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# Research: Care Delivery

# Clinical, metabolic and psychological outcomes and treatment costs of a prospective randomized trial based on different educational strategies to improve diabetes care (PRODIACOR)

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## Abstract

**Aim** To evaluate the effect of system interventions (formalized data collection and 100% coverage of medications and supplies) combined with physician and/or patient education on therapeutic indicators and costs in Type 2 diabetes.

**Methods** This was a randomized 2 × 2 design in public health, social security or private prepaid primary care clinics in Corrientes, Argentina. Thirty-six general practitioners and 468 adults with Type 2 diabetes participated. Patients of nine participating physicians were selected randomly and assigned to one of four structured group education programmes (117 patients each): control (group 1), physician education (group 2), patient education (group 3), and both physician education and patient education (group 4), with identical system interventions in all four groups. Outcome measures included $HbA_{1c}$, BMI, blood pressure, fasting glucose, lipid profile, drug consumption, resource use and patient well-being at baseline and every 6 months up to 42 months.

**Results** $HbA_{1c}$ decreased significantly from 4 mmol/mol to 10 mmol/mol by 42 months ($P < 0.05$); the largest and more consistent decrease was in the groups where patients and physicians were educated. Blood pressure and triglycerides decreased significantly in all groups; the largest changes were recorded in the combined education group. The World Health Organization-5 Lowe score showed significant improvements, without differences among groups. The lowest treatment cost was seen in the combined education group.

**Conclusions** In a primary care setting, educational interventions combined with comprehensive care coverage resulted in long-term improvement in clinical, metabolic and psychological outcomes at the best cost-effectiveness ratio.

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## Introduction

The chronic complications of Type 2 diabetes result in high morbidity, mortality and socio-economic costs, which can be significantly reduced by control of hyperglycaemia and associated cardiovascular risk factors—a situation which is unfortunately achieved infrequently [1–10]. Such a situation results from failure to (1) pay for preventive interventions [11], (2) achieve adequate knowledge and skills by practitioners [11–13], (3) have adequate access to care and self-care education, (4) address the psychological impact of diabetes [14] and (5) appropriately monitor outcomes and make adjustments [9,15].

Whereas both physician and patient education significantly improve outcomes [16–18], little is known about the relative effectiveness and costs when system changes and educational interventions are combined [16]. Further, a recent large review on the impact of education upon Type 2 diabetes outcomes concluded that additional studies are needed to support the potential long-term effect of education [19].

To address the limitation of our current understanding of the relative costs and benefits of combining system changes and education interventions, we implemented a 3-year prospective intervention of diabetes education in primary care settings of the city of Corrientes (PRODIACOR). The

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programme provided the structure and resources to deliver quality diabetes care and analysed their relative effectiveness on $HbA_{1c}$ (primary endpoint), blood pressure, lipid profile and other psychological, clinical, metabolic and therapeutic indicators, and treatment cost-effectiveness ratio.

## Patients and methods

The study protocol was evaluated and approved by an external ethical committee and participants gave informed consent according to the guidelines from the International Conference on Harmonization and the World Health Organization (WHO) good clinical practice standards. The study design has been previously described [20]. Briefly, it was a randomized 2 × 2 design trial to address the effectiveness of system changes and the education of physicians and people with diabetes.

### Patient population

Included patients had Type 2 diabetes (using the American Diabetes Association criteria) [21] for at least 2 years, and were between 25 and 75 years of age. Patients with Type 1 diabetes, severe kidney disease, class III/IV heart failure, blindness, cancer, alcohol or other drug addiction, and incapacity to self-care were excluded.

### Sample size estimation and patient recruitment

For sample size determination in each of the four groups, we considered the change in $HbA_{1c}$ from baseline to the end of the study as the primary outcome variable. We also considered that correlations of patients from the same physician would be very small, from 0.20 to 0.30.

To estimate sample sizes, we applied a two-step approach. First, we estimated the sample sizes required for the detection of effects, assuming independence. This was carried out using a two-sided test at the 5% level of significance and 80% power using a paired *t*-test. The second step was to inflate the sample size to account for non-independence. We chose to increase the sample size at the first step by 25%, assuming that there would be a 20% dropout or failure to follow up. Hence, the sample size chosen was increased by 20% at the second step. Assuming 1.5 as the standard deviation of the change in $HbA_{1c}$, 73 patients were required in each group at the first step to detect a decrease of 0.5. This resulted in 111 patients for each group after adjusting for correlation and dropout or failure to follow up.

