

Pharmaceutical Care Practice and Consequences on Quality of Life and Satisfaction of Diabetic Patients: A Randomized Clinical Trial

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The pursuit of quality of life, which has become marked in recent years, has translated into important population health benefits. This study assessed the quality of life of patients with type 2 diabetes (T2DM) who received pharmaceutical care, and their satisfaction with the service provided in community pharmacies. This single blind, randomized controlled clinical trial included 100 patients. The intervention group (N=47) received pharmaceutical care by a clinical pharmacist and the control group (N=42) received standard care. The Quality of Life Diabetes Questionnaire (DQOL) was used to measure all participants' quality of life at study enrollment and six months later. Satisfaction of the participants in the intervention group was measured using a validated 14-items questionnaire. At the end of the study, participants in the intervention group had a statistically significant improvement in DQOL scores (-0.62×1.57 , $p < 0.001$) and were highly satisfied with the intervention (96% excellent satisfaction scores). Pharmaceutical care practice was associated with high satisfaction and increased quality of life scores in T2DM patients. These results underscore the important role of pharmacists to improve the health of diabetic patients.

Keywords: Pharmaceutical Services. Diabetes Mellitus. Type 2. Quality of Life. Patient Satisfaction.

INTRODUCTION

Pharmacists can influence the health of patients through specific practical activities known as pharmaceutical care. A pharmaceutical care program is "the responsible provision of drug therapy in order to obtain concrete results that improve the quality of life of patients" (Hepler, Strand, 1990). This definition suggests that pharmacists can contribute to therapeutic results by playing an active role in patient care, helping them

to control their disease and improve their quality of life (Spinewine, Fialova, Byrne, 2012).

The effects of this intervention are more evident in the treatment of chronic diseases such as type 2 diabetes mellitus (T2DM), a highly prevalent disorder with serious complications that can lead to biological, psychological, and social consequences (Saleem *et al.*, 2015). The treatment of T2DM generally involves the use of oral hypoglycemic agents, sometimes associated with insulin. Patients with T2DM can develop many complications, including microangiopathy, retinopathy, nephropathy, peripheral neuropathy, atherosclerosis, diabetic ketoacidosis, and nonketotic hyperosmolar coma (Fernandes, Damascena, Portela, 2019).

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In 2017, 12.5 million Brazilians received a diagnosis of diabetes. The prevalence of diabetes in the country is 8% in the 20-79 years age group, making it an important clinical and social problem (Malta *et al.*, 2019). A growing number of Brazilian diabetics present at pharmacies seeking information about their disease. Pharmacists can help with pharmacotherapy to minimize diabetic complications, and by referring patients to doctors when necessary.

Possible health improvements should be measured using suitable and sufficiently sensitive tools that can reflect changes in quality of life over time (Correr *et al.*, 2008). The importance of quality of life (QOL)-related health and its value as a health outcome has evolved over the last 20 years (Salazar-Ospina *et al.*, 2012). The health-disease process is influenced by external factors such as living, working, cultural, and environmental conditions, among others (Akranaviciute, Ruzeviciu, 2015).

The pursuit of quality of life has translated into important population health benefits. The assessment of QOL is critical to measure the effect of therapy. This is currently measured using structured instruments with validated psychometric properties (Dreischulte, Fernandez-Llimos, 2016). Another way of evaluating health interventions takes into account humanistic outcomes, such patient satisfaction. Satisfaction is a subjective parameter that reflects patient preferences and expectations with the care provided, especially in terms of technical and interpersonal aspects, thereby allowing the assessment of professional performance and health outcomes (Hamid *et al.*, 2015).

The positive influence of pharmaceutical care practices on the quality of life of Brazilian patients has been reported in a non-randomized trial (Correr *et al.* 2009) and in studies without control groups (Lyra Junior *et al.*, 2007; Guiar *et al.*, 2016). There is a need for randomized clinical trials to assess the quality of life and satisfaction of Brazilian patients who receive pharmaceutical care (Carina *et al.*, 2010).

