



The beneficial effect of a comprehensive diabetes care model on high-risk relatives accompanying patients with type 2 diabetes

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ABSTRACT

Aims: Assess the effect of a diabetes program on lifestyle, metabolic, and mental health parameters in relatives of patients with T2D, and correlate changes between relatives and patients.

Methods: Relatives were included in a structured program for patients with T2D. They received individualized interventions or were asked to follow lifestyle modifications indicated to their patient with diabetes. Outcomes were change in BMI, fat loss, patients achieving LDL-c and triglycerides goals, exercise, and mental health indicators at three and twelve months.

Results: We included 200 relatives. Obesity was present in 42 %, hypertension in 8.5 %, hypercholesterolemia in 29.5 %, and hypertriglyceridemia in 46 % of relatives. Relatives lost – 3.7 kg and – 3.0 kg of body fat at three months and one-year evaluations. At least 60 % achieved normal triglycerides and LDL-c, and 40 % exercised at least 150 min/week. Anxiety symptoms dropped from 37 % to 22 % ($p = 0.001$), and depressive symptoms from 22 % to 12.9 % ($p = 0.01$) at three months. Correlations were found between the changes in relatives and patients in weight at three months ($r = 0.22$, $p = 0.001$), one year ($r = 0.3$, $p < 0.001$), and the number of goals achieved at one year.

Conclusion: Relatives of patients with diabetes attending a multidisciplinary program for T2D benefit in metabolic, lifestyle, and mental health indicators.

1. Introduction

Between 1993 and 2016, the number of adults in Mexico with diabetes increased [1–3]. The most effective way to reduce the burden of diabetes is identifying those who are at risk and implement preventive initiatives [4,5]. Randomized studies focusing on lifestyle have shown to prevent diabetes progression [6,7]. These have aided in implementing

new guidelines for managing prediabetes, highlighting the need for early intervention, which may be the most cost-effective strategy for preventing diabetes and its complications.

The Diabetes Prevention Program (DPP) and the Finnish Diabetes Prevention Study (DPS) provided scientific evidence on the prevention and delay of diabetes, reducing 58 % the risk through reduced fat and calorie intake, increasing physical activity, and achieving weight loss

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5–7 % [6,7]. Both trials observed substantial improvement in metabolic markers compared to a control group [8].

Relatives and people living with patients with diabetes may have a role in implementing lifestyle changes. Some studies, including the Diabetes Attitudes, Wishes and Needs Study (DAWN2), have looked at the impact of family on the quality of life and clinical progress of patients with diabetes, showing mixed results [9–11]. Diabetes is linked to distress in patients with diabetes and their relatives. As a result, educating individuals with diabetes may limit their ability to make essential lifestyle modifications. [12,13] Better outcomes were linked to successful collaboration between relatives and patients with diabetes [14,15].

This study aims to assess the effect of a multidisciplinary diabetes program on lifestyle indicators, metabolic, and mental health parameters in relatives of patients with type 2 diabetes and describe the correlations between the changes in the parameters between family members and patients with diabetes.

2. Methods

This is a prospective, open, interventional study in relatives of patients with diabetes.

2.1. Participants

The Center of Comprehensive Care for the Patient with Diabetes (CAIPaDi, acronym in Spanish) is a prospective multidisciplinary program in a tertiary care center in Mexico City [16,17]. Individuals with diabetes, < 70 years old, with diabetes for less than five years, without disabling complications, and non-smokers are eligible. Between June 2017 and December 2020, we asked > 18-year-old relatives (spouses, siblings, offspring, or second-degree relatives) living with the person with diabetes more than four days/week to participate. Established diagnosis of diabetes, self-reported tobacco use, body mass index > 45 kg/m², or any other health condition limiting life expectancy were exclusion criteria for the relatives. Participating relatives whose individuals with diabetes were removed from the CAIPaDi program (due to tobacco use, failure to complete the program, or lack of diabetes) were removed from the study. The protocol was approved by the Research and Ethics Committees of the Instituto Nacional de Salud Pública and the Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán (Ref 2145). All participants signed an informed consent form.

