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Effectiveness of a primary care nurse delivered educational intervention for patients with type 2 diabetes mellitus in promoting metabolic control and compliance with long-term therapeutic targets: Randomised controlled trial

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ABSTRACT

Background: Systematic reviews and meta-analyses have shown very different values for the effectiveness of education in type 2 diabetes mellitus. However, the achievement of therapeutic targets after educational programs has been poorly evaluated.
Objective: Evaluate the effectiveness of a structured and individualised education program for type 2 diabetes, provided by a primary care nurse, which featured educational reinforcements and family support to achieve metabolic control, and long-term therapeutic targets.
Methods: Randomised controlled clinical trial with two arms: Intervention and control group. The intervention consisted of six face-to-face sessions of 30 min and follow-ups after 12 and 24 months for 236 participants with type 2 diabetes mellitus in a primary care setting in Andalusia (Spain). The primary outcome variables were the values and achievement of the type 2 diabetes mellitus control targets established by the American Diabetes Association: Glycated haemoglobin, fasting blood glucose, total cholesterol, low-density lipoprotein-cholesterol, high-density lipoprotein-cholesterol, triglycerides, systolic and diastolic blood pressure. The secondary outcome variable was body mass index.
Results: From an overall total of 236 participants, 54.2% were male and the average age was 65.1 ± 9.5. After 12 months, the glycated haemoglobin level and systolic blood pressure decreased in the intervention group. After 24 months, the following variables significantly improved among the intervention group participants: basal glycemia, glycated haemoglobin, total cholesterol low-density lipoprotein cholesterol, and diastolic blood pressure. The glycated haemoglobin target (<7%) was better achieved in the intervention group than in the control group (35.2% vs 24.7%, $p < 0.003$). The rest of the targets were not met.
Conclusion: Continual diabetes education with reinforcement sessions provided by a nurse achieved reductions in glycated haemoglobin, basal glycaemia, total cholesterol, low-density lipoprotein-cholesterol and systolic blood pressure in both the medium and long term. It also increased the proportion of participants who achieved the therapeutic target of glycated haemoglobin.

What is already known about the topic?

- Evidence-based guidelines have established quality standards for diabetes education programs.
- The effectiveness of diabetes education in terms of improvements in glycated haemoglobin and other cardiovascular risk factors has shown very different values.

What this paper adds

- The structured and individualised, education intervention, delivered by an expert nurse, has been effective in reducing biochemical parameters in the medium and long term.

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- Glycated haemoglobin was the therapeutic target that showed significant long-term improvements.
- Innovative strategies such as educational reinforcements and involving family members could increase glycemic control.

1. Introduction

Diabetes mellitus has now reached global epidemic proportions, with a worldwide prevalence of 8.5% in the adult population. Within the European Union, the prevalence varies between countries: 6% in Austria; 7.4% in Germany; 8% in France; 9.4% in Spain; 9.5% in Poland; 9.6% in the Czech Republic; 10% in Hungary; and 10.3% in Bulgaria (World Health Organization, 2016).

Globally, in 2017, the North America and Caribbean region had the highest prevalence of diabetes mellitus (11.0%). The South-East Asia region had intermediate prevalence (10.1%) and the Africa region had the lowest prevalence (4.4%) likely due to lower levels of urbanisation, lower prevalence of obesity and higher rates of communicable diseases (International Diabetes Federation, 2017a).

The type 2 diabetes epidemic has been attributed to urbanisation and environmental transitions (work and diet pattern changes) which favour sedentary occupations and a rise in caloric consumption (Ley et al., 2014).

There is scientific evidence that type 2 diabetes mellitus prevalence in children and young people is increasing in some countries. It is strongly associated to the dramatic rise in obesity prevalence and physical inactivity among children and adolescents. Type 2 diabetes mellitus in childhood could become a real public health issue in some countries (Al-Saeed et al., 2016).

Diabetes is a major cause of morbidity and mortality because it can cause blindness, kidney failure, myocardial infarction, stroke, and lower limb amputation. Diabetes is thought to have been the direct cause of 1.6 million deaths in 2015. In addition, 2.2 million people died from cardiovascular disease, attributable to hyperglycaemia, of which 43% occurred in people younger than 70 years old (Sarwar et al., 2010; Bourne et al., 2013; Saran et al., 2015; World Health Organization, 2016).

Moreover, the economic costs related to diabetes in the form of loss of work and income, medication, hospitalisation and ambulatory care are very high, both for patients and health systems. Furthermore World Health Organization projections predict that diabetes will be the seventh cause of mortality in 2030 (Mathers and Loncar, 2006; World Health Organization, 2016).

Nowadays, cost-effective interventions are available to control diabetes through diet, physical activity, medication, measuring blood pressure and blood lipids, and periodic examinations to detect any injury to eyes, kidneys or feet. All these measures can prevent or delay the complications of diabetes. Comprehensive diabetes care requires that action is taken through diabetes education programs, aimed at improving people knowledge and behaviour regarding the self-management of diabetes (Powers et al., 2015).