The objectives of our study were to assess changes in the quality of life of patients with T2DM who received pharmaceutical care and their satisfaction with the service provided in community pharmacies.

MATERIAL AND METHODS

Ethical Aspects

The study was approved by the Research Ethics Committee of Paraíba State University-Brazil (n° 0166.0.133.000-08) and was registered in the Clinical Trials.gov platform (NCT01580904). We obtained written informed consent from all participants upon enrollment. We followed CONSORT reporting recommendationS.+

Study Setting, Design, Recruitment and Randomization

This single blind randomized controlled clinical trial involved patients with T2DM managed in two community pharmacies in João Pessoa-PB, Brazil. The study was conducted with the support of municipal and federal health authorities. The two pharmacies had the necessary infrastructure to conduct the study, including an exclusive pharmacy room for patients. Participants were randomized into two groups. All participants received monthly treatments, totaling six sessions for each patient. In the intervention group, the pharmacist conducted a pharmacotherapy follow-up based on the Pharmacotherapy Workup adopted by the Minnesota Pharmaceutical Care Project (Cipolle, Strand, Morley, 2004). The control group received standard treatment, with no additional service besides the delivery of the drugs.

Patients were recruited at pharmacies, when they were purchasing their diabetes medications, over a one-year period. They were selected randomly and by spontaneous demand.

A table of random numbers was used to randomize the participants (Callegari, Silva, 2003). All patients recruited in the pharmacies were referred to a single central laboratory for routine exams. The results of these exams were given to the researchers and, based on their laboratory registration numbers, each patient was allocated a constant number in the random table in a continuous sequence. We determined, a priori, that the persons with even numbers in this table would be allocated to the intervention group, and those with odd numbers would be allocated to the control group. Both

pharmacies included patients in the intervention and the control groups. Patients were blinded as to which group they belonged to, from the onset until the end of the study. It was not possible to blind the pharmacists because they provided the pharmaceutical care to the patients.

At the end of one year, 100 patients were recruited. 52 were randomized to the intervention group and 48 to the control group.

Inclusion and Exclusion Criteria

The study inclusion criteria were: age > 30 years, T2DM, and use of oral hypoglycemic agents with or without insulin. We excluded participants who developed infectious or contagious diseases during the study, those who missed three consecutive visits, and those who stopped using hypoglycemic medication as mandated by a physician.

Study Protocol

Intervention Group

On the first session, the pharmacist collected personal information, clinical history, and life habits of each patient. Participants were instructed to bring the medications that they were currently taking at each of the subsequent visits. At the end of the visit, the patient received a card with the date of the next meeting.

In each of the successive sessions, the pharmacist analyzed the clinical history and drug use of each patient to identify any medication-related problems (MRP). In case the patient had a MRP, the pharmacist tried to solve it and prevent other potential MRPs using the pharmacotherapy workup methodology (Cipolle, Strand, 2004).

Pharmacist interventions consisted of MRP resolution, pharmaceutical advice, and educational measures. To resolve MRPs, the pharmacist changed medication times, encouraged patients to adhere to drug treatment, and resolved possible adverse reactions. In cases of problems involving the prescriber, the pharmacist wrote a letter to the physician, to be

delivered by the patient at his/her next meeting with the doctor. Several patients were referred to the Family Health Strategy program to schedule an appointment with an endocrinologist through a community health worker or nurse.

On the fifth and sixth sessions, the pharmacist prepared a health care plan for each patient with information on recommended practices and medication use. This plan was discussed with the patient. After the patient agreed with the plan, it was registered and documented in each individual patient record.

Educational measures included recommendations about lifestyle changes, healthy eating, and physical activity. The pharmacist also handed out pamphlets on diabetes, heart health, a food guide for diabetics, and appropriate use of medications.