2.2. Multidisciplinary program interventions

The CAIPaDi intervention has been previously documented [16,17]. Sessions with a physician, dietitian, psychologist, psychiatrist, physical activator, diabetes educator, dentist, foot care specialist, and ophthalmologist/optometrist were held at each of the four monthly appointments.

Patients returned to the Center annually after the initial four visits for reinforcement and clinical evaluation. The relatives either received individualized interventions or followed the lifestyle modifications indicated to their patients with diabetes. For this analysis, we include all relatives as a single group. [Supplementary Table 1](#) describes the aims of each intervention.

2.3. Clinical and biochemical measurements

Fasting glucose, creatinine, lipid profile, urinary albumin/creatinine ratio (ACR) (colorimetric technique with Synchron CX System), and HbA1c (HPLC method with Bio-Rad Variant II Turbo HbA1c Kit 2) were assessed during each visit. ISO 90001:2015, the National Glycohemoglobin Standardisation Program, and the College of American Pathologists have certified the laboratory. Bioimpedance was used to determine body composition (body composition analyser JAWON

medical ioi353).

At the first evaluation, the health state of relatives was assessed. Hypertension was considered when blood pressure (BP) was > 140/90 mmHg or current antihypertensive drugs. LDL cholesterol (LDL-c) concentration > 130 mg/dl or statin medication use were considered hypercholesterolemia. Hypertriglyceridemia was defined as a > 150 mg/dl triglyceride concentration or when fibrate treatment was taken. Finally, hyperuricemia was defined as uric acid concentration > 6.8 mg/dl or when receiving treatment for hyperuricemia.

The International Physical Activity Questionnaire assessed physical activity (IPAQ) [18]. Performance of aerobic, resistance, or both types of exercise was also registered. We requested a three-day meal recall of two weekdays and one weekend day to quantify energy intake (calories/day) [19]. We utilized the Hospital Anxiety and Depression Scale (HAD) to assess anxiety and depression, with a score of 0–7 indicating normal, 8–10 borderline, and 11–21 abnormal [20].

2.4. Outcomes

Metabolic, mental health, and lifestyle indices are among the variables examined.

Changes in parameters were evaluated at three months and one year, including change in body mass index, fat loss, percentage of patients achieving LDL-c and triglycerides goals, percentage of relatives exercising, and mental health indicators.

2.5. Statistical analysis

According to the Kolmogorov-Smirnov test, results were expressed as means (SD) if they followed a normal distribution, or medians and interquartile ranges (25–75) if they did not. For discrete values, percentages were employed. McNemar test was used to examine changes in metabolic control, and Chi-square test was used to compare categorical variables. The metabolic parameters and questionnaires were compared from the baseline to the three-month evaluation and then to the one-year evaluation using T-tests for related samples. The impact of relatives on the metabolic benefits in patients with diabetes was assessed with correlation coefficients for HbA1c, BP, lipid profile, and weight.

3. Results

3.1. Study population

We included 266 relatives with their respective patients with diabetes. We excluded 66 participants: 27 (40.9 %) because their relative with diabetes did not meet the CAIPaDi program's inclusion criteria, 24 (36.3 %) because diabetes was diagnosed at the first evaluation, 11 smokers (16.6 %), 2 with a body mass index (BMI) > 45 kg/m² (3.0 %), one person (1.5 %) was < 18 years old, and one (1.5 %) was pregnant. A total of 200 relatives and 200 patients with diabetes (400 participants) were enrolled. The relatives included were 49.9 % spouses, 25.2 % offspring, 6.7 % parents, and 13.4 % siblings. At the time of this analysis, 76 participants (38 %) abandoned the program, 109 completed the three-month evaluation, and 37 relatives completed the one-year follow-up ([Fig. 1](#)).