Evidence-based guidelines consider diabetes education to be one of the keys in managing diabetes (Guideline NICE, 2015). Quality standards for diabetes education programs have been established (International Diabetes Federation, 2017b). Likewise, American Diabetes Association advises compliance with therapeutic targets of glycated haemoglobin <7%, fasting blood glucose between 80 and 130 mg/dL, blood pressure <140/90 mmHg and low-density lipoprotein-cholesterol <100 mg/dL, in order to reduce or delay the micro and macro-vascular complications of diabetes (American Diabetes Association, 2018).

The effectiveness of education in terms of seeing an improvement in glycated haemoglobin and other cardiovascular risk factors has shown very different values in systematic reviews and meta-analyses with average reductions in glycated haemoglobin of −0.74%, ranging from −2.5% to 0.6% vs. −0.17%, ranging from −1.7% to 1.5% in control groups, depending on the intervention's characteristics (individualised or group, duration, frequency and evaluation of follow-up, short-term or long-term) (Chrvala et al., 2016; Odgers et al., 2017). Nevertheless, the achievement of the therapeutic targets following educational programs has been poorly evaluated.

The main objective of this study was to evaluate the effectiveness of using a structured, individualised type 2 diabetes education program, provided by a primary care nurse, to control type 2 diabetes mellitus patients, evaluated through the participant's glycated haemoglobin, blood pressure, body mass index measurements and their lipid profile as well as whether or not they achieve, the therapeutic targets of long-term control.

2. Methods

2.1. Design

A randomized controlled clinical trial with two arms: an intervention group (carried out by a nurse), and a control group (usual care), with a follow-up after 12 and 24 months.

The sample size was calculated to obtain a confidence level of 95%, a statistical power of 90%, a minimum difference to be detected regarding glycosylated haemoglobin of 1% and, a variance of 4% (Khunti et al., 2012). A sample size of 69 participants was obtained in both the intervention and control group.

The inclusion criteria were: Patients with type 2 diabetes mellitus, between 18 and 80 years of age, who agreed to participate in the study and signed the informed consent. The exclusion criteria were: cognitive impairment, significant alteration of physical mobility, not accepting the educational advice, type 1 diabetes mellitus, gestational diabetes.

2.2. Recruitment of the participants

Participants were recruited from a primary care centre in the Bahía de Cádiz-La Janda district, Andalusia (Spain), identified through electronic medical records. Four hundred patients of both genders with type 2 diabetes mellitus were eligible between June 2014 and June 2017.

During the first month, all patients diagnosed with type 2 diabetes mellitus were invited to participate in the study through nursing consultations, or telephone calls. Out of the 400 patients, 53 refused to participate, and 65 were excluded. The rest of the patients were individually met in the consulting room to inform them about the study. In the end, 236 participants completed the study: 97 participants in the intervention group and 139 participants in the usual care group (Fig. 1). The loss of follow-up in the intervention group was 30% ($n = 43$). Reasons for loss to follow-up were death ($n = 2$), moved to another city ($n = 1$) and declined ($n = 40$, due to too busy, lack of time or out of contact). The sample loss in the usual care was 0.7% (1 death).

2.3. Intervention

The intervention consisted of 6 face-to-face sessions lasting 30 min. They consisted of structured, individualised education, carried out by one trained nurse with more than 10 years of experience in type 2 diabetes mellitus education. The educational sessions were delivered over a period of 6 months, with educational reinforcements after 12 and 18 months. The participant had to attend the sessions accompanied by a family member/caregiver. The contents were based on those proposed by American Association of Diabetes Educator (2018): basic knowledge of diabetes, healthy eating, physical activity, self-monitoring of blood glucose, medication, risk reduction, problem solving, and effective coping.

