the study. Statistical significance was set at $p < 0.05$ (two-tailed). Data were analysed with the statistical package for the social sciences (SPSS) statistical program for Windows, version 18.0. The multilevel mixed analysis was performed with the Statistical Package StataSE 12.1 for Windows.

3. Results

A total of 1217 diabetic smokers were approached, 88.5% ($n = 1077$) of which agreed to participate in the study. There were 525 patients assigned to the intervention group and 552 to the control group. However, 69 patients in the intervention group and 60 in the control group were excluded because no information on the initial TTM stage was available. Of the remaining 948 (88.0%) patients, in 226 (111 in the intervention group and 115 in the control group) it was not known if they continued to smoke or their motivation stage at the end of the study. Therefore, the analysis was restricted to 722 patients (345 in the intervention group and 377 in the control group) who completed the study. The flow chart of the study population is shown in Fig. 1.

Table 1 shows the comparison of baseline data of patients included in the study ($n = 722$) and those with missing data ($n = 226$). There were no significant differences in relation to age, number of male patients, age at smoking initiation, number of cigarettes consumed daily in the last 2 weeks,

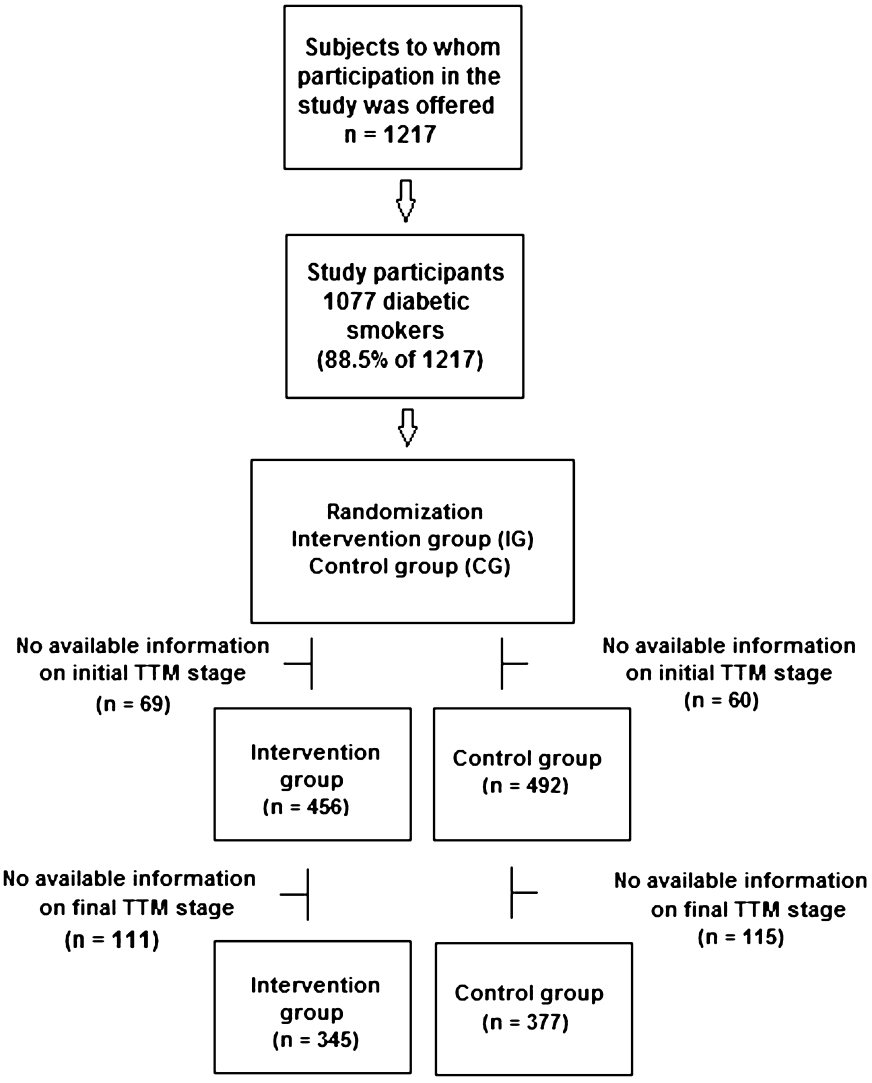

Fig. 1 – Flow chart of the study population. (TTM): transtheoretical model of change.

