

# Original Article: Organisation and Delivery of Care

## Implementation of a systematic approach to diabetes in primary care in Bahia, Brazil improves metabolic outcomes: PRODIBA—Programa de Interiorização da Assistência ao Diabetes na Bahia (Project for Dissemination of Diabetes Care in the State of Bahia)

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### Abstract

**Background** Staged Diabetes Management (SDM) improves glycaemic control and reduces diabetes-related complications in primary care.

**Methods** An 18-month randomized controlled cohort study was conducted in two municipalities in the state of Bahia, Brazil, involving 100 patients with Type 2 diabetes in each municipality. In one municipality, healthcare professionals were trained to use SDM customized protocols for clinical decisions and, in the other municipality, no protocols for diabetes care were implemented. We hypothesized that, in the municipality with SDM trained professionals, patients would have better outcomes, including a fall in glycated haemoglobin (HbA<sub>1c</sub>).

**Results** Improvements in some metabolic parameters were observed in the SDM group, including a 22% decrease in mean random glucose, a significant 15% decrease in mean HbA<sub>1c</sub>, a 6% decrease in systolic blood pressure and an 11% decrease in diastolic blood pressure. There were no differences in body mass index and lipid profile.

**Conclusions** SDM customized algorithms are effective, practical and easy to use in primary healthcare teams with very limited resources.

**Keywords** Brazil, diabetes, glycated haemoglobin, primary care, staged diabetes management

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**Abbreviations** CEDEBA, Centre for Diabetes and Endocrinology in the State of Bahia; HbA<sub>1c</sub>, glycated haemoglobin; PRODIBA, Project for Dissemination of Diabetes Care in Bahia State; PROJAD, Project for Implantation of Diabetes Care in Municipalities of the State of Bahia; SDM, Staged Diabetes Management

### Introduction

Type 2 diabetes is a major chronic health problem, causing increased morbidity and mortality rates, decreased productivity

in the population and an ever-increasing financial burden [1–3]. Today, it is recognized as a major public health problem worldwide, leading to pressure on governments to develop effective programmes for prevention and control.

A fall of 1% in glycated haemoglobin (HbA<sub>1c</sub>) decreases the risk of macrovascular complications in Type 2 diabetes by 16% and microvascular complications by 25% [4]. The association between cardiovascular risk and glycaemic control was recently demonstrated by a reduction in incidence of myocardial

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infarction in the intensive treatment group of the UK Prospective Diabetes Study (UKPDS) 10 years after the end of the randomized study [5]. Improved control of hypertension decreases the incidence of cerebrovascular events, congestive heart failure and death related to diabetes [6].

Responsibility for the care of people with diabetes has shifted away from hospitals to primary care [1]. Several strategies are needed for better management of Type 2 diabetes: (i) a well-organized primary care system; (ii) a well-trained staff for diabetes prevention, treatment and management of chronic complications; (iii) educational programmes for patients and relatives; (iv) commitment from the local health authorities to provide access for this population to health care and medications. Many previous randomized trials have demonstrated that, if regular review of patients is guaranteed, the standard of primary care can be equivalent to or better than hospital outpatient care in the short term [7–10]. However, the quality of care given to large numbers of patients at the community level remains suboptimal. [8] Many guidelines and diabetes management programmes have been developed worldwide to improve diabetes care at the community level.

One of these programmes is the ‘Staged Diabetes Management’ (SDM), developed by the International Diabetes Center (Minneapolis, MN, USA). It is a comprehensive, scientifically based programme designed for primary care. SDM uses practice guidelines and algorithms to guide clinical decisions and improves glycaemic control and reduces the incidence of diabetic complications [11–14].

