

## Original article

## Effectiveness of an intervention to improve diabetes self-management on clinical outcomes in patients with low educational level



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## ABSTRACT

**Objective:** To determine whether an intervention based on patient-practitioner communication is more effective than usual care in improving diabetes self-management in patients with type 2 diabetes with low educational level.

**Methods:** 12-month, pragmatic cluster randomised controlled trial. Nine physicians and 184 patients registered at two practices in a deprived area of Granada (Andalusia, Spain) participated in the study. Adult patients with type 2 diabetes, low educational level and glycated haemoglobin (HbA1c) > 7% (53.01 mmol/mol) were eligible. The physicians in the intervention group received training on communication skills and the use of a tool for monitoring glycaemic control and providing feedback to patients. The control group continued standard care. The primary outcome was difference in HbA1c after 12 months. Dyslipidaemia, blood pressure, body mass index and waist circumference were also assessed as secondary outcomes. Two-level (patient and provider) regression analyses controlling for sex, social support and comorbidity were conducted.

**Results:** The HbA1c levels at 12 months decreased in both groups. Multilevel analysis showed a greater improvement in the intervention group (between-group HbA1c difference= 0.16; p=0.049). No statistically significant differences between groups were observed for dyslipidaemia, blood pressure, body mass index and waist circumference.

**Conclusions:** In this pragmatic study, a simple and inexpensive intervention delivered in primary care showed a modest benefit in glycaemic control compared with usual care, although no effect was observed in the secondary outcomes. Further research is needed to design and assess interventions to promote diabetes self-management in socially vulnerable patients.

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## Efectividad de una intervención para mejorar los resultados clínicos con autogestión de la diabetes en pacientes con bajo nivel educativo

## RESUMEN

**Objetivo:** Determinar si una intervención basada en la comunicación médico-paciente es más efectiva que la atención habitual en la mejora del autocontrol de la diabetes en pacientes con diabetes tipo 2 con bajo nivel educativo.

**Métodos:** Ensayo controlado aleatorizado pragmático por agrupación de 12 meses. Participaron en el estudio nueve profesionales médicos y 184 pacientes registrados/as en dos centros de salud en una zona pobre de Granada (Andalucía, España). Criterios de inclusión: adultos/as con diagnóstico de diabetes tipo 2, con bajo nivel educativo y hemoglobina glucosilada (HbA1c) >7% (53,01 mmol/mol). Los/las sanitarios/as del grupo de intervención recibieron entrenamiento en las habilidades de comunicación y en el uso de una herramienta para la monitorización del control glucémico y proporcionar información a los/las pacientes. El grupo control continuó la atención estándar. La medida de resultado fue la diferencia en la HbA1c después de 12 meses. Otras medidas de resultado fueron la dislipidemia, la hipertensión arterial, el índice de masa corporal y la circunferencia abdominal. Se realizó una regresión con dos niveles (paciente y proveedor) controlando por sexo, apoyo social y comorbilidad.

## Palabras clave:

Diabetes mellitus tipo 2

Atención primaria de salud

Desigualdades en salud

Autocuidado

Ensayo clínico controlado aleatorizado

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**Resultados:** La HbA1c a los 12 meses disminuyó en ambos grupos. El análisis multinivel mostró una mayor mejoría en el grupo de intervención (diferencia entre grupos HbA1c =  $-0,16$ ;  $p = 0,049$ ). No se observaron diferencias estadísticamente significativas entre los grupos para la dislipidemia, la hipertensión arterial, el índice de masa corporal y la circunferencia abdominal.

**Conclusiones:** Este estudio pragmático mostró que una intervención sencilla y de bajo coste ofrecida en atención primaria alcanzó un modesto beneficio en el control glucémico en comparación con la atención habitual, aunque no se observó ningún efecto en los resultados secundarios. Se necesita más investigación para diseñar y evaluar intervenciones para promover el autocontrol de la diabetes en pacientes socialmente vulnerables.