Control Group

Participants in the control group only received pamphlets, in addition to their prescribed medication.

Quality of Life

The primary outcome 'quality of life' was measured by the Brazilian Portuguese version of the Diabetes Quality of Life Measure (DQOL) (Correr *et al.*, 2008). This instrument has 44 multiple-choice questions, divided into four domains: satisfaction (15 questions), impact (18), social/vocational concern (7), and diabetes-related concerns (4). A 5-point Likert scale is used to measure the degree of satisfaction (1 - excellent satisfaction, 2 - very satisfied, 3 - moderately satisfied, 4 - slightly satisfied, 5 - not satisfied), or the frequency of the other domain questions (1 - never, 2 - hardly ever, 3 - sometimes, 4 - frequently, 5 - always).

Participants in both groups filled the DQOL-Brazil questionnaire on their first and on their last (6-month) visit. The questionnaire was self-completed by most participants. A structured interview was used for patients with limited reading or writing skills. The pharmacists were trained to remain neutral during the completion of the questionnaires, only encouraging patients to answer every question.

Patient Satisfaction Measurement

We used the Portuguese version of a structured questionnaire to assess the satisfaction of participants in the intervention group (Larson, Rover, MacKeigan, 2002, Lyra Junior *et al.*, 2005). The questionnaire has 14 questions divided in four dimensions: quality of advice, humanistic treatment by the pharmacist, professional competence, and pharmacotherapy management. A final question assesses the overall satisfaction with the care received. Each question has five alternatives (5 = always, 4 = almost always, 3 = sometimes, 2 = hardly ever, 1= never).

The questionnaire was completed by intervention group participants on their last visit, without the presence of the research pharmacist. Another pharmacist, not involved in the study, talked with patients who had reading or writing difficulties, and then left them to complete the questionnaire.

At this stage, appropriate participation by the interviewer was important to minimize interference in study results. For ethical reasons, responses remained confidential and questionnaires were kept anonymous until the end of the study, when data were analyzed.

Statistical Analyses

The R system, version 2.14, was used for statistical analyses. We used Chi square statistics to compare proportions and Student's t-test for independent populations. We present 95% confidence intervals (CI) for proportions and standard deviations for means. P-value < 0.05 was considered significant.

RESULTS

The study recruited 100 patients; 52 were randomized to the intervention group and 48 to the control group. We included in the analyses 89 patients: 47 in the intervention group and 42 in the control group. Five patients randomized to the intervention group did not complete the study: two moved to another neighborhood, one withdrew because his professional activities did not allow him to come to all sessions, one had a heart attack, and one died. Five participants in the control group did not complete the study: three moved and two withdrew because professional activities did not allow them to come to all sessions. One additional patient in the control group was excluded by the researchers because he stopped using oral hypoglycemic medication following his physician's orders. **Figure 1.**