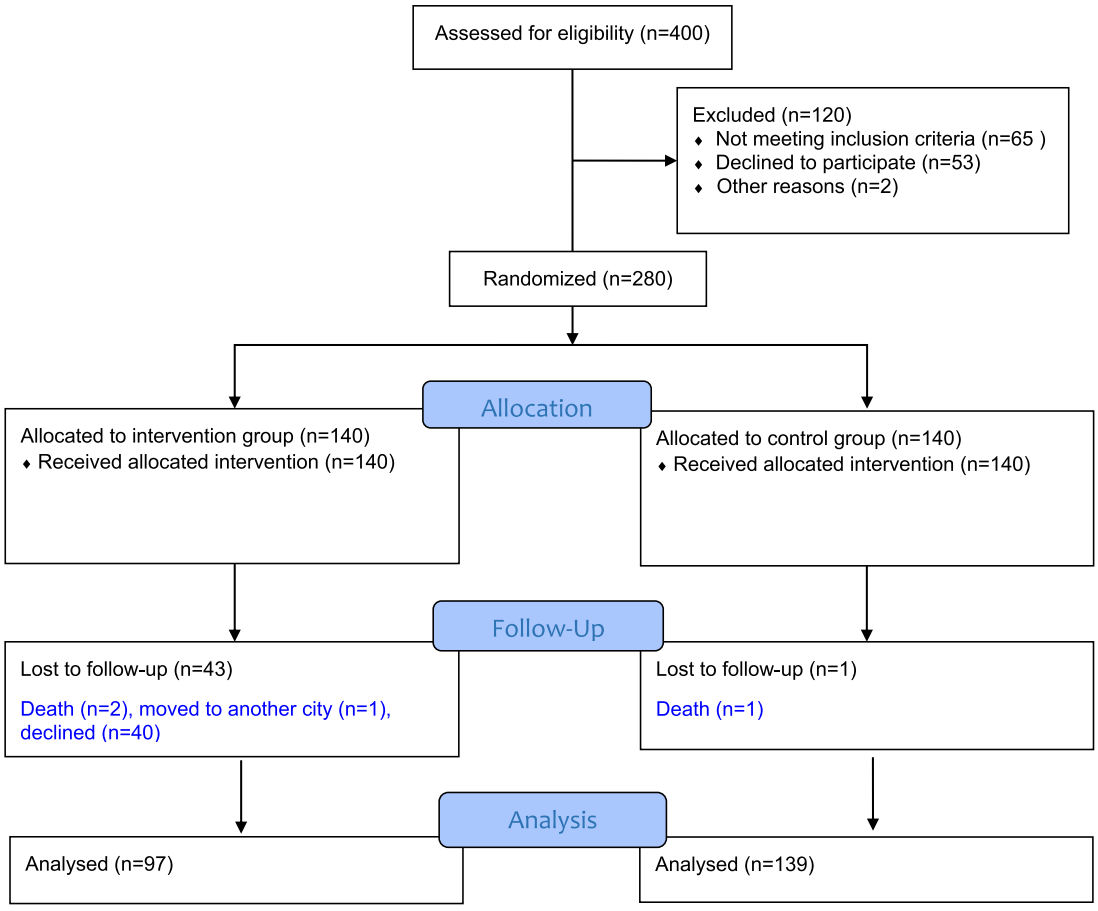

Fig. 1. Flowchart of the progress of individuals in the phases of the controlled clinical trial. CONSORT 2010 flow diagram.

A brochure containing educational contents, control objectives, and a self-management booklet were provided to the participants. Goal setting and motivational interviewing techniques were used. The educational model was based on the model of empowerment: promoting participation and strengthening the person's autonomy (Asimakopoulou et al., 2012; Inzucchi et al., 2012). Active recruitment of diabetic participants who did not attend voluntarily was performed by telephone when necessary. Telephone calls were made when participants were absent from any scheduled appointments, as indicated in the protocol, in order to encourage them to participate. A date was proposed. Participants who attended at least three sessions during the first 12 months were eligible for follow up.

The control group received usual medical care at the health centre. The usual care consisted of advice on healthy lifestyle choices carried out by nurses at the health centre during the routine appointments with control group participants for clinical and analytical assessment (at least twice a year) as per the Primary Care protocol, but no structured diabetes education was provided.

2.4. Outcome measures and data collection

The primary outcome variables were the values and achievement of type 2 diabetes mellitus control targets established by the American Diabetes Association (2011): Glycated haemoglobin concentration (<7%), fasting blood glucose (<130 mg/dL), plasma concentration of total cholesterol (<200 mg/dL), low-density lipoprotein cholesterol (<100 mg/dL), high-density lipoprotein cholesterol (>40 mg/dL in males and >50 mg/dL in women), triglycerides (<150 mg/dL). The blood samples were collected by health centre nurses early in the morning after fasting overnight (at least 10 h), for glycated haemoglobin and lipid measurements. All determinations were performed at the same laboratory at the reference hospital (University Hospital of Puerto Real). Glycated haemoglobin levels were measured using high-performance liquid chromatography (AKRAY HA 8180V, Menarini Diagnostics) and lipid levels were measured using enzymatic colorimetric assay.

Systolic blood pressure (<130 mmHg) and diastolic blood pressure (<80 mmHg) were also primary variables. Blood pressure was measured by a nurse in the consulting room using a professional digital sphygmomanometer, applying accepted methods (Chobanian et al., 2003). The secondary outcome variable was body mass index calculated as [weight (kg)/height^2 (m)]. Weight was measured by a nurse with participants removing shoes or heavy clothing, using standard calibrated scales (Seca 711, Hamburg, Germany) to the nearest 0.1 kg. Height was measured by a nurse using a portable stadiometer (Seca 264 height rod) to the nearest 0.1 cm. The variables were measured before the intervention, and after the intervention: after 12 months, and after 24 months. Blinding was used in the database registry and results analysis.

2.5. Statistical analysis

For the statistical analysis, the IBM SPSS (version 24.0) program was used. Quantitative and qualitative descriptive statistics were carried out on the results using the mean ± standard deviation and frequencies. For the comparison of means, the Student's *t*-test was used when the variables presented normal distribution, and

Table 1
Baseline data for intervention and control groups.