Richmond test and initial TTM stage. However, patients with missing data were significantly younger (mean [SD] age 57.7 [12.3] *vs.* 59.7 [11.3] years, $p = 0.024$) and showed a median (Q1–Q3) higher value in the Fagerström test for nicotine dependence (3 [1–4] *vs.* 2 [1–4], $p = 0.030$) as compared with patients included in the study.

Table 2 compares characteristics among patients in intervention and control groups. Both groups showed similar characteristics regarding mean age at smoking initiation (17.6 [6.2] *vs.* 17.9 [6.0], $p = 0.518$), median (Q1–Q3) number of cigarettes smoked daily in the last 2 weeks (16.5 [8–20] *vs.* 15 [10–20], $p = 0.531$). Education level, comorbidities, diabetes-related complications, duration of diabetes, and previous attempts to quit smoking were similar in the two groups. Oral antidiabetic drugs were given to 66% of patients, oral antidiabetic agents combined with insulin in 12.4%, insulin in 11.8% and only diet in 9.8%. The distribution of treatment modalities among patients in the two study groups was also similar.

As shown in Table 3, patients in the intervention arm as compared with controls showed significantly higher scores in the Richmond test (median [Q1–Q3] 5 [3–7] *vs.* 4 [2–5], $p < 0.001$). Moreover, there were statistically significant ($p < 0.001$) differences in baseline TTM stages, with a lower percentage of patients in the precontemplation stage (27.8% *vs.* 49.6%) and a higher percentage in the preparation/action stage (38.6% *vs.* 20.4%) in patients in the intervention group than in controls.

At the end of the study (Table 3), continued abstinence was recorded in 157 (21.7%) patients, 90 (26.1%) in the intervention group and 67 (17.8%) in controls ($p = 0.007$) with 8.3% more patients in the intervention group quitting smoking than the control group. The median (Q1–Q3) in the reduction of the daily number of cigarettes was also higher among patients in the intervention group than in the control group (−2 [−10–0] *vs.* 0 [−6–0], $p = 0.020$). Also, patients in the intervention group had a significantly lower number of cigarettes smoked daily in the last 2 weeks (median [Q1–Q3] 7 [0–18] *vs.* 10 [4–20], $p = 0.003$)

Table 1 – Characteristics of patients and tobacco consumption of patients included in the study and those excluded because of missed data.

Variables	Patients with 1-year follow-up (n = 722)	Patients with missed data (n = 226)	p Value
Male patients, no. (%)	549 (71.1)	168 (74.3)	0.709
Age, years, mean (SD)	59.7 (11.3)	57.7 (12.3)	0.024
Age at starting smoking, years, mean (SD)	17.8 (6.1)	18.3 (7.2)	0.300
Daily cigarettes smoked in the last 2 weeks, median (Q1–Q3)	15 (10–20)	20 (10–20)	0.165
Fagerström test score, median (Q1–Q3)	2 (1–4)	3 (1–4)	0.030
Richmond test score, median (Q1–Q3)	4 (3–6)	4 (2–6)	0.893
TTM stage, no. (%)			0.155
Precontemplation	283 (36.7)	74 (32.7)	
Contemplation	229 (29.7)	85 (37.6)	
Preparation/action	210 (27.2)	67 (29.7)	

SD: standard deviation; Q1–Q3: first–third quartiles (25th–75th percentile); TTM: transtheoretical model of change.

and median (Q1–Q3) score of the Fagerström test (0 [0–2] *vs.* 1 [0–3], $p = 0.010$).

In the group of 157 patients with continued abstinence at 1 year (Fig. 2), there was a higher percentage of those classified in the precontemplation plus contemplation stages at baseline (21.2%, $n = 45$)) in the intervention group than in controls (13.7%, $n = 41$) ($p = 0.024$). However, among patients initially classified in the preparation/action TTM stage 33.8% of patients in both the intervention and control group showed continued abstinence at 1 year. Significant differences in precontemplation and contemplation stages at baseline were not observed.

Patients in the intervention group attended a median (Q1–Q3) of 4 (2–6) visits, with a total cumulative time of all visits of 100 (48.8–183.3) min and a median time spent per visit of 22.1 (15–37.7) min.

In the multilevel mixed-effects logistic regression with random effect estimates for primary care team clusters

Table 2 – Characteristics of patients in the intervention and control groups.