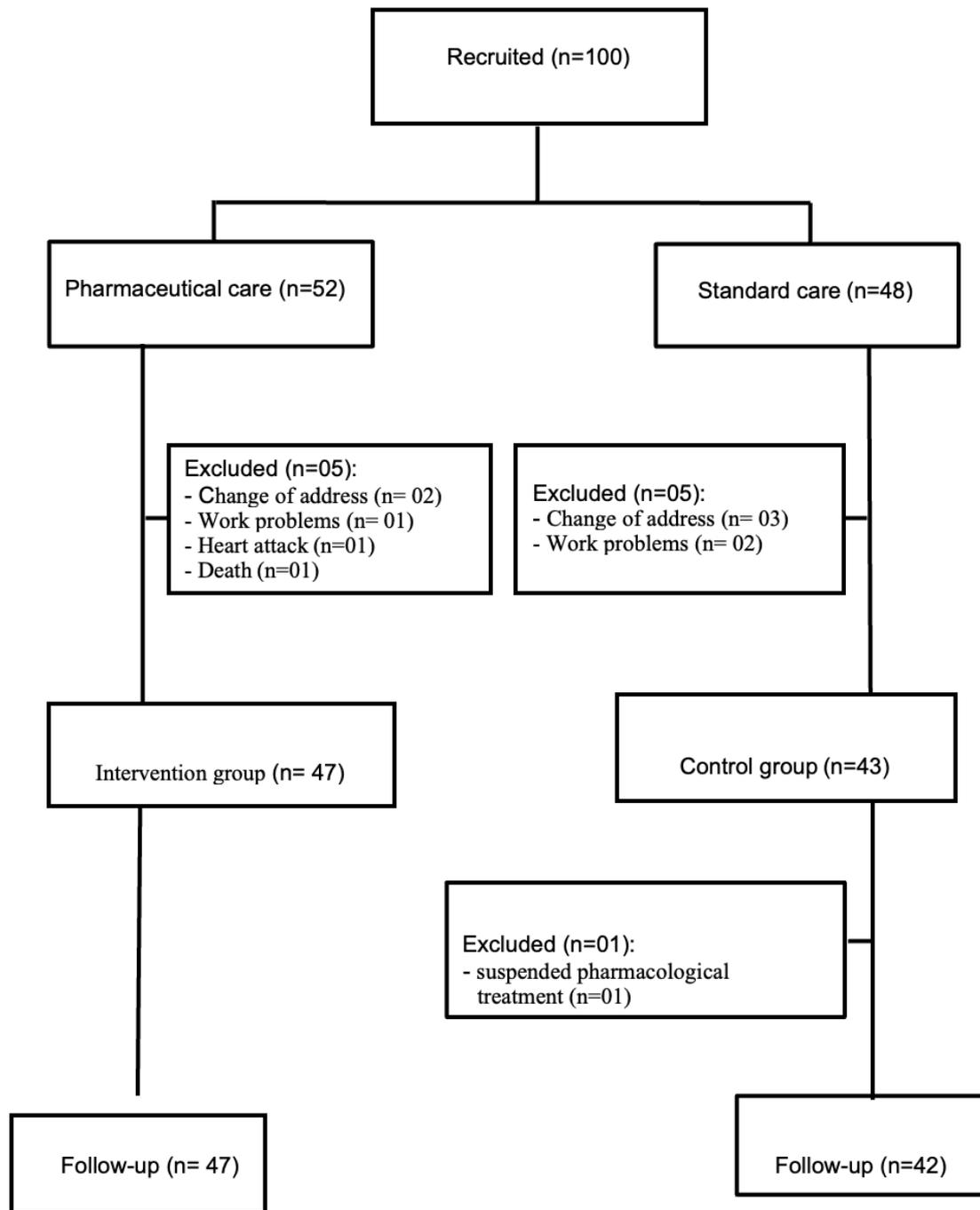


FIGURE 1 - The CONSORT diagram with the allocation and follow-up of patients, Paraíba - Brasil

A total of 562 meetings were held between the pharmacists and the patients (292 in the intervention group and 270 in the control group). Table I presents the

main demographic and clinical characteristics of the participants.

TABLE I - Values of the variacles at the start of follw-up

Variable	Intervention Group (N=47)	Control Group (N=42)	P - Value	
Male	20 (42.5%)	20 (47.6%)	0.632	
Age (years)	56.9 (10.0)	59.6(9.0)	0.184	
Time since last medical consultation (months)	4.4 (3.7)	5.7 (4.1)	0.116	
Diabetes duration (years)	6.6 (6.8)	7.2 (6.6)	0.692	
Family history of diabetes	Yes	38(80.9%)	38(90.5%)	0.199
	No	9(19.1%)	4(9.5%)	0.199
Access to health service	Public	31(66.0%)	25(59.5%)	0.531
	Private	11(23.4%)	5(11.9%)	0.158
	Both	5(10.6%)	12(28.6%)	0.032
Schooling	3(6.4%)	5(11.9%)	0.363	
Incomplete elementary	12(25.5)	14(33.3%)	0.419	
Complete elementary	2(4.3%)	3(7.2%)	0.555	
Complete secondary	23(48.9%)	12 (28.6%)	0.050	
Complete university	7(14.9%)	8(19.0%)	0.601	
Income (number of minimum monthly wages)	4.1 (4.6)	3.7 (3.2)	0.621	