Variables	TG $n=236$	IG $n=97$	CG $n=139$	*P*
Age (years)	65.1 ± 9.5	64.5 ± 9.6	65.5 ± 9.5	0.434
Males %(*n*)	54.2 (128)	54.6 (53)	54.0 (75)	1.000
Diabetes years	7.6 + 4.1	8.8 ± 4.4	6,7 ± 3,6	0.000[a]
BMI (kg/m^2)	30.8 ± 4.3	31.4 ± 4.5	29.3 ± 3.6	0.022
SBP (mmHg)	135.91 ± 17.28	133.47 ± 16.79	138.22 ± 17.50	0.112
DBP (mmHg)	77.19 ± 10.20	76.79 ± 9.10	77.57 ± 11.14	0.941
FBG (mg/dl)	145.0 ± 45.0	140.5 ± 35.3	148.2 ± 50.6	0.255
HbA1c 1 (%)	7.5 ± 1.4	7.6 ± 1.4	7.4 ± 1.5	0.532
TC (mg/dl)	204.2 ± 40.0	199.0 ± 38.8	208.9 ± 40.7	0.109
LDL-c (mg/dl)	121.3 ± 34.3	115.4 ± 32.9	125.9 ± 34.8	0.077
HDL-c (mg/dl)	49.3 ± 13.1	48.0 ± 12.9	50.3 ± 13.2	0.270
TG (mg/dl)	159.6 ± 84.8	146.2 ± 62.4	169.0 ± 96.5	0.075
Diet/exercise treatment	6.8 (15)	7.3 (7)	6.5 (8)	0.795
OADs treatment	67.7 (149)	67.7 (65)	67.6 (84)	1.000
Insulin treatment %	25.5 (56)	25.0 (24)	25.8 (32)	1.000

TG: Total Group. IG: Intervention Group. CG: Control Group.
[a] Mann–Whitney *U* test. BMI 1: body mass index at the beginning of the study. SBP 1: systolic blood pressure at the beginning of the study. DBP 1: diastolic blood pressure at the beginning of the study. FBG: fasting blood glucose. HbA1c 1: glycated haemoglobin at the beginning of the study. TC 1: total cholesterol at the beginning of the study. LDL-c: cholesterol bound to low density lipoprotein at the beginning of the study. HDL-c: cholesterol bound to high density lipoprotein at the beginning of the study. TG: triglycerides. OADs: oral antidiabetics.

the Mann–Whitney *U* and Wilcoxon tests were applied if the variables were not normally distributed. For the comparison of proportions, the Pearson Chi-square test was used. A value of $p < 0.05$ was considered statistically significant.

2.6. Ethical considerations

The study was conducted under the standards and ethical criteria of the Helsinki declaration, and was submitted to the approval of the Ethics and Research Committee of the Bahía de Cádiz-La Janda Health District. All participants were informed about the nature of the study and their consent to participate in it was requested.

3. Results

The baseline characteristics of the participants are shown in Table 1. Among these participants, 54.2% were male, and the mean age was similar in both groups 65.1 ± 9.5. The mean number of years of onset of type 2 diabetes mellitus was 7.6 years ± 4.1 years, somewhat lower in the control group. At the beginning of the study, both groups were comparable since no statistically significant differences were observed in the outcome variables between the intervention and control groups, except for lower body mass index in the control group. The baseline glycated haemoglobin levels in the intervention and control groups were moderately elevated and similar in both groups. (7.6% vs 7.4, $p = 0.532$).

Table 2 shows the mean values ± standard deviation and the difference of means, 95% CI, of the outcome variables after 12 and 24 months of follow-up. After 12 months of follow-up, a decrease in glycated haemoglobin was observed in the intervention group, but not in the control group (−0.55, 95% CI −0.20, −0.90, $p < 0.001$ vs +0.06, −0.14, +0.28, $p = 0.530$). However, the difference between the groups was not statistically significant at this stage of follow-up. Systolic blood pressure was statistically lower after 12 months in the intervention group (−1.7, 95% CI −5.2, +1.8 vs +0.9, 95% CI −3.6, +5.5, $p < 0.024$).

After 24 months of follow-up, a significant decrease in fasting blood glucose was detected in the intervention group (−8.1 mg/dL, 95% CI −19.8, +3.4 $p < 0.015$). Decreases were also detected in glycated haemoglobin (−0.82%, 95% CI −0.50, −1.14, vs +0.08, 95% CI −0.20, +0.37, $p = 0.003$), total cholesterol (−17.7 mg/dL, 95% CI −26.7, −8.7 vs −2.3, 95% CI −12.5, + 7.8, $p < 0.008$), low-density lipoprotein cholesterol (−12.1 mg/dL, 95% CI −21.0, −3.1 vs −1.2, 95% CI −11.8, +9.3, $p < 0.040$), and systolic blood pressure (−3.5 mmHg, 95% CI% −7.7, + 0.5 vs +2.6, 95% CI −1.3, +6.7, $p < 0.000$). High-density lipoprotein cholesterol, triglycerides, diastolic blood pressure and body mass index values were not modified.