Patients were recruited from healthcare institutions of the three Argentinian health subsectors (public, social security and prepaid system). The Corrientes team identified 100 potential participant physicians who saw more than 30 patients with diabetes per month and invited them to participate in the study. Thirty-six physicians were recruited (those with the largest number of patients seen per week) and randomly allocated to each study group; thereafter, each physician selected chronologically the first 13 patients attending their office who met the inclusion criteria described above. With this procedure, physicians identified 600 patients, from which 132 were excluded based on the inclusion/exclusion criteria (Fig. 1). As assignment of patients to each study group was nested by physician, all the patients of an individual physician belonged to the same group. Thus, there were four groups of 117 patients each: a control group with neither patient nor physician education (group 1), physician education (group 2), patient education (group 3) and patient and physician education (group 4).

### Educational strategies

We used the Diabetes Training Course for Physicians and the Diabetes Structured Education Courses for People with Type 2 Diabetes, whose characteristics and effectiveness have been reported [17,22]. The Training Course for Physicians consisted of a 25-structured module interactive course conducted by trained diabetologist educators to groups of 10–15 physicians in a highly interactive setting. The modules had five thematic axes: (1) diagnosis, classification and socio-economic impact, (2) associated cardiovascular risk factors, (3) chronic complications, (4) control, treatment and follow-up and (5) special conditions. Learning was assessed by written evaluation after each module and a final evaluation that included a practical test.

The Diabetes Structured Education Courses for People with Type 2 Diabetes were conducted by trained educators to groups of up to 10 ambulatory patients; they encouraged interaction between the educator and participants. There were four 90- to 120-min weekly teaching units and a reinforcement session at 6 months. The first unit included general concepts about Type 2 diabetes, symptoms of hypo-/hyperglycaemia and glucose self-monitoring, with strong emphasis on active patient participation and self-care. The second unit was about the effect of obesity on insulin sensitivity, the advantages of weight reduction and how to classify and select foods according to their calories. The third unit explained the importance of foot care and regular physical activity. In the fourth unit, patients learnt 'sick day' rules and the examinations and laboratory tests necessary to monitor diabetes care. Illustrated educational materials were used and each patient received a programme book.

### Data collection

Patient clinical, biochemical and therapeutic data before and after PRODIACOR were recorded using the Physician Data Form (Annual and Six-Month Clinical Record Form) and the Feedback Report Form [8,23]. A software programme compared $HbA_{1c}$, serum lipids and blood pressure, and their study goals on sequential encounters; a Feedback Report for physicians and patients was generated, including

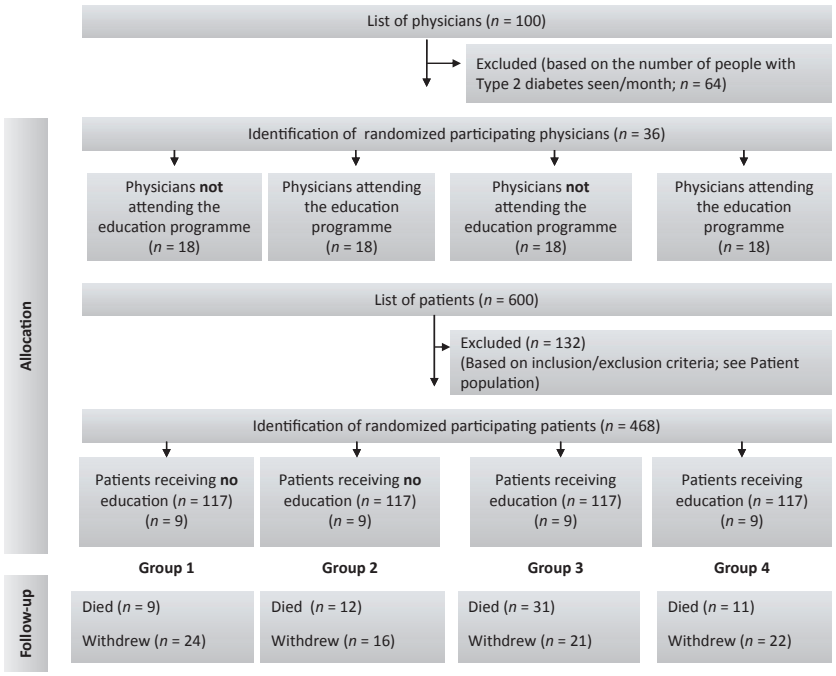


**FIGURE 1** Flow diagram of the study. According to this schedule, in group 1, neither patients nor providers received education; in group 2, only physicians received education; in group 3, only patients received education; and in group 4, both physicians and patients received education.

recommendations about appropriate treatment to achieve therapeutic goals. Psychological state was measured by a Patient Questionnaire, based on the one used in the Diabetes Advantage Program (DAP), which includes questions about disease adjustment, and the World Health Organization-5 questionnaire [24].

