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Impact of an educational intervention in the management of individuals with uncontrolled type 2 diabetes mellitus using insulin therapy

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ABSTRACT

Objective: To investigate the effects of problematizing intervention in the treatment of individuals with type 2 diabetes mellitus.
Methodology: A randomized clinical trial was conducted in 41 patients ages 18 to 64 with type 2 diabetes who were treated with insulin and had glycosylated hemoglobin greater than 7.0%. The mean age of participants was 55.9 (SD = 5.49). A high percentage of patients had comorbidities such as hypertension (92.7%), dyslipidemia (68.3%), overweight (95%), retinopathy (41%), and neuropathy (39%). The patients in the intervention group participated in 6 educational groups using problematization methodology, whereas the patients in the control group attended only routine consultations. Sociodemographic, clinical, behavioral, and lifestyle variables were assessed.
Results: After 6 months of follow-up, no statistically significant difference in glycemic control and anthropometric parameters was observed between participants in either study group. The intervention group showed an increase in knowledge about the disease, and an improvement in total cholesterol and uric acid levels.
Conclusion: The use of a problematizing intervention provided an improvement in behavioral as well as specific clinical parameters, compared to routine diabetes care. However, longer follow-up time for these patients could bring benefits regarding glycemic control.

1. Introduction

In most countries, diabetes mellitus (DM) has stood out due to the significant increase in its prevalence. Data from the International Diabetes Federation indicate that about 9% of the population from 20 to 79 years old have DM [1,2].

Type 2 diabetes mellitus (T2DM) is characterized by metabolic disorders resulting from defects in the action and/or secretion of insulin. It has a multifactorial etiology associated with genetic and environmental factors. Thus, persistent hyperglycemia can reduce life expectancy and increased mortality [2,3].

With an aim toward preventing complications associated with DM, treatment is based on lifestyle changes, especially in the adaptation of eating habits and physical activity, in addition to the use of antidiabetic agents and/or insulin therapy [4]. However, recent data indicate that despite all the therapeutic and technological advances, most patients remain outside the control goals, representing a major challenge to the health care team [5,6].

However, the importance of the DM education process is observed in the literature. The aim is to promote healthy behaviors, support self-care measures and adherence to treatment, optimize metabolic control, increase quality of life, and reduce complications related to the disease [7,8].

In this sense, recent studies point to the benefits of conducting health education groups based on the exchange of experiences and the dialogue of their participants, seeking to empower patients to promote autonomy-

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oriented practices [9,10].

In this context, the problematizing methodology becomes a strategy for the treatment of individuals with chronic diseases because it can facilitate disease management. This method is based on the reality of the participants, so that the learner can seek the knowledge required to change his or her reality and develop critical awareness for a change of attitude towards treatment. The educator stands out as a driver of this process and an information provider to individuals and families [11,12].

Previous studies that used the problem-solving methodology through activities in groups called "culture circles" have pointed out that these spaces present an active strategy for patient participation in the treatment because they enable skills for self-care, in addition to the search for generative attitudes towards changes [13].

Therefore, the main objective of this study is to investigate the effects of a problematizing educational intervention in patients with T2DM, treated by a secondary health care service in the southeastern region of Brazil.

2. Methodology

2.1. Study design

This is a randomized, longitudinal clinical trial intervention study with repeated measurements over time.

2.2. Participant selection

This is a randomized clinical trial conducted involving patients 18 to 64 years old with T2DM who were treated with insulin and had glycosylated hemoglobin greater than 7.0%, at the outpatient clinic of the Endocrinology and Metabolism Service of the Federal University of Juiz de Fora's University Hospital, Minas Gerais, Brazil. The information was collected between August 2018 and May 2020.

Sample calculation [14] was based on a 95% confidence interval (bilateral), 80% power, a sample size ratio (intervention/control) of 1, a coefficient of variation of 20%, an estimation error (relative) of 10%, and a calculated sample size of 16 per group.

Patients not included in the study had gestational DM, T1DM, latent autoimmune diabetes in adults, maturity-onset diabetes of the young, DM secondary to pancreatitis, institutionalized DM, and other chronic complications in advanced stages.