With regard to the achievement of therapeutic objectives (Table 3), attaining the glycated haemoglobin target (<7%) was statistically higher after 24 months in the intervention group: 35.2% vs 24.7%, $p < 0.003$. There was no improvement of the control goal in other variables: fasting blood glucose, total cholesterol, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, triglycerides, or blood pressure.

4. Discussion

Our study found that the educational intervention had favourable effects in the medium and long term on fasting blood glucose, glycated haemoglobin, total cholesterol, low-density lipoprotein cholesterol and systolic blood pressure. Likewise, the therapeutic objective that showed significant long-term improvements with the educational intervention was glycated haemoglobin.

At the beginning of the study, both intervention and control groups were comparable as shown by the similar figures in the outcome variables (Table 1). Baseline glycated haemoglobin levels were not excessively high (7.6% vs 7.4, $p = 0.532$). In general, studies that include participants with higher baseline glycated haemoglobin levels (8–9%) tend to experience more significant differences than those with lower levels (Chrvala et al., 2016).

Response rates of our study were high after two years of follow-up: 70% of participants in the intervention group and 99% in the control group. This compares positively with other self-management education interventions that obtained long term follow up data in the intervention group from 51% (Mohamed et al., 2013) to 60% (Eakin et al., 2014) of the original participants. Overall, interventions and follow up periods of shorter duration have shown lower loss of follow up (Kim et al., 2015; Merakou et al., 2015). However, some of these programmes have found no difference in biomedical outcomes at long term (Khunti et al., 2012; Mash et al., 2014). The optimal dose of intervention would have to be examined in further studies. The attendance of participants at educational sessions and therefore exposure to the intervention is also considered as an important factor in the success of the educational programme.

Table 2
Change in outcomes at 12 and 24 months.

	IG mean ± SD difference of means (CI 95%)	*p*	CG mean ± SD difference of means (CI 95%)	*p*	*P* (IG)/(CG)
FBG					
12 months	135 ± 42 −6.8 (−15.9, +2.3)	0.141	144.2 ± 51.4 −3.2 (−11.5, +5.1)	0.446	0.154
24 months	132.3 ± 42.3 −8.1 (−19.8, +3.4)	**0.015**[a]	139.7 ± 41.8 −6.2 (−16.6, +4.1)	0.234	0.214
HbA1c%					
12 months	7.06 ± 1.26 −0.55 (−0.20, −0.90)	**0.001**[a]	7.42 ± 1.36 +0.06 (−0.14, +0.28)	0.530	0.105
24 months	6.82 ± 0.96 −0.82 (−0.50, −1.14)	**0.000**[a]	7.37 ± 1.25 +0.08 (−0.20, +0.37)	0.565	**0.003**[a]
TC					
12 months	201.5 ± 40.2 +2.3 (−6.4, +11.1)	0.593	209.8 ± 38.5 +6.6 (−2.2, +15.4)	0.139	0.449
24 months	183.0 ± 31.1 −17.7 (−26.7, −8.7)	**0.000**	201.9 ± 40.2 −2.3 (−12.5, +7.8)	0.644	**0.008**
LDL-c					
12 months	120.6 ± 35.1 +5.3 (−2.2, +12.9)	0.168	127.4 ± 30.8 +7.6 (−0.4, +15.8)	0.065	0.989
24 months	104.9 ± 27.2 −12.1 (−21.0, −3.1)	**0.009**	120.9 ± 34.0 −1.2 (−11.8, +9.3)	0.816	**0.040**
HDL-c					
12 months	47.8 ± 12.0 0.08 (−2.0, −2.2)	0.935	49.3 ± 12.9 −0.44 (−2.34, +1.45)	0.642	0.999
24 months	47.9 ± 11.5 −0.6 (−2.7, +1.5)	0.572	53.3 ± 16.8 +1.92 (−2.04, +5.88)	0.337	0.428
TG					
12 months	146.3 ± 57.9 −2.8 (−17.7, +12.0)	0.703	164.2 ± 76.5 −3.2 (−20.0, +13.6)	0.705	0.285
24 months	147.9 ± 59.4 −1.3 (−16.5, +13.9)	0.863	155.2 ± 82.9 −11.0 (−30.3, +8.1)	0.255	0.598
SBP					
12 months	131.7 ± 14.4 −1.7 (−5.2, +1.8)	0.336	139.5 ± 18.6 +0.9 (−3.6, +5.5)	0.670	**0.024**[a]
24 months	129.8 ± 13.8 −3.5 (−7.7, +0.5)	0.086	141.4 ± 19.4 +2.6 (−1.3, +6.7)	0.188	**0.000**
DBP					
12 months	75.5 ± 7.5 −1.2 (−3.3, +0.8)	0.233	77.0 ± 10.5 −0.60 (−3.39, +2.19)	0.669	0.899
24 months	73.9 ± 8.7 −2.5 (−4.9, −0.05)	0.057	76.5 ± 12.2 −1.2 (−4.3, +1.9)	0.448	0.285
BMI					
12 months	30.7 ± 3.7 −0.4 (−0.9, +0.04)	0.074	29.3 ± 3.7 −0.2 (−0.8, +0.3)	0.402	0.691
24 months	31.1 ± 4.0 +0.04 (−0.4, +0.5)	0.853	29.1 ± 3.1 −0.02 (−0.58, +0.53)	0.937	0.279