Data collection was completed with the Personalized Checkbook, the aim and content of which have been published elsewhere [17]. The Checkbook is used to order procedures, consultations, laboratory tests, prescription of drugs and strips for glucose self-monitoring, and to record and communicate results. It also records costs of procedures and drug consumption.

### Laboratory test performance

During the study period, all the laboratory tests were performed at the same place in order to use a homogeneous methodology, particularly $HbA_{1c}$ assay (immunoturbidimetric procedure), and to avoid any possible inter-laboratory variation. As, at the time of recruitment, many patients had no recorded $HbA_{1c}$ measurement, and in some laboratories $HbA_{1c}$ was being measured [20], we had to repeat all measurements at time 0 (baseline); consequently, the average values are different from those included in the original report.

### Study and data management

The Corrientes Coordinator and the Central Coordinating Center (CENEXA) oversaw the education courses and the overall trial and maintained regular contact with the participating physicians. A medical monitor reviewed physician and patient performance and the quality of the data recorded by the physicians at 6-month intervals for completeness; data were then forwarded by mail to the Central Coordinating Centre.

### Resource utilization and costs

These data included all direct medical items used by each programme participant; they were obtained from the utilization and cost records of the participating health coverage entities and the data in the Personalized Checkbooks.

Utilization was classified as follows: (1) hospitalizations, (2) drugs and supplies, (3) diagnostic tests, (4) special studies and (5) physician office visits. Very few hospitalizations occurred, the highest (64% of total cost) and most precisely recorded resource utilization was drug consumption. Subsequently, only this was used to measure the economic impact of the different education strategies. Drug costs were assessed from local retail prices (Alfabeta.net), adjusted to July 2004 using the health chapter of the local Consumer Price Index from the Argentinian Statistics Office [33]. Costs were expressed in Argentinian pesos ($) of July 2004 (Exchange rate: $ 2.96 = 1 US Dollar).

The estimated initial drug cost for the control of $HbA_{1c}$, blood pressure and triglycerides and the reduction experienced by each of these treatments within each treatment group was used to construct marginal figures of cost ratio. We calculated such ratio figures for each experimental group

by establishing the difference between the initial and final value of every clinical/biochemical variable and the same difference for the cost of its treatment. As initial and final values were not identical, either for biological variables or for treatment costs, for the sake of comparison we expressed the total drug cost associated with the following decreases in the main outcomes: $ by each 1% $HbA_{1c}$, $ by each 10 mmHg systolic blood pressure or $ by each 10-mg/dl triglyceride level. We did not include the costs of the educational interventions themselves and the administrative activities of the programme.

### Statistical analysis

To estimate the effects of the different educative interventions tested, we used the intention-to-treat analysis, widely recommended as the preferred approach to the analysis of most clinical trials [34]. For that purpose, the last observation carried forward was applied to missing data for the primary endpoint. In addition, we used a multivariate analysis of prognostic factors to predict the most likely outcome in those lost to follow-up for any reason, imputation of outcomes by carrying the last known outcome status forward and analysis of best-case and worst-case scenarios. By doing that, we assumed that, although this analysis cannot minimize bias introduced by loss to follow-up [25,26], such loss would be within the expected rate and similarly distributed among the different intervention groups.

Initial univariate differences among groups for quantitative data were analysed by one-way ANOVA (Bonferroni post hoc test). Factorial ANOVA and two-way ANOVA models (Bonferroni post hoc tests) were used to assess the differences among groups throughout the study. ANOVA was also used to explore initial vs. end-of-study differences among quantitative data. Differences among qualitative measures were explored by the $\chi^2$-test (Yates corrected). *P*-values less than 0.05 were considered as significant (two-tailed). The software used was CSS/Statistica version 6.0 (StatSoft Inc., Tulsa, OK, USA).

### Ethical approval

This study was approved by the Fundación de Estudios Farmacológicos y de Medicamentos (FEFYM) Research Ethics Committee.

## Results

### Population characteristics

Baseline data revealed a well-balanced subject allocation within groups regarding gender, age, BMI, systolic blood pressure, $HbA_{1c}$ and triglyceride levels (Table 1). Most patients were overweight and their baseline systolic blood pressure, fasting blood glucose, $HbA_{1c}$ and triglyceride levels were above the target values recommended by international guidelines.

As previously reported [20], acute diabetic complications and hospitalizations were infrequent in our sample population during the 42-month follow-up period, which is the reason why these data were not included in the analysis.

### Patient dropout

During the 42 months of the PRODIACOR study, of the total number of patients included in this analysis, 125 (27%) dropped out: 58 died (46%) and 67 (54%) abandoned the study mainly because they moved to another city (65%). Thus, only 23 out of 468 people abandoned the study for personal reasons. Causes of death included neoplasms (27%), cardiopathies (12%), infectious diseases (24%), sudden death (10%), stroke (10%) and other causes (27%).

Despite that the dropout was slightly higher than originally estimated to define the sample size, its number by group was

**Table 1** Clinical and metabolic characteristics; baseline data

| | Group 1* (control group) | Group 2 (physician education) | Group 3 (patient education) | Group 4 (patient and physician education) |
|---|---|---|---|---|
| Age (years) | 62.0 ± 8.4 z | 62.4 ± 9.1 | 62.2 ± 8.4 | 62.2 ± 9.0 |
| Gender (%) | 67.5 | 70.1 | 66.7 | 62.4 |
| Diabetes duration (years)* | 9 (5–15) | 10 (6–14) | 8 (4–16) | 8 (5–14) |
| BMI (kg/m$^2$)* | 29.3 (26.5–32.5) | 30.0 (27.1–33.3) | 29.0 (26.0–33.0) | 30.1 (27.7–33.9) |
| Systolic blood pressure (mmHg) | 142 ± 19 | 142 ± 14 | 145 ± 19 | 141 ± 18. |
| Fasting blood glucose (mg/dl) | 147.5 ± 48.9 | 142.4 ± 43.6 | 146.6 ± 43.8 | 145.3 ± 57.9 |
| $HbA_{1c}$, mmol/mol (%) | 62 ± 9 (7.8 ± 1.2) | 58 ± 12 (7.5 ± 1.5) | 62 ± 11 (7.8 ± 1.4) | 61 ± 10 (7.7 ± 1.3) |
| Total cholesterol (mg/dl) | 207.0 ± 39.1 | 209.7 ± 39.4 | 209.3 ± 41.9 | 195.7 ± 35.3 |
| Triglycerides (mg/dl) | 151.3 ± 39.1 | 170.1 ± 40.6 | 173.5 ± 77.5 | 168.1 ± 47.5 |

*Group 1, control group with no patient or physician education.
Data presented in the table show values recorded at time 0 of the study. In all cases, $n = 117$.
Data are mean ± SD, except for *(median; interquartile range). In these instances, the *P*-value was estimated using the Kruskal–Wallis test.

similar [control group with neither patient nor physician education (group 1) 33; physician education (group 2) 28; patient education (group 3) 31; patient and physicians education (group 4) 33]; therefore, it did not affect the power of statistical data analysis (Fig. 1). No significant differences were recorded either in the baseline clinical or in the metabolic characteristics of completers and those who dropped out from the study.

### Education

The knowledge acquired was measured in patients and physicians before and after their courses using previously validated multiple-choice questionnaires and is reported as a percentage.

### Patients

No differences among groups were detected regarding initial knowledge (scores approximately 40%). After the courses, a comparable increase was recorded in the patient education group (group 3) and the patient and physician education group (group 4) (73 vs. 77, respectively; $P = 0.8$).

### Physicians

There were no significant differences among groups at baseline (average percentage score: 47%). After the course, a comparable increase was observed in the physician education group (group 2) and the patient and physician education group (group 4) (81 vs. 83, respectively; $P < 0.6$ from baseline).

### BMI

None of the PRODIACOR groups showed significant changes in this variable.

### $HbA_{1c}$

There were no significant differences among groups at baseline. $HbA_{1c}$ decreased significantly ($P < 0.05$) in the control group with neither patient nor physician education (group 1), the physician education group (group 2) and the patient and physicians education group (group 4) by the end of the study, attaining target values in the physician education group (group 2) and the patient and physician education group (group 4) (53 mmol/mol; ≤ 7%). The largest reduction

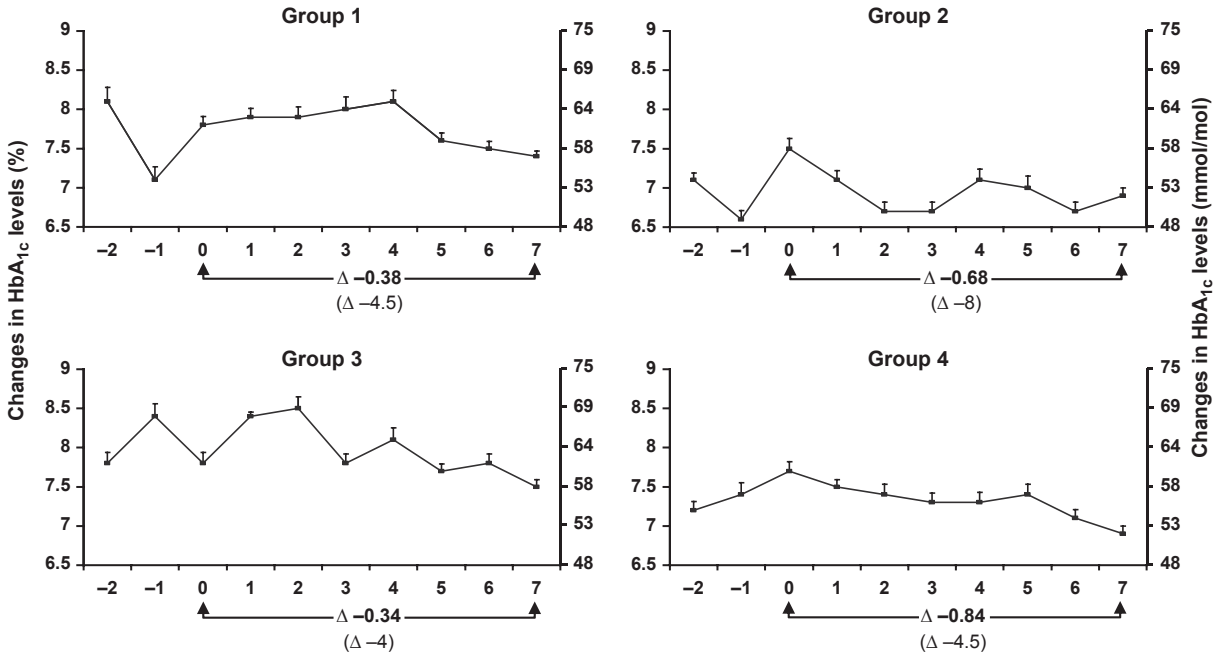


**FIGURE 2** Changes in $HbA_{1c}$ levels expressed in % (left axis) and mmol/mol (right axis). Each point represents the mean ± SEM of the $HbA_{1c}$ levels recorded in each group at a given time. Each point recorded in the abscissa was collected every 6 months. In every group, a significant difference was observed between the value recorded at time 0 and 7 (42 months). This difference was larger in the patient and physician education group (group 4). There were no significant differences among groups at time 0, while significant differences ($P < 0.05$) were recorded between groups at different times: time 1, physician education (group 2) vs. patient education (group 3); time 2, physician education (group 2) vs. patient education (group 3); time 6, physician education (group 2) vs. control group with no patient or physician education (group 1) and patient education (group 3) and patient and physician education (group 4) vs. patient education (group 3); time 7, physician education (group 2) vs. no patient or physician education (group 1) and patient education (group 3) and patient and physician education (group 4) vs. no patient or physician education (group 1) and patient education (group 3). In each group, Δ values between time 0 and 7 are expressed as % and mmol/mol.

was in the patient and physician education group (group 4) (Fig. 2). Potential interaction was tested using the ANOVA model and the interaction term that resulted was non-significant ($P = 0.331$). There were also differences in the $HbA_{1c}$ pattern of decrease among the study groups: the slope of the curve only showed a continuous and consistent decrease in the patient and physician education group (Fig. 2).

### Blood pressure

Systolic blood pressure also had an inconsistent profile before the intervention (Fig. 3). Although it decreased significantly at the end of the study in all groups, the greatest decrease was again recorded in the patient and physician education group (group 4) ($P < 0.05$). When these values were sequentially plotted, the most consistent decrease pattern was also observed in that group (Fig. 3).

### Serum triglyceride concentrations

Serum triglyceride concentrations showed an uneven pattern before the intervention (Fig. 4). A significant decrease in their values was recorded in the physician education group (group 2), the patient education group (group 3) and the patient and physician education group (group 4) at the end of the study ($P < 0.05$), while the control group with no patient or physician education (group 1) showed a significant increase compared with baseline values. Again, the largest and most continuous and consistent decrease was observed in the patient and physician education group (group 4) (Fig. 4).

### Psychological aspects

The WHO-5 well-being questionnaire had low baseline scores in all groups and, according to the score of Lowe *et al.* [27], most patients needed psychological support (Table 2). Although no special psychological care was provided, the WHO-5 scores improved significantly by the end of the study ($P < 0.05$), with no significant differences among groups.

### Drug treatment costs

As mentioned before, during follow-up the greatest and most precisely recorded resource consumption was drug consumption (64% of total cost). Thus, we analysed only this item to measure the economic impact of the different education strategies. Within this cost, treatment of hyperglycaemia, which includes the cost of blood glucose strips, was the most expensive component, representing 48% of drug treatment costs.

