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The Use of Conversation Maps in the Metabolic Control of Diabetes in Brazilians: A Randomized Clinical Trial

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ABSTRACT

Clinical, randomized and prospective trial, without blinding, in two Basic Health Units in an inner city of the state of Sгo Paulo. The study aims at evaluating the effects of an educative intervention over the Self-Monitoring of Blood Glucose (SMBG) at home for metabolic control. A total of 91 people with diabetes participated, recruited from the home capillary blood glycemia self-monitoring program. Two groups of participants were formed: one group participated in the SMBG program at home and with usual care (control group), while the other group participated in the SMBG at home and with educative intervention (intervention group). In total there were 12 meetings, three for each conversation map in the control of diabetes, during four months in 2011 and 2012. For the analysis, two non-parametric tests were used. Pearson's chi square and Fisher's exact tests were used for comparing proportions. On the other hand, the chi-square test of linear trend was used to evaluate the proportional trends of either increase or decrease between the ordinal variables. For all the analysis, a significance statistical level of 5% ($p \leq 0.05$) was adopted. Similar characteristics could be observed when comparing the results of both groups. Most part of participants were females, married, with an average age of 62.1 years old and schooling from four to seven years of study. In the intervention group, an improvement was observed in the following measures: body mass index, abdominal circumference, diastolic blood pressure, fasting plasma glucose, HDL cholesterol, LDL cholesterol and triglycerides. The control group showed improvement in measures of systolic and diastolic blood pressure, fasting plasma glucose, HDL cholesterol and LDL cholesterol. Moreover, an increase on the values of glycated hemoglobin was observed in both groups. It was observed that

there was not statistical significant improvement of the metabolic control. However, it was possible to confirm that an educative intervention for SMBG at home presented a clinical significance, which in turn, resonates in a special way on the health of participants. The study was registered with the Clinical Trials Registry under number NCT01475422.

INTRODUCTION

For satisfactory management of diabetes, health education assists in promoting good glycemic and metabolic control, as well as optimizing the use of reagent strips, the appropriate handling of the blood glucose meter, and encouraging people with DM to make behavioral changes in their lifestyle[1-5].

In this regard, various studies have shown the importance of people with DM participating in diabetes education groups so that they can interpret the results obtained in tests and, if necessary, adjust their diet, the amount of exercise they take, and their medications-in particular insulin[6-11].

As a result, the knowledge acquired in diabetes education groups makes it possible to be aware of the values for normality to be expected, the factors which influence the biochemical results, and the interpretation of these in order to make joint decisions regarding modifications in dosages of antidiabetic agents or insulin. Furthermore, the skills acquired allow the appropriate handling of the equipment, such as the blood glucose meter, the reagent strips and the lancing devices. The goals of education in diabetes have been achieved when, besides promoting adherence to drug treatment, dietary advice or regular physical exercise, the professionals are also able to offer people with DM emotional and social support, either in groups or individually.

It is therefore crucial to offer educational interventions for people with DM who are being treated in the health services[12]. To our knowledge, there is a paucity of randomized clinical trials in Latin America related to this topic, as well as of investigations assessing the use of health education in promoting either SMBG in the home setting, or metabolic control. The present study's objective, therefore, was to evaluate the effects of the educational intervention, based in conversation maps focusing on the metabolic control of people with DM, located in the non-metropolitan area of the State of Sao Paulo (SP), Brazil.

Although the Conversation MapsTM in diabetes have been used in over 90 countries, at the time of writing, their efficacy has not been rigorously evaluated. The present investigation is proposed because this is an innovative (among Latin Americans) and interactive educational tool, as yet explored but little in the literature[13].

MATERIALS AND METHODS

This is a randomized, prospective clinical trial, without blinding, aiming to evaluate the effect of an educational intervention for SMBG in the home setting. An intervention study was therefore held with two groups through a randomization process. The control group was made up of service users with DM who carry out SMBG in the home setting and as part of their normal care, while the intervention group was made up of service users with DM who carry out SMBG in the home setting and who were participating in an educational program focusing on SMBG.

For the protection of the study subjects, the project was approved by the Research Ethics Committee of the Centro de Saude Escola of the Faculty of Medicine of Ribeirao Preto, of the Universidade de Sro Paulo, under Protocol N. 418, on 12 November 2010, and was registered under number NCT01475422 on the Clinical Trials system (ClinicalTrials.gov Protocol Registration System), with the title: Effectiveness of the self-monitoring of capillary blood glucose at home.

