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Original Article

Pharmacotherapeutic empowerment and its effectiveness in glycemic control in patients with Diabetes Mellitus

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ABSTRACT

Aims: To develop an intervention and evaluate its effectiveness in pharmacotherapeutic empowerment of patients with type 2 diabetes mellitus (T2DM).
Method: This is an intervention study with before and after evaluation. The intervention was conducted between 2015 and 2016 with users of the Unified Health System (SUS) in Brazil. The study was divided into six stages: initial evaluation, three individual patient-pharmacist meetings every 15 days over 6 weeks, clinical discussion between pharmacists, and final evaluation. At each meeting with the patient, specific themes for empowerment were addressed using educational booklets and pharmaceutical care. Clinical and laboratory evaluations and questionnaires on self-efficacy (IMDSES), self-care (QAD) and distress (PAID-5) were conducted before and three months after the intervention.
Results: 47 patients completed the intervention. Glycated hemoglobin of patients had a median reduced from 7.0% to 6.6% after the intervention ($p = 0.02$). There was a significant difference ($p < 0.01$) in the reduction in total cholesterol, fasting glycemia, creatinine and blood pressure. Participants showed significant improvements ($p < 0.01$) in scores related to self-efficacy and self-care and less distress related to T2DM.
Conclusion: The results of the study suggest that the strategy developed is effective in promoting the empowerment of T2DM patients, improved glycemic control and self-care.

1. Introduction

Diabetes Mellitus (DM) is a disease that affects 8.3% of the worldwide adult population in 2017. Currently there are 425 million people worldwide with diabetes and by 2045 it is estimated to be 629 million [1]. In Brazil, the prevalence of DM in 2014 was 8.0%, being 7.3% among men and 8.7% among women [2].

DM requires continuous clinical care and permanent focus on self-care to prevent acute complications and reduce the risk of chronic complications [3]. Patients with DM perform a fundamental role in the treatment [4,5]. Promoting health education, with information on diet control, the use of medications is essential in helping achieve glycemic control [6].

However, despite advances in traditional DM treatment and access to health services, many patients with type 2 DM (T2DM) still do not have controlled glucose levels [6]. Glycemic control remains below ideal with an estimate that only 56.8% of patients with DM have their glycated hemoglobin (HbA1c) within the therapeutic goal [7,8].

In this context, empowering patients in DM self-care has been shown to be effective in glycemic control [9–13]. Empowerment can be defined as helping patients discover and develop the inherent ability to be responsible for their life and gain mastery over the disease [14]. In empowerment, patients should be assisted to learn more about DM, reflect on values and goals related to DM treatment, and set goals for improving glycemic control [15]. In pharmacotherapeutic empowerment, the clinical pharmacist enables the patient so that they can make appropriate decisions about their daily activities, as well as take responsibility for their needs related to medication, in collaboration with the patient and with other health professionals [16,17].

Thus, empowerment strategies should be developed, among them pharmacotherapeutic empowerment. This study aimed to develop an intervention and evaluate its effectiveness in pharmacotherapeutic empowerment of patients diagnosed with T2DM.

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2. Methods

2.1. Study design, site of investigation, population

This is an intervention study with before and after evaluation. It was developed in the city of Divinópolis, Brazil, which has an estimated population of 213,016 inhabitants [18]. The intervention was conducted between April 2015 and February 2016.

The eligibility criteria to participate in this research were patients with T2DM, aged 18 years or over and registered in the Hiperdia System [19]. The Hiperdia is the registration system of patients with hypertension and/or DM, attended by the Unified Health System - SUS. In this system, patients are classified in relation to cardiovascular risk according to the *Framingham* score, being low, moderate and high risk. Exclusion criteria were patients with high cardiovascular risk because they receive specialized attendance in specialized care centers, individuals with cognitive deficits that compromise the understanding of the questionnaire, and patients who participated in another intervention in DM.

Patients were selected from five primary health care units belonging to the SUS. Contact was initiated with all patients who met the inclusion criteria until the required sample limit was reached.

2.2. Sampling

A required minimum sample of 60 patients was estimated so that it was possible to detect a difference of 0.67 in mean HbA1c before and after the intervention, a parameter proposed by Naik et al. (2011) [20]. The parameters used were: 95% confidence interval, 80% statistical power, and variance of 1.69.

2.3. Intervention

Intervention for empowerment was developed in six main stages (Fig. 1): an initial evaluation (application of questionnaires to evaluate empowerment and laboratory tests), three individual patient-pharmacist meetings over six weeks, clinical discussion among clinical pharmacists, and a final evaluation three months after the end of the intervention (questionnaires and laboratory tests). The meetings were held individually by the clinical pharmacist in the health units of which the patients were attended, or at the patients' home.

In each patient meeting the seven standards required for self-care proposed by the American Educators Association in DM were discussed: healthy eating, physical activity, glycemia monitoring, medication use, resolution of acute problems, healthy confrontation, and reducing risks [21]. The meetings lasted 30 min on average and were conducted by a clinical pharmacist and were aimed at following the intervention protocol defined in order to promote the empowerment of the participants. The clinical pharmacist responsible was previously trained for six months on theoretical and practical pharmaceutical care courses. In the first meeting all patients received two educational booklets, one on general guidelines on self-care in DM and the other on the use of medication for DM, the contents of which were previously validated by experts using the Delphi technique [22]. Educational pamphlets were written in simple language and contained colorful pictograms, and diaries to provide an incentive for glycemia monitoring.

The medications used by the patients were analyzed in a clinical discussion between a team of clinical pharmacists, after the initial evaluation. The pharmacist team identified and categorized potential pharmaceutical problems (PPT) in accordance with the proposal of Cipolle, Strand and Morley (2004) [23]. A PPT is defined as an unwanted event, presented by the patient from, or probably from, medication therapy that interferes or may interfere with the therapeutic goals [23]. After the clinical discussion, if the patient presented a PPT, an individualized care plan that was later presented to the health care team to discuss and seek a possible solution was prepared. After discussion with the health team, the care plan was presented to the patient in the third meeting with the clinical pharmacist. In the final evaluation it was examined whether the PPT had been solved.

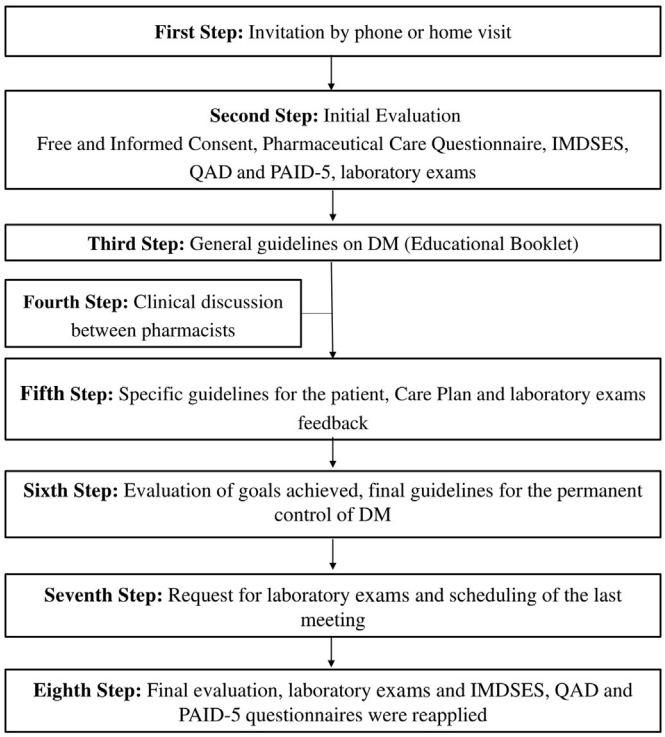

Fig. 1. Flowchart of the study steps.
DM: Diabetes Mellitus; IMDSES: Insulin Management Diabetes Self-Efficacy; QAD: Self-care activities with diabetes Questionnaire; PAID-5: Problem Areas in Diabetes Scale.

2.4. Instruments used and clinical parameters of evaluation

The initial and final evaluation consisted of laboratory tests and questionnaires to measure self-care and self-efficacy. The initial assessment was performed at baseline, following the consent of the participant. The final evaluation was performed three months after the conclusion of the meetings between the participant and clinical pharmacist. Four collection instruments and clinical parameters were used, as described below:

- ***Pharmaceutical Care Questionnaire:*** an individual questionnaire which led the pharmacotherapeutic interventions, divided into six parts. The first part conducted the initial evaluation and addressed the information on socioeconomic and demographic characteristics; self-reported access to health services; clinical conditions; and medication use. The other parts concerned the three meetings with the patient, a session with the intention of clinical discussion among pharmacists for PPT classification, and the final evaluation.
- ***Insulin Management Diabetes Self-Efficacy*** – **IMDSES:** a validated instrument which assesses the patient's self-efficacy relative to DM and contains three subscales (diet, general

management, and insulin). Self-efficacy reflects the belief of the individual on their performance capability in specific activities. The IMDSES scale contains 20 questions with answer options in Likert scale format of four points. The interpretation of the scale is made from the average of the scores computed for each subscale. The subscale "Diet" can range from 0 to 24 points, "General Management" can range from 0 to 15 points and "Insulin" 0–21 points, with higher values related to greater self-efficacy. For patients who were not using insulin, only the diet components and general management were assessed [24.].

- **Self-care activities with diabetes Questionnaire (QAD):** contains six dimensions and 15 items of self-care assessment with DM. It includes variables related to adherence to medication use, diet, physical activity, glycemic monitoring, and foot care. The questionnaire evaluates the frequency with which patients performed the activities or behaviors during the past seven days and the answers can be given as zero to seven days, zero being the least desirable situation and seven to best adherence, except for the dimension of diet, in which the questions related to the consumption of sweet and fatty foods [25].
- ***Problem Areas in Diabetes Scale* (PAID-5)**: a scale that allows the rapid detection of anxiety in patients with DM. Each of the five answer choice items has the Likert scale five point format. The total score in PAID-5 can range from 0 to 20, with higher scores suggesting greater emotional distress related to DM. In this study the cutoff point for the emotional suffering used a score ≥9, which was more accurate for measuring emotional distress related to DM [26,27].
- **Clinical and Laboratory Parameters:** Before and three months after the intervention, patients had the following parameters evaluated: blood pressure, body mass index, and laboratory exams: HbA1C, fasting glycemia, total cholesterol and fractions (LDL - low density lipoprotein and HDL - high-density lipoprotein), triglycerides, creatinine, urinalysis, microalbumin from a single urine sample, and glomerular filtration rate (GFR) using the equation proposed by the Chronic Kidney Disease Epidemiology Collaboration group (CKD-EPI) [28]. All laboratory exams were performed by a private laboratory hired for the research.

2.5. Statistical analysis

For the analysis of the baseline, a descriptive analysis of the data by frequency distribution and central tendency measures was carried out. For comparison analysis before and after the intervention, the paired *T test* for normal distribution data and the Wilcoxon test for data with asymmetric distribution, were used. All analysis were carried out considering the significance level of 5%. Analyses were performed by the STATA - *Data Analysis and Statistical Software*® version 12.0® program.

This study was approved by the Ethics Committee for Research Involving Human Beings of the Federal University of São João del Rei on July 29, 2014- Approval Protocol: 731,321. All participants signed the Free and Informed Consent (FIC).

3. Results

3.1. Characteristics of the study population

A total of 352 patients registered in the Hiperdia and followed in five health units were identified and selected for the study. Of these, 62 patients were included in the intervention. During follow-up there was a 24% loss with 47 patients completing the strategy (Fig. 2).

The characteristics of the 62 participants interviewed are shown in Table 1. The mean age was 53.2 years (±11.3) and the most frequent age range was 40–59 years (61.3%). Regarding education, 8.1% have never attended school and 46.9% attended from 1st to 4th grade (1st fundamental cycle).

Regarding diseases and clinical conditions self-reported by patients, hypertension (56.5%) and dyslipidemia (56.5%) were the most prevalent chronic conditions among participants, and 23 patients (37.1%) presented the two comorbidities. The DM diagnostic time ranged from one to 31 years, with an average of nine years, and 40.3% of patients were diagnosed in the 41–50 years age group. A total of 342 medications were identified (Average: 5.5 medications; SD ± 2.7) for 62 patients with 60 different drugs.

Of the 62 patients who started the strategy, only 75.8% (n = 47) completed all the steps, resulting in a loss of 24.2% (n = 15) of the

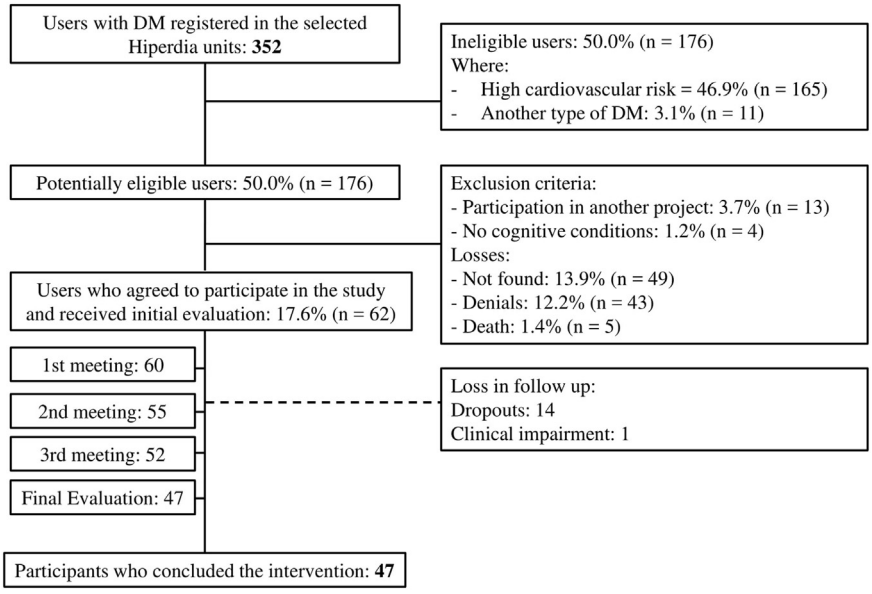

Fig. 2. Recruitment flowchart and follow-up strategy.
DM: Diabetes Mellitus.

Table 1
Socio-demographic characteristics of the participants of the Individual Strategy for Pharmacotherapy Empowerment of patients with T2DM in Divinópolis-MG, Brazil, 2015 (n = 62).

Variable	n	%
Sex		
Male	14	22.6
Female	48	77.4
Age Group		
Less than 40 years	7	11.3
From 40 to 59 years	38	61.3
60 years or more	17	27.4
Marital Status		
Married/Stable Relationship	44	71.0
Single/Widowed/Separated	18	29.0
Education		
Never attended school	5	8.1
1st cycle of elementary school incomplete	29	46.9
2nd cycle of elementary school incomplete	11	17.7
Elementary school completed	9	14.5
High school completed	8	12.9
Skin colour or self reported race		
Black	9	14.5
Mixed race	23	37.1
White	25	40.3
Oriental	2	3.2
Do not know	3	4.8
Per capita income		
Less than one minimum salary	51	82.3
From one to two minimum salaries	9	41.5
More than two minimum salaries	2	3.2

initial sample. Dropout patients were considered as those who requested their withdrawal from the study, those who were unable to attend the meetings for personal reasons, or those who did not respond to at least three contact attempts. When comparing the sociodemographic characteristics between the 47 finishers with the 15 lost, there were no significant differences for any of the baseline characteristics ($p > 0.05$).

3.2. Changes in clinical parameters after intervention

Table 2 shows the clinical parameters before and after completing the strategy for the 47 patients. Laboratory parameters of total cholesterol, fasting glycemia, HbA1C, serum creatinine and glomerular filtration rate showed significant improvement after the intervention ($p < 0.05$). It is also observed that the systolic and diastolic blood pressure values were significantly reduced before and after the intervention, as well as the average waist circumference in women ($p < 0.05$).

3.3. Changes in psychosocial parameters and self-care after surgery

Changes in outcome measures related to self-efficacy, emotional distress, adherence to medication use and self-care are presented in Table 3. The components: diet, physical activity, foot care, and medication use showed significant differences after the intervention ($p < 0.01$), indicating higher self-efficacy at the end of the study.

In the PAID-5 questionnaire before and after intervention it was observed that the scores ranged from 0 to 20, and in the interview 29.8% (n = 14) of patients had a score of PAID-5 ≥ 9, which indicates high emotional distress related to DM. In the final evaluation this ratio decreased to 17.2% (n = 8). The median of the interview scores was 4.0 (IQR: 1.0–10.5) and final evaluation 2.0 (IQR: 1.0–6.5), with a significant difference before and after ($p < 0.01$).

3.4. Pharmacotherapeutic problems

The number of pharmacotherpeutic related problems (PPTs) at baseline was 69, and the most prevalent were related to pharmacological treatment (69.6%). The average PPT per patient was 1.47 at baseline, and 80.9% (n = 38) of patients had at least one PPT. By the end of the intervention, 60.9% (n = 42) PPTs were resolved, being 50.0% (n = 35) related to adherence, 5.8% (n = 4) related to effectiveness (low dose), 1.3% (n = 1) security - adverse drug reaction and 2.9% (n = 2) security - very high dosage.

4. Discussion

This “before and after” study type assessed an intervention strategy to increase the empowerment of patients with DM, presenting positive results with significant improvement in laboratory parameters (total cholesterol, fasting glycemia, HbA1C, creatinine and GFR), blood pressure and self-efficacy scores, emotional distress, self-care and adherence to medication use.

Our study population (n = 62) had as predominant characteristics: females, aged 40–59 years, with low education and low income. Of the patients who initiated this study, only 47 completed the intervention, featuring a loss of 24.0%. By comparing the sociodemographic and clinical variables of the baseline between the patients who completed and those who were lost it is suggested

Table 2
Comparison of laboratory parameters before and after the follow-up Strategy for Pharmacotherapy Empowerment of patients with T2DM in Divinópolis-MG, Brazil, 2015 (n = 47).

Clinical Parameter	Before	After	p value
HDL Men	45.2 (5.3)	43.3 (4.3)	0.9266[a]
HDL Women	45.2 (4.3)	44.7 (4.4)	0.6808[a]
LDL	93.8 (32.2)	86.9 (27.1)	0.0565[a]
Total Cholesterol	168.0 (146.0–205.0)	161.0 (141.5–181.5)	**0.0051**[b]
Triglycerides	167.0 (102.0–207.0)	134.0 (111.0–201.5)	0.0845[b]
Fasting gylcemia	133.0 (111.0–196.0)	107.0 (98.5–147.0)	**0.0001**[b]
HbA1C	7.0 (6.4–8.2)	6.6 (6.1–7.4)	**0.0212**[b]
Serum creatinine	0.8 (0.8–1.0)	0.8 (0.7–0.8)	**0.0007**[b]
Microalbumin	4.8 (2.9–12.8)	5.0 (3.0–8.0)	0.1735[b]
GFR	81.5 (16.7)	87.8 (17.5)	**0.0026**[a]
Systolic Pressure (mmHg)	130.0 (120.0–142.0)	120.0 (110.0–130.0)	**0.0007**[b]
Diastolic Pressure (mmHg)	82.0 (78.0–90.0)	80.0 (70.0–84.4)	**0.0139**[b]
Body Mass Index (kg/m2)	28.8 (25.4–33.1)	28.8 (25.0–32.6)	0.0914[b]
Waist Circumference Men (cm)	101.1 (14.4)	100.3 (15.2)	0.3376[a]
Waist Circumference Women (cm)	100.2 (10.9)	98.6 (11.7)	**0.0407**[a]

HbA1C: Glycated Hemoglobin; GFR: glomerular filtration rate HDL: high density lipoprotein; LDL: low-density lipoprotein.
[a] Parametric data expressed as mean (standard deviation) and statistical analyzes performed by the paired *t*-test.
[b] Nonparametric data presented in median (Interquartile Range-IQR: 25–75%) and statistical analyzes by the Wilcoxon Signed Rank Sum test. [bold]: statistically significant.

Table 3
Comparison of the scores obtained in the IMDSES (diet, general management and insulin), QAD and PAID-5 questionnaires before and after following the Pharmacotherapy Empowerment Strategy in Divinópolis-MG, Brazil, 2015 (n = 47).

Score	Before	Crombach α	After	*p* value
Self efficacy				
Diet (0–24)	9.0 (5.0–12.5)	0.7727	19.0 (16.0–20.0)	**0.0000**[a]
General Management (0–15)	10.0 (8.0–12.0)	0.5151	13.0 (11.0–14.0)	1.0000[a]
Insulin (0–21)	5.14 (3.18)	0.9824	6.0 (2.2)	0.2555[b]
Distress				
PAID-5 (0–20)	4.0 (1.0–10.5)	0.8473	2.0 (1.0–6.5)	**0.0065**[a]
Self Care				
General Diet		0.6982		
Following a healthy diet	0.0 (0.0–5.0)		7.0 (3.5–7.0)	0.3274[a]
Following diet guidance from a health professional	5.0 (0.5–7.0)		6.0 (3.0–7.0)	**0.0001**[a]
Specific Diet		0.2995		
Eating five or more portions of fruits and vegetables	3.0 (0.0–5.0)		3.0 (0.5–6.0)	0.7748[a]
Eating diet rich in fat	7.0 (4.0–7.0)		2.0 (1.0–5.0)	**0.0000**[a]
Eating sweets	1.0 (0.5–2.5)		0.0 (0.0–1.0)	**0.0006**[a]
Physical activity		0.8612		
Performing physical activity for at least 30 min.	0.0 (0.0–3.0)		2.0 (0.0–5.0)	**0.0301**[a]
Performing specific physical activity	0.0 (0.0–2.5)		2.0 (0.0–3.0)	0.1526[a]
Monitoring Glycemia		0.9616		
Evaluating blood sugar	0.0 (0.0–4.0)		0.0 (0.0–1.0)	0.4660[a]
Evaluation of conforming to recommended blood sugar	0.0 (0.0–2.0)		0.0 (0.0–1.0)	1.0000[a]
Care with feet		0.4547		
Examining feet	7.0 (0.0–7.0)		7.0 (7.0–7.0)	**0.0002**[a]
Examining inside shoes	5.0 (0.0–7.0)		7.0 (7.0–7.0)	**0.0005**[a]
Dry space between toes	7.0 (7.0–7.0)		7.0 (7.0–7.0)	0.0952[a]
Medication		0.9626		
Taking medication	7.0 (5.0–7.0)		7.0 (7.0–7.0)	**0.0003**[a]
Taking the indicated number of tablets	7.0 (5.0–7.0)		7.0 (7.0–7.0)	0.0622[a]

[a] Nonparametric data presented in median (Interquartile Range- IQR: 25–75%) and statistical analyzes by the Wilcoxon Signed Rank Sum test.
[b] Parametric data presented in mean (Standard Deviation-DP) and statistical analyzes performed by the paired *t*-test. [bold: statistically significant.

that none of the evaluated variables are related to following or not the empowerment strategy.

The patients in the present study had glycemic control as recommended in the literature at baseline (median of HbA1c: 7.0%), and after the intervention the HbA1c reduced to an optimal level (median 6.6%) [3]. Several studies have investigated the impact of strategies for empowerment in reducing HbA1C [11,29–31]. In a meta-analysis conducted in 2017 on strengthening DM, seven studies with individual short-term strategies (up to 6 months) were included, the mean reduction in HbA1c level was 0.13% with no statistical significance [13]. The optimal reduction of HbA1c values may be related to the strategy developed, which associated empowerment and pharmaceutical care. Furthermore, the glycemic control of patients at baseline may indicate that they are more likely to take care of their health. According to a study conducted by the UK Prospective Diabetes Study (UKPDS) Group, a sustained 1.0% reduction in HbA1C is associated with a significant reduction of complications related to DM, leading to a decrease of 37.0% in the occurrence of microvascular disease and a reduction of 14.0% in myocardial infarction [32]. Thus, interventions that lead to a reduction in HbA1c may contribute to the prevention of chronic complications in patients with T2DM.

In addition to improvements in HbA1C values in this study, significant improvements in fasting glycemia ($p = 0.0001$), total cholesterol ($p = 0.0051$), serum creatinine ($p = 0.0007$) and systolic ($p = 0.0007$) and diastolic ($p = 0.0139$) blood pressure after the intervention were observed. Other studies based on strategies for empowerment were also able to induce changes in these parameters [33]. Tang and colleagues (2010), in an intervention using weekly group sessions for empowerment of patients with T2DM, achieved a significant improvement in blood pressure, total cholesterol and LDL [34]. The improvements in metabolic control indicators may be related to the adoption of self-care practices, improvement in eating habits, better adherence to medication use, pharmaceutical intervention, and frequent contact with the clinical pharmacist.

Approaches to empowerment in patients with DM have proven effective in solving problems and improving psychosocial needs [35]. Emotional distress related to DM evaluated in this study by the PAID-5 showed a significant reduction in scores after intervention, indicating less emotional distress related to DM. Corroborating the results obtained in this study, another research found an average reduction of 2.94 points ($p = 0.04$) in long-term scores using the same questionnaire [36]. Psychosocial improvements obtained in this study reflect the healthy confrontation of DM, an important strategy for self-care focused on meetings.

This intervention also had a positive impact on the diet component, assessed by the IMDSES questionnaire. Peña-Purcell, Boggess and Jimenes (2011) found significant improvements in components related to diet, physical activity and glycemia monitoring [29]. Thus, the results point to evidence that the strategy for empowerment leads to positive results in self-care, reflecting in clinical benefits. In addition, patients with a higher level of self-efficacy are more motivated to assume behavior in accordance with their knowledge.

In this strategy, 69 PPTs were identified at baseline, the majority (69.6%) related to adherence. By the end of the strategy 60.9% of PPTs were resolved, and in interventions involving the doctor 35.0% were resolved. In a study conducted by Borges et al. (2010), 54.2% of PPTs identified at baseline were related to adherence, 62.7% of PPTs were resolved at the end of the intervention and 73.0% of presented interventions were accepted by the doctor [15]. The number of resolved interventions involving physicians in this study was lower than that described in the literature, but this can be explained by a short-term study that may not be sufficient to perform the intervention or evaluation of the proposed intervention.

This study has some limitations. The first refers to the recruitment of patients registered in the Hiperdia, which may have favored the selection of patients with better metabolic control. Another point to consider is the sample size. Despite efforts in the

search for DM patients in health units of the city, some difficulties were encountered by the researchers, such as occurrence of other studies with patients with DM and loss of follow-up. Another limitation is that the reduction in average HbA1C was lower than estimated, however, it is highlighted that patients already had an adequate initial HbA1C value (mean 7.0%), and even then significant improvements were obtained.

Lastly, the results of the study suggest that the strategy developed is effective in promoting the empowerment of patients with T2DM, improved glycemic control, self-efficacy, self-care and distress. The strategy for empowering patients with T2DM has improved the state of health of patients, and the pharmacist's role may be important to help patients to have dominion over their condition. The strategy for empowerment tested presented a viable alternative with easy application, low cost, using non-complex technologies, which can be adopted in any primary care service after training the team.

Conflicts of interest

None.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.dsx.2018.08.002.

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