During the study period, the costs of drugs used to control hyperglycaemia, hypertension and dyslipidaemia increased unevenly but significantly in all groups (Table 3). As the clinical and metabolic improvements recorded in each of the intervention groups were of a different magnitude, it was not easy to compare the cost-effectiveness of the drugs. To overcome this problem, and as explained above (see Patients

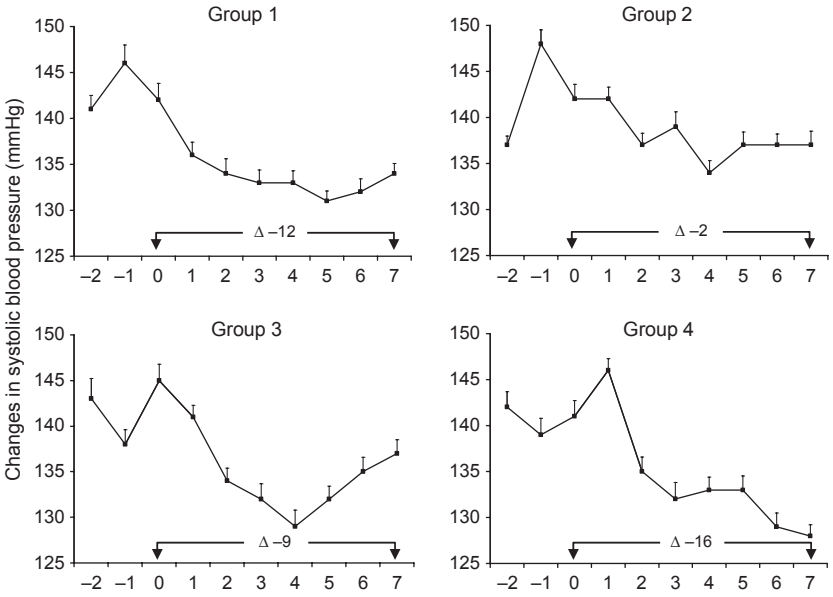


**FIGURE 3** Changes in systolic blood pressure (mmHg). Each point represents the mean ± SEM of the systolic blood pressure values recorded in each group at a given time. Each point recorded in the abscissa was collected every 6 months. At time 0 there were no significant differences among groups; significant differences ($P < 0.05$) were recorded between groups at different times: time 1, control group with no patient or physician education (group 1) vs. patient and physician education (group 4); time 6, physician education (group 2) vs. patient and physician education (group 4); time 7, physician education (group 2) vs. patient and physician education (group 4).

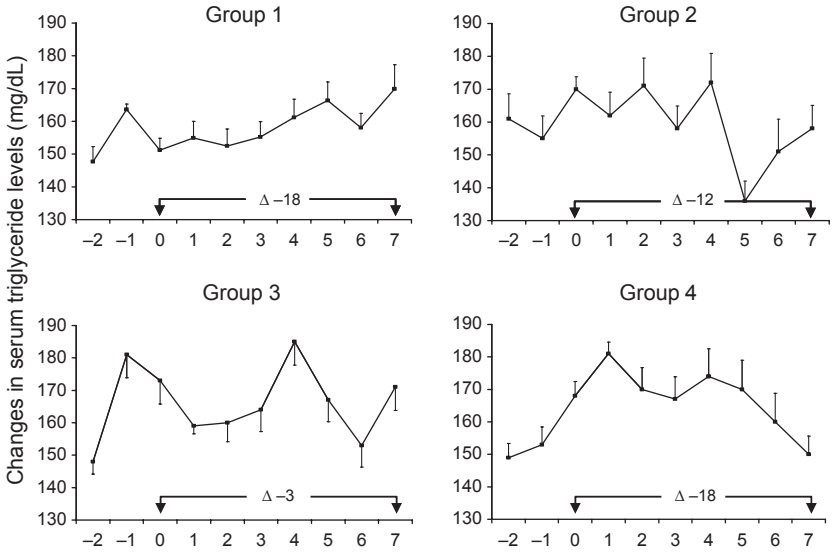


**FIGURE 4** Changes in serum triglyceride levels (mg/dl). Points represent the mean ± SEM of serum triglyceride levels recorded in each group at a given time. Each point recorded in the abscissa was collected every 6 months. At time 0, there is a significant difference among groups ($P < 0.05$; see Table 1); additionally, significant differences ($P < 0.05$) were recorded at time 7 [patient and physician education (group 4) vs. control group with no patient or physician education (group 1) and patient education (group 3)].

**Table 2** Well-being questionnaire

| | WHO-5 Well-Being Index (× 4) | | | | |
|---|---|---|---|---|---|
| | Group 1* (control group) | Group 2 (physician education) | Group 3 (patient education) | Group 4 (patient and physician education) | $P^{\dagger}$ |
| Basal | 18 (0–48) | 24 (0–64) | 16 (0–48) | 16 (0–48) | 0.407 |
| Final | 48 (16–80) | 48 (22–80) | 48 (16–80) | 52 (16–80) | 0.797 |
| $P^{\ddagger}$ | 0.0042 | 0.0051 | 0.0039 | 0.0033 | |