3.2. Baseline characteristics

The mean age of the relatives was 46.7 + 12.6 years (from 18 to 70, interquartile range 38–56), and 69.5 % were women. For the patients with diabetes, the mean age was 53.8 + 9.1 years, 45.5 % were women, and the time since diagnosis was 1 year (0–5). [Table 1](#) shows the metabolic, lifestyle, and mental health variables at the baseline, three-month, and one-year visits.

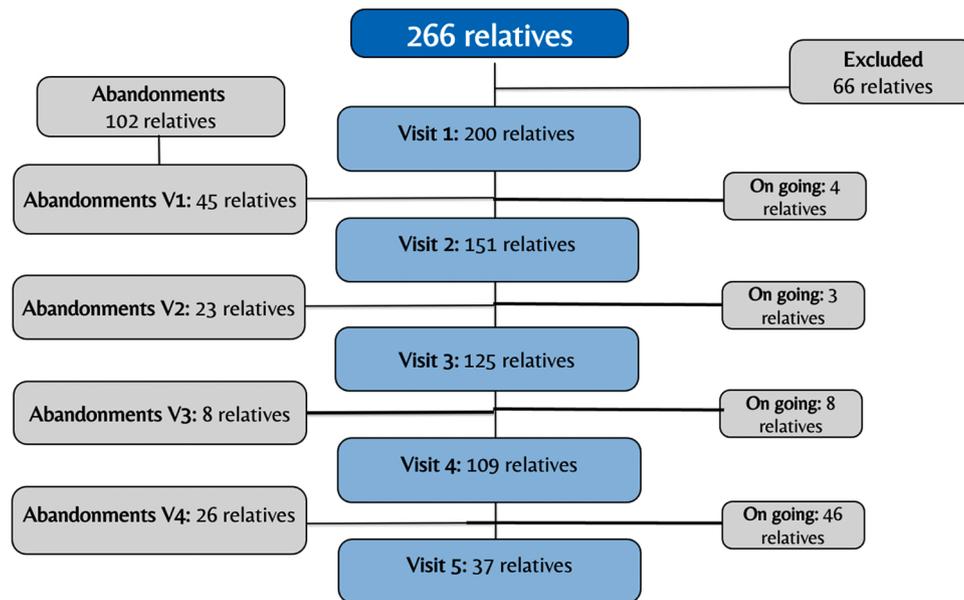


Fig. 1. Flowchart of relatives of patients with diabetes.

Table 1

Characteristics at baseline, three-months and one-year follow-up of relatives included in the multidisciplinary program for patients with diabetes.