The Centre for Diabetes and Endocrinology in the State of Bahia (CEDEBA—Centro de Diabetes e Endocrinologia do Estado da Bahia) is a public-supported diabetes referral centre in the State of Bahia, Brazil, that utilizes a multidisciplinary team and is committed to organizing and improving diabetes care. Between 1998 and 2001, the Project for Implantation of Diabetes Care in Municipalities of the State of Bahia (PROJAD) was developed. The primary goal of this project was to encourage local government to engage in improving diabetes care in each municipality by planning their budget based on their local needs and, even with limited resources, to be able to provide better diabetes care. The programme consists of training the local staff on Portuguese-customized SDM protocols and encouraging them to organize primary care with a focus on prevention of diabetes-related chronic complications. The programme was implemented in 71% of 417 municipalities of the State of Bahia, Brazil. Two years after finishing implementation of PROJAD, this current study, Projeto de Interiorização da Assistência ao Diabetes no Estado da Bahia (PRODIBA—Project for Dissemination of Diabetes Care in Bahia State), was undertaken. The main aims of the study were: to determine if Portuguese-customized SDM protocols could be conducted efficiently at a Brazilian community-based level with very limited resources; and to determine if glycaemic control improved in the patients in this community. We compared outcomes from two different municipalities. In one municipality, healthcare professionals were trained and SDM

customized protocols were implemented during the PROJAD programme. In the other municipality, no protocols for diabetes care were implemented and this municipality was not included in the PROJAD programme. In both communities, equal access to medications for diabetes and hypertension was available. CEDEBA’s local team formed the staff of PRODIBA.

We hypothesized that the patients who received diabetes care based on Portuguese-customized SDM protocols would achieve better outcomes than the ones who did not.

## Research design and methods

This 18-month observational cohort study compared the metabolic outcomes of patients from a municipality where the professionals had been trained with SDM protocols (intervention municipality) with patients from a municipality where the professionals were trained with basic standard diabetes care without implemented protocols (control municipality). The study was developed in the state of Bahia, Brazil between April 2000 and December 2002. Lauro de Freitas was the municipality whose professionals were trained with SDM protocols (intervention municipality). Conceição do Coité was considered the control municipality, where the professionals had not been trained in any diabetes protocols. For ethical reasons, professionals in the control municipality received one update session on diabetes care at the beginning of the study. PRODIBA was reviewed and approved by the CEDEBA Ethical Committee at Bahia State Health Secretary and written informed consent was obtained from each participant before enrolment in the study.

Lauro de Freitas is a small community located 37 km from Salvador, the capital of the state of Bahia. Of the total population, 55 529 are male and 58 014 are female. The majority of the population lives in the urban area (108 385 inhabitants), while only 5158 people remain in the rural boundaries. The estimated number of assisted diabetic patients in the municipality was 2077 people. Most primary health care is provided free of charge through the national healthcare system and is delivered in six primary care clinics and three hospitals by a multidisciplinary team which includes doctors, nurses, pharmacists and health technicians. Two years before starting this study, during the PROJAD programme implementation, professionals from Lauro de Freitas (the intervention team) were trained to use Portuguese-customized SDM protocols during a 16-h training programme. During this training, SDM methodology was explained, the goals of treatment stated and the systematic steps to be followed to guide clinical decisions for managing hyperglycaemia, dislipidaemia and hypertension control described. The teaching also covered training facilities for nutritional and exercise planning, and during the programme participants learned how to use glucose reflectance meters. The measurement of random capillary glucose during the medical appointment is important to guide treatment decision making in the Portuguese customized flow chart. The professionals also received a booklet with protocols, including a Master Decision Path, 22 decision paths for treatment of hyperglycaemia and three decision paths for treatment of hypertension and dyslipidaemia. At the beginning of this study, the intervention team underwent one 16-h session review in SDM protocols. During this session, the SDM protocols were reviewed to ensure that the team was

familiar with all the decision paths. During the study, update training was performed every 6 months, with case discussions, to ensure that the SDM protocols had been used effectively in current practice.

Conceição do Coité is a small rural municipality located 220 km from the capital, with a population of 28 209 men and 28 108 women. The estimated assisted diabetic population was 742 people. About half the population lives in the urban area and half in rural boundaries. Most primary health care is provided free of charge through the national healthcare system and is delivered in eight primary care clinics and four hospitals. A multidisciplinary team is responsible for the clinics: a doctor, a nurse, a pharmacist and health technicians. The health professionals in this municipality were not trained during the PROJAD programme and had not had any specific training in diabetes care previously. This control group received a single 4-h update session, focused on diabetes care, with no protocols.

In both municipalities, the project was supported by the local government. There was no dietitian or free distribution of lipid-lowering agents in either municipalities and the patients could not afford to buy these drugs or devices to perform self-glucose monitoring.