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## Introduction

The prevalence of type 2 diabetes mellitus (T2DM) rapidly rose over the past three decades worldwide.<sup>1</sup> In Spain, the prevalence of T2DM (2012) is 14%,<sup>2</sup> and the mortality rate associated with the condition is 18.3/100,000 men and 24.9/100,000 in women.<sup>3</sup>

T2DM does not impact all population groups equally, existing important differences according to sex, socioeconomic status and ethnicity.<sup>3–5</sup> Socially disadvantaged groups are more exposed to obesogenic environments, and experience more difficulties in adopting healthy lifestyles (i.e. eating habits, physical activity, etc.), caused by social determinants of health.<sup>5–12</sup> Several studies have observed an inverse association between educational level and worse prognosis of T2DM,<sup>3–5</sup> which has been attributed to increased difficulties in processing oral communication,<sup>13</sup> less awareness of the importance of diabetes self-management<sup>14</sup> and less cohesive support networks<sup>14,15</sup> in patients with a lower educational level.

A number of studies have examined the effectiveness of different types of interventions specially designed to improve diabetes self-management in socially vulnerable patients.<sup>15–19</sup> Most of these interventions consisted in the use of psychoeducational strategies and targeted ethnic minorities or groups with lower socioeconomic status. Although, there was a great diversity of procedures and type of interventions, a moderate reduction of HbA1c outcome were observed in these systematic reviews.<sup>15–19</sup>

Evidence suggests that adequate patient-practitioner communication has a number of different benefits, including positive effects on patients' compliance with medical recommendations.<sup>20</sup> However, there is a scarce evidence available regarding the potential of interventions based on improving patient-practitioner communication to improve diabetes self-management in patients with low educational levels, much more if the intervention was performed by a medical doctor. Thus, Chapin et al.<sup>21</sup> evaluated the effectiveness of an intervention consisting in the use of a visual tool to provide feedback to patients by displaying glycosylated haemoglobin values graphically over time, and relating them to the patients' self-reported self-management activities. The authors observed that after the intervention 51% of the patients achieved adequate glycaemic control (HbA1c <7%, 53.01 mmol/mol). Because its low cost of the intervention and easy transferability to routine clinical practice, we decided to adapt this intervention, implement it in a primary care setting in Spain, and evaluate its impact on patients' health.

The aim of this study was to test whether an intervention based on improving patient-practitioner communication, compared with standardised usual care can improve diabetes self-management in patients with a low educational level.

## Methods

A detailed description of the methodology used of this study is available elsewhere.<sup>22</sup>

## Study design

Pragmatic cluster randomised controlled trial (Fig. 1).

## Setting

The study was conducted in two general practices in the city of Granada (Andalusia, Spain). A total of nine general practitioners (GPs) in the two practices participated in this study, those practices were selected because they were located in a highly deprived area. We used computerised randomisation to allocate the GPs to the intervention or control group.

## Participants

Patients were eligible if they had T2DM, were aged  $\geq 18$  years, had and HbA1c level  $>7\%$  (53.01 mmol/mol) at the assessment visit, and had a low educational level (no studies or only primary school education). Exclusion criteria were having a serious physical or mental health condition that would prevent to follow trial procedures or being taking part in a different study.

## Sample size

The sample size was calculated assuming that at the end of the intervention 10% of the control group and 30% of intervention group A would achieve improved diabetes control (with HbA1c values falling to below 7%). So initially, we attempted to achieve a sample size of 90 patients in each group (control and intervention) in order to provide a statistical power of 89.4% to detect significant differences in the percentage of controlled diabetic patients in both groups.

## Intervention

The intervention, performed by participant practices, consisted in using a diabetes self-management record sheet (DSMRS) as part of the consultation. GPs and patients work together to complete the DSMRS, which included two parts: 1) a graph showing the patient's previous HbA1c levels, and 2) five patient-reported items on self-management activities.<sup>21</sup> The aim of the DSMRS was to prompt discussions/reflections about the importance of adequate diabetes self-management and its impact on glycaemic control and in turn on diabetes-related complications. At the end of the session, patients were offered a take home copy of the DSMRS and encouraged discuss it with their relatives. The intervention was delivered every 3 months, during the course of a year (i.e. four sessions by the end of the study period). To standardise the intervention style, the GPs received training in cognitive, emotional and communication aspects. In addition, every six months a joint meeting of researchers and GPs was held to address potential problems, monitor the progress of the study and ensure adherence to the study protocol.

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