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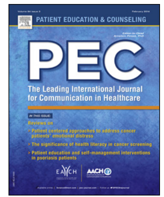

Short communication

Effect of the statin choice encounter decision aid in Spanish patients with type 2 diabetes: A randomized trial

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ABSTRACT

Objective: Statin choice, an encounter decision aid (DA), was developed in the USA to facilitate shared decision making between patients and clinicians about the use of statins to reduce cardiovascular risk. We aimed to assess the efficacy of this DA, compared to usual primary care, in Spanish patients with type 2 diabetes.

Methods: Cluster randomized trial with 29 clinicians and 168 patients. Knowledge of statins, cardiovascular risk perception, decisional conflict, anxiety and satisfaction with the decision making process were assessed immediately after intervention, and self-reported adherence at three months.

Results: Intervention significantly improved knowledge ($p = 0.01$), perception of the 10-year risk of myocardial infarction without ($p = 0.01$) and with statins ($p = 0.08$), and satisfaction ($p = 0.01$). There were no significant differences in decisional conflict, anxiety, consultation time or adherence, although more intervention patients reported taking all pills during the last week (92.7% vs. 81%; $p = 0.19$).

Conclusion: The statin choice DA improved the quality of decision making about statins.

Practice implications: This trial contributes to the body of evidence substantiating the efficacy of statin choice and extending it to Spanish clinicians and their patients with type 2 diabetes.

Trial registration: This trial is registered with the European Union Clinical Trials Register (EudraCT: 2010-023912-14).

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1. Introduction

Guidelines recommend statins, cholesterol-lowering drugs that effectively reduce cardiovascular risk, to at-risk patients [1,2]. The underuse of statins in high risk patients, overuse in low risk ones, and poor patient adherence reduce the value of this recommendation [3–5]. Lack of risk-based discussions that involve patients in the decision to use statins may contribute to this low-quality practice [6,7].

Encounter decision aids (DAs) are tools designed to facilitate collaborative deliberation between patients and clinicians [8–10], by including evidence-based information about the options and their relative merits. Statin choice is an encounter DA about the use of statins [11,12], which consists of a 3-page pamphlet listing cardiovascular risk factors, an estimate of the 10-year cardiovascular risk based on these (e.g., for patients with diabetes using the UKPDS risk equation [13]) presented using pictographs with or without statins, and a list of adverse effects of statins and their incidence. The tool is designed for use during the clinical encounter, often taking a few minutes [14].

Two previous trials conducted in U.S. have shown that this DA improves patients' risk perception of cardiovascular risk and their decisional conflict about the use of statins [11,12,14–16]. Results on 3-months adherence have been mixed [11,12]. The aim of this study

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was to assess the efficacy of this tool in a different health system and cultural context (Spanish primary care patients).

2. Method

A cluster randomized trial was conducted in 14 primary care centers in Tenerife (Spain). Physicians who consented to participate were randomized to intervention or usual care by means of a computer-generated list. They were encouraged to recruit at least 13 patients each (Fig. 1). Physicians in the intervention group were trained to apply the DA by a member of the research team, in group sessions of one hour. Patients were eligible if they were 18 or older, had type 2 diabetes, spoke Spanish language and did not present cognitive or sensorial impairments.

Patients completed the baseline measures in the practice with the physician. Then, physicians in the intervention group applied the DA (patients received a copy to take home). Post-visit measures were collected immediately after the visit by a researcher. Three-month questionnaires and a return envelope were sent by post.

The authors of the DA developed a Spanish version of the tool for use with Hispanic patients in U.S. We carried out a qualitative study to perform a cross-cultural adaptation of that version [17]. The final adapted version was almost the same, except for the exclusion of a sentence about statins' out-of-pocket costs, as statins are reimbursed in whole or in part by the Spanish Public Health System (Fig. 2).

2.1. Measures

- Knowledge about statins*: a 14-items scale [11] with three response options: "true", "false" and "I don't know". The total number of true responses represents the total score. Eight items were addressed in the DA, and six were not.
- Perception of cardiovascular risk*: we applied the question used by Mann et al. [12] "Out of 100 people like you, how many do you think will suffer a heart problem in the next 10 years?" either in the case of being taking statins or not, with five response options: (approximately) 1, 10, 20, 50, or almost all of them.

