

# Original Psychoeducative groups help control type 2 diabetes in a primary care setting

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#### Abstract

Introduction: The purpose of this study is to measure the impact of a psychoeducational group intervention in diabetes using glycosylated haemoglobin (HbA1c), the body mass index (BMI) and cardiovascular risk factors (CVRF) compared with conventional educational measures provided individually.

*Methods:* A quasi-experimental study (pre/post-intervention) with a non-equivalent control group was conducted, including 72 type 2 individuals with diabetes (mean data: age 63.08 years, HbA1C 6.98%, BMI 30.48 kg/m<sup>2</sup>).The beneficial effect of psychoeducational group therapy in the study group (PGT) was compared with conventional diabetes education in the control group (CG).

*Results:* The PGT had a higher mean HbA1c reduction  $(-0.51 \pm 1.7 vs. -0.06 \pm 0.53\%, p 0.003)$ , met the objectives of optimal control of HbA1c to a higher degree (80% vs. 48%, p 0.005) and greater mean weight reduction (-1.93 ± 3.57 vs. 0.52 ± 1.73 kg, p 0002) than the CG.A significant improvement in total cholesterol, LDL cholesterol, triglycerides, systolic and diastolic blood pressure was achieved in PGT (all p < 0.05).

*Conclusions:* PGT patients achieved a significant improvement in HbA1C, BMI and CVRF, and outperformed the conventional diabetes education group in achieving the optimal diabetes control objectives. Structural changes in the assistance programs should be considered to introduce these more efficient therapies for diabetes education in primary care.

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Key words: Diabetes mellitus. Type 2. Psychoeducative. Groupal education. Primary care.

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#### LA TERAPIA PSICOEDUCATIVA GRUPAL EN ATENCIÓN PRIMARIA AYUDA EN EL CONTROL DE LA DIABETES TIPO 2

#### Resumen

*Introducción:* Los cambios en el estilo de vida mejoran el control de los diabéticos tipo 2, pero no sabemos cuales son las estrategias más eficientes para conseguir estos cambios. Hemos medido el impacto de una intervención psicoeducativa grupal en diabetes mediante hemoglobina glicosilada (HbA1c), índice de masa corporal (IMC) y factores de riesgo cardiovascular (FRCV).

*Métodos:* Se trata de un ensayo clínico controlado, randomizado y multicéntrico, de 72 pacientes diabéticos tipo 2, edad media 63,08 años, 50% mujeres, HbA1c media 6.98% e IMC medio 30,48 kg/m<sup>2</sup>. Se comparó el efecto terapéutico de una intervención psicoeducativa grupal(GSE) con una educación diabetológica convencional (GC).

*Resultados:* El GSE presentó una mayor reducción media de HbA1c,  $-0.51 \pm 1.07 vs -0.06 \pm 0.53\%$  (p 0.003), un mayor grado de cumplimiento de los objetivos de control óptimo de HbA1c, 80% vs 48% (p 0.005) y una mayor reducción media de peso,  $-1.93 \pm 3.57 vs 0.52 \pm 1.73 kg$  (p 0.002), que el GC. También se objetivó una mejoría significativa de colesterol total, colesterol LDL, triglicéridos, tensión arterial sistólica y diastólica en GSE (todas las p < 0.05).

*Conclusiones:* Los GSE de diabéticos tipo 2 consiguieron una mejoría significativa de HbA1c, IMC y FRCV, y superaron a la educación diabetológica convencional en el grado de cumplimiento de los objetivos de control óptimo de la diabetes. Debemos plantearnos cambios estructurales en nuestros programas asistenciales para introducir estos avances más eficientes en educación terapeútica de diabetes en atención primaria.

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Palabras clave: Diabetes mellitus. Tipo 2. Psicoeducativo. Educación grupal. Atención primaria.

## Abbreviations

PC: Primary care. HbA1c: Glycosylated haemoglobin. BMI: Body mass index. CVRF: Cardiovascular risk factors. PGT: Psychoeducational Group. CG: Control Group. SBP: Systolic blood pressure. DBP: Diastolic blood pressure. NS: Non significant.