	Baseline (n = 200)	Three-months (n = 109)	One-year (n = 37)	p (+)	p (++)
Systolic blood pressure (mmHg)	119 ± 13	112 ± 12	112 ± 12	<0.001	0.001
Diastolic blood pressure (mmHg)	74 ± 7	70 ± 6.5	70 ± 7	<0.001	0.002
Triglycerides (mg/dl)	173 (111–191)	129 (93–156)	146 (95–186)	<0.001	0.17
LDL-cholesterol (mg/dl)	120 ± 30	102 ± 30	118 ± 26	<0.001	0.07
Glucose (mg/dl)	90 ± 16	87 ± 11	86 ± 9	0.02	0.07
Glycated hemoglobin (%) (mmol/mol)	5.5 ± 0.40	5.5 ± 0.36	5.5 ± 0.48	0.03	0.19
	37.0 ± 5	37.0 ± 3	37.0 ± 5		
Creatinine (mg/dl)	0.74 ± 0.15	–	0.76 ± 0.16	–	0.15
Uric acid (mg/dl)	5.4 ± 1.2	–	5.1 ± 1	–	0.07
ALT (U/l)	33 (15–31)	–	26 (16–30)	–	0.94
AST (U/l)	22 (16–25)	–	22 ± 7.3	–	0.66
GGT (U/l)	35 (16–42)	–	28 (15–31)	–	0.01
Body mass index (kg/m ²)	29.3 ± 5	28.3 ± 4.7	27.6 ± 3.9	<0.001	0.06
Waist circumference (cm)	96.1 ± 13	93.0 ± 11	92.2 ± 10.5	<0.001	0.19
Calories consumed (kcal)	1670 ± 507	1378 ± 320	1410 ± 388	<0.001	0.03
Carbohydrates (gr)	191 (137–237)	143 (108–180)	147 (114–169)	<0.001	0.03
Proteins (gr)	76 ± 21	69 ± 16	72 ± 18	0.03	0.36
Fat (gr)	66 ± 21	58 ± 14	60 ± 16	0.002	0.22
Body fat (%)	35.7 ± 6.1	35.5 ± 6	34.2 ± 6.8	0.006	0.07
Lean mass (kg)	44.1 ± 9.1	41.8 ± 8.5	41.0 ± 7.3	0.001	0.38
Fat mass (kg)	27.9 ± 9.1	25.8 ± 7.8	24.9 ± 6.8	<0.001	0.11
Calories indicated (kcal)	1311 ± 171	1321 ± 155	1302 ± 134	0.007	0.08
Exercise (days/week)	1 (0–3)	4 (2–5)	2 (0–5)	<0.001	0.12
Moderate exercise (minutes/week)	0 (0–150)	150 (50–300)	115 (0–221)	<0.001	0.05
Anxiety (%)					
normal	63.0	78.0	76.7	0.001	0.36 month
border	19.5	11.9	6.7		
abnormal	17.5	10.1	16.7		
Depression (%)					
normal	78.0	87.2	76.7	0.01	0.54
border	14.5	8.3	20.0		
abnormal	7.5	4.6	3.3		

+ Baseline vs three-months, ++ Baseline vs one-year.

3.3. Metabolic indicators

At the beginning of the program, 8.5 % of relatives had hypertension, 46 % hypertriglyceridemia, 29.5 % hypercholesterolemia, and 13 % hyperuricemia. We found significant changes in all metabolic parameters at three months (Table 1). At the one-year evaluation, only BP improved significantly compared to the baseline visit (p = 0.001), while the remaining parameters showed improvement. However, statistical significance was lost.

Overweight and obesity were present in 39.5 % and 42 % of relatives, respectively. The percentage of relatives with overweight decreased from 39.5 % to 23.9 % at three-month, and obesity decreased from 42 % to 37.6 % (p = 0.26). At the annual evaluation 35.1 % had a normal BMI, 32.4 % were overweight and 32.4 % with obesity (p = 0.30). In the beginning, body fat was 27.9 ± 9.1 kg and decreased to 25.8 ± 7.8 kg (p < 0.001). The body fat in the evaluation at one year was 24.9 ± 6.8 kg (p = 0.1). Thus, 15.6 % of the relatives lost more than 3 kg of body fat in three months, whereas in the annual evaluation, this

percentage increased to 20 % (p = 0.12).

For HbA1c, 64.6 % of the relatives had an HbA1c < 5.8 % (40 mmol/mol) at baseline. This percentage increased to 70.6 % at three months (p = 0.01) and 86.7% at one year of follow-up (p = 0.03). Regarding triglycerides concentration, at the beginning of the program, 33.3% (n = 10) had triglyceride levels < 150 mg/dl. At three months this percentage increased to 67.1 % (n = 53) (p = 0.01) and at one year this increased to 71.4 % (p = 0.02). As for LDL-c, 71.5 % of the relatives had < 130 mg/dl at the beginning of the program. This percentage increased to 92.7 % after three months (p < 0.001) and decreased to 76.6 % at one year of follow-up (p = 0.15). Initially, 44.5% of the relatives had both LDL-c and triglyceride goals. After three months, this percentage increased to 68.8 % and 46.7 % in the annual evaluation.

For blood pressure (BP), 91.5 % of patients had < 140/90 mmHg at the beginning of the study. This percentage increased to 97.2 % (p = 0.10) at three months, and at the one-year evaluation, 100 % of patients had BP controlled (Table 2).

3.4. Lifestyle indicators

We found that relatives consumed significantly less total energy, carbohydrates, proteins, and fat per day at three months. Furthermore, at one-year significant differences persisted in total energy and carbohydrates consumption per day (p = 0.03), while the statistically significant difference in the rest of the nutritional parameters was lost (Table 1). At the three-month and one-year evaluations, the calories consumed were similar to the indicated by the dietitians, indicating a good adherence to the nutritional plan.

Regarding exercise, the days exercising improved from one day to 4 days/week at the three-month evaluation (p < 0.001), and the duration of moderate exercise increased from 0 to 150 min/week (p < 0.001). The one-year evaluation showed that the days of exercise decreased to 2 days/week and lost significance compared to the baseline visit (p = 0.12). However, the duration of moderate exercise was still significantly higher (115 min/week, p = 0.05) (Table 1).

It was found at the baseline visit that 59 % of the relatives did not perform any exercise, 29.5 % performed aerobic exercise, 0.5 % resistance, and 10.5 % performed both. These percentages improved at three months to 22 % of relatives who did not exercise, 56 % did aerobic exercise, 1.8 % did resistance exercise, and 20.2 % did both (p < 0.001). At the one-year evaluation, we found that 31.4 % of the relatives did not perform any exercise, 42.9 % did aerobic exercise, 0 % resistance exercise, and 11.4 % did both types of exercise (p = 0.34). Although statistical significance is lost in the one-year evaluation, the percentages of exercise are better than those reported at the beginning.

In the exercise performance goal, 29.5 % of the relatives performed more than 150 min a week of moderate exercise at baseline. This percentage changed to 54.1 % at three months and decreased to 40 % at the one year of evaluation.

Table 2
Percentage of metabolic goals achieved in relatives.

		Baseline	Three-months	One-year	p (+)	p (++)
HbA1c	<5.8 % (40 mmol/mol)	64.6 %	70.6 %	86.7 %	0.01	0.03
Blood pressure	<140/ 90 mmHg	91.5 %	97.2 %	100 %	0.10	–
LDL-c	<130 mg/dl	71.5 %	92.7 %	76.6 %	0.001	0.15
Goals achieved	None	2.5	–	–	0.01	0.23
	One	12.6	2.8	6.7		
	Two	39.9	33.9	23.3		
	Three	44.9	63.3	70.0		

+ Baseline vs three-months, ++ Baseline vs one-year.

3.5. Mental health indicators

Anxiety symptoms (>8 points) were prevalent in 37 % (n = 74) of relatives at the beginning of the program. At three months this percentage dropped to 22 % (n = 24) (p = 0.001 from baseline), and this remained at 23.4 % (n = 9) at one year (p = 0.36 from baseline).

Depressive symptoms (>8 points) were evident in 22 % (n = 44), 12.9 % (n = 14) (p = 0.01), and 23.3 % (n = 86) (p = 0.54) at baseline, three months, and one-year, respectively.

Table 1 shows the distribution of relatives with normal, border, or abnormal scores for anxiety and depression.

3.6. Patients with diabetes

The outcomes of patients with diabetes in the CAIPaDi program have been previously published [17]. Briefly, these patients were 45.5 % women, 53.8 + 9.1 years old, with 1 (0–5) years of diagnosis. The percentage of patients with diabetes with HbA1c < 7 % (53 mmol/mol), BP < 130/80 mmHg, LDL-c < 100 mg/dl and the percentage of patients achieving 1, 2, or 3 goals were also evaluated.

For glycemic control, we found that 34 % of patients with diabetes at the beginning of the program had HbA1c < 7 % (53 mmol/mol). This percentage increased to 78.4 % at three months and was 71.2 % at the one-year evaluation (p < 0.001, both compared to the baseline evaluation). For BP, 68 % of patients with diabetes had < 130/80 mmHg. The percentage increased to 86.6 % at three months and 77.3 % at one year (p = 0.001 and p = 0.14, respectively). For LDL-c, 40.5 % of patients with diabetes had < 100 mg/dl. The percentage increased to 81.9 % at three months and decreased to 56.1 % after one year of follow-up (p < 0.001 and p = 0.07, respectively). Regarding the number of goals achieved, we observed that 13.5 % of patients with diabetes did not have any of the three metabolic goals at the beginning of the program. Only 10.5 % of the patients with diabetes had the three goals achieved. These percentages changed to 1.4% and 56.8 %, respectively, at three months of follow-up (p < 0.001). At the one year evaluation, percentages were 3 % of the patients without any of the goals achieved and 34.8 % of the patients with the three goals achieved (p = 0.007 vs. the baseline visit).

Regarding the impact of relatives in patients with diabetes, a positive correlation in weight between relatives and patients with diabetes was found at the three-month evaluation (r = 0.22, p = 0.001). Also, at one year, a correlation of r = 0.3, p < 0.001 was found. A significant correlation was also found for HbA1c concentration at three months and one year of follow-up, BP at three months of follow-up, LDL-c at three months and one year, as well as the number of goals achieved at one year of follow-up (Supplementary material Table 2).

4. Discussion

In this study, we found that relatives who join a multidisciplinary program as observers or active participants benefit from medical, lifestyle, and mental health interventions focused on patients with diabetes. Relatives of patients with diabetes showed positive results in the diverse parameters.

Few studies have looked at the impact of a multidisciplinary program on relatives. Studies based on the influence of the social environment (relatives) found a significant improvement in anthropometric measurements and diabetes awareness among the participants [21,22]. A first-degree relative with metabolic syndrome could predict incident diabetes in healthy relatives. In that study, the authors highlighted the need for early interventions on high-risk individuals to avoid or delay the onset of diabetes [23]. Diabetes was diagnosed in 10.1 % of relatives at the first evaluation, and were enrolled in the multidisciplinary program for patients with a confirmed diagnosis.

Dyslipidemia, hypertension, hyperuricemia, and overweight-obesity are well-known factors associated with an increased risk for diabetes. Dyslipidemia (high triglycerides, low HDL-c, and high LDL-c) was linked

to the start of diabetes in a 14-year follow-up cohort [24]. Another research of relatives reported an incidence of hypertension of 27.4 %. We found hypertension in 8.5 % of relatives. In addition, hypercholesterolemia, hypertriglyceridemia, and hyperuricemia were highly prevalent in our study group. Knowing that these are modifiable risk factors for diabetes, these must be addressed as soon as possible.

Weight control is one of the pillars in the treatment and prevention of diabetes, given the high incidence of obesity worldwide (particularly in our nation) and hereditary susceptibility. Our research found a significant reduction in BMI in relatives and patients, meaning that it is not required a specific or expensive strategy to achieve significant changes with long-term protective metabolic effects. In a study of 1085 subjects who entered a multidisciplinary obesity management program, one-third of the participants lost > 5 % of the initial weight in the first three months. Almost 50 % of the patients achieved it at six months [25, 26]. In our study, relatives achieved important weight loss. Although the BMI increased at the 1-year evaluation, it was lower than the baseline.

Kolbawovsky et al. conducted another study that looked at behavioral methods in a weekly organized 5-session program. A psychologist conducted each session in groups of 5–10 patients, with carers or relatives accompanying them. In that study, anxiety was present in 20 % of patients. At the end of the sessions, the change in metabolic parameters in patients with diabetes was noticeable [27]. Anxiety was seen in a similar proportion of relatives in our study, improving at the three-month visit [28].