The study was undertaken in two Primary Healthcare Centers (PHC) in the city of Ribeirao Preto, State of Sao Paulo (SP), Brazil: Jardim Presidente Dutra and Vila Recreio. In these health centers, the service users with DM are registered on the SMBG in the home setting program, set up in November 2005, in accordance with Municipal Law N. 10,299/04, which establishes the standards for protection for people with DM and guarantees the provision of products for carrying out SMBG in the home setting. Data collection took place in August to December 2011.

The study's target population was made up of 401 service users with DM registered with the SMBG Program between 1st November 2005 and 31st May 2011.

The inclusion criteria established were: service users with DM, registered on the SMBG Program in the above-mentioned PHC, with type I or type II DM, aged 18 years old or over, of both sex, resident in Ribeirao Preto (SP) or the region, available to participate in the activities proposed, and able to hear and verbally respond to the questions formulated. The exclusion criteria were: service users with gestational DM, individuals aged below 18 years old, those who died in the period proposed for the study, service users with DM who could not be located by the health information systems, older adults resident in long-term care institutions, service users with amaurosis, and those with difficulties in participating in the study due to their work hours.

The participants were recruited through three methods of contact: if the service user did not respond to one, a further attempt was made using a different means. As shown by **Figure 1**, of the 342 subjects contacted as potential participants in the study, only 91 accepted to participate. Consequently, the sample calculation was not undertaken, as the sample consisted of the total number of service users with DM registered on the SMBG in the home setting program.

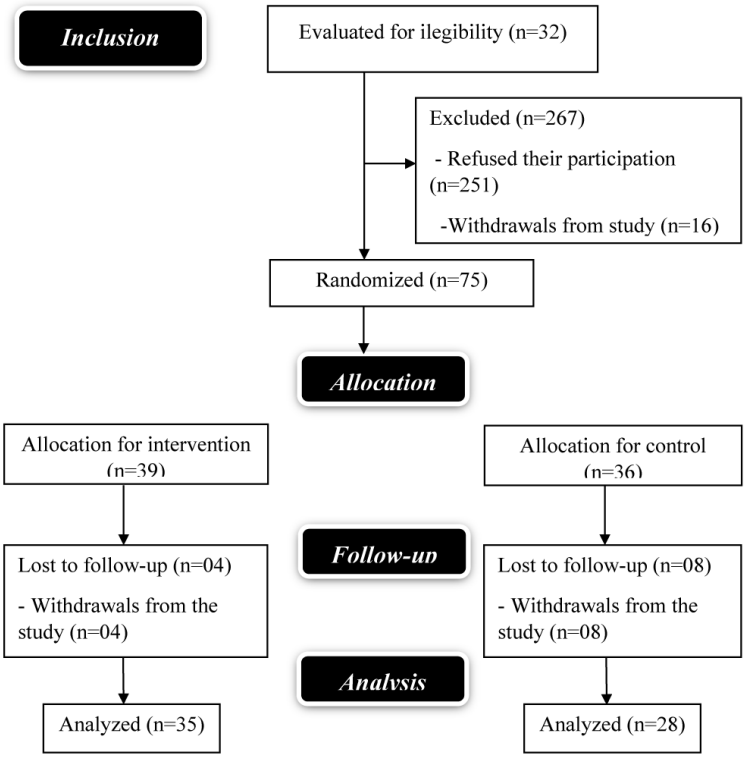

Figure 1: Flowchart.

The randomization of the control and intervention groups was undertaken based on the 91 service users with DM registered on the SMBG in the home setting program in the Primary Healthcare Centers selected, and who accepted to participate in the study.

In order to reduce the researchers' conscious or unconscious biases, the casual allocation was of the simple randomization type, undertaken by statistician using software. Random numbers were generated such that each individual was allocated to either the control or intervention group. Bias was therefore reduced, as the researchers only learned later which service users with DM belonged to which groups.

Two groups were therefore formed, made up of individuals with similar characteristics; proportions by sex and age range were taken into consideration. The first group (control) was made up of 45 service users with DM who remained only in the SMBG in the home setting program, and receiving their usual treatment, while the second group (intervention) was made up of 46 service users with DM who, in addition to their participation in the SMBG in the home setting program and their usual care, received an educational intervention. However, as shown in **Figure 2**, because of those who did not attend and losses, the control and case group were made up, respectively, of 36 and 39 participants.