	Intervention group (n = 345)	Control group (n = 377)	p Value
Male patients, no. (%)	263 (77.4)	286 (76.5)	0.780
Age, years, mean (SD)	60.0 (10.9)	59.5 (11.6)	0.618
Age at starting smoking, years, mean (SD)	17.6 (6.2)	17.9 (6.0)	0.518
Education level, % patients			0.349
Illiterate	2.3	0	
Primary level	72.4	65.6	
Secondary level	19.5	23.0)	
Higher education (graduate, university)	5.7	11.5	
Comorbidities, % patients			
Hypertension	57.1	56.1	0.759
Chronic obstructive pulmonary disease	19.4	16.1	0.192
Cerebrovascular events	4.3	3.7	0.600
Acute myocardial infarction	10.7	12.7	0.355
Dyslipidemia	57.4	55.2	0.519
Diabetes-related complications, % patients			
Cardiac	11.6	13.2	0.464
Retinopathy	8.2	10.2	0.306
Neuropathy	4.8	6.3	0.332
Treatment of diabetes, % patients			0.279
Diet	11.2	7.8	
Oral antidiabetic drugs	64.0	68.8	
Oral antidiabetic drugs and insulin	15.7	7.8	
Insulin	9.0	15.6	
Duration of diabetes, years, median (Q1–Q3)	6 (3–11)	7 (4–11)	0.836
Previous attempts to quit, % patients			0.936
None	28.3	28.8	
One	19.3	19.7	
Two	14.6	16.3	
Three	11.0	10.4	
More than three	26.7	24.9	

Q1–Q3: first–third quartiles (25th–75th percentile).

Table 3 – Baseline data and results at 1 year in the two study groups.

	Intervention group (n = 345)	Control group (n = 377)	p Value
Baseline visit			
Daily cigarettes smoked in the last 2 weeks, median (Q1–Q3)	16.5 (8–20)	15 (10–20)	0.531
Fagerström test score, median (Q1–Q3)	2 (1–4)	2 (1–4)	0.273
Richmond test score, median (Q1–Q3)	5 (3–7)	4 (2–5)	<0.001
TTM stage, no. (%)			
Precontemplation	96 (27.8)	187 (49.6)	<0.001
Contemplation	116 (33.6)	113 (30.0)	
Preparation/action	133 (38.6)	77 (20.4)	
Visit at 1 year			
Smoking abstinence	90 (26.1)	67 (17.8)	0.007
Duration of smoking abstinence, days, median (Q1–Q3)	180 (90–334)	180 (105–317)	0.982
Reduction in the number of daily cigarettes, median (Q1–Q3)	−2 (−10–0)	0 (−6–0)	0.020
Fagerström test score, median (Q1–Q3)	0 (0–2)	1 (0–3)	0.010
Richmond test score, median (Q1–Q3)	2 (0–6)	3 (0–5)	0.086
Daily cigarettes smoked in the last 2 weeks, median (Q1–Q3)	7 (0–18)	10 (4–20)	0.003
TTM stage, no. (%)			
Precontemplation	125 (36.2)	148 (39.3)	<0.003
Contemplation	115 (33.3)	125 (33.2)	
Preparation/action	15 (4.3)	37 (9.8)	

SD: standard deviation; Q1–Q3: first–third quartiles (25th–75th percentile); TTM: transtheoretical model of change.

adjusted by TTM stage at inclusion in the study, a cluster effect in the primary care teams was observed (Table 4). The effect of the intervention was not statistically significant (odds ratio [OR] = 0.813, 95% confidence interval [CI] 0.542–1.220, $p = 0.317$). When the precontemplation stage was taken as the reference (OR = 1.0), preparation/action stage at baseline showed a protective effect, decreasing 3.41 times the odds of continuing smoking (OR = 0.293 95% CI 0.179–0.479, $p < 0.001$). Contemplation stage at baseline also showed a protective effect, decreasing 1.93 times the odds of continuing smoking (OR = 0.518, 95% CI 0.318–0.845, $p = 0.008$) (Table 4).

4. Discussion

The main finding of the study is that an intensive intervention designed for diabetic patients who were active smokers, and implemented in the primary care setting, was effective in achieving continued smoking abstinence in 26.1% of cases. This percentage is clinically meaningful and significantly higher than 17.8% observed in patients assigned to the control group. Also, patients who continued smoking benefitted from the intervention because of the reduction in the number of cigarettes smoked per day.