IG: Intervention Group. CG: Control Group. BMI: body mass index. SBP: systolic blood pressure. DBP: diastolic blood pressure. FBG: fasting blood glucose. HbA1c 1: glycated haemoglobin. TC: total cholesterol. LDL-c: cholesterol bound to low density lipoprotein. HDL-c: cholesterol bound to high density. TG: triglycerides.
[a] Wilcoxon.

In our study, we observed a statistically significant average decrease in glycated haemoglobin in the intervention group compared to the control group after 12 months (−0.55 vs +0.06, $p = 0.530$) and after 24 months (−0.82%, vs +0.08, $p = 0.003$) (Table 2). These results may be clinically relevant since in accordance with the UK Prospective Diabetes Study (UKPDS,1998), a 0.9% decrease in glycated haemoglobin is associated with a 25% reduction in microvascular complications, a 10% decrease in mortality related to diabetes and a 6% reduction in all causes of mortality. After 24 months of education, glycated haemoglobin decreased by 0.8%, revealing that our participants could benefit from these improvements.

However, there are unanswered questions concerning the ideal way to provide type 2 diabetes mellitus education, such as the type of education (individual or group; face-to-face or distance), frequency and number of sessions, contact time between the educator and the participant, type of educator (nurse, health worker, diabetes mellitus type 2 patients), training, educator experience, use of new technologies and barriers to self-management (Coppola et al., 2016).

The type of education used in our study was individual. Whether to use individual or group education, is a controversial issue. The main advantage of individual education is that it enables personalised intervention and creates mutual trust and strong interaction between the participant and educator. The biggest advantage of group education is its greater cost-effectiveness, since it is possible to group more participants with a single educator. However, it can be difficult to implement group education due to logistical and organisational problems. (Coppola et al., 2016).

A recent systematic review with meta-analysis that included 47 studies with 8533 type 2 diabetes mellitus participants found that group education was more effective in improving clinical outcomes than usual care and individual education (Odgers et al., 2017). The greatest reductions in glycated haemoglobin were obtained with group education compared to the control group after 12–14 months and 24 months, with an average difference of −0.33%. After 36–48 months there was a difference of −0.93%, but no difference was found after 24 months. As we can observe, the effects of the intervention also vary depending on the time at which it is followed up. The evaluations in our study were

Table 3
Compliance with targets at 12 and 24 months.

Variables % (*n*)	Total *n* = 236	IG *n* = 97	*p* within the IG[a]	CG *n* = 139	*p* within the CG[a]	*p* IG/CG
FBG baseline	41.6 (77)	38.2 (29)		44.0 (48)		0.452
12 months	48.3 (98)	53.4 (47)	**0.031**	44.3 (51)	1.000	0.206
24 meses	51.5 (103)	25,5 (51)	**0.008**	26.0 (52)	0.424	0.203
HbA1c baseline	44.6 (75)	40.7 (33)		48.3 (42)		0.354
12 months	53.3 (104)	59.1 (55)	**0.011**	48.0 (49)	0.481	0.151
24 months	59.9 (109)	35.2 (64)	**0.001**	24.7 (45)	0.383	**0.003**
TC baseline	50.9 (85)	55.7 (44)		46.6 (41)		0.279
12 months	44.0 (81)	45.7 (42)	0.263	42.4 (39)	0.238	0.767
24 months	55.8 (106)	28.4 (54)	0.078	27.4 (52)	1.000	0.142
LDL-c baseline	27.4 (37)	32.2 (19)		23.7 (18)		0.332
12 months	22.3 (39)	23.9 (21)	0.503	20.7 (18)	0.109	0.717
24 months	30.9 (54)	14.9 (26)	0.267	16.0 (28)	0.267	0.746
HDL-c baseline	63.2 (98)	64.8 (46)		61.9 (52)		0.741
12 months	60.6 (106)	59.1 (52)	0.227	62.1 (54)	1.000	0.758
24 months	65.0 (115)	31.1 (55)	0.553	33.9 (60)	1.000	0.755
TG baseline	56.7 (102)	60.8 (45)		53.8 (57)		0.364
12 months	56.9 (99)	61.2 (52)	1.000	52.8 (47)	0.571	0.287
24 months	62.8 (120)	30.4 (58)	0.134	32.5 (62)	0.265	0.552
BP baseline	17.2 (30)	17.6 (15)		16.9 (15)		0.615
12 months	20.0 (39)	23.4 (22)	0.344	16.8 (17)	0.617	0.285
24 months	23.3 (44)	11.6 (22)	0.307	11.6 (22)	0.371	0.604

IG: Intervention Group. CG: Control Group. BMI: body mass index. BP: blood pressure. FBG: fasting blood glucose. HbA1c 1: glycated haemoglobin. TC: total cholesterol. LDL-c: cholesterol bound to low density lipoprotein. HDL-c: cholesterol bound to high density. TG: triglycerides.