# Introduction

Diabetes is a growing concern in healthcare because of its high prevalence and direct cause of death, disability and high healthcare costs. It thus constitutes a priority area for interventions in healthcare plans in Spain. Cardiovascular disease is the leading cause of death (65%) among type 2 diabetic patients.<sup>1</sup> There is a high comorbidity associated with diabetes (diabetic retinopathy, diabetic nephropathy, ischemic heart disease, cerebrovascular disease, and diabetic foot). Diabetic retinopathy is the most common cause of blindness in people over 50 years in Western countries, and it also accounts for 20% of patients on dialysis. This comorbidity leads to a high level of health care spending and reduced life expectancy of diabetic patients to 40 years after diagnosis.

Integrated care for diabetic patients has not only proven to reduce the rate of chronic complications but it is also decreasing hospital admissions for acute complications and average hospital stay.<sup>2-7</sup> Achieving this goal requires the use of all available health resources, their rationalization, and effective and efficient coordination between different levels of health settings through multidisciplinary units, which should cover prevention, recovery and rehabilitation of the disease.

The Area VII-East Murcia Diabetes Unit was created in 2007 in the context of the new single management area, assisting a population of about 210,000 inhabitants. The unit, coordinated by endocrinologists, is responsible for diabetes doctors and nurses in 10 primary care (PC) centres and all the specialized services of the Reina Sofía University Hospital in Murcia that are related to complications of this disease (ophthalmology, diabetic foot surgery, rehabilitation, cardiology, nephrology, neurology, nutrition, intensive care, anaesthesia and psychiatry).

As a general objective, the diabetes unit aims to reduce mortality and morbidity of diabetic patients by reducing the incidence of acute and chronic complications of diabetes. For its achievement, the PC centres initiated action geared toward patients aimed at increasing the degree of knowledge, responsibility, self-control and self-management of diabetes. Therapeutic strategies in diabetes education were established through the creation of psychoeducational group activity for addressing the personal, social and family situation of being a diabetic, monitored by educators as an alternative and/or complement to conventional therapy in diabetes education, which was done individually.

The main objective of this study was to measure the impact of a psychoeducational group activity in the PC setting as a tool to improve diabetes self-management through the reduction of glycosylated haemoglobin (HbA1c), the body mass index (BMI) and cardiovas-cular risk factors (CVRF), compared with conventional educational measures provided individually.

# Materials and methods

A quasi-experimental study (pre/post-intervention) with a non-equivalent control group was conducted on 72 diabetic patients; 36 men and 36 women, aged between 30 and 75 years, belonging to the PC centres of The Health Area VII: East Murcia. Doctors and nurses, members of the Diabetes Unit, from four of the ten PC centres in the area (El Carmen, Monteagudo, Infante and Puente Tocinos) took part in the study in a coordinated manner.

Patients were selected from among those who came to the doctor's or nurse's consultation at the PC centre and met the inclusion criteria (fig. 1). They were split into two groups: a Psychoeducational Group (PGT; those patients who agreed to be part of a psychoeducational group for diabetes) and a Control Group (CG; patients who only received conventional diabetes education individually).

This study was carried out in accordance with the recommendations of the Declaration of Helsinki. The Human Research Ethics Committee of the Reina Sofía University Hospital approved the study. Written informed consent was obtained from all participants in this study.

# Study design

The study was conducted over a period of a year, between 2010 and 2011, and was divided into three phases:

- Phase I or pre-intervention period: Training of leaders of the psychoeducational groups, selection of group members in each PC centre, and preintervention data collection.
- Phase II or intervention period: Development of the group intervention training consisting of a mixed type, with components of education, selfassessment and feedback to the group of patients studied. Each group consisted of twelve patients, and two healthcare professionals responsible for diabetes: one or two leaders and one observer. The