The prevalence of cigarette smoking in diabetic patients in our environment is around 15%, which is in the range between 12.4% and 21% reported by other authors [32,33,13,34], although a decreasing trend as compared with previous studies is observed (22% in the study of Canga et al. [18] and 23.6% in the Behavioral Risk Factor Surveillance System for 1990–2001 found by Ford et al. [35]). Recent studies carried out in Spain have shown a reduction in the prevalence of smoking in people with diabetes to 13% [35]. In a study of 286,791 patients with type 2 diabetes carried out in 2009, the prevalence of current smokers was 15.4% [31]. There are variations from one country to another in accordance to changes in smoking patterns in the general population of these countries.

In our study, most patients were males (76.6% of the cases), which is consistent with other studies [34] due to the higher

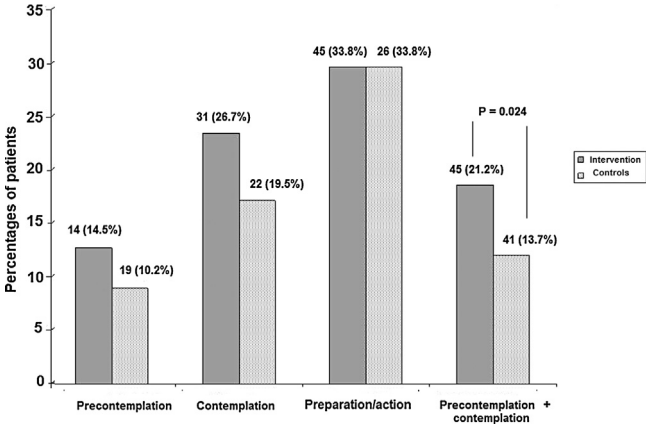

Fig. 2 – Differences in the initial stages of the transtheoretical model of change between patients in the intervention group and controls in the subset of 157 patients with continued abstinence at 1 year.

Table 4 – Results of multilevel mixed-effects logistic regression with random effect estimates for primary care team clusters adjusted by TTM stage at inclusion in the study.

	Coefficient (ß)	Odds ratio (95% confidence interval)	P value
Intercept	2.513		
Intervention	−0.207	0.813 (0.542–1.122)	0.317
TTM stage			
Precontemplation		1.0	
Contemplation	−0.658	0.518 (0.318–0.845)	0.008
Preparation-action	−1.228	0.293 (0.179–0.479)	<0.001

prevalence of smoking among males between 50 and 70 years compared with women of the same age group. The median daily number of cigarettes was 15, which is lower than 29 found in the study of Solano Reina et al. [37] in which patients were referred to specialized centres after previous treatment in primary care, so that a higher profile of consumption may be assumed. On the other hand, the percentage of 23% of patients lost during study seems reasonable given the intensive follow-up requirements over 1-year study period. Studies carried out in specialized consultations showed a lower percentage of patients who failed to keep with their appointments during the follow-up and not received the complete intervention program, 12% in the study of Albareda et al. [33] and 18.7% in the study of Canga et al. [18].

In relation to the stage of change, 70.9% of our patients were initially classified in the precontemplation and contemplation stages, which is in agreement with data reported by others (82% in the study of Albareda et al. [33]). In the study of Ruggiero et al. [28], 57.8% of current smokers were in the precontemplation stage as compared with 39.3% in our series. Higher motivation was associated with a higher percentage of success. There were no differences between the intervention and control groups in the percentage of patients with continued abstinence for those who were classified into the preparation/action stage at the initial visit. By contrast, the effectiveness of the intervention greater in patients who were in the precontemplation and contemplation stages at baseline, in which the percentage of subjects who stopped smoking was significantly higher in the intervention arm (21.2%) than in controls (13.7%). Accordingly, traditional action-based interventions targeting only those in the preparation stages are likely to be a mismatch for the majority of diabetic smokers and therefore ineffective in producing much change in smoking. Moreover, people with diabetes who smoke are less likely to be active in self-care or to comply with diabetes care recommendations [38] and, although smokers with diabetes indicate that they are aware of the negative impact of smoking on diabetes and their complications, they are especially resistant to change [27,28]. It has been argued that diabetic patients may believe that their lives are excessively constrained by demands on maintaining good metabolic control and may be less willing to accept an additional lifestyle prohibition regarding smoking [18]. In addition, they are usually diagnosed with diabetes several years before, and had probably received health professional's advice to quit smoking repetitively. On the other hand, weight gain concerns is one of the factors of particular relevance to people with diabetes and may be associated with difficulty in achieving long-term abstinence from smoking [6].