Data are means ± standard deviation (SD) or numbers and percentages

In the intervention group, we conducted and documented 158 pharmaceutical interventions, with a mean of 3.4 interventions per patient. Fifty consisted of referrals to a doctor, with a problem resolution rate of 84% (42/50), and 108 interventions were resolved directly with the patient. In 27 of these, the goal was to improve medication adherence, with a 70% acceptance rate (19/28); in 81, lifestyle changes were implemented with a 79% improvement (64/81).

Some health problems were detected in the patients' initial laboratory exams. To resolve these, the pharmacists

conducted pharmaceutical orientation procedures and educational measures, such as encouraging physical activity, healthy eating, and discontinuation of tobacco and alcohol. At the end, 79% (64/81) of these cases were resolved, as confirmed by subsequent exams.

Quality of Life

Table II presents the DQOL-Brazil domain scores at baseline and after 6 months, in the intervention and control groups.

TABLE II - Changes observed in the quality of life indices of patients in the intervention and control groups after 6 months of study (n=89)

Outcome	Intervention Group (n=47)		Control Group (n=42)		p (baseline)	p (change)
	Baseline*	Changes after 6 months**	Baseline*	Changes after 6 months**		
General DQOL	2.26 (0.48)	-0.62 (-0.75 to -0.49)	2.28 (0.45)	1.57 (1.43 to 1.71)	0.865	0.000
Satisfaction domain	2.7 (0.6)	-0.88 (-1.05 to -0.71)	2.61 (0.7)	1.33 (1.11 to 1.55)	0.563	0.000
Impact domain	2.22 (0.6)	-0.54 (-0.7 to 0.38)	2.29 (0.46)	2.02 (1.87 to 2.16)	0.576	0.000
Social and vocational concerns domain	1.46 (0.64)	-0.28 (-0.47 to 0.08)	1.47 (0.56)	0.75 (0.49 to 1.01)	0.937	0.020
Diabetes- related concerns domain	2.19 (0.88)	-0.65 (-0.92 to 0.38)	2.38 (0.84)	1.89 (1.60 to 2.17)	0.315	0.000

*Baseline scores presented as means (standard deviations).

**Change in scores presented as mean difference (6 months – baseline scores) and 95% CI

At baseline, there were no significant differences between groups in mean total DQOL scores (2.26 vs 2.28, $p=0.865$) nor in individual domain scores (Table II)

At the end of the study, there was a significant increase in the quality of life, assessed by the DQOL tool, in the intervention compared to the control group: total score change (-0.62 vs 1.57 $p<0.001$), satisfaction (-0.88 vs 1.33 $p<0.001$), impact (-0.54 vs 2.02 $p<0.001$), social/vocational concerns (-0.28 vs 0.75 $p=0.020$) and diabetes concerns (-0.65 vs 1.89 $p<0.001$). See Table II.

Patient satisfaction

On their last visit, the 47 patients in the intervention group completed the satisfaction questionnaire. Scores were high for the pharmacists and for the care provided (Table III). Over 90% of the participants gave the highest possible score ('Always') to nine of the 14 questions (1, 2, 3, 4, 6, 8, 9, 12, 14) where this was the best ratings. Over 84% of the participants gave the highest possible score ('Never') to the five questions (5, 7, 10, 11, 13) where this was the best rating.