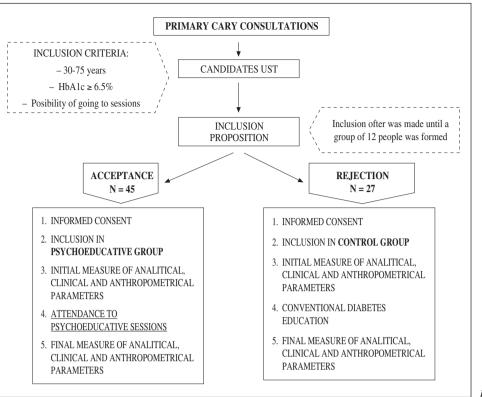


Fig. 1.—Work scheme.

psychoeducational program consisted of 11 sessions of 90 minutes duration, which took place in the PC centre. The methodology consisted of a presentation of the session, development, final conclusions, questions, measurement, and the outline of the subject of the following session. The contents of the sessions were: 1. Presentation, 2. Self-concept of diabetes and its control, 3. Finding themes of interest and identifying needs, 4. Concept and importance of diabetes, 5. Physical activity, 6. Diet, 7. Hygienic care, 8. Acute complications of diabetes: hypoglycaemia, 9. Acute diabetic complications: hyperglycaemia, 10. Chronic diabetic complications, 11. Conclusion and closure.

Phase III or post-intervention period: Post-intervention data collection. A specific database and data collection sheets were designed for the study, including social and demographic variables *—age*, sex, years of evolution of diabetes-, clinical variables —weight (kg), height (m), body mass index (BMI) (kg/m<sup>2</sup>), systolic blood pressure (SBP) (mmHg), diastolic blood pressure (DBP) (mmHg)—, type of treatment —insulin use, type of insulin pattern, oral agents, diet, exercise and treatment combinations-, and laboratory variables —total cholesterol (mg/dl), HDL cholesterol (mg/dl), LDL cholesterol (mg/dl), triglycerides (mg/dl), HbA1c (%)-. Results were compared in both groups at baseline and three months after completing the training.

### Statistical analysis

Statistical analyses were performed using the SPSS 15.0 software for Windows (SPSS, Chicago, IL, USA). Quantitative variables were expressed as mean ± standard deviation and qualitative variables as percentages. Demographic, clinical and analytical characteristics of patients in both groups were recorded, presenting a descriptive analysis. A comparative analysis of the evolution of clinical and laboratory variables of patients in both groups was performed. Quantitative variables were compared between groups using Student's t-test for independent samples, and the Student t-test for paired samples was used to analyze the patients' evolution in each group. Similarly, qualitative variables comparison was performed using the Pearson Chi Squared and McNemar test for paired samples. The significance level was set at 95% in all cases.

#### Results

A total of 72 type 2 diabetic patients were selected in scheduled consultations from four of the ten PC centres of the health area. Patients had a mean age of  $63.08 \pm 10.68$  years, with an even gender distribution (50:50), initial mean HbA1c of  $6.98 \pm 1.18\%$  and initial mean BMI  $30.48 \pm 4.98$ kg/m<sup>2</sup>. 75% of patients had been diagnosed with type 2 diabetes for less than 15 years, while 25% of them had had the disease for more than

	Со	Control group $(n = 27)$ Psychoeducative g		lucative group (n =	ve group $(n = 45)$		Comparison between groups	
							Initial	Final
	Initial	Final	$p^a$	Initial	Final	$p^{\scriptscriptstyle b}$	$p^{c}$	$p^{d}$
HbA1c (%)	$7.03 \pm 1.20$	6.97 ± 1.30	0.592	6.89±1.16	$6.38 \pm 0.88$	0.003	0.726	0.04
Use of insuline (%)	11.1	14.8	1.000	20.0	24.4	0.500	0.327	0.330
Weight (kg)	$77.49 \pm 16.38$	$77.54 \pm 16.00$	0.877	$83.70 \pm 13.63$	81.77 ± 12.52	0.001	0.104	0.398
Body Mass Index (kg/m <sup>2</sup> )	$29.66 \pm 5.02$	$29.74 \pm 4.89$	0.521	$31.31 \pm 4.94$	$30.60 \pm 4.46$	0.001	0.177	0.515
Total Cholesterol (mg/dl)	$199.11 \pm 31.52$	$191.52 \pm 69.73$	0.609	$190.07 \pm 42.36$	$178.38 \pm 41.30$	0.006	0.307	0.170
Total LDL-Cholesterol (mg/dl)	$112.81 \pm 26.78$	$104.48 \pm 27.03$	0.173	$108.80 \pm 33.762$	$99.47 \pm 29.88$	0.001	0.436	0.172
Total HDL -Cholesterol (mg/dl)	$56.30 \pm 15.80$	$51.56 \pm 14.42$	< 0.0001	$55.76 \pm 21.99$	54.71 ± 20.84	0.368	0.716	0.582
Triglycerides (mg/dl)	$143.07 \pm 64.28$	143.96±83.13	0.935	$146.53 \pm 70.75$	$117.56 \pm 52.89$	< 0.001	0.855	0.139
Systolic Blood Pressure (mmHg)	$136.30 \pm 15.92$	$133.63 \pm 14.81$	0.252	$137.25 \pm 17.92$	$129.18 \pm 16.90$	0.004	0.643	0.178
Diastolic Blood Pressure (mmHg)	$74.46 \pm 11.13$	$72.96 \pm 8.44$	0.429	$79.55 \pm 9.77$	$75.72 \pm 11.43$	0.039	0.055	0.967
Diabetic patient percentage who achiev	ved control objectives							
HbA1C < 7 (%)	44.4	48.1	1.0	55.6	80.0	0.001	0.361	0.005
HbA1C < 6.5 (%)	29.6	33.3	1.0	35.6	55.6	0.035	0.606	0.067
LDL-Cholesterol < 100 mg/dl (%)	33.3	44.4	0.375	40.0	51.1	0.125	0.572	0.584
HDL -Cholesterol > 40 mg/dl ( $\stackrel{\diamond}{}$ ), 50 mg/dl ( $\stackrel{\diamond}{}$ ) (%)	81.5	63.0	0.125	71.1	77.8	0.453	0.325	0.174
Triglycerides < 150 mg/dl (%)	63.0	66.7	1.0	64.4	80.0	0.039	0.899	0.206
SBP < 130 mmHg (%)	25.0	29.2	1.0	29.5	43.2	0.180	0.609	0.256
DBP < 80 mmHg (%)	54.2	66.7	0.375	47.7	63.6	0.143	0.612	0.803

 Table I

 Pre and post-educational intervention comparison of control versus psychoeducative groups

Data are Mean ± Standard Deviation; HbA1c: glycosylated haemoglobin.

pa: Pre/post intervention control group comparison.

pb : Pre/post intervention psychoeducative group comparison.

pc: Comparison of both groups pre-intervention.

pd: Comparison of both groups post-intervention.

15 years. In the study, 15% of the patients were taking insulin, while the remaining 85% were controlled just with oral hypoglycaemic agents. Of the 72 diabetic patients included in the study, 62.5% (n = 45) became part of the PGT, while 37.5% (n = 27) joined the GC.

At baseline, both groups were similar in demographic and diabetes related characteristics: age (66.37  $\pm$  11.96 vs. 61.04  $\pm$  9.54 years); sex (51.9 vs. 48.9%); duration of diabetes (25.9 vs. 24.4% over 15 years of diabetes); and percentage of patients treated with insulin versus oral hypoglycaemic agents alone (11.1 vs 20%). They were also similar in degree and fulfilment of the goals of diabetes: lipids and blood pressure; plasma concentrations determined by HbA1c; total cholesterol; LDL cholesterol; HDL cholesterol and triglycerides; SBP and DBP and BMI. These parameters are shown in table I.

After the educational intervention in diabetes conducted on the patients in the study, there were no differences between the CG and the PGT in terms of the drug treatments prescribed. They did not differ in the increase in the percentage of insulin taken (3.7 *vs.* 4.4%, p NS), or in the percentage change in general

pharmacological treatment for diabetes or other associated CVRF, such as lipid lowering and antihypertensitivity (14.8 *vs.* 33.3%, p NS).

The PGT showed a statistically significant mean reduction in plasma HbA1c of  $0.51 \pm 1.07\%$  (p 0.003), while it only decreased  $0.06 \pm 0.53\%$  in the CG. Therefore, differences in mean plasma concentrations of HbA1c of  $6.38 \pm 0.88\%$  versus  $6.97 \pm 1.3\%$  (p 0.04) in psychoeducational and control groups, respectively, were achieved at the end of the study (tables I and II). Thus, 80% of PGT patients managed to meet the goal of optimal diabetes control, considered as HbA1c < 7%, while in the CG this goal was only achieved in 48.1% of cases (p 0.005). Moreover, if we intensify this objective to the optimal control of diabetes in HbA1c < 6.5%, statistically significant differences were also found in the PGT response to this parameter, from 35.6% of patients who met this goal at baseline to a 55.6% accomplishment after completion of the educational intervention (p 0,035), as shown in table I and figure 2.

Likewise, the PGT presented a statistically significant mean body weight reduction of  $1.93 \pm 3.57$  kg (p 0.001). On the other hand, the CG had a mean body

 Table II

 Changes in measures of diabetes control, weight and Body Mass Index among participants seen after the intervention period

	Control group	Psychoeducative group	р
Weight (kg)	$0.52 \pm 1.73$	$-1.93 \pm 3.57$	0.002
Body Mass Index (kg/m <sup>2</sup> )	$0.08 \pm 0.65$	$-0.71 \pm 1.31$	0.001
HbA1c (%)	$-0.06 \pm 0.53$	$-0.51 \pm 1.07$	0.044
Total Cholesterol (mg/dl)	$-7.59 \pm 76.15$	$-11.69 \pm 21.17$	0.789
LDL-Cholesterol (mg/dl)	$-8.33 \pm 30.89$	$-9.33 \pm 17.16$	0.878
HDL-Cholesterol (mg/dl)	$-4.74 \pm 6.04$	$-1.04 \pm 7.71$	0.037
Triglycerides (mg/dl)	$0.89 \pm 56.06$	$-28.98 \pm 49.70$	0.021
Systolic Blood Pressure (mmHg)	$-2.67 \pm 11.12$	$-8.07 \pm 17.70$	0.128
Diastolic Blood Pressure (mmHg)	$-0.05 \pm 1.73$	$-1.93 \pm 3.57$	0.409

Data are Mean ± Standard Deviation; HbA1c: glycosylated haemoglobin.

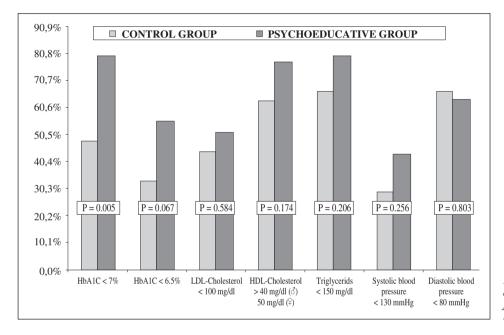


Fig. 2.—Post-intervention achievement of control objectives. (HbA1C: glycosylated haemoglobin).

weight increase of  $0.52 \pm 1.73$  kg. Therefore, the response of body weight (p 0.002) and BMI (p 0.001) to the educational intervention was different between both groups (tables I and II, fig. 3). If we consider weight loss as one of the objectives of our study, considering that we are dealing with an overweight population of diabetic patients, we found 57.8% of patients reduced their BMI in the PGT, while only 22.2% of patients achieved this target in the CG (p 0.003, table I, fig. 2).

Regarding the lipid profile of the diabetic patients studied, the PGT showed a statistically significant mean reduction in plasma triglycerides of  $28.98 \pm$ 49.70 mg/dl (p < 0.001). However, the CG worsened, showing a mean increase in plasma triglyceride levels of 0.89 ± 56.06 mg/dl. Therefore, the response of triglycerides to the educational intervention was also different between the two groups for the PGT (p 0.021, tables I and II, fig. 3). Thus, 80% of patients in the PGT achieved the objective of optimal control plasma triglyceride below 150 mg/dl, while for the CG, this goal was only achieved in 66.7% of cases (p 0.039, fig. 2).

In relation to plasma concentrations of total cholesterol and LDL cholesterol, the PGT showed a statistically significant mean reduction in both parameters of  $11.69 \pm 21.17$  (p 0.006) and  $9.33 \pm 17.16$  (p 0.001), respectively. However, the downward trend of these parameters did not reach statistical significance in the CG (tables I and II, fig. 3). No significant differences were found in the response depending on the type of educational intervention between both groups. However, considering that before starting the educational intervention, less than half of our patients had achieved an objective optimal control of LDL cholesterol (< 100 mg/dl) after completion of diabetes education, 60% of PGT subjects reduced their LDL cholesterol plasma concentrations, while only 33.3% of the subjects of the CG achieved this goal (p 0.028, fig. 2).

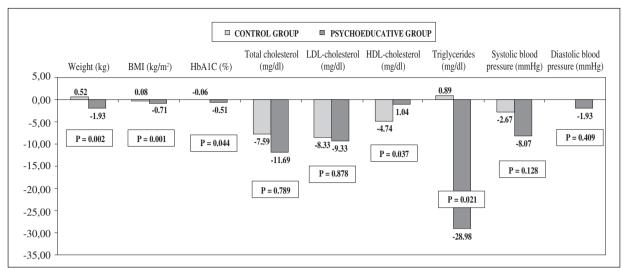


Fig. 3.—Response to psychoeducative intervention. (HbA1C; glycosylated haemoglobin; BMI: Body Mass Index).

On the other hand, the CG presented a statistically significant decline in plasma HDL cholesterol  $4.74 \pm 6.04$  mg/dl (p < 0.001). The PGT only showed a non-significant reduction trend in plasma HDL cholesterol of  $1.04 \pm 7.71$  mg/dl. Therefore, HDL cholesterol response in people who received diabetes educational intervention was also different (p 0.037, table II and fig. 3).

The PGT of diabetic patients showed a mean SBP reduction of  $8.07 \pm 17.70$  mmHg (p 0.004), while the CG only managed to reduce the SBP in 2.67 ± 11.12 mmHg (table II and fig. 3). Taking into account that before starting the educational intervention, less than one third of patients had achieved optimal target blood pressure control (SBP < 130mmHg), after diabetes education 52.3% of the components of PGT reduced their levels of SBP, compared with only 29.2% of the components of the CG (p 0.067) (fig. 2).

In this regard, 50% of the components of the PGT reduced their DBP levels, whereas only 20% of the components of the CG did so (p 0.019). The PGT showed a mean DBP reduction of  $1.93 \pm 3.57$ mmHg (p 0.039), while the CG barely reduced this parameter in  $0.05 \pm 1.73$  mmHg (table II and fig. 3).

## Discussion

Our study consisted of a multicenter educational intervention, selecting a sample of 72 patients from our population of type 2 diabetic patients, who came from 4 of the 10 PC centres from our health area, with a matched distribution of sexes (50%), mean age (63.08  $\pm$  10.68 years), mean baseline HbA1c (6.98  $\pm$  1.18%) and initial mean BMI (30.48  $\pm$  4.98 kg/m<sup>2</sup>). This sample is representative of 14,484 type 2 diabetic patients registered in the electronic medical record (OMI-AP program) in health area VII-East Murcia (mean age 65.69  $\pm$  14.31years, 50.8% male, mean HbA1c 6.93  $\pm$  1.43% and mean BMI 30.88  $\pm$  5.21kg/m<sup>2</sup>).

Patients, who, meeting the inclusion criteria, refused to join psychoeducational groups were considered as members of the CG. As several authors have shown that low levels of health knowledge contribute to the achievement of worse outcomes in diabetes.8 we wanted this CG to receive the same level of diabetes knowledge as the PGT, but through individual consultation. Moreover, one might think that diabetics in the CG were less interested in self-care by refusing to participate in therapeutic groups, and that this constituted a confounding variable in assessing the response of glycosylated haemoglobin. This limitation was taken into account, but could not be remedied because it was unethical to randomize the application of a treatment that would result in the patient's benefit, since the strict adherence to patient education program in diabetes management has shown to reduce the risk of diabetes complications.9-13

Furthermore, when comparing both groups before the educational intervention, significant differences were not found in any of the following variables: demographic characteristics; factors related to the duration of diabetes; the percentage of patients taking insulin; or the degree of accomplishment of the objectives of diabetes management and control of other CVRF, such as HbA1c, BMI, lipids and blood pressure. That made us think the CG had more limitations for diabetes self-care.

The PGT showed a statistically significant mean reduction in plasma HbA1c of  $0.51 \pm 1.07\%$ , which at the end of the educational intervention led to significant differences in final mean plasma concentrations (HbA1c, PGT:  $6.38 \pm 0.88\%$  versus the CG:  $6.97 \pm$ 1.3%). The best response of the HbA1c in the PGT could be partly due to the fact that these patients received the information necessary for diabetes selfcare with more dedicated time. Thus, there are studies documenting that when the consultation duration is very limited, patients with diabetes are less able to achieve optimal results in the control of their disease.<sup>14</sup> In fact, a recent study has shown that a program based on: (a) weekly visits to the clinic; (b) treatment adjustment with glucose analysis; and (c) a multidisciplinary intervention; improved glycemic control, compared with results obtained by performing three semestral visits to the clinic.<sup>15</sup>

Another improvement strategy applied in our study which influences the best response of HbA1c in PGT, is to change diabetes therapy equipment, increasing the role of PC nurses specializing in diabetes. They led these PGT, together with and under the medical supervision of diabetologists, while the non-specialised nurses performed diabetes education on the CG on an individual basis. Other authors have demonstrated an improvement in diabetes control due to the presence of the figure of the skilled nurse in healthcare plans.<sup>16-19</sup> Therefore, our diabetes unit design had, in addition to physicians, between 2 or 3 skilled nurses in diabetes education in the hospital, including 10 or 14 more diabetes nurse educators in PC.

However, we must also attribute some of this response to other changes in the treatment strategy, such as the educational group intervention, with patient interaction, yet with a psychological approach to the diabetic patient in order to facilitate lifestyle adaptation changes, using the model of psychoeducational groups in diabetes.

It is essential to achieve the active participation of patients in their own diabetes self-care. In fact, a lack of self-care has been associated with the highest number of diabetes emergencies.20 Diabetes self-care is influenced by psychosocial factors that limit the patients' ability to manage their disease and achieve good metabolic control. In this regard, several authors have shown that diabetic patients often need to make significant lifestyle changes to manage their disease and prevent the occurrence of diabetes complications and comorbidities, whose prevalence is increased when there is a failure to change patient habits.<sup>14</sup> Diabetics experience stress due to the responsibility of optimizing glycemic control and it has been reported that the association of depression can interfere with diabetes self-care.<sup>21</sup> Psychotherapy in diabetic patients is associated in some studies with less stress and improved glycemic control.22

In a meta-analysis of 12 clinical trials in type 2 diabetics, psychological intervention achieved a better HbA1c response than usual diabetes care, achieving a mean difference of -0.32%.<sup>23</sup> But our PGT achieved an even greater mean HbA1c difference, -0.45%, which can be attributed to the sum of the effect of psychotherapy plus the effect of the group approach. In this sense, improved quality of life in people with diabetes through self-education programs, support groups and cognitive behavioural therapy has been described.<sup>24,25</sup> increasing patient safety in diabetes self-

care. Moreover, Shojania found maximum mean HbA1c reductions of up to 0.42% after making changes to patients' therapeutic strategies aimed at increasing diabetes self-management and allowing the patient to adjust their medication doses without waiting for their doctor's approval.<sup>26</sup>

As a direct consequence of these changes in therapeutic strategy, 80% of our PGT patients met the goal of optimal diabetes control, while this level of optimized control is usually only achieved in 42% of diabetic patients according to research published in the U.S.<sup>27</sup> We consider this cut-off concentration of target HbA1c < 7%, instead of HbA1c < 6.5%, because of the average age of our patients (63.08 ± 10.68 years) and the recent controversies on the optimal HbA1c cut-off point when the population of diabetic patients are older.<sup>28,29</sup>

On the problem of overweight diabetic patients, 57.8% of PGT patients reduced their BMI through the intervention. Those patients had a mean body weight reduction of 1.93kg, representing a decrease of 2.36% of their initial weight within 3 months. The Look AHEAD study, conducted in 5,145 overweight type 2 diabetics in the U.S., achieved a reduction of 8.6% of initial weight at 1 year in the intensive lifestyle intervention group and they acceptably managed to maintain weight loss at 4 years.<sup>30,31</sup> This study compared intervention in diabetes education, nutrition and exercise, along with behavioural therapy. The intensive group consisted of weekly visits, while in the control group they were quarterly, and alternating group meetings with individual visits of diabetic patients were mixed in both groups. The patients in this trial started from a higher initial obesity degree (BMI =  $35.8 \text{ kg/m}^2$ ) while our PGT patients were based on an initial BMI of 31.3 kg/m<sup>2</sup>. Nevertheless, our psychoeducational groups showed a similar trend in the percentage of initial weight loss after the intervention. Similarly, diabetics in the Look AHEAD trial had a mean HbA1c reduction of 0.64%, starting from an initial average HbA1c of 7.25% and achieving an annual average HbA1c of 6.65%, whereas in our PGT patients, the mean HbA1c reduction was slightly lower, at 0.51%. The reason for this was that our initial mean HbA1c was fairly streamlined, 6.89%, and therefore, we achieved a better final mean HbA1c (6.38%) than in the U.S. study, which can also be explained by the lesser degree of obesity in our patients.

On the other hand, our CG had a mean body weight increase of 0.52 kg in 3 months, although we did not find differences with the PGT that could explain either the increase in the percentage of patients using insulin or the percentage increase of patients with drug change due to the intervention. Other studies assessing type 2 diabetic groups with conventional treatment have shown that only a small percentage of diabetics are able to achieve and maintain significant weight loss, and that these patients gain weight due to the use of some drugs for diabetes, such as sulfonylureas and insulin.<sup>32</sup>

In relation to other CVRF, 80% of PGT patients managed to meet the goal of optimal control in plasma triglycerides and HDL cholesterol, achieving a mean triglyceride reduction of 28.9 mg/dl, explained by weight loss and improvement in HbA1c, and because they managed to maintain HDL cholesterol plasma concentrations, that were already highly optimized before the intervention. PGT also showed a significant mean reduction in total cholesterol (-11.69 mg/dl), SBP (-8.07 mmHg) and DBP (-2.67 mmHg), achieving results comparable to the Look AHEAD study, except for the LDL cholesterol, whose average reduction was higher in our PGT (-9.33 mg/dl) compared with the U.S. trial (-5.2 mg/dl). For this reason, we achieved these goals to a higher degree in this difficult to control target: LDL cholesterol < 100 mg/dl (51.1% vs 43.0%),which can be attributed to the lower degree of obesity of our patients. However, the goal of SBP < 130 mmHg was fulfilled to a lesser degree (43.0% vs 68.0%), which may be associated with a slightly more advanced mean age in our diabetics (61.04 vs 58.9 years). Nevertheless, the patients in the present study fulfilled the objective of TAD < 80 mmHg to a similar degree as in the US trial (63.6% vs. 68.0%).

To conclude, new health strategies for the comprehensive care of diabetic patients in PC, such as psychoeducational treatment groups, led by the figure of the diabetes education nurse and the physician responsible for diabetes in each PC centre, exceed the level of achievement necessary to fulfil the objectives of optimal control of HbA1c, reaching 80%, unlike the conventional individualized diabetes education for these patients. Furthermore, psychoeducational groups showed a better response to weight loss and an improvement in other CVRF such as total cholesterol, LDL cholesterol, triglycerides, SBP and DBP compared with conventional diabetes care. Therefore, we must consider structural changes in our diabetes health care programs, to replace conventional care with these more efficient approaches (therapeutic education, psychoeducational groups of diabetic patients and nurses specializing in diabetes education in PC).

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