[a] McNemar. Target of BG ≤ 130 mg/dl%, Target of HbA1c < 7%, Target of TC ≤ 200 mg/dL, target of LDL-*c* < 100 mg/dL, target of HDL-c males > 40 mg/dL women > 50 mg/dL, target of TG < 150 mg/dl, target of BP < 130/80 mmHg.

performed for medium term (after 12 months) and long term (after 24 months) outcomes. In both, beneficial effects were observed in the variables studied.

Chrvala et al. (2016) performed a systematic review of 118 studies, in which they observed an average reduction in glycated haemoglobin of 0.74% in the intervention group and 0.17% in the control group. They state that the programs that used a combination of individual and group methods obtained the best results in decreasing of glycated haemoglobin (−1.10%) compared with only group (−0.62%) or individual education (−0.78%).

The number and frequency of education sessions, as well as the ideal total contact time between the educator and the patient are also controversial issues. In the aforementioned meta-analysis by Odgers et al. (2017), the greatest reduction in glycated haemoglobin was obtained in longer intervention periods (13–60 months) (−0.66%), compared to shorter interventions (<1 month, 1–3 months, 4–6 months, 7–12 months); <5 sessions (−0.46%) compared to more numerous ones (6–10 sessions, 11–20 sessions and > 21 sessions); ≤ 8 h contact time (−0.45%) compared to those with a higher number of hours (9–12 h, 13–18 h, 19–30 h, ≥31 h); and with the participation of a family member (−0.36%). The intervention in our study consisted of six educational sessions of 20–30 min over 18 months. Four of the sessions took place in the first 6 months with reinforcements after 12 and 18 months. The total contact time was 2–3 h. The participant agreed that they would attend the diabetes education sessions with a family member. Family involvement and support is important to achieve the objectives that are proposed.

In contrast, in the aforementioned systematic review by Chrvala et al. (2016), several studies that obtained a significant reduction in glycated haemoglobin emphasized a higher number of contact hours. Furthermore, in patients with high glycated haemoglobin values (>9%), a significant decrease was also observed. The authors concluded that the way education is provided, its contact hours and the baseline glycated haemoglobin influence improvements in glycated haemoglobin.

Another study conducted in the USA, examined a mixed intervention (group and later individual telephone advice once a month) over 12 months. It achieved a reduction of 1–1.3% glycated haemoglobin (Kim et al., 2015). On the contrary, in a study carried out in Australia, in which the intervention consisted only of telephone calls over a period of 18 months, evaluated after 24 months, no changes were obtained in metabolic markers (Eakin et al., 2014).

In our study, as well as the initial 6 months of diabetes education, we performed reinforcement sessions after 12 and 18 months. There is evidence that educators who contact their diabetes mellitus patients more regularly have better results (Chrvala et al., 2016). The importance of continuing education is evident in short studies (4 months) that do not observe metabolic changes one year after the intervention (Mash et al., 2014). The results obtained from the educational intervention generally drop over time. Therefore, it is important to reinforce education through regular sessions. In a recent systematic review of the effectiveness of diabetes education in Chinese adults, the authors concluded that glycemic control was better in studies that used continuous education with information reinforcement strategies (Choi et al., 2016).

As for the type of educator, in our study, the diabetes education was provided by a primary care nurse. Different studies have shown the effectiveness of diabetes education DE provided by different types of educators and levels of training: nurses, doctors, dieticians or nutritionists, health teams, health workers or diabetes mellitus patients. However, nurses are the most common educators (Coppola et al., 2016).

Regarding the other outcome variables, fasting blood glucose in the meta-analysis of Odgers et al. (2017) 0.68 mmol/L (12 mg/dL) decreased, only after 12–14 months, but not at the other time intervals. The fasting blood glucose figure should be maintained <130 mg/dL in individuals with type 2 diabetes mellitus (American Diabetes Association, 2018) to reduce the progression of microvascular complications. In our study, fasting blood glucose decreased significantly by 8 mg/dL in the intervention group after 24 months, but not in the control group. However, the data suggest that the improvements in fasting blood glucose appear to be less clinically important than those of glycated haemoglobin.

With regard to body mass index, our results show no significant decreases after the intervention. It is known that sustained weight loss (>12 months) of 5 kg in patients with diabetes melli-

tus type 2 improves fasting blood glucose, lipid profile, and blood pressure. These results coincide with previous systematic reviews. In the study by Odgers et al. (2017) body mass index was not significantly modified either.

Our results show significant improvements after the 24 months interventions, both in total cholesterol and low-density-lipoprotein cholesterol and after 12 and 24 months in the systolic blood pressure. The clinical significance of these results is highlighted, since improving lipids and controlling of blood pressure in diabetes mellitus type 2 patients can reduce the risk of micro and macrovascular complications (Stratton et al., 2000). Nevertheless, Odgers et al. (2017) did not observe significant changes in systolic blood pressure, total cholesterol, low-density lipoprotein cholesterol, or high-density lipoprotein cholesterol.

A study conducted in Sweden, featuring education over 6 months and a 12 month follow-up, showed that both group and individual education were similar in terms of reducing glycated haemoglobin (−0.5% and −0.4%) after 12 months. However, the rest of the anthropometric and lipid variables were not modified (Jutterstrom et al., 2016). Unlike these studies, in Greece, a brief 3-week group intervention using conversational mapping saw improvements in glycated haemoglobin, lipids, and body mass index, after 6 months (Merakou et al., 2015).

Another group study (4 sessions: 4 h) developed in Qatar, found a decrease in glycated haemoglobin and body mass index after 12 months, but not in the lipid profile (Mohamed et al., 2013). A Belgian study, using telephone telecoaching, managed to reduce glycated haemoglobin, lipids and body mass index (Odnoletkova et al., 2016). Pérez et al. (2015) also observed with their diabetes education program that they had a positive impact on glycated haemoglobin, but not on lipids or body mass index. Similarly, in a study carried out by health workers in the US, with a 12-month, 7-h individual education program, glycated haemoglobin decreased, but not blood pressure BP, body mass index BMI, or lipids (Prezio et al., 2013). A recent meta-analysis that included 28 studies, showed that culturally adapted education resulted in a reduction in glycated haemoglobin over a 24-month period. However, it did not obtain benefits in other variables such as blood pressure and lipids (Creamer et al., 2016). Therefore, the variable that decrease most frequently is glycated haemoglobin. Body mass index, blood pressure and plasma lipids do not usually benefit from the intervention in the same way.

With regard to achieving therapeutic objectives, our study found that achieving glycated haemoglobin <7% target was significantly higher in the intervention group than in the control group (35.2% vs. 24.7%, $p = 0.003$), while the rest of the objectives (fasting blood glucose, lipids and blood pressure) were not improved. Due to scientific evidence showing that the control of these factors helps to reduce type 2 diabetes mellitus complications, the American Diabetes Association advises to achieve the therapeutic objectives for these patients (American Diabetes Association, 2018). However, there are studies that show that achieving of the three therapeutic targets (glycated haemoglobin <7%, low-density lipoprotein-cholesterol <100 mg/dL and blood pressure <130–80 mmHg) happens in only 18.8% of American diabetic patients (Stark et al., 2013). In addition, in most diabetes education trials, the reduction in the figures of each variable after the intervention is analysed, but target achievements is not.

There are many barriers to self-managing diabetes mellitus type 2 including cultural, motivational and, cognitive as well as poor self-management skills. These must be identified by educators. For this purpose, individual sessions may be more useful than group sessions. Individual sessions can also be episodically used even when the education program is based on group sessions (Coppola et al., 2016). A recent systematic review has shown that the cost of education programs for diabetes self-management is modest and probably cost-effective in the long term (Lian et al., 2017).

The strengths of the present trial include the recruitment of a representative sample of patients with diabetes mellitus type 2 in primary care, long-term follow-up (24 months), the goal of evaluating the achievement of therapeutic targets, and the homogeneity of baseline figures in the intervention and control group. All these signal that the intervention carried out produced a favourable response in the clinical parameters.

4.1. Limitations

Among the limitations of the trial, it should be noted that no blinding was used regarding group allocation, which is difficult in this type of study. Secondly, changes in medication were not taken into account. Medication adjustments in these participants are inevitable, and they may have an influence both on the intervention and control group. Finally, the sample came from a single health centre. Therefore, the results cannot be generalised for the entire population. However, as we can see, the figures of the outcome variables are similar to those observed in the different reviews and meta-analyses, which support the representativeness of the sample.

4.2. Implications for practice

The present study has clinical and research implications. Education in diabetes can optimise glycemic control in patients, and ongoing diabetes education intervention can achieve favourable long-term results. Thus, innovative strategies such as educational reinforcements and family involvement could increase glycemic control. The educator's level of qualification and continual training; the availability of material and human resources; and the planning and continuous evaluation of the diabetes education programs are necessary to strengthen this program.

5. Conclusion

In conclusion, this study shows that our educational intervention in diabetes provided by a primary care nurse over six months, with reinforcement sessions after 12 and 18 months, together with family support can achieve reductions in glycated haemoglobin, fasting blood glucose, total cholesterol, low-density lipoprotein cholesterol and systolic blood pressure in the medium and long term. It also causes an increase in the number of participants who meet the therapeutic target of glycated haemoglobin. Our intervention could be interpreted as a way of delaying the progression of the disease.

Conflict of interest

None.

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