The eligibility criteria to enroll in this study were: subjects over 30 years old with previous documented diagnosis of Type 2 diabetes according to Brazilian Diabetes Society diagnostic criteria (fasting plasma glucose > 7.0 mmol/l and/or a random postprandial glucose > 11.1 mmol/l). All pregnant women and individuals with Type 1 diabetes were excluded from the study.

In the intervention municipality, we reviewed the notes of all diabetic patients followed at the primary care clinics to find eligible individuals. From the pool of all patients who met the criteria in this municipality, a randomly selected sample of 120 patients were invited to meet the staff of PRODIBA. The study was explained individually and the first 100 subjects who agreed to give written informed consent were enrolled in the study.

As there was no specific diabetes care in any primary care unit in Conceição do Coité, a publicity campaign was conducted to recruit subjects with Type 2 diabetes. Posters were displayed in public buildings and buses and announcements made in churches, on the local radio station and by a car-mounted megaphone. During this campaign, 1398 subjects were screened and 502 patients were confirmed as having Type 2 diabetes. Screening utilized blood glucose and further tests were performed by the municipality central laboratory to confirm the diagnosis. If fasting blood glucose was 5.6–11.1 mmol/l, an oral glucose tolerance test (OGTT) was performed; if random blood glucose was > 11.1 mmol/l, a venous glucose measurement was performed. From the 502 individuals confirmed as having Type 2 diabetes, 120 patients were randomized and invited to meet the PRODIBA team. The study was explained individually and the first 100 subjects who agreed to give written informed consent were enrolled.

The study began in April 2000 in the control group and April 2001 in the intervention group, with 100 patients in each municipality. At baseline, subjects underwent measurements of weight, height, blood pressure, waist circumference, random glucose, total cholesterol and HbA<sub>1c</sub>.

Subjects in the intervention group were examined at 3, 6, 9, 12, 15 and 18 months and at 6, 9, 12, 15 and 18 months in the control group. They underwent metabolic testing and answered questionnaires in every visit.

Either Advantage<sup>®</sup> (Roche, Indianapolis, IN, USA) or Precision<sup>®</sup> (Abbott Laboratories, Abbott Park, IL, USA) meters were used to measure capillary glucose levels and the Accutrend<sup>®</sup> (Roche, Indianapolis, IN, USA) meter to measure capillary cholesterol levels. Capillary HbA<sub>1c</sub> was analysed using an A1C Now (DRx Metrika<sup>®</sup>, Bayer HealthCare AG, Leverkusen, Germany) meter at baseline in the control municipality. Further HbA<sub>1c</sub> measurements in both groups were carried out at CEDEBA's laboratory (Biorad A1C, Bayer Diagnostic, Leverkusen, Germany). Venous blood samples were drawn to validate capillary measurements in both sites using a concordance analysis test and kappa statistics, and the assays were also conducted at CEDEBA's laboratory in Salvador, using chromatography and immunoenzymatic techniques to measure HbA<sub>1c</sub> and blood glucose (Biorad-Diastat, Bayer Diagnostic, Leverkusen, Germany), respectively. An aneroid sphygmomanometer was used to measure blood pressure, an anthropometric scale to measure height and weight and a tape measure to check the waist circumference. Body mass index (BMI) was calculated as weight (kg) divided by height (m) squared. Sitting blood pressure was measured after 5-min rest. Questionnaires were performed to obtain demographic and clinical information and determine the distribution and receipt of insulin and oral drugs.

All statistical analysis was performed using the SPSS 9.0 for Windows software statistical suit (SAS Institute, Cary, NC, USA) and statistical significance was assumed at  $P < 0.05$ . A Student's  $t$ -test for paired samples was performed in order to determine the difference between the means for each parameter at different time points. Comparison of the baseline characteristics from those individuals who did and did not finish the study was carried out using a  $t$ -test for independent variables. A  $\chi^2$ -test was applied to test whether there were differences between the frequency of parameters in patients at baseline and at the end of the study. The same test was used to compare the characteristics of the patients from both municipalities at baseline. Yates continuity correction and Fisher exact test were used when necessary.

## Results

Baseline characteristics of the subjects in the two municipalities are shown in Table 1.

In both communities, the majority of subjects were females aged > 50 years. Duration of diabetes was > 5 years in 60% of the subjects in the intervention group and in 39% of the control group. Mean random glucose, HbA<sub>1c</sub> and waist circumference in females were higher in the intervention group. Mean cholesterol and blood pressure (systolic and diastolic) were higher in the control group at baseline.

