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Long-term effectiveness of a type 2 diabetes comprehensive care program. The CAIPaDi model

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ABSTRACT

Aims: To evaluate the effectiveness of a comprehensive care program to achieve and maintain goals in patients with type 2 diabetes.
Methods: The CAIPaDi program includes 9 interventions delivered in 7 h. It seeks to achieve metabolic goals, identify and resolve barriers that would make implementation difficult, and provide self-efficacy and empowerment to patients by identifying personal profiles to establish individualized strategies. The program consists of a 4 intervention visits (1, 2, 3, and 4 months) and two follow up visits (12 and 24 months). Outcomes are compared between every visit. Main outcome was the attainment of the USA National Committee for Quality Assurance treatment goals.
Results: 1104 patients completed the first 4 visits, 545 the 12 month evaluation, and 218 the 24 month evaluation. After the conclusion of the four monthly sessions, 80.6% had HbA1c <7%, 72.1% had BP <130/80 mmHg and 71.6% had LDL- cholesterol <100 mg/dl. After twelve months, the percentage of goals achieved were 65.9%, 67.7% and 43.3% respectively ($p < 0.001$). For the 2-year evaluation the percentages were 61.0%, 70.6%, and 40.8% respectively ($p < 0.001$). All patients had renal, eye, foot and dental evaluations. Empowerment and quality of life showed significant changes; anxiety and depression scores remained low at annual follow-ups.
Conclusions: The CAIPaDI program results in sustained improvement and maintenance of treatment goals.

1. Introduction

Healthcare systems face big challenges to provide effective and high quality diabetes care. Achievement of the treatment goals is low, especially in the developing world. Type 2 diabetes is a major challenge for the Mexican Healthcare System due to its high prevalence, high rate of disabling complications and concerning direct and indirect costs [1–4].

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Patient-centered, comprehensive care programs are among the top actions to decrease the burden of the disease. These efforts are a work in progress. They have moved from purely informative sessions to multidisciplinary interventions designed to bring benefits in obtaining metabolic control goals, and reducing hospitalizations, emergency services visits and mortality rates [5–7].

These interventions include patient-centered medical care, mental health evaluations, the adoption of a healthy lifestyle and diabetes education programs. The core and processes of such programs are diverse, depending on available resources and characteristics of the target population (as reviewed by Lim and coworkers) [8]. However, the interventions' effects are transient if empowerment (getting essential competencies for self-care) is not promoted by the program [8,9]. Patient empowerment ensures capability to take the best decisions with available resources to accomplish control in patient's conditions [10].

In 2013, the Center of Comprehensive Care for the Patient with Diabetes (CAIPaDi – an acronym for its name in Spanish) was created with the purpose of developing a patient-centered, multidisciplinary model focused on the resolution of the most common barriers that preclude adherence to therapy and the attainment of treatment goals [11]. It is composed by nine structured interventions implemented in a single visit executed by a multidisciplinary team. The program's target population are patients within their first 5 years after diagnosis and free of chronic, disabling complications. Empowerment is considered as a primary goal in this program and the standardized protocols focus on self-efficacy and co-responsibility. The program also includes elements of the World Health Organization chronic disease care model such as the use of procedure manuals, treatment algorithms based on available resource, usage of an electronic registry system and the evaluation of quality indicators of medical care [12].

The aim of this report is to provide results about the effectiveness of a comprehensive care program (CAIPaDI) based upon empowerment techniques to achieve metabolic goals, in recently diagnosed type 2 diabetes, after 2 years of program participation.

2. Materials and methods

This is a program evaluation study. The CAIPaDi program consists of two phases (Fig. 1). The first comprises an initial and 3 visits one month apart (visits 1, 2, 3 and 4 respectively), each one taking place in a single 7 h shift. The interventions are: medical care, diabetes education, nutrition, physical activity, psychological evaluation, psychiatric assessment, eye exam, foot and dental care. These are delivered by one nurse, two endocrinologists, a diabetes educator (DE), a nutritionist, an ophthalmologist, a psychologist, a psychiatrist, a physical activity instructor and a dentist. Each intervention follows a procedure manual and has: (1) a specific goal, (2) a self-management strategy and (3) prespecified indicators. Each session is 30 to 60 min long; some of them are group meetings in which a predesigned dynamic is executed. Blood test, EKG, weight and height are obtained at arrival; blood test results are available in 2 h and attached to every medical record so specialists can adapt and adjust the treatment according to their results.