Data reported in other studies carried out in diabetic smokers are difficult to compare because of differences in the study population, methodology, characteristics of the intervention and primary endpoints. In the randomized controlled study of Canga et al. [18], the intervention consisted of a 40-min nurse visit that included counselling, education and a negotiated cessation date, with telephone calls, letters and visits at follow-up. At 6 months, the smoking cessation rate was 17.0% in the intervention group and 2.3% in the usual care group, which is much lower than the rates attained in our study, in which the intensity of the intervention was tailored to the stage of the Prochaska and DiClemente's model. In the multicenter study of Persson et al. [17], the intervention program consisted of eight group sessions in a 2-month period led by nurses with special education in smoking cessation. Each group meeting lasted for 45 to 60 min. Issues discussed during the sessions were motivation to stop smoking, and advice on how to break the habit and how to prevent relapse. The 1-year abstinence rate was 20% in the intervention group and 7% in the control group, which is lower than 26.1% and 17.8% achieved in our study. In the randomized trial of Hokanson et al. [16] based on face-to-face motivational interviewing plus telephone counselling and offering medication, the abstinence rate was marginally significant at 3 months (24% *vs.* 9%, $p = 0.077$) but there was no significant difference between groups at 6 months. However none of these studies used an intensive individualized intervention adapted according to the stage of the patient.

The design of the study was pragmatic in terms of time and material resources needed. Also, the unit of randomization was the primary health care team rather than the patient. Strengths of the study also include high number of patients ($n = 722$) who completed the 1-year follow-up. This study population is larger than patients reported in previous studies [16–18]. Also, the high number of professionals ($n = 423$) both general practitioners and nurses from the primary care setting should be emphasized.

The study has some limitations. First, the effect of smoking cessation on some variables such as glycated hemoglobin or patient's weight was not assessed. Second, the short-term (increase of appetite) or long-term (depressive symptoms) effects of smoking abstinence were not determined. Third, there were differences in TTM stages at baseline, with a lower percentage of patients in the precontemplation stage among those assigned to the intervention. It may be possible that previous training of health care personnel in the intervention group may have resulted in a greater interest to implement the intervention for smoking cessation, as well as higher difficulties in the recruitment of patients in the precontemplation stage. Similar findings with higher percentages of controls in the precontemplation stage were reported in the studies of Canga et al. [18] Ruggiero et al. [28], In the study of Cabezas et al. [39], the percentage of controls in the precontemplation stage was 25.4% in controls and 21.2% in the intervention group, although this study was carried out in a general population attended in primary care rather than in patients with diabetes. Finally, in a large number of patients ($n = 226$) it was not possible to assess the smoking status and motivation stage at the end of the study and, for this reason, these subjects were excluded. However, a selection bias seems unlikely given that patients included in the study and those with missing data showed similar characteristics at baseline, particularly in relation to TTM stage (Table 1).

In summary, an intensive intervention adapted to the individual stage of change delivered in primary care for diabetic smokers was feasible and effective, with a smoking cessation rate of 26.1% after 1 year, as well as a reduction in the number of cigarettes smoked per day. Patients in the preparation/action stage of change showed the same percentage of success independent of whether they were assigned to the intervention of the control group. Patients in the

precontemplation and contemplation stages received the most benefit from an intensive smoking intervention in primary care.

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Authors' contributions

S. Pérez-Tortosa participated in the design, coordination and execution of the study, interpretation of data, writing of the manuscript and supervision of the project.

L. Roig participated in the design, coordination and execution of the study, interpretation of data, writing of the manuscript and supervision of the project. This article will be used in his doctoral thesis in the Department of Medicine, Universitat Autonoma de Barcelona (UAB)

J.M. Manresa participated in the analysis and interpretation of data, critical revision of the manuscript and approval of the final draft.

C. Martin-Cantera and E. Puigdomènech participated in the research team, contributed to the study design, interpretation of data, critical revision of the manuscript and approval of the final draft.

A. Armengol participated in the research team, contributed to the study design, interpretation of data, critical revision of the manuscript and approval of the final draft.

M. Advani participated in the research team, contributed to the study design, interpretation of data, critical revision of the manuscript and approval of the final draft.

Conflicts of interest statement

The authors declare that they have no conflicts of interest in relation to this study.

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