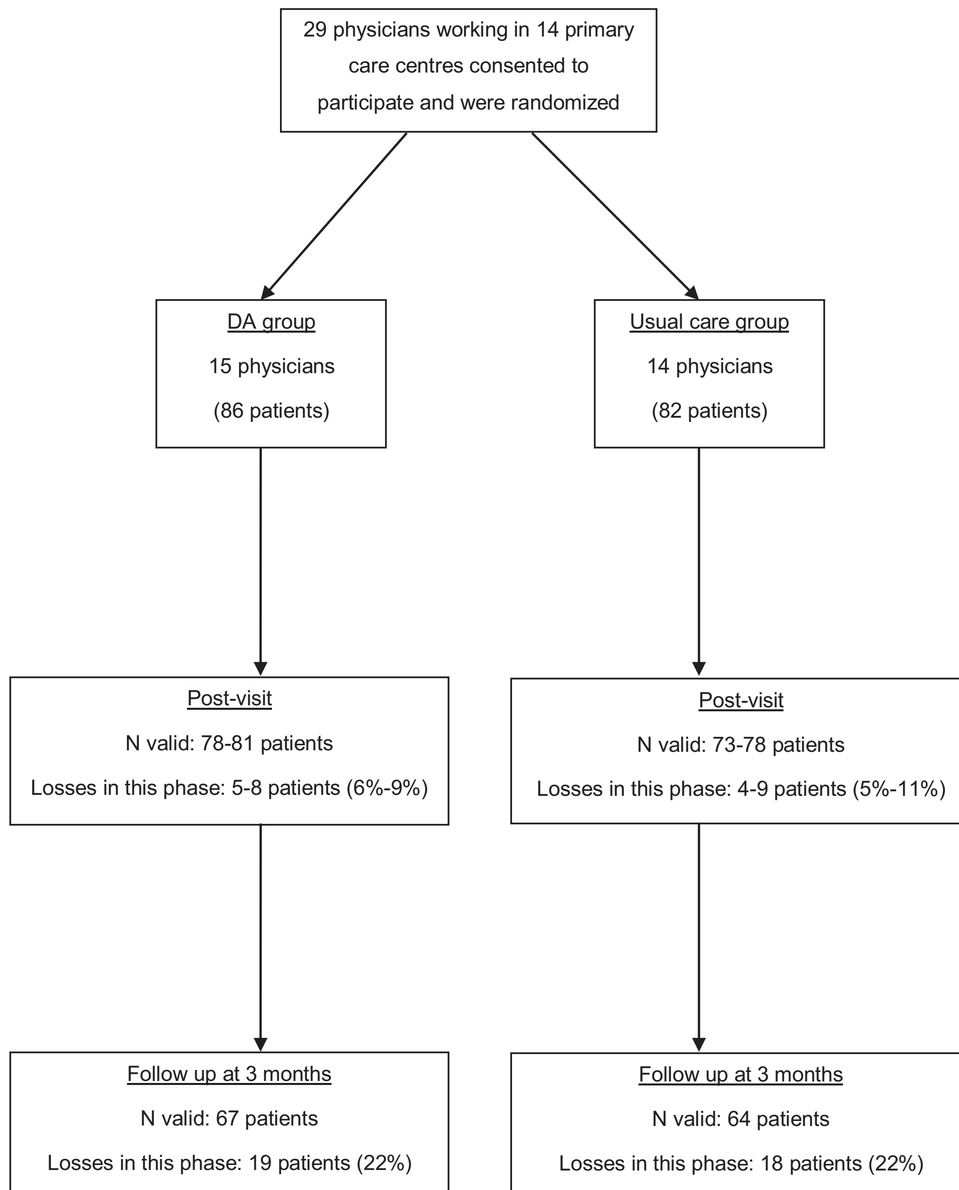

Fig. 1. CONSORT flow diagram of participants through the study.

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