The study patients were randomized into 2 groups. The intervention was represented by the problematizing methodology, developed within educational groups. The randomization process was carried out via proportional allocation of the participants as they entered the study, with the aid of a randomization list for randomized clinical trials in blocks generated by the Blockrand package [15] for R version 1.3.11.

2.3. Definition of project steps and variables

The study was conducted in 3 periods: T0 (inclusion of participants in the study), T3 (3 months after the beginning of the intervention), and T6 (6 months after the beginning of the intervention).

In time T0, sociodemographic data and health literacy levels were assessed. In T0 and T6, medication adherence was assessed, in addition to clinical, behavioral, anthropometric, laboratory test, and lifestyle variables. In T3, only anthropometric assessments and laboratory tests were analyzed.

2.4. Variables analyzed

Sociodemographic and clinical information was collected through a preformulated questionnaire.

Medication adherence was assessed using the Morisky–Levine Adherence Scale [16], which assesses the possible reasons for the inadequate use of medication.

To obtain behavioral characterization data, the Diabetes Knowledge Scale (DKN-A) [17] questionnaire was applied. Regarding the assessment of attitudes towards the disease, the Diabetes Attitudes Questionnaire (ATT-19) was used [17].

In addition, regarding lifestyle data, diet was assessed using food frequency questions [18], and the practice of physical activity was assessed through the International Physical Activity Questionnaire (IPAQ) [19], short version.

In the clinical assessment, body weight (kilograms) and height (centimeters) were assessed to calculate BMI, in addition to waist circumference (centimeters) [20] as well as measurement of systolic and diastolic blood pressure.

Regarding the laboratory evaluation, after being advised to fast for 12 h, blood samples were collected for analysis of fasting blood glucose and glycated hemoglobin (HbA1c), calculation of estimated mean blood glucose (eMBG), and analysis of creatinine for calculating the glomerular filtration rate (CKD-EPI) [21], uric acid, complete blood count, total cholesterol, HDL-c, and triglycerides [22]. The albumin/creatinine ratio was done on an isolated urine sample.

Health literacy, in turn, was assessed using the Short-Test of Functional Health Literacy in Adults [23,24].

2.5. Problematizing methodology

The educational intervention used in this study was based on the problematizing pedagogical methodology [25–27], which consists of the following elements:

–Demand analysis (survey of prior knowledge on the subject)
–Preanalysis of the context and group issues (planning)
–Survey of generating themes and definition of focus (execution)
–Evaluation, through the verbalization of solutions applicable to the participants' reality

In this sense, 6 teaching plans were elaborated to direct the activities developed within the educational groups carried out only with the intervention group participants. In this way, all groups followed a sequence of steps. Thus, the groups began with a dynamic of relaxation with the participants. Then, a question was presented to the participants that would guide the theme worked on in the group. Afterwards, there was a moment of theoretical foundation, reflection, and elaboration of collective answers, as well as the synthesis of the patients' experiences in the group. Finally, participants were asked to give their thoughts about their participation in the educational group.

The lesson plans were composed of the following themes: autonomy and self-care; the diet of patients with DM; guidance in specific situations of diabetes; the importance of correct use of medications and glycemic monitoring; healthy habits in diabetes; and myths and truths about the diet of people with diabetes.

The educational groups were held in 6 monthly meetings, in which topics suggested by the patients with DM, who had gone to the outpatient clinic in a preliminary assessment, were addressed [26].

2.6. Statistical methods

Data were entered using the Research Electronic Data Capture research management software and online database. Using the Stata statistical program, an analysis of categorical variables was performed using Pearson's χ^2 test to compare the degree of homogeneity of the control and intervention groups. The comparison between the control group and the intervention group for all variables (i.e., DKN-A, ATT-19, IPAQ, anthropometrical and laboratorial variables) was performed using variation from T0 to T6 (T6–T1, Δ). An unpaired *t* test was used for parametric variables, and the Mann–Whitney test was used for nonparametrical variables. In all analyses, a significance level of 5% was adopted.

2.7. Ethical aspects

This study was approved by the Federal University of Juiz de Fora University Hospital Research Ethics Committee under opinion number 2.670.781. The study was registered in the Brazilian Registry of Clinical Trials. All participants signed the informed consent form.

3. Results

After surveying the patients registered, the sample was comprised of 41 participants, with 20 individuals (48.8%) being allocated to the intervention group and 21 (51.2%) to the control group. Six participants were lost during the study, 3 from the intervention group and 3 from the control group. The main reasons observed were the loss of telephone contact among the participants ($n = 3$), who subsequently did not attend consultations or groups; loss to follow-up (n = 2); and refusal to undergo the biochemical tests ($n = 1$; Fig. 1).

Sociodemographic and clinical data are described in Table 1. The mean age was 55.9 (SD = 5.49) and the mean time since diagnosis of DM was 10.6 years (SD = 8.72). At baseline, the groups were considered homogeneous in terms of sociodemographic and clinical characteristics, except for the frequency of neuropathy, which was higher in the intervention group participants.

With respect to the classification of the Medication Adherence Scale, the mean score for this instrument among all participants in T0 was 2.6 (SD = 1.27) points, with the majority of patients (92.5%) considered "non-adherent to the medication treatment." In T6, no participant was considered adherent to the medication treatment. No statistical differences were observed between the groups in T0 and T6 over time.

Concerning the score for the DKN-A scale and the ATT-19 questionnaire, the data are described in Table 2. Note that in T6, the intervention participants had higher levels of knowledge regarding the disease; accordingly, the average level of knowledge increased significantly in this group over time.

Regarding lifestyle, the analysis of data from the food frequency questionnaire and physical activities did not show statistically significant differences between the groups at the time of inclusion in the study and after the intervention period.

Table 3 shows anthropometrics variables. No differences were identified in terms of BMI and waist circumference values throughout the study.

In general, the assessment of blood pressure did not show statistically significant differences between the 2 groups during follow-up, but in relation to the anthropometric data, a reduction in waist circumference was verified.

No statistically significant differences were observed for the analysis of parameters related to fasting blood glucose control, triglyceride, and renal function between the 2 groups during follow-up, as described in Table 4. However, the averages of total cholesterol and uric acid levels were lower at T6 than they were at T0 among participants in the intervention group but did not show significant differences over time in the control group. On the other hand, the average of the glycated hemoglobin were higher at T6 than they were at T0 among participants in the intervention group, whereas the control group did not show significant differences over time. Moreover, no significant differences were found between the control and intervention group at each time point.

The health literacy assessment showed no statistically significant differences occurred between the control and intervention groups in the assessed sample. The mean total literacy score among all the participants in T0 was 60.8 (SD = 25.2), wherein the mean for the control group was 62.5 (SD = 25.6) and the intervention group was 59.0 (SD = 25.3) points. The total score of this instrument classified 36.6% of the participants in the inadequate range and 14.6% in the marginal range of literacy. The remaining participants (48.8%) were classified with an adequate score.

4. Discussion

This study showed that a significant portion of the sample was comprised of married females who had low levels of education and family income and who had a high percentage of self-reported comorbidities, in addition to unfavorable self-rated health and low medication

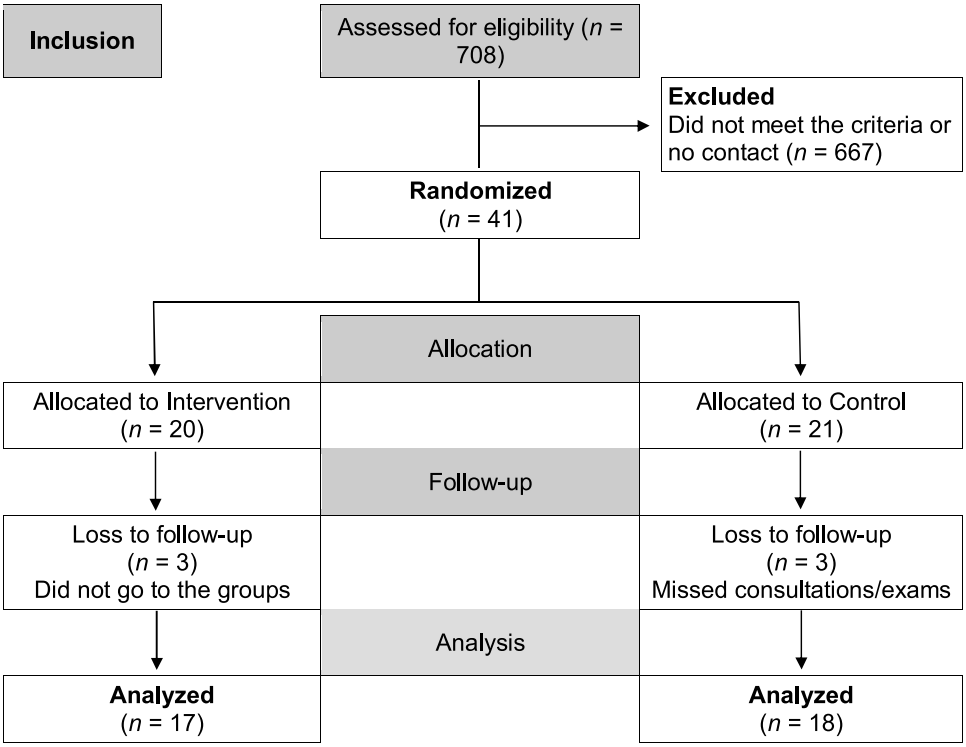

Fig. 1. Study participant flowchart.

Table 1
Distribution of sociodemographic and clinical variables at the time of inclusion in the study.

	Variables (n = 41)	Frequency (%)	CG (n = 21)	IG (n = 20)	P
Gender	Female	25 (61)	12	13	0.606
	Male	16 (39)	9	7	
Skin color/ race	White	20 (48.8)	13	7	0.150
	Black, Brown/ Mulatto	21 (51.2)	8	13	
Marital status	Married	24 (58.5)	11	13	0.831
	Single	10 (24.4)	6	4	
	Widowed	3 (7.3)	2	1	
	Separated	4 (9.8)	2	2	
Family income	2 × minimum wage	34 (82.9)	16	18	0.535
	3–5 × minimum wage	6 (14.6)	4	2	
	6–10 × minimum wage	1 (2.5)	1	0	
Education	1st to 4th grade	12 (29.3)	5	7	0.504
	5th to 8th grade	14 (34.2)	7	7	
	High school	10 (24.4)	5	5	
	Higher education	1 (2.4)	0	1	
	Technical school	1 (2.4)	1	0	
	Graduate degree	1 (2.4)	1	0	
	Other	2 (4.9)	2	0	
Smoking	Smoker	1 (2.5)	1	0	0.618
	Nonsmoker	22 (55)	11	11	
	Ex-smoker	17 (42.5)	9	8	
Comorbidities	SAH	38 (92.7)	19	19	0.578
	Dyslipidemia	28 (68.3)	16	12	0.265
	CVDs	8 (19.5)	3	5	0.387
	Kidney diseases	6 (14.6)	1	5	0.160
	Retinopathy	17 (41.5)	7	10	0.279
	Neuropathy	16 (39)	4	12	0.017 *
	Foot disorders	5 (12.2)	3	2	0.675
	Other diseases	19 (46.3)	11	8	0.427
Self-rated health	Excellent	0	0	0	0.108
	Very good	0	0	0	
	Good	10 (25.6)	8	2	
	Fair	24 (61.6)	10	14	
	Poor	5 (12.8)	2	3	

χ^2 test; CG: control group; IG: intervention group; SAH: systemic arterial hypertension; CVDs: cardiovascular diseases.
* $P < 0.05$.

Table 2
Analysis of knowledge and attitude variables during a 6-month intervention with a problematization methodology.

Scales	Treatment	T0	T6	Δ (Variation)	P
DKN-A	CG	9.23 ± 1.92	9.52 ± 1.98	0.31 ± 2.03	0.042
	IG	9.45 ± 2.03	10.80 ± 1.20	1.73 ± 1.83	
ATT-19	CG	56.38	58.31	1.89 ± 7.50	0.74
	IG	58.30	58.46	0.46 ± 13.27	

DKN-A: Diabetes Knowledge Scale; ATT-19: Brazilian version of the Attitudes Questionnaire; T0: inclusion of participants in the study; T6: 6 months after the start of the intervention; CG: control group; IG: intervention group.

Table 3
Analysis of anthropometric variables during follow-up, Juiz de Fora (Minas Gerais), Brazil.

Anthropometric variables	Treatment	T0	T6	Δ (Variation)	P
Waist circumference (cm)	CG	110.35 ± 14.45	113.73 ± 8.90	1.92 ± 6.70	0.92
	IG	105.79 ± 11.48	104.44 ± 11.31	2.13 ± 4.76	
BMI (kg/m^2)	CG	35.18 ± 7.05	35.55 ± 6.53	−0.07 ± 1.37	0.49
	IG	31.80 ± 4.78	31.59 ± 5.13	0.23 ± 1.14	

CG: control group; IG: intervention group; T0: inclusion of participants in the study; T6: 6 months after the start of the intervention; Δ: delta.

Table 4
Analysis of biochemical variables among participants during follow-up, Juiz de Fora (Minas Gerais), Brazil.

Variables	Treatment	T0	T6	Δ (Variation)	P
TG (mg/dL)	CG	152.85 ± 86.90	174.68 ± 112.46	17.37 ± 65.02	0.084
	IG	230.55 ± 252.49	159.47 ± 97.84	−68.11 ± 190.51	
e-GFR (mL/ min)	CG	84.03 ± 21.26	88.47 ± 26.49	3.50 ± 13.94	0.37
	IG	85.33 ± 25.73	94.94 ± 19.71	−1.24 ± 14.55	
TC (mg/dL)	CG	169.23 ± 43.29	179.18 ± 48.69	7.56 ± 22.41	0.037*
	IG	192.95 ± 61.33	181.41 ± 49.80	−15.05 ± 35.47	
LDL-c (mg/ dL)	CG	96.38 ± 34.25	99.25 ± 37.14	2.62 ± 20.01	0.50
	IG	104.73 ± 35.48	107.76 ± 34.36	−2.56 ± 22.97	
HDL-c (mg/ dL)	CG	42.33 ± 11.34	45.06 ± 11.75	1.43 ± 6.93	0.14
	IG	42.40 ± 9.98	41.64 ± 8.30	−1.82 ± 5.56	
UA (mg/ dL)	CG	4.20 ± 1.07	4.25 ± 1.02	0.16 ± 0.44	0.01*
	IG	4.59 ± 1.33	3.65 ± 1.06	−0.40 ± 0.51	
FPG (mg/ dL)	CG	193.3 ± 70.5	159.1 ± 66.2	−19.7 ± 75.34	0.84
	IG	207.5 ± 79.4	181.4 ± 69.5	−24.7 ± 67.18	
HbA1c (%)	CG	8.74 ± 1.64	8.84 ± 2.56	0.57 ± 1.73	0.67
	IG	8.18 ± 1.45	9.13 ± 1.71	0.82 ± 1.56	

TG: triglycerides; e-GFR: estimated glomerular filtration rate; TC: total cholesterol; LDL-c: LDL cholesterol; HDL-c: HDL cholesterol; UA: uric acid; FPG: fasting plasma glucose; HbA1c: glycated hemoglobin; CG: control group; IG: intervention group; Δ: delta; T0: inclusion of participants in the study; T6: 6 months after the start of the intervention.

adherence. However, after conducting the educational groups, positive effects of the problematizing methodology were seen in the studied sample, with regard to the levels of knowledge about the disease and improvements in specific metabolic parameters, including total cholesterol and uric acid.

Regarding the analysis of knowledge levels, a statistically significant increase was observed in this variable after the intervention over time. Thus, in 6 months, the average knowledge about the disease in the intervention group increased by 1.73 ± 1.83 points in comparison to only 0.31 ± 2.03 in the control group. However, no differences were identified for the variable on attitudes towards the disease. Similarly, a previous study pointed out that after carrying out an educational intervention with T2DM, with a 2-year follow-up, patients increased

their knowledge about the disease as well as their personal care skills, which suggests that in the long run, the increase in knowledge can contribute to self-care measures [28].

We also highlight the difficulty with glycemic control in the assessed sample during follow-up, represented by HbA1c higher than 7.0%. We understand that a set of various factors could influence the metabolic control of patients with diabetes, one of them being the therapeutic regimen. In line with this, a study aimed at identifying factors associated with glycemic control in people with T2DM pointed out weaknesses with the therapeutic regimen through insulin therapy and, consequently, an inadequacy in glycemic control [29,30].

In this context, the low medication adherence identified in the study can be considered one of the main factors that explain the difficulty of metabolic control. Previous studies that evaluated medication adherence in individuals with DM in developing countries such as Brazil indicated that fewer than 30% are considered adherent to the medication treatment [31–33]. Previous studies have also shown the relationship between insulin use and the difficulty with glycemic control [34,35].

Low levels of regular physical activity have been documented among individuals with DM. More than 96% of the participants with DM from the Elsa-Brasil survey, which investigates the incidence and risk factors for chronic diseases, in particular cardiovascular diseases and diabetes, reported not practicing physical activities [36].

We could not demonstrate any increase in physical activity during the study either in control or in the intervention group. A systematic review study pointed out several benefits of carrying out educational programs for patients with DM, but the entire effort of these programs comes up against complicating factors such as the lack of availability and willingness to practice physical activity [37].

Some results found in this study are similar to a previous study that also used the problematizing methodology, especially the increase in knowledge levels [38]. Nevertheless, in the present study, an interaction occurred in the educational intervention offered with the evaluation time for the response regarding serum uric acid and total cholesterol levels. Participants in the intervention group showed a significant reduction in this indicator, which was not observed in the participants in the control group.

A previous study using an education program for adults with T2DM also showed reductions in total cholesterol after 6 months of follow-up [39].

The reduction in uric acid and total cholesterol levels observed in the present study is an important finding in the intervention group. According to literature, this may be associated with a reduction in the risk of cardiovascular events, because it has been described in the literature that both are important risk factors for cardiovascular disease [40–43].

Complementarily, another study carried out with patients with hypertension, which was based on the same problematizing methodology, pointed out that the present intervention showed positive impacts on training for self-care and attitudes that generate change, and these are important benefits that need to be developed in patients with chronic diseases [13].

Although the study has inherent limitations, such as sample size and follow-up time, we report that it is a homogeneous sample in terms of inclusion and exclusion criteria and it is believed that the data collected will allow us to describe the effects of the methodology used on different variables related to a specific sample of patients — those with T2DM who are on insulin therapy and outside the glycemic control goals. Despite all the care taken with the selection of participants, a statistically significant difference was identified at baseline in terms of neuropathy among participants in the intervention group. However, after performing the analyses, it was found that neuropathy did not interfere in the analyzed responses.

5. Conclusions

The use of the problematizing methodology had a positive effect on the levels of knowledge, uric acid, and total cholesterol in uncontrolled individuals with T2DM using insulin. The specifics of the assessed population should be noted, especially with regard to the high percentage of comorbidities and low levels of health literacy and medication adherence.

We emphasize that although there was no reduction in blood glucose levels, the behavioral and clinical changes observed in the study can provide benefits in metabolic control for this class of patients in the long term. Difficulty with glycemic control is observed in a significant portion of patients with diabetes and is explained by the influence of several factors.

In this way, problematizing interventions are more effective than the usual care is and can be integrated as a complementary resource in the treatment of patients with T2DM assisted in the secondary health care service.

The development of new studies with longer follow-up time can help to investigate the effects on the long-term methodology in this class of patients.

Statement of authorship

All authors participated in the study conception and design, data analysis and interpretation, and manuscript writing.

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Conflict of interest

The authors declare no conflict of interest.

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