From the initial 100 patients in each municipality, 71% were followed up for 1 year in the control group and 47% completed the 18-month study. In the intervention group, 85% of the subjects were followed up for 1 year and 66% completed the 18 months. In the control group, 2% died, 3% moved away and 48% were lost to follow-up. In the intervention group, 3% moved away, 1% died and 40% were lost to follow-up. There were no statistical differences between the baseline data of subjects who completed the study and those who dropped out in each municipality as shown in Table 2.

**Table 1** Baseline characteristics of the patients

		Control group ( <i>n</i> = 100)		Intervention group ( <i>n</i> = 100)		<i>P</i>
		Mean ± SD	Frequency (%)	Mean ± SD	Frequency (%)	
Sex	Male		25.0		31.0	0.345
	Female		75.0		69.0	
Age (years)	30–39		7.0		4.0	0.071
	40–49		7.0		19.0	
	50–59		43.0		36.0	
	≥ 60		43.0		41.0	
Random glucose (mmol/l)	< 7.8	12.0 ± 6.0	34.0	13.6 ± 5.65	17.0	0.021
	7.8–11.1		19.0		22.0	
	> 11.1		47.0		61.0	
HbA <sub>1c</sub> (%)	< 7.0	8.1 ± 2.91	43.0	8.9 ± 2.64	23.0	0.006
	7.0–9.5		26.0		35.0	
	> 9.5		29.0		36.0	
	N/A		2.0		6.0	
BMI (kg/m <sup>2</sup> )	< 25	25.8 ± 4.80	40.0	26.5 ± 4.95	38.0	0.451
	25–29.9		37.0		30.0	
	≥ 30		18.0		24.0	
	N/A		5.0		8.0	
Cholesterol (mmol/l)	< 5.2	5.4 ± 0.84	35.0	5.3 ± 1.07	50.0	0.017
	5.2–6.24		32.0		16.0	
	> 6.24		14.0		16.0	
	N/A		19.0		19.0	
Systolic blood pressure (mmHg)	< 130	148 ± 23	16.0	139 ± 23	26.0	0.047
	130–139		9.0		15.0	
	140–159		37.0		34.0	
	160–179		36.0		21.0	
	≥ 180		0.0		0.0	
	N/A		2.0		4.0	
Diastolic blood pressure (mmHg)	< 85	91 ± 13	37.0	85 ± 14	56.0	0.030
	90–99		30.0		19.0	
	100–109		17.0		14.0	
	≥ 110		14.0		7.0	
	N/A		2.0		4.0	

BMI, body mass index; HbA<sub>1c</sub>, glycated haemoglobin; N/A, not available; SD, standard deviation.

**Table 2** Comparison of baseline characteristics of all the patients with those of patients who completed the study

	Protocol completed	Control group			Intervention group			<i>P</i> †
		<i>n</i>	Mean ± SD	<i>P</i> *	<i>n</i>	Mean ± SD	<i>P</i> *	
Age (years)	Yes	47	59.5 ± 11.22	0.496	64	59.1 ± 11.30	0.069	0.855
	No	53	58.1 ± 9.76		36	55.3 ± 11.19		0.231
Random glucose (mmol/l)	Yes	47	13.0 ± 6.42	0.133	64	13.6 ± 5.61	0.065	0.559
	No	53	11.1 ± 5.54		36	13.3 ± 5.75		0.077
HbA <sub>1c</sub> (%)	Yes	45	8.6 ± 3.16	0.095	44	8.9 ± 2.49	0.831	0.806
	No	53	7.6 ± 2.59		50	9.3 ± 2.66		0.001
BMI (kg/m <sup>2</sup> )	Yes	44	25.3 ± 3.98	0.203	59	26.2 ± 4.99	0.970	0.349
	No	55	26.2 ± 5.37		32	27.0 ± 6.09		0.487
Cholesterol (mmol/l)	Yes	38	5.6 ± 0.78	0.159	42	5.2 ± 1.1	0.848	0.104
	No	43	5.3 ± 0.89		40	5.3 ± 1.06		0.956
SBP (mmHg)	Yes	46	150 ± 23	0.534	57	139 ± 24	0.801	0.021
	No	52	147 ± 22		39	138 ± 22		0.067
DBP (mmHg)	Yes	46	92 ± 13	0.480	57	84 ± 14	0.898	0.004
	No	52	90 ± 13		39	86 ± 16		0.292

\*Comparison within each municipality. †Comparison of both municipalities.