In our study, relatives were younger than patients with diabetes. It is important to address people at risk of developing diabetes, regardless of their age. Since the creation of the CAIPaDi program, the participation of relatives of patients with T2D in the care process was considered essential. One of the inclusion criteria in the original project was to have a family member or responsible person to accompany them at each visit. For this reason, it was considered important to include all family members in this study, regardless of their baseline status. In addition, more than a half of relatives (55.1 %) had at least one criteria of metabolic syndrome which is an opportunity to prevent diabetes and cardiovascular disease.

The success in the fight against chronic diseases is preventing new cases with interventions promoting changes in lifestyle. Including relatives promotes a supportive environment for the patients and helps them attain therapeutic goals. Decisions regarding dietary guidelines, physical activity, medication intake, and the ability to control emotional stress influence treatment outcomes [26,27]. Having a relative with diabetes is likely to drive relatives without diabetes to change their attitudes, beliefs, and knowledge about the condition, thereby supporting healthy behaviors [29]. Denial or disengagement from difficulties should be thoroughly investigated. The emotions underlying this intuitive response must be explored and discussed. Emphasis should be made on easily accessible metrics and goals (e.g., steps per day) (e.g., to achieve ideal weight). Changes in behavior aid achieving specified objectives. Our research reports that relatives with a healthy lifestyle (lower calories and grams of carbohydrates) and at least 150 min/week of moderate exercise improved their metabolic markers.

Our study is the first to look at the impact of a multidisciplinary program aimed at patients with diabetes and their relatives, considering metabolic, lifestyle, and mental health factors. To overcome hurdles and eliminate health disparities, more services and research targeted at specific person's needs are essential [3,22,29]. The metabolic syndrome's complexity and heterogeneity need multiple health experts working in multidisciplinary teams [17].

Limitations, such as a high rate of abandonment and relatively small sample size, should be acknowledged. The main reasons for abandonment were other occupations (work), or not feeling that they were receiving the same care as the patient with diabetes. Other relatives mentioned that they could not adhere to diet or exercise during the pandemic and preferred to retake treatment later. Also, two relatives got divorced and did not want to take visits with the ex-spouse. The results

at 3 months follow-up are valid, but the results at one year follow-up lose validity since we could only analyse 15 % of the population. On the one-year evaluation, the abandonment rate was higher since the pandemic was a limitation to continue their attention.

Our population included patients with diabetes < 70 years old, with less than five years of diagnosis, and without disabling complications, and non-smokers, as these criteria have been already defined to participate in the CAIPaDi program. We acknowledge that these characteristics might not be representative of the majority of patients with diabetes.

Another limitation of the study is that we did not analyse the degree of involvement of the family member in the patient care was not known.

We did not analyse the involvement of family members with the care of the patients with diabetes. Relatives were spouses, parents, offspring or siblings. We agree that living together does not guarantee commitment in helping the patient, but since they are family members, genetics and social environment are important factors that predispose relatives to developing diabetes.

Another limitation is that the CAIPaDi model includes sessions with nine different specialists. This structure might be difficult to apply in real clinical practice. These interventions can be simplified and adapted to the population of each place.

In conclusion, a comprehensive and multidisciplinary care program for patients with type 2 diabetes also showed benefits in metabolic, lifestyle, and mental health indicators in the relatives included.

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Author contributions

Research idea and study design **ACGU** and **SHJ**; data acquisition: **ACGU**, **MDP**, and **ARG**; data analysis/interpretation: **ACGU** and **NAV**; statistical analysis: **ACGU** and **NAV**; manuscript drafting: **ACGU**, and **PAV**; Supervision or mentorship: **CAS**, **SHJ**, **PAV**, **MKH**, and **GTM**. Each author contributed important intellectual content during manuscript drafting or revision and accepts accountability for the overall work by ensuring that questions pertaining to the accuracy or integrity of any portion of the work are appropriately investigated and resolved.

Conflicts of interest

The authors declare no potential conflicts of interest concerning this article's research, authorship, and publication

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Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at [doi:10.1016/j.pcd.2022.09.008](https://doi.org/10.1016/j.pcd.2022.09.008).

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