The second phase consists of 2 annual evaluations (visits 5 and 6) where all interventions from the initial phase are reinforced. During each annual visit, prespecified outcomes are measured [11]. A continuous at-distance support system was implemented to maintain communication with patients via e-mail, phone calls, text messages, and through the hospital's webpage. (http://innsz.mx/opencms/contenido/departamentos/CAIPaDi).

The main outcome is the achievement of treatment goals defined by the National Committee for Quality Assurance criteria (NCQA): HbA1c, blood pressure (BP) and LDL-cholesterol. NCQA parameters provide an integrative score of the program performance [13]. Secondary outcomes include the percentage of patients: (1) achieving the 3 metabolic goals, (2) with diabetes-related complications and (3) treated with aspirin, antihypertensive and lipid-lowering drugs.

2.1. Study population

The patients for this study were enrolled from November 1st, 2013 to June 30th, 2018. Inclusion criteria were: type 2 diabetes patients, ≤5 years of diagnosis, without disabling complications (blindness, renal failure, stroke, limb amputations, ischemic heart disease) and non-smokers; when smokers, patients attended a Smoking Cessation Clinic as part of the treatment for 6 months before entering the program given the negative impact of smoking in diabetes [14,15]. If selected, patients received a phone call and an e-mail with the information of their first visit appointment and questionnaires (mentioned later in this section) to be answered in each visit.

2.2. Procedures

The Institutional Ethics and Research Committees from the National Institute of Medical Sciences and Nutrition Salvador Zubirán (INCMNSZ for its name in Spanish) approved this study (Ref 1198) and it was registered in ClinicalTrials.gov (NCT02836808). All patients signed an informed consent form.

Each visit was held at the CAIPaDi Center. Patients could participate in groups of 10 people in individual sessions depending on the intervention, with a close relative being encouraged to participate with them. Every one of these interventions followed a procedure manual and included a checklist of the main actions to be implemented and variables to be measured. The aim of visit 1 was to obtain a complete assessment of the patient and provide basic information to start the required changes. On visit 2, patients underwent a problem-oriented evaluation, where the recommendations were selected based on patient´s profile. Visit 3 focused on the identification of potential barriers that may impede metabolic control achievement and visit 4 aimed to reinforce the knowledge already acquired and evaluate the initial results of interventions. During visits 5 and 6, the barriers and their proposed solutions were reviewed. In summary, a collaborative, iterative process was applied in each intervention. To

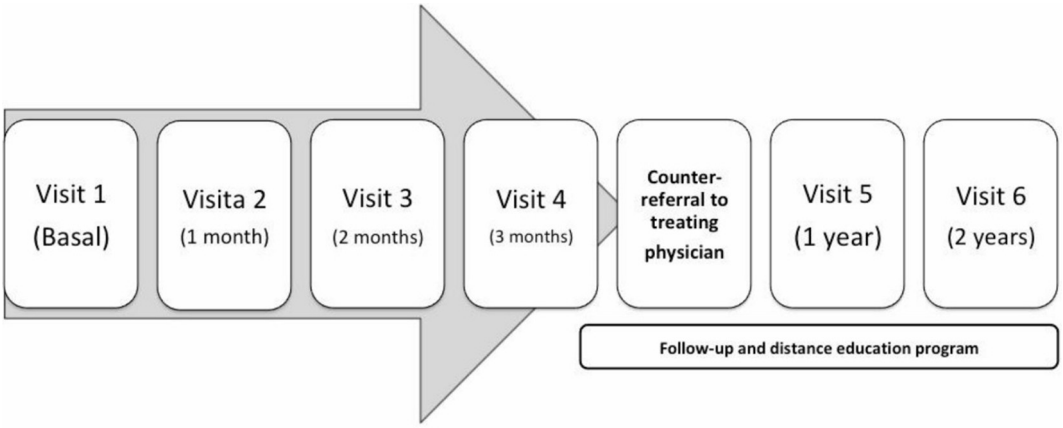

Fig. 1 – The CAIPaDi program is conformed of a baseline and 3 monthly visits (phase 1) and then a reevaluation at 1 and 2 years (phase 2).

evaluate the competencies acquired in every visit, a structured exam was applied to each patient asking them to undertake activities related to self-care (check their feet, glucose monitoring, toothbrushing. . .). All interventions were applied in every visit.

Although many aspects were reviewed in each intervention, the strategies applied to empower patients were directed to their needs, beliefs (regarding diet and exercise according to geographic area and preferences) and resources. Table 1 summarizes the 9 interventions and the health professional delivering each part of the program. When not evaluated by the program (time between visits), patients were regularly checked by their personal general physician.