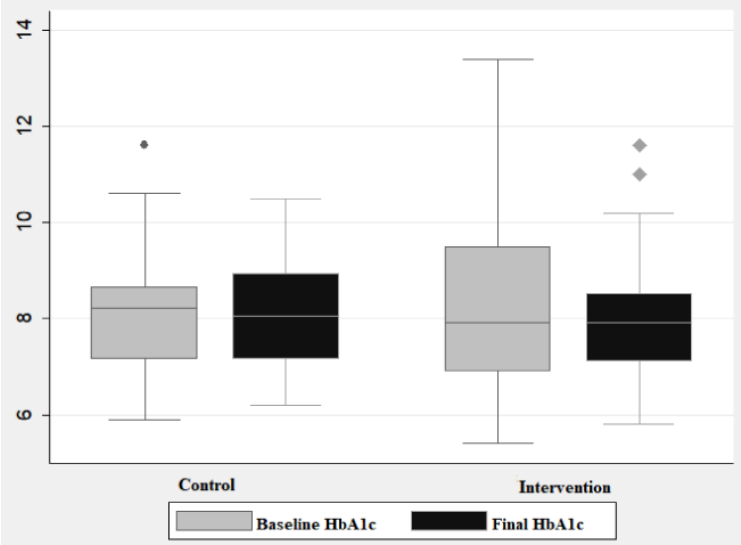

Figure 2: Distribution of the values for HbA1c of the participants in the control (n=28) and intervention (n=35) groups. Ribeirão Preto, São Paulo, 2014. Mann-Whitney test.

Two evaluations were made in the control and intervention groups-one baseline and one at the end of the study. The baseline evaluation consisted of obtaining data referent to the socio-demographic and clinical variables, lifestyle habits, variables related to the SMBG Program, weight, height, abdominal circumference, blood pressure and laboratory examinations (HbA1c, fasting blood sugar levels (fasting plasma glucose concentrations)), total cholesterol, LDL cholesterol, HDL cholesterol and triglycerides. The final evaluation consisted of checking weight, abdominal circumference, blood pressure and the results of the above-mentioned laboratory tests.

The control group received the usual care in their respective health services through the SMBG Program, while the case group was offered a structured educational intervention, as a group, on a weekly basis over a 12-week period, with each meeting lasting 60 min. The tool used for conducting the educational activities was the Conversation Maps in Diabetes tool.

Four Conversation Maps were used: 1-How the body and diabetes work; 2-Healthy eating and physical exercise; 3-treatment with medication and blood glucose monitoring; 4-Achieving goals with insulin.

For the organization and analysis of the data, these were entered using double keying, using Microsoft Excel (Windows XP) (Microsoft Corporation, USA). After being input and checked, these were exported to the STATA v.8 software (StataCorp - College Station, Texas) for treatment and to generate results. The treatment of the data consisted of the generation of further variables and the construction of the principal indicators used in the study.

The initial analysis of the data was based on the description of the totals of the study's main variables (socio-demographic, clinical, lifestyle habits and participation in the SMBG in the home setting program), stratified according to control and intervention group. To this end, descriptive measures were used for the continuous variables (means, standard deviation and medians), while uni and bivariate frequency distribution was used for the nominal and ordinal variables.

The bivariate analyses were undertaken with the aim of describing and verifying proportional differences between the groups, according to the study's variables of interest. Due to the sample size, the nonparametric Pearson Chi squared test and Fisher's exact test were used for comparison between proportions, while the Chi squared test for linear trend was used for evaluating proportional tendencies for increase or reduction between the ordinal variables. The level of statistical significance of 5.0% ($p \leq 0.05$) was adopted in all the analyses.

RESULTS

Before the beginning this clinical trial we have observed that both groups were similar in relation to the sociodemographic variables (p value ≥ 0.05) and time since diagnosis with DM (p value p=0.481). That is, they were not different in relation to these variables. For this item, there was a predominance of people who had DM $\geq$ 15 years (36.5%).

Most of the study participants were female, aged between 61-70 years old, mean age (standard deviation)=62.1 ± 10.3 years old, were married or in a stable relationship, and had spent between four and seven years in education. Most

participants' monthly income varied between US$ 620 and US$ 1,240. Under the item 'occupation', most of the participants in the case group stated that they were housewives (Table 1).

Regarding the type of DM, we observed a predominance of people with DM 2 (73%), in relation to DM 1 (1.6%). Moreover, 25.5% of participants did not know what type of diabetes they had.

The treatments used for control of this disease were drug therapy (46.0%), drug therapy and diet (19.1%), drug therapy and physical activity (19.1%), and the combination of drug therapy, physical activity and diet (15.8%). In relation to the use of medications, 61 (96.8%) used insulin combined with oral agents, and 2 (3.18%), used oral agents alone.

Regarding length of participation in the SMBG in the home setting program, 26 (41.3%) participants mentioned a time of less than three years, 26 (41.3%) from four to six years, and 11 (17.4%) seven years or over. The number of blood glucose tests prescribed by the physician varied from 1-4 per day, with a predominance (53.9%) of those who measured their blood sugar twice daily (Table 2). Approximately 19% of the sample did not fully comply with the SMBG in the home setting program.

In relation to family support received for checking blood sugar at home, 80.9% undertook it independently, while 19.1% needed the help of family members or health professionals. Trends for proportionate increase or reduction between the groups were not observed in relation to these variables (p value ≥ 0.05) (Table 2). Regarding the values for HbA1c in the baseline evaluation, 75.0% of the service users with DM from the control group and 74.3% from the intervention group presented raised values. We did not observe statistically significant variations in the values for HbA1c at the end of participation in the experiment ($p>0.05$) (Table 3).

Table 1: Distribution of the service users with DM registered on the SMBG in the home setting program in the control (n=28) and intervention (n=35) groups, by sociodemographic variables. **Key:** [a]Pearson Chi squared test; [b]Chi squared test for linear trend.

Variables	Total n (%) n=63	Group		*p* value
		Control (n=28) n (%)	Intervention (n=35) n (%)	
Sex				
Male	22 (34.9)	11 (39.3)	11 (31.4)	0.617[a]
Female	41 (65.1)	17 (60.7)	24 (68.6)	
Age range (in years) *				0.58b
≤ 50	3 (4.8)	1 (3.6)	2 (5.7)	
51 – 60	22 (34.9)	9 (32.1)	13 (37.1)	
61 – 70	29 (46.0)	14 (50.0)	15 (42.9)	
≥ 71	9 (14.3)	4 (14.3)	5 (14.3)	
Marital situation				
Married/partners	46 (73.0)	22 (78.6)	24 (68.6)	0.403a
Single (single, divorced, widowed)	17 (27.0)	6 (21.4)	11 (31.4)	
Education (in years of study)				
≤ 3	20 (31.7)	9 (32.1)	11 (31.4)	0.998[a]
4 to 7	27 (42.9)	12 (42.9)	15 (42.9)	
8 and over	16 (25.4)	7 (25.0)	9 (25.7)	
Monthly family income (in US$)				
293 to 586	37 (58.7)	18 (64.3)	19 (54.3)	0.52b

879 to 1,465	25 (39.7)	9 (32.1)	16 (45.7)	
1,466 to 2,930	1 (1.6)	1 (3.6)	...	
Occupation				
Housewife	29 (46.0)	10 (35.7)	19 (54.3)	
Retired	24 (38.1)	12 (42.9)	12 (34.3)	
Salaried worker	6 (9.5)	1 (3.6)	1 (2.8)	
Domestic worker	2 (3.2)	2 (7.1)	...	
Self-employed	2 (3.2)	3 (10.7)	3 (8.6)	

Table 2: Distribution of service users with diabetes mellitus, registered on the SMBG in the home setting program, in the control (n=28) and intervention (n=35) groups, by variables related to participation in the Program. Ribeirao Preto, Brazil, 2011. **Key:** [a]Chi squared test for linear trend.

Variables	Total n (%) n=63	Group		*p* value[a]
		Control (n=36) n (%)	Intervention (n=39) n (%)	
Time in the SMBG Program (in years)				
Up to 3	26 (41.3)	10 (35.7)	16 (45.7)	0.52
4 to 6	26 (41.3)	13 (46.4)	13 (37.2)	
7 and over	11 (17.4)	5 (17.9)	6 (17.1)	
Number of tests prescribed per day				
1	18 (28.6)	6 (21.4)	12 (34.3)	0.84
2	34 (53.9)	19 (67.9)	15 (42.8)	
3	10 (15.9)	2 (7.1)	8 (22.9)	
4	1 (1.6)	1 (3.6)	...	
Frequency of tests				
Once daily	23 (36.5)	8 (28.6)	15 (42.9)	0.49
Twice daily	32 (50.8)	17 (60.7)	15 (42.9)	
3 times daily	5 (7.9)	3 (10.7)	2 (5.7)	
4 times daily	2 (3.2)	...	2 (5.7)	
Twice weekly	1 (1.6)	...	1 (2.8)	
Family support for SMBG in the home setting				
User	51 (80.9)	21 (75.0)	30 (85.7)	
Family member	9 (14.3)	7 (25.0)	2 (5.7)	
Professionals from the PHCs	2 (3.2)	...	2 (5.7)	

Others	1 (1.6)	...	1 (2.9)	

Regarding the lipid profile, at the end of the study, we observed a percentage rise of those with HDL-C>45 mg/dL, LDL-C ≤ 100 mg/dL and triglycerides with values <150 mg/dL, in comparison with values at the start of the study. These differences, however, were not statistically relevant (Table 3).

Table 3: Distribution of the participants from the control (n=28) and intervention (n=35) groups, by variables for glycemic and metabolic control. Ribeirão Preto, São Paulo, 2014.

Variables	Baseline Evaluation (n=63)			Final Evaluation (n=63)		
	Control n (%)	Intervention n (%)	p valuea	Control n (%)	Intervention n (%)	*p* value[a]
HbA1c						
≤ 7.0%	7 (25.0)	9 (25.7)	1.000	4 (14.3)	6 (17.1)	1.000
> 7.0%	21 (75.0)	26 (74.3)		24 (85.7)	29 (82.9)	
Fasting Blood Sugar						
< 130 mg/dL	11 (39.3)	9 (25.7)	0.286	12 (42.9)	17 (48.6)	0.800
≥ 130 mg/dL	17 (60.7)	26 (74.3)		16 (57.1)	18 (51.4)	
Total cholesterol						
< 200 mg/dL	24 (85.7)	30 (85.7)	1.000	23 (82.1)	29 (82.9)	1.000
≥ 200 mg/dL	4 (14.3)	5 (14.3)		5 (17.9)	6 (17.1)	
HDL						
> 45 mg/dL	...	4 (11.4)	0.122	8 (28.6)	18 (51.4)	0.078
≤ 45 mg/dL	28 (100)	31 (88.6)		20 (71.4)	17 (48.5)	
LDL						
≤ 100 mg/dL	16 (57.1)	19 (54.3)	1.000	22 (78.6)	23 (65.7)	0.400
> 100 mg/dL	12 (42.9)	16 (45.7)		6 (21.4)	12 (34.3)	
Total Triglycerides						
< 150 mg/dL	16 (57.1)	16 (45.7)	0.450	13 (46.4)	17 (48.6)	1.000
≥ 150 mg/dL	12 (42.9)	19 (54.3)		15 (53.6)	18 (51.4)	

It also stands out that the median values, in the two groups, in the baseline evaluation of Hba1c, remained at 8.0% (>7.0%) and that in the final evaluation, both groups reduced the median value to 7.9%. In figure 2 we have observed that glycated hemoglobin (HBA1c) values it has presented high variability in both groups. However, this variability did not show any statistically significant differences between the groups about this variable (p>0.05) **(Figure 2)**.

DISCUSSION

Among the 63 (100%) service users with DM, a predominance of females was observed (65.1%). This data is in consonance with Brazilian and international studies, which show a higher frequency of women[9,10,14,15]. The high percentage of women may be related to the tradition that women are more likely than men to seek the help of the health services[15].

In the control and intervention groups, the mean age was 62.1 years old (sd=10.3 years). In both groups, 46.0% of the service users with DM were in the age range from 61-70 years old. Randomized clinical studies in people with DM undertaking SMBG have presented a mean age similar to that found in this study[14,16,17,18].

The predominance of people who are married or in a stable relationship, ascertained in this study, corroborates the findings of other researchers[19]. Marital status may influence the disease's management, as in some cases the loss of the companion leads to changes in health such as depression, despondency and loss of the will to live[20]. Moreover, in primary healthcare in Brazil, it is very common for the woman to be seen as the companion and as the supervisor of healthcare for her husband and family.

Educational level was another variable with levels below those stipulated by international bodies. In contrast, people with DM, carrying out SMBG in the home setting, who have been educated to a higher level, are more likely to achieve success and participate over a longer period in educational interventions. Authors also reveal that a low educational level favors worse glycemic and metabolic control and higher rates of retinopathy[21]. On the other hand, people with DM with a higher educational level are more likely to adhere to treatment and maintain good metabolic control[22, 23].

The fundamental approach of the Conversational Maps educational tool is based in a basic belief that sustainable personal change requires significant discussion focusing on facts and questions about the disease, along with verbal commitment to change. As a result, change in behavior, the acquiring of responsibility and the establishing of goals as a means of improving the health care results requires a certain level of prior skill[14].

The variabilities in glycated hemoglobin values did not present statistically significant differences in both groups. Thus, it is possible that for the effects of behavior in eating, exercising, and taking medications, it would take longer to apply the conversation maps. At this time, we cannot indicate that the use of conversation maps in diabetes for 12 weeks is sufficient for clinical changes and metabolic control of diabetes.

The increase in the number of service users with DM with values for HbA1c above what is recommended may be related to the time taken to collect blood samples after the end of the intervention. It is possible that, were there to be an evaluation of HbA1c three months after the end of the study, one might observe a reduction in these values. However, the international literature supports the presence of reduction in HbA1c after only three months of the educational intervention. Three studies have shown positive results in HbA1c three months after the implementation of the educational program[24] and five clinical trials, after six months of education on diabetes[14,25,26]. Of these, only one evidenced a statistically significant reduction in HbA1c[14].

Regarding the values for fasting blood sugar, it was observed that after the study had been in progress for 12 weeks there was an improvement in the values for blood sugar levels; however, the values were still outside the parameters proposed by the Brazilian Society of Diabetes[27]. Similar results were found in clinical trials consulted, with the baseline values being changed in both the control and intervention groups[28,29].

Studies undertaken in the United States of America, Costa Rica and in Brazil have also shown mean values for fasting blood sugar above what is recommended, varying from 189 mg/dL to 214 mg/dL[30-32].

SMBG is a tool which could optimize better blood glucose levels, as was evidenced in various studies consulted[33,34]. However, researchers have concluded that good glycemic control is independent of the type or frequency of SMBG in the home setting and that, over time, the success obtained by the person with DM tends to deteriorate in the absence of systematic monitoring, family support and involvement of the health team[14,24,35,25].

In relation to the lipid profile, there was a reduction in the percentage of service users with DM with total cholesterol within normal parameters in both groups. Nonetheless, at the end of the intervention, the levels for HDL-C and LDL-C presented increased and decreased serum levels, respectively. It is important to highlight that, clinically, the separate evaluation of these lipoproteins is more important than total cholesterol, the evaluation of which in Brazil has all but fallen into disuse, as qualitatively it reveals little.

When the values for the triglycerides in the baseline and final evaluations of the study are compared, these are shown to be high in the control group, while there was a slight improvement in the intervention group. The data did not show, however, statistically significant differences between the groups (p>0.05). Clinical results detected in a similar study resembled those found in the present study but differed in relation to the statistical significance.

The use of SMBG concomitantly with a structured educational program favors greater adherence to recommendations regarding diet, medications and physical exercise. This could be decisive in helping with lipid control.

CONCLUSION

Based on our research findings, even though no statistically significant values for glycemic and metabolic control could be observed, it is possible to affirm the educational program for home AMCG presented clinical significance, with a

particular repercussion on the participants' health. In addition, we noticed an increasing number of people with Diabetes Mellitus have HbA1c values higher than recommended, which can be related to the time for blood collection after the end of the intervention. For example, if there was an evaluation of HbA1c three months after the end of the study, reductions in those values were likely you be observed. However, the international literature supports the presence of HbA1c reduction with only three months of educational intervention.

Therefore, it is important to consider other variables that may influence the values collected for glycemic and metabolic control (i.e. the health beliefs that were not object of the present investigation). Health beliefs may have an interaction effect and influence positively or negatively on the managing Diabetes Mellitus. Finally, one should also consider the fact that people could have different understandings of disease control due to sociocultural inequalities that may exist between them and health professionals.

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