BMI, body mass index; DBP, diastolic blood pressure; HbA<sub>1c</sub>, glycated haemoglobin; SBP, systolic blood pressure; SD, standard deviation.

**Table 3** Clinical parameters in 47 patients who completed the study in the control municipality

	<i>n</i>	Time			Variability		<i>P</i> *
		Baseline	12 months	18 months	Absolute	Relative	
Random glucose (mmol/l)	47	13.0 ± 6.42	11.8 ± 5.66	13.2 ± 6.87	0.27 ± 0.45	2.09%	0.770
HbA <sub>1c</sub> (%)	45	8.6 ± 3.18	8.2 ± 2.56	8.2 ± 2.49	-0.42 ± 0.89	-4.87%	0.170
Cholesterol (mmol/l)	38	5.6 ± 0.78	5.3 ± 0.86	6.4 ± 1.58	0.83 ± 0.8	14.95%	0.005
BMI (kg/m <sup>2</sup> )	44	25.3 ± 3.98	25.5 ± 4.45	25.8 ± 4.30	0.48 ± 0.32	1.90%	0.020
SBP (mmHg)	46	150 ± 23	152 ± 23	157 ± 23	7.31 ± 0.48	4.88%	0.047
DBP (mmHg)	46	92 ± 13	92 ± 11	93 ± 11	1.94 ± 1.52	2.12%	0.355

\*Calculated by comparing average difference between baseline and 18 months.

BMI, body mass index; DBP, diastolic blood pressure; HbA<sub>1c</sub>, glycated haemoglobin; SBP, systolic blood pressure.

**Table 4** Clinical parameters in 66 patients who completed the study in the intervention municipality.

	<i>n</i>	Time			Variability		<i>P</i> *
		Baseline	12 months	18 months	Absolute	Relative	
Random glucose (mmol/l)	64	12.7 ± 5.17	11.0 ± 5.63	10.5 ± 4.18	-2.19 ± 0.99	-17.01%	0.004
HbA <sub>1c</sub> (%)	46	9.2 ± 2.28	8.3 ± 1.99	7.7 ± 1.57	-1.60 ± 0.71	-16.27%	< 0.001
Cholesterol (mmol/l)	43	5.3 ± 1.09	5.2 ± 1.18	5.8 ± 1.88	0.45 ± 0.79	8.55%	0.221
BMI (kg/m <sup>2</sup> )	60	26.5 ± 4.28	26.5 ± 3.99	26.4 ± 4.33	-0.15 ± 0.05	-0.57%	0.622
SBP (mmHg)	59	139 ± 23	138 ± 24	131 ± 17	-8.15 ± 6.57	-5.85%	0.006
DBP (mmHg)	59	85 ± 16	81 ± 13	76 ± 9	-9.32 ± 6.99	-10.95%	< 0.001

\*Calculated by comparing average difference between baseline and 18 months.

BMI, body mass index; DBP, diastolic blood pressure; HbA<sub>1c</sub>, glycated haemoglobin; SBP, systolic blood pressure.

Tables 3 and 4 give the results of the parameters measured at baseline, 12 and 18 months and their absolute and relative variability in each municipality.

Table 3 demonstrates no significant improvement in any metabolic parameter and a deterioration in mean cholesterol and systolic blood pressure in the control municipality during the study.

Table 4 demonstrates an improvement in the metabolic profile in the intervention municipality. There was a significant 2.2 mmol/l decrease in mean random glucose ( $P = 0.004$ ), a 1.6% decrease in HbA<sub>1c</sub> ( $P < 0.001$ ), an 8-mmHg decrease in systolic blood pressure ( $P = 0.006$ ) and a 9-mmHg decrease in diastolic blood pressure ( $P < 0.001$ ). As the municipality did not have a weight loss programme or dietitian, changes in cholesterol and BMI were not significant, as expected, nor was there free distribution of lipid-lowering drugs.

## Discussion

Important and beneficial changes in several clinical markers in patients from the intervention municipality were observed (SDM customized programme implemented), while neither a change or even a deterioration was observed in some clinical parameters in patients from the control municipality.

As seen in observational studies, some differences between control and intervention groups should be carefully considered in the interpretation of these results. The control group was selected from a rural municipality with a smaller general population than the intervention group. The intervention and control group differed at baseline in several clinical parameters. The rural characteristic of the control group might have contributed to baseline higher systolic blood pressure and deterioration during follow-up as there is difficulty accessing electricity and the population use salt-cured meat in their habitual diet to preserve food. The higher HbA<sub>1c</sub> seen in the intervention group at baseline may contribute to their better results as, the poorer the baseline situation, generally the more noticeable the impact of any intervention. Otherwise, there was no difference in the baseline characteristics of patients who completed the study in both municipalities (Table 2).

The high drop-out rate was another important limitation. One of the reasons for the high drop out was a change in the political scenario in the country and the development of a nationwide health family programme in primary care. In this programme, health teams comprising doctors and nurses are expected to provide medical care at the patient's home. A higher drop-out rate was observed particularly in the control municipality, where the majority of the population lived in the

rural boundaries, far from the city centre, Medical facilities were available, but, despite knowing that they would receive free medication, the lack of transportation and their low financial resources made it difficult for these participants to access the clinics. In the intervention municipality, 85% of the patients were followed for 1 year and 66% for 18 months, compared with 71 and 47%, respectively, in the control municipality. In similar studies conducted in Latin America, the drop-out rates were also usually high. In a study conducted over 12 months in 10 Latin American countries, 67% of the patients completed the study. Limited economic resources are cited as the main cause [15]. Arauz *et al.*, in Costa Rica, reported that only 51% of their patients completed metabolic testing after a 4-month educational intervention [16]. The percentage of the population followed up at our 12 and 18 months study are therefore similar with other studies performed in Latin America. Completion rates are also low in community population-based studies in developed countries: Gary *et al.*, in the USA, reported only 84% of the patients continued the study after 24 months [17]. Even in an American academic clinic, HbA<sub>1c</sub> could be measured in only 81% of patients in the SDM trained group and 68% of the control groups in a follow-up of 15 months [18]. Thus, the follow-up rate seen in our intervention municipality was actually better than in previous studies.

In some studies with a similar design, where the educational intervention is given to healthcare teams and/or structural interventions are performed at the primary care level, the effect on patient outcomes may not be marked [19]. In a study by Renders *et al.*, in which general practitioners participated in a quality improvement programme, no noticeable changes in blood pressure, HbA<sub>1c</sub> or lipids were seen after 42 months [20]. In PRODIBA, we observed in the intervention group an increase in the percentage of patients with HbA<sub>1c</sub> ≤ 7.0% from 15.2% at baseline to 30.4% at the end of the study, while in the control group this percentage increased only from 13 to 18%. In the intervention group, there was a reduction of 1.6% in HbA<sub>1c</sub> compared with 0.4% in the control group. In a French study exploring training with SDM in primary care, the HbA<sub>1c</sub> was 0.87% lower in the intervention than in the control group after 12 months [13]. Benjamin *et al.* reported a 0.9% reduction in HbA<sub>1c</sub> at 15 months with SDM-implemented protocols in primary care provided by an academic centre [18].

More than 50% of patients in the intervention group who completed the study reached the blood pressure target. In the French study, no improvement in blood pressure or lipid profile was seen [13]. In our study, the reduction in the mean systolic and diastolic blood pressures in the intervention group was bigger than in a Danish trial of structured care [21].

In our study, the lack of a dietitian may have contributed to our failure to achieve significant changes in cholesterol and BMI. In addition, lipid-lowering drugs were not distributed freely in either municipality. In a study by de Sonnaville *et al.*, where structured diabetes care with a nutritionist as part of

the health team was offered, an improvement in lipid profile was observed [22].

Diverse studies in healthcare facilities both in the USA and other countries around the world have demonstrated that SDM protocols are a very cost-effective approach to the treatment of Type 2 diabetes [12–14,23]. The main contribution of this study was to show that a SDM customized programme can be efficiently conducted in communities with very limited resources and that improved metabolic control can be obtained in a group of patients cared for by a health team using protocols for diabetes care. After this study was completed, we began training health professionals for the state family medical programme, which was developed while this study was in progress.

## Competing interests

Nothing to declare.

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