2.3. *Outcome measurements*

Fasting concentrations of glucose, creatinine, lipids and HbA1c (Bio-Rad Variant II Turbo HbA1c Kit 2, with HPLC method) were assessed in each visit. Albuminuria/creatinuria ratio (ACR) (SYNCHRON CX system with colorimetric method) was used for screening diabetic nephropathy at baseline and annual visits. The laboratory is certified by ISO 90001:2015 and the College of American Pathologist. Body composition was assessed by bioimpedance (body composition analyzer JAWON medical ioi353).

Validated questionnaires were applied for: empowerment (The Diabetes Empowerment Scale-Short Form [DES-SF]) [16], anxiety and depression symptoms (Hospital Anxiety and Depression Scale [HADS]) [17,18], quality of life (Diabetes Quality of Life Measure [DQoL]) [19,20], diabetes-specific emotional distress (Problem Areas in Diabetes Questionnaire [PAID]) [21] and Diabetes Knowledge Scale [22]. To retrieve information about fitness, the International Physical Activity Questionnaire [IPAQ] was answered [23], and the 6-minutes walking test was done in every visit [24]. Patients completed a 3-days food record to register calories consumed per day [25].

Evaluation of social support was classified into 3 categories: (1) Functional: included family or friends providing emotional and/or economic support and being involved in treatment strategies; daily activities did not affect adherence. (2) Partial: family or friends giving partial emotional and/or economic support, were not completely involved in treatment strategies and patients' daily activities affected adherence. (3) Dysfunctional: family or friends not aware of diagnosis or patients had activities with negative impact in health.

The clinical diagnosis of periodontal disease was established according to the criteria of the American Academy of Periodontology [26]. The classification included periodontal health, gingivitis and periodontitis. Likewise, chronic periodontitis was classified as slight (1–2 mm of clinical attachment loss [CAL]), moderate (3–4 mm CAL) and severe (>5 mm CAL) and according to extension as localized (<30% of sites are involved) and generalized (≥30% of sites are involved).

The ankle/brachial index was evaluated according to the Guidelines of the American College of Cardiology/American Heart Association [27].

2.4. *Statistical analysis*

Results were reported as means (±SD) if they followed a normal distribution or medians and interquartile ranges (25–75) if they did not have a normal distribution, according to Kolmogorov-Smirnov test. Percentages were used for discrete values. Changes in the NCQA scores were compared using McNemar test, and for comparing categorical variables or Chi-square test. Analysis by protocol was performed and included T-test for related samples of changes in scores of questionnaires and laboratory tests. Non-parametric values were log-transformed for regression models. Analysis included T-test or U-Mann Whitney for related samples when appropriate. We performed a principal component analysis (PCA) to evaluate variables explaining target goals reached using varimax rotation on the coefficients to assess consistency. The number of components was evaluated using sedimentation graphs.

We evaluated through an explanatory model the association of the components with metabolic goals. This analysis included variables from visits 4, 5 and 6. The variables were included using two-step logistic regression models. In the first model, components obtained from PCA analyses considered if

Table 1 – Interventions and members of the CAIPaDi team.

Member of CAIPaDi team	Intervention
Endocrinologist	(1) Checked metabolic outcomes. Adjusted drug treatment (following treatment algorithms for glucose, lipids and blood pressure control, depending on patient's resources). Evaluated any potential dermatological, neurological and vascular complication
Diabetes educator	(2) Provided individual or group sessions depending on the topic to be reviewed: glucose monitoring, timely detection and adequate treatment of hypoglycemia, foot care (patients were taught about proper use of footwear, cream, powder and nail clipping to prevent injuries), eradicate diabetes-related myths and proper actions during a sickness day
Nutritionist	(3) Prepared diet plan depending on patients' preferences and resources, based initially on a "simplified plan" (start avoiding the most deleterious customs) and then escalates to improve their feeding choices. Elaborated specific dietary cards to help patients adhere to their plan if barriers as: "having to eat outside home" or "at work" or "no place to have healthy snacks" were identified
Psychologist	(4) Searched for anxiety, depression or any other emotional factor that could limit adherence to treatment. Addressed social support, cognitive resources and emotional status for helping patients overcome barriers in different areas and solve daily problems
Dentist	(5) Performed general dental exam and treated specific diseases if identified. Empowered patients by teaching them dental health topics, the correct technique for toothbrushing and usage of dental floss. Initial non-surgical treatment of periodontitis and referral to more specialized treatment
.Psychiatrist	(6) Detected personality traits that may alter response to therapy. Treated depression, anxiety or eating disorders. Prescription of drugs for the treatment of psychiatric disorders
Physical therapist	(7) Explained differences between physical activity and exercise. Start avoiding sedentarism (increase steps per day) and start exercise programs including aerobic and strength activities. Identified barriers to do exercise and proposed activities to help patients increase daily steps
Foot Care	(8) Evaluated dermatological, neurological, vascular factors for foot health. A session for abnormal pressure points included step analysis, where individualized soles were indicated when necessary
Ophthalmologist	(9) Evaluated vision acuity, ruled-out diabetic retinopathy and macular edema using a no-mydriatic camera for retinal review. Pupillary pharmacological dilation was performed when photographs had poor quality

the patient achieved metabolic goals as a dependent variable. For the second step, models were adjusted for age, sex, baseline HbA1c, body mass index (BMI), medications for diabetes, hypertension and lipid control. Harrell's C-statistic evaluated the predictive capacity of the models and 95% confidence intervals. These latter were computed using the DeLong method. SPSS Statistics version 21 was used for data analysis and a p-value < 0.05% was considered as significant.

3. Results

A total of 1837 patients were enrolled within study's time period. From these, 444 patients (24.1%) abandoned the program in the initial four visits and 150 patients are still taking part in the first phase, so 1243 patients finished the first phase and were included for analysis. Of this total, 262 (20.9%) did not attend to their 1-year follow-up. For the visit 5 analysis we included 628 patients (353 patients are still ongoing for this visit). At visit 6, 99 (15.7%) of 628 did not attend to their appointment, and 241 are still ongoing this visit. In this report we included 1243 patients who finished visits 1 to 4, 628 who completed visit 5 and 288 for visit 6 (Fig. 2).

The mean age was 51.1 ± 10.3 years, 56.2% were women, with time since diagnosis 1 (0–5) year. The mean BMI was 29.5 ± 5 kg/m^2. All patients had renal, dental, foot and eye exam. Renal evaluation was performed with albuminuria/creatinuria ratio at the visits 1, 5 and 6. The basal median of ACR was 7.4 (4.2–18.8) mg/g and 16.3% had >30 mg/g. We observed 80 patients with gingivitis and 431 with periodontitis at visit 1. Periodontal disease (gingivitis and periodontitis) was present initially in 92.3% of the patients. In foot evaluation, 30.2% of the patients had an altered tuning fork test. Also, in vascular evaluation, we found 2% with an altered ankle/brachial index. The eye exam included an evaluation for retinopathy and macular edema. At visit 1, 14.1% of the patients had any level of retinopathy, and 3.3% had macular edema.

3.1. *Outcomes*

We evaluated the performance of the program using the approach proposed by the NCQA [13]. Table 2 shows the total score and each one of the NCQA parameters. The program reached all the NCQA goals after the first 4 visits. As a result, the maximal score (100 points) was achieved and remained the same at visit 5.

At visit 1, only 8.1% of the patients had met the 3 main goals (HbA1c, blood pressure, and lipids). In contrast, at the end of visit 4, 47.4% of the patients achieved the 3 goals (p < 0.001). 24.3% and 23.2% of patients met the 3 goals in visits 5 and 6 respectively (p = 0.003). The effect of the intervention in the metabolic parameters is shown in Table 3.

The absolute change in HbA1c was −1.2 (−3.4 to 0.3)% after the initial four visits and it remained −0.4 (−2.0 to 0.2)% at visit 5 and −0.1 (−1.5 to 0.5)% at visit 6. The same trend was

observed for fasting glucose, blood pressure, and lipid concentrations. All changes are statistically significant ($p < 0.001$).

3.2. *Lifestyle modifications obtained in the CAIPaDi program*

As measured by IPAQ, patients achieved a remarkable increase of the minutes devoted to moderate physical activity. They reported moving from 0 (0–151) to 180 (120–300) minutes/week ($p < 0.001$) after the fourth visit. The minutes decreased to 150 (0–240) minutes/week in visit 5, but still in agreement with the minimal goals ($p < 0.001$ vs baseline). At visit 6, the minutes reported were 150 (0–245) minutes/week ($p < 0.001$ vs baseline). The results of the 6-minute test in treadmill increased from 418 (337–470) meters to 464 (400–500) meters in 4 months ($p < 0.001$). At visit 5, it changed to 450 (386–492) meters ($p < 0.001$), and 450 (386–498) meters ($p = 0.04$) in visit 6. The average of calories consumed reported in visit 1 was 1581 ± 437 kcal. At the end of the first phase, patients consumed 1373 ± 266 kcal ($p < 0.001$). In visit 5, the consumption of calories was 1411 ± 304 calories/day ($p < 0.001$, compared with the first visit) and 1392 ± 304 kcal at visit 6 ($p < 0.001$, compared with the first visit). Despite the changes in physical activity and caloric intake, the weight change was marginal. Important parameters that help in weight follow-up are lean and fat mass, which relate to metabolic control. The patients in the program had important changes in both parameters, losing fat and maintaining lean mass (Table 3).

Empowerment scores changed from 72.6 ± 17 to 82.4 ± 12.7 ($p < 0.001$) and 82.3 ± 13.6 at visits 5 and 6 ($p < 0.001$). Up to 38.9% of the patients had depression in the first visit. This percentage changed to 12.4% at visit 4 and 21.3% and 15.1% at visits 5 and 6, respectively ($p < 0.001$ for all visits). At the beginning of the program, 46.4% of the patients had anxiety, which diminished to 16.3% at visit 4 and 20.8% and 15.1% for visits 5 and 6 ($p < 0.001$ for all visits). The DQoL score reduced 24% and continued as such in the annual visits (Table 3). DQoL scores changed from 90.9 ± 24.5 to 71.0 ± 17.8 ($p < 0.001$) and 72.5. ± 18.6 at visit 5 and 71.4 ± 18.2 at visit 6. ($p < 0.001$).

In the Diabetes Knowledge Scale, 72.7% of the patients had adequate knowledge (adequate being >18 points). At visits 4, 5 and 6 zero patients had inadequate knowledge. Ninety seven percent of the patients had adequate knowledge ($p < 0.001$ compared with basal) in visit 4. For visits 5 and 6, 98% and 95% had adequate knowledge ($p < 0.001$, both visits compared with baseline).

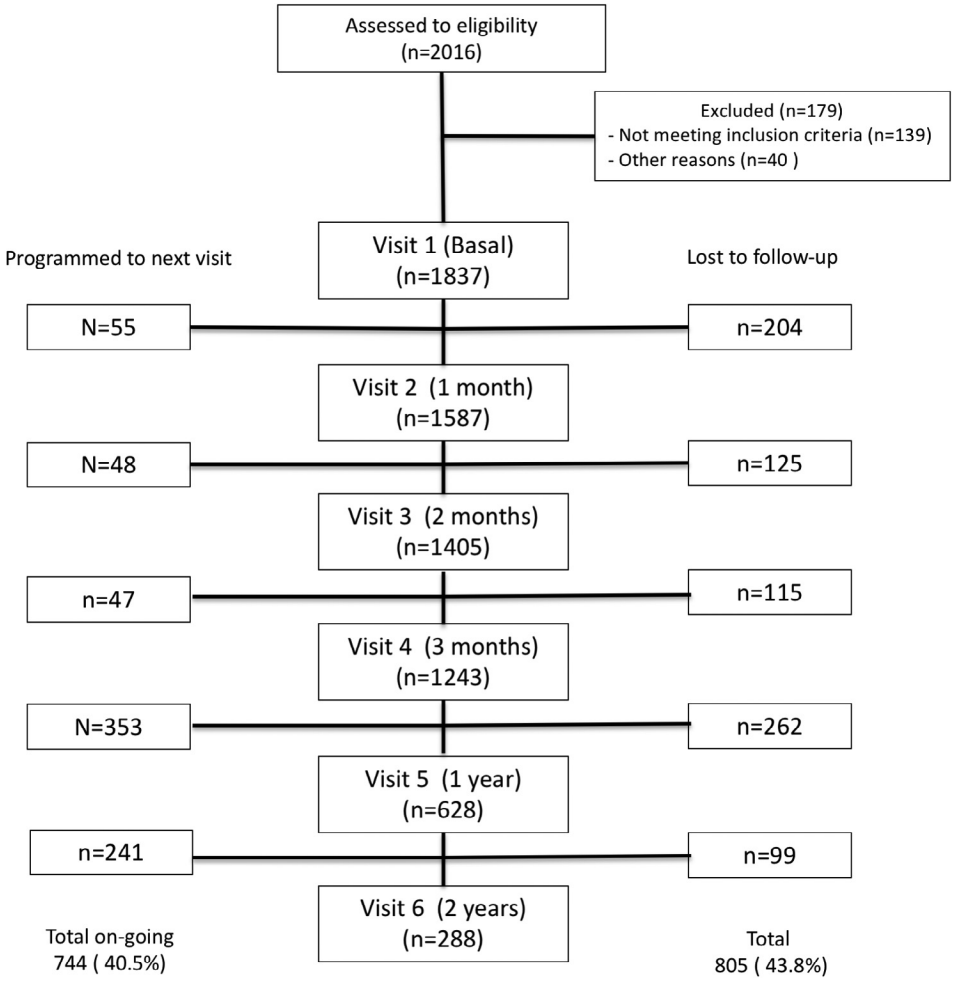

Fig. 2 – Flow chart of patients enrolled in the CAIPaDi program, dropouts and ongoing patients.

Table 2 – National Committee for Quality Assurance parameters in the CAIPaDi program.

Parameter	Goal (% of patients)	Visit 1 (n = 1837)	Visit 4* (n = 1243)	Visit 5* (n = 628)	Visit 6*,+ (n = 288)
HbA1c > 9%	≤15%	35.3	2.2	9.0	11.1
HbA1c < 8%	>60%	52.4	93.0	82.1	79.1
HbA1c < 7%	>40%	37.0	79.8	65.7	59.3
BP ≥ 140/90	≤35%	17.9	5.0	7.3	5.5
BP < 130/80	>25%	50.6	83.7	65.6	68.7
LDL-c ≥ 130	≤37%	32.9	3.8	18.6	15.9
LDL-c < 100	>36%	34.3	82.6	57.3	59.3
Eye exam	60%	ND	100	100	100
Foot exam	80%	ND	100	100	100
Renal evaluation	80%	ND	100	100	100
Smoking Status and Cessation Advice or Treatment	80%	ND	100	100	100

BP: Blood pressure, HbA1c: glycated haemoglobin, LDL-c: Low-density lipoprotein cholesterol, ND: Non-determined.
* $p < 0.001$ for differences in HbA1c, BP and LDLc between 3 months vs basal, 1-year vs basal and 2 years vs basal.
+ $p = 0.004$ for differences in HbA1c between 2 years vs basal.

3.3. *Changes in the use of pharmacological treatment*

According to the ADA Guidelines, all patients with diabetes and >50 years old are candidates for antiplatelet treatment [28]. Following this recommendation, the use of antiplatelet agents moved from 9.74% before starting the program to 54.4% after the first visit. In visit 4, 64.9% of patients received antiplatelet treatment, 64.9% and 68.4% at visit 5 and 6 respectively ($p < 0.001$ for all visits). Before starting the program, only 14.0% of patients were receiving statin therapy. This is a low percentage considering that 64.6% of patients had LDL values that qualified for pharmacological treatment [28]. At visit 4, 75% of patients received statin therapy ($p < 0.001$). Only 26.8% remained above the LDL target despite moderate-intensity statin therapy.

For blood pressure drugs, 24.5% of patients were taking antihypertensive drugs before starting the program. This percentage increased to 37.0% patients receiving treatment in the first visit. At visit 4, 42.6% patients received antihypertensive drugs. At visits 5 and 6, the percentages of patients with antihypertensive drugs increased to 44.8% and 46.8% respectively.

Before starting the program, 13.9% of patients were not taking any type of hypoglycemic drug. Up to 54% were taking only 1 drug, 30.6% were taking a combination of 2 drugs and 1.7% were using 3 glucose-lowering drugs. In the first visit, 93.7% had treatment indicated to achieve glycemic control. The number of hypoglycemic agents per patient was 1 (0–3), being metformin the most common. In the fourth visit, 5.26% of patients were controlled without taking any hypoglycemic drugs. At visit 5, 32 patients (5.0%) were controlled without hypoglycemic drugs. At visit 6, only 17 patients (5.9%) were controlled without hypoglycemic treatment.

3.4. *Logistic regression models*

A PCA for visit 4 identified 11 components that explain 13.78% the variance for subjects who reached all three goals. Step-wise logistic regression identified three components associated with target goals in this visit. The first associated component had a significant correlation with empowerment (rho = −0.519). The second component had a significant correlation with dietary fat intake (rho = 0.715). The third component was psychological evaluation (rho = 0.779). The adjusted model was statistically significant ($r2 = 0.081$, $p < 0.001$) and had a good performance identifying patients who reached goals at visit 4 (AUC 0.639, 95% CI 0.610–0.668).

For the fifth visit, we identified 12 components that explained 14.04% of the variance to identify subjects who reached goals. Logistic regression analyses identified three components associated. These were cognitive/emotional resources (rho = 0.632), PAID questionnaire (rho = 0.769), and social support (rho = −0.417). The adjusted model explained 7.7% of the variance ($r2 = 0.077$, $p < 0.001$), with a good performance (AUC 0.693 95% CI 0.646–0.740).

For the sixth visit the components associated were social support (rho = −0.558), nutritional status (rho = −0.411), motivation stage (rho = 0.536), and empowerment (rho = 0.550). The adjusted model explained 16.8% of the variability in identifying subjects who reach goals ($r2 = 0.168$, $p < 0.001$) with good performance (AUC 0.820, 95% CI 0.768–0.872). The models are shown in Supplementary data.

4. Discussion

In several reports it has been shown that with the comprehensive approach that includes the use of strategies centered on the patient with diabetes produce better metabolic results and reduce complications [5]. The efforts that have been made in several sites with models of comprehensive care require greater complexity of operation but have provided a great opportunity to innovate [29]. Knowledge, motivation and competencies are three main components of the treatment in diabetes. On this basis, our program aimed to improve the quality of life of patients with diabetes and reduce disabling and costly complications such as amputations, blindness and renal failure. For this, the main activities are the identification and solution of barriers to reach the control goals, to promote self-efficacy and co-responsibility in the treatment, the identification of patient profiles to

establish specific approaches, and the application of cost-effective strategies based on evidence and feasibility according to the resources of each patient.

According to the evaluation of the diabetes care quality standards established by the NCQA, the CAIPaDi program achieved a high score and shows an improvement in the majority of the target goals. Most important is that the beneficial effect of the intervention remained significant after one and two years. The program maintained 20% of the 3 control goals compared to 1% of a previous report in Mexican male patients [30].

Some features of the CAIPaDi program should be highlighted. The multidisciplinary interventions concentrated in the same place and in the same day ensures compliance by avoiding appointments of separate consultations as carried out in the traditional care model. A strength of the model is that renal, ophthalmological, dental and foot evaluations are ensured for all patients with diabetes. This allows the establishment of appropriate treatment and referral strategies. The program has a strong behavioral intervention, planned to stimulate empowerment and self-care. Workshops, group dynamics, and participation of a close relative were strategies applied. The progression of complications and related factors will be data for analysis in a different publication.

Empowerment is a determinant of long-term effects of the treatment of chronic diseases [31–37]. The CAIPaDi program has a remarkable positive effect on empowerment, knowledge of diabetes, anxiety, depression, and quality of life as shown in Table 3. High scores were an independent predictor for reaching metabolic goals in the first phase (Table 3, Supplementary data). All these areas impact reducing the interference of the disease with the daily life of patients, as seen with the PAID evaluation.

The short-term effect of CAIPaDi is similar to what is described in other programs [36]. The major changes observed in CAIPaDi were in the HbA1c levels. Drug therapy is an important area in diabetes treatment. In the first-visit, the prescription of statins increased to 75% of the patients, more than 40% of the patients had antihypertensive treatment, and 95% had hypoglycemic treatment. The percentage of patients receiving these pharmacological treatments is high compared with national surveys [2], but the model uses the most common and least expensive treatments to achieve goals. The results in weight reflect the complex nature of the treatment of obesity. In CAIPaDi, physical activity and reduced caloric intake are maintained for 2 years.

In the traditional diabetes care model, in most cases the patients are treated only by the general practitioner or a family physician, and sometimes by nutritionists. Unfortunately, most of the complementary consultations are directed to specialists who treat complications (cardiologists, neurologists, angiologists, nephrologists, etc.) [38]. For patients, CAIPaDi program is affordable in costs and time. Also, it only takes them 1 day to have all the laboratory tests and evaluations, which makes it easier for work permissions. A cost-effectiveness and cost-benefice analysis needs to be examined in the future. It will show the importance of multidisciplinary interventions, including the cost of drugs and medical consultations.

A great concern is that even with less than 5 years of evolution, 14% already have retinopathy, 16% albuminuria and 30% altered sensitivity to vibration, for which preventive strategies become more compelling.

A limitation of this report is the lack of replication of intervention in different settings. We did not include patients with complications or more than 5 years of diagnosis. Our group focused the strategies in newly diagnosed patients to avoid disabling complications in the mid-term. Other limitations are the lack of a control group and the high dropout rate seen after the first visit. From visits 2 to 4, the number of patients attending the program is consistent. As expected, the second dropout seen is for the annual visit since some patients feel they didn't do well in a year and don't wanted to get checked again. This has been a great area of opportunity and to make efforts for improving quality of care.

