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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.

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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

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