Thresholds suggested by Lowe *et al.* were used to analyse the results of the WHO-5 questionnaire [27]; accordingly, scores ≤ 28 suggest the need of immediate psychological support; scores between 29 and 50 require further assessment of psychological status; and scores ≥ 51 do not require psychological support. Data are presented as median (interquartile range).
*Group 1, control group with no patient or physician education.
†Kruskal–Wallis test.
‡Wilcoxon's signed-rank test.

and methods: Resource utilization and costs), we expressed the incremental costs of drugs necessary to decrease an arbitrary unit of each variable; i.e. what was the incremental cost for a 10-mmol/mol (1%) decrease of $HbA_{1c}$, a 10-mmHg decrease in systolic blood pressure or a 10-mg/dl decrease of triglyceride levels? Using this procedure, the best cost-effective ratio for every variable measured was recorded in the patient and physician education group (group 4) (Table 3).

## Discussion

Our data show that clinical, metabolic and psychological indicators improved significantly after implementing different targeted educational interventions at the primary care level in a population with a median 10-year duration of Type 2 diabetes over a 42-month follow-up. Such improvement could reduce the development and progression of the chronic complications of diabetes [2–5], resulting in an ultimate reduction of the cost of patient care [1,6,7]. The inconsistent profile of $HbA_{1c}$, systolic blood pressure and triglyceride values observed in patient records from all groups before starting the PRODIACOR study (Figs 3–4) indicates that the improvement can be ascribed to the educational interventions rather than to a simple regression to the mean values. These improvements were not associated with significant changes in BMI, suggesting that patients and physicians were more prone to adhering to drug treatment than to adopting healthy lifestyle habits.

Even although psychological support was not provided, the WHO-5 scores initially recorded had significantly improved by the end of the study, with no significant

**Table 3** Costs of drug treatment

| Variable | | Group 1* (control group) | Group 2 (physician education) | Group 3 (patient education) | Group 4 (patient and physician education) |
|---|---|---|---|---|---|
| Hyperglycaemia($HbA_{1C}$)† | Initial cost | 332 | 400 | 151 | 230 |
| | Final cost | 540 | 516 | 314 | 365 |
| | Δ $ | 208 | 116 | 163 | 135 |
| | Δ $HbA_{1c}$% | –0.38 | –0.68 | –0.34 | –0.84 |
| | Δ$/1% $HbA_{1c}$ decrease | 547 | 171 | 479 | 161 |
| Hypertension | Initial cost | 116 | 100 | 115 | 122 |
| | Final cost | 208 | 129 | 165 | 148 |
| | Δ $ | 92 | 29 | 50 | 36 |
| | Δ mmHg | –12 | –2 | –9 | –16 |
| | Δ$/10 mmHg decrease | 77 | 145 | 56 | 23 |
| Triglycerides | Initial cost | 74 | 94 | 189 | 85 |
| | Final cost | 172 | 170 | 236 | 163 |
| | Δ $ | 98 | 76 | 47 | 78 |
| | Δ mg/dl | 18 | –12 | –3 | –18 |
| | Δ$/10 mg/dl decrease | 54 | 63 | 157 | 43 |

Data are shown as mean values; Δ in $ were also expressed as the amount necessary to decrease an arbitrary unit selected for each variable.
*Group 1, control group with no patient or physician education.
†For this estimation, Δ $HbA_{1c}$ is expressed in Diabetes Control and Complications Trial (DCCT) units.

differences among groups. These data suggest that both the care and the educational strategies implemented provided some psychological support, which, in many cases, reduced the negative psychological impact of the disease.

Several authors have shown in many populations that educational programmes with a theoretical basis using cognitive reframing are associated with improved outcomes [22,28,29]. A structured group education programme for patients with newly diagnosed Type 2 diabetes (the DESMOND study) resulted in greater improvements in weight loss and smoking cessation and in positive beliefs about illness, but had no effect on $HbA_{1c}$ up to 12 months after diagnosis [30]. It also showed that the programme was cost-effective (with 66% using trial-based intervention costs and 70% using 'real world' costs) at a threshold of £20 000 per quality-adjusted life year. Brownson *et al*. also reported that self-management programmes for Type 2 diabetes implemented at the primary care level were cost-effective from the perspective of a healthcare system, when considering cost savings as a result of reductions in long-term complications [31]. In our case, all the educational interventions tested significantly improved the primary outcomes. Altogether, the evidence strongly suggests that education, regardless of the method used, is an effective tool to improve the care and outcomes of people with Type 2 diabetes.

We demonstrated that, although educational strategies directed to different audiences (patients, physicians or combined implementation) were effective in achieving many therapeutic goals, their relative efficacy was not the same. In fact, the implementation of the combined education of patients and physicians provided the greatest as well as the most consistent and sustained clinical and metabolic improvement at the best drug treatment cost-effective ratio. Such characteristics, only recorded in this group, would enhance the prevention power of the clinical and metabolic improvement associated with the combined education strategy. In addition, physician education occupied the second position in magnitude of induced changes; this is not a minor point as the study was dealing with primary care physicians, this being the level suitable to start the promotion of early diagnosis as well as timely and appropriate diabetes treatment.

Despite the evidence of improvement of diabetes outcomes using educational interventions reviewed here and demonstrated in this paper, some authors claim that the long-term effectiveness of educational interventions in people with Type 2 diabetes remains unproven [19]. Perhaps this scepticism underlies the reason why educational interventions are prescribed at a significantly lower rate than other prevention strategies [11]. Further, in one systematic review, the authors concluded that more studies were needed, particularly on the long-term benefit of educational interventions [19]. Recently, a long-term multi-centre, 13-hospital trial was implemented in Italy by Trento *et al*., aimed at improving diabetes control through lifestyle intervention in 815 patients with recently diagnosed Type 2 diabetes [32]. These authors found that, in the intervention group, healthcare behaviours, quality of life and knowledge of diabetes were significantly better than in the control subjects. Additionally, they had lower $HbA_{1c}$, total cholesterol, LDL cholesterol, triglyceride, systolic blood pressure and diastolic blood pressure, BMI and serum creatinine, and higher HDL cholesterol than control subjects despite receiving a similar pharmacological treatment. The data presented herein further support these conclusions in primary care settings and in people with 10-year average Type 2 diabetes duration.

While our data show a significant improvement in quality of care and optimization of economic investment, particularly in drug costs, they are limited by the possibilities that:

(1) the physicians collecting the data were not blinded to outcomes, with the carrying forward of last data for primary endpoint; (2) the full healthcare coverage simultaneously provided to all PRODIACOR participants, irrespective of the group allotted, could be partly responsible for the improvements obtained; and (3) the cost analysis should consider not only drug costs but also other costs, including those directly related to the educational interventions themselves.

In brief, our data show that long-term implementation of different targeted educational interventions at the primary care level in people with Type 2 diabetes of long duration significantly improved clinical, metabolic and psychological outcomes at a reasonably marginal cost. Even the simple provision of structured written information and the implementation of a continuous monitoring of quality of care, associated with periodic feedback reports for patients and physicians [the control group with patients and physicians not educated (group 1)] resulted in significant improvements; the high motivation of patients and physicians would have been partially responsible for the success in this group. This is not a minor issue, particularly for developing countries that are facing a continuous growth of diabetes prevalence without a parallel increase in their healthcare budgets. Maximal effect at lower economic cost was seen when education was simultaneously delivered to people with diabetes and their healthcare providers; i.e. when both sides share common aims. Further, the importance of including physician education to optimize treatment-target goals is also shown. As the participating organizations operate at national level and the public healthcare sector is common to each province of Argentina, the successful outcomes of this model could be easily reproduced in other provinces. It could be also adapted and adopted by other developing countries with similar healthcare settings. Such implementation would result in better outcomes and in the optimization of drug consumption, making feasible secondary prevention and the improvement of the quality of life of people with diabetes.

### Funding sources

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### Competing interests

None declared.

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## Appendix

### List of study participants

General Coordinator of PRODIACOR: J. J. Gagliardino. Local Coordinator in Corrientes: S. Lapertosa. Executive Committee at CENEXA: N. V. Cédola, C. González, J. E. Caporale, E. Rucci, L. González, A. Sánchez. Executive Committee at Corrientes: P. Torales, M. A. Yordan and J. Murua, Unidad de Gestión y Participación, Programa de Atención Médica Integral (UGP-PAMI); M. Villagra, Health Ministry of Corrientes; G. Ojeda, Sistema de Prevención Social (SPS); A. Valmagia and A. Silva, Programa Federal de Salud (PROFE); D. Dos Santos, Health Ministry of Corrientes; C. Segersbol, B. De la Vega, A. Karatanazopulos, R. Esquercia and R. Degregorio, Instituto Obra Social de Corrientes (IOSCOR); F. Marcopulos, J. Migueles and M. Polimeni, Obra Social para la Actividad Docente (OSPLAD). Intersectorial Committee at Corrientes: R. Cardozo and R. Pinchetti, Health Ministry of Corrientes; I. Rigonatto, Instituto Nacional de Servicios Sociales para Jubilados y Pensionados (INSSJYP); D. Mondaini, Universidad Nacional del Nordeste; B. Benitez, Sociedad Argentina de Cardiología, Corrientes; D. Dionisi, Sociedad Argentina de Diabetes, Northeast Chapter. National Advisory Committee: J.M. Domínguez. International Advisory Committee: C. Clark Jr, Indiana University.

The forms and questionnaires used in the study are available upon request (direccion@cenexa.org).