In conclusion, according to the proposed model to consider Diabetes Centers of Excellence [39], the CAIPaDi program has the infrastructure and abilities across the medical team necessary to guide a comprehensive care. It is a health-care system focused on quality improvement, outcome assessment, education and dissemination.

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Table 3 – Analysis by protocol of changes in metabolic parameters, body measurements and questionnaire scores from the first visit to the fourth, fifth and sixth evaluations.

	N = 1, 243		N = 628		N = 288	
	Basal	Visit 4	Basal	Visit 5 (1st year)	Basal	Visit 6 (Second year)
Glucose (mgl/dl)	135 (107–188)	107 ± 29	147.8 ± 66.4	112 (98–134)	143.1 ± 63.1	124.9 ± 41.7
HbA1c (%)	8.5 ± 2.5	6.4 ± 0.9	8.07 ± 2.36	7.0 ± 1.5	7.77 ± 2.22	7.16 ± 1.62
Triglycerides (mg/dl)	177 (128–253)	116 (93–150)	177 (128–253)	142 (107–195)	177 (128–253)	138 (106–197)
LDL cholesterol (mg/dl)	115 ± 37	87 ± 24	115.7 ± 37.4	109 ± 33**	114.9 ± 37.9	114.94 ± 37.98***
Systolic BP (mmHg)	126 ± 16	119 ± 13	127.9 ± 15.75	122 ± 12.5	128.9 ± 16.4	120.86 ± 11.83
Diastolic BP (mmHg)	78 ± 8	73 ± 7.1	77.9 ± 7.76	75 ± 7	78.4 ± 7.87	74.06 ± 6.86
BMI (kg/m^2)	29.5 ± 5	28.7 ± 4.6	29.0 ± 4.50	28.8 ± 4.3	29.19 ± 4.27	28.8 ± 4.2
Waist circumference women (cm)	97.3 ± 12.5	93.6 ± 12	96.1 ± 11.3	94.2 ± 11.5	96.5 ± 10.6	94.52 ± 11.45
Waist circumference men (cm)	100.7 ± 12.2	98 ± 11.4	100.6 ± 11.5	99.3 ± 10.9**	99.6 ± 10.6	98.69 ± 10.26^
Lean mass women (kg)	39.6 ± 5.7	38.9 ± 5.4	38.8 ± 5.09	38.3 ± 5.3**	39.04 ± 5.05	38.61 ± 5.17**
Lean mass men (kg)	52.5 ± 7.3	52.1 ± 7.6*	52.08 ± 7.08	52.4 ± 6.7	51.81 ± 7.14	51.77 ± 5.97
Fat mass women (kg)	28.2 ± 8.4	26.7 ± 7	27.36 ± 7.67	26.9 ± 7.5^	27.72 ± 7.73	27.89 ± 7.59
Fat mass men (kg)	26.7 ± 9.1	25.1 ± 8	26.33 ± 8.06	25.7 ± 7.5*	26.03 ± 7.46	25.06 ± 7.22ç
HAD anxiety (%)	46.4	15.7	46.4	20.8	46.4	15.1
HAD depression (%)	39.5	19.3	39.5	21.3	39.5	16.5
PAID	37.5 (20–55)	11.2 (5–22.5)	36.7 ± 23.1	12.5 (3.7–26.2)	35.38 ± 22.10	15.47 ± 15.58
DQoL	93 ± 25	71 ± 18	89.1 ± 23	72 ± 18	86.82 ± 22	71.41 ± 18
Empowerment	72.6 ± 17	82 ± 13	73.1 ± 16	82 ± 14	73.36 ± 18	82.34 ± 13

BMI: Body Mass Index. BP: Blood pressure. DQoL: Diabetes Quality of Life Measure. HAD: Hospital Anxiety and Depression Scale. HbA1c: glycated haemoglobin, LDL-c: Low-density lipoprotein colesterol. PAID: Problem Areas in Diabetes Questionnaire.

All $p < 0.001$.

* $p = 0.01$.

** $p = 0.002$.

*** $p = 0.005$.

ç $p = 0.03$.

^ NS.

Conflict of interest statement

No potential conflicts of interest relevant to this article were reported.

Author contribution

S.H.J. and A.C.G.U. wrote the manuscript. A.C.G.U. and O.Y.B.C made the statistical analysis. The remaining authors revised the manuscript critically for important intellectual content. The group of study CAIPaDi are all the health-care professionals attending the patients.

S.H.J. is the guarantor of this work and takes responsibility for the integrity of the data.

Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.diabres.2019.04.009.

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