TABLE III - Assessment of Patient Satisfaction

ITEMS	FREQUENCY	F (%)	F(%)	F (%)	F (%)
	(%) Never	Hardly Ever	Some times	Almost always	Always
1. Does the pharmacist stay with you as long as necessary?	-	-	0.5%	0.5%	99%
2. Does the pharmacist explain the possible side effects that new medication could cause?	-	-	-	-	100%
3. If you have any doubts regarding the prescription, is there always a pharmacist available to help you?	1.5%	-	-	3.5%	95%
4. Does the pharmacist know how to explain things in a clear way?	-	-	2%	-	98%
5. Is the pharmacist not as detailed as he/she could be?	96%	-	2%	-	2%
6. Does the pharmacist make sure you understood how to take the medication?	-	-	-	-	100%
7. Does the pharmacist sometimes not stay with you long enough?	89%	-	4.5%	-	6.5%
8. Is the pharmacist friendly with you?	-	-	-	-	100%
9. Is the pharmacist a competent professional?	-	-	-	-	100%
10. Do you have to wait long before seeing the pharmacist?	85%	4.5%	6.5%	2%	2%
11. 11. Is the pharmacist difficult to understand?	89%		7%	2%	2%
12. Is the pharmacist sincerely interested in you as a person?	-	-	-	-	100%
13. Are there many distractions (in the Pharmaceutical Care room) that prevent you from receiving good care?	94%	2%	-	2%	2%
14. Are you satisfied with the care provided by the pharmacist?	-	-	-	-	100%

Larson *et al.* (2002) adapted to Portuguese by Lyra Jr. *et al.* (2005)

DISCUSSION

Pharmaceutical care improved the quality of life of T2DM patients at the end of six months, and the vast majority was satisfied with the service provided. These results suggest that this intervention can have a positive impact on the life of T2DM patients.

At six months, participants in the intervention group had significantly higher quality of life scores (overall and in individual domains) than those in the control group, as seen in other studies (Silva *et al.*, 2017, Viswanathan *et al.*, 2015). Our results differ from those of Hajj, SHammad, Afifi, (2014), who did not report significant improvements in social/vocation or diabetes-

related concerns. As reported by Melchioris et al (212), a program of pharmaceutical care practices developed by pharmacists at community pharmacies can improve the quality of life of patients. We found no significant changes in quality of life scores in our control group participants.

We assessed patients' satisfaction with the pharmaceutical care provided using a questionnaire with several dimensions. The participants attributed excellent scores to the service and the pharmacist domains. Our results were better than patient satisfaction with traditional dispensing practices (Lima *et al.*, 2015), and equivalent to the findings reported by similar studies that used the same type of assessment tool (Lyra Junior *et al.*, 2005).

In the quality of advice domain (Table III), most patients reported that the research pharmacists satisfactorily explained the correct use of medications. This could be due to our use of visual, auditory, verbal and written communication strategies and skills (Radovanovic *et al.*, 2016). This was confirmed by spontaneous participant comments to the research pharmacist such as "Just by coming here, I felt better after our conversation" (APS, 61-year-old woman). Her husband who came to pick her up said: "Did you ask everything you wanted to know, so you won't forget?" and the patient replied "Yes, about simvastatin and AAS. Now I know". Another 55-year-old man (LVT) said: "I didn't get the flu vaccine because I thought that diabetics couldn't. But now I will have the vaccine". A 67-year-old man (JES) said: "I used to keep my medications in the refrigerator. But after your advice, I don't anymore". However, five (11%) participants had difficulties understanding the pharmacists (question 11). This may have been due to the low educational level and cognitive (visual or auditory) impairments of some participants.

The quality of advice is often not material, but rather sensitive and perceptive. Satisfaction is a combination of values that interact, where personal care supersedes any other type of care provided in the orientation process. Discussions should include not only health issues but also their interaction with the "real world" of family, work, leisure, and other activities (Moon *et al.*, 2016).

The mean time spent on meetings with the pharmacist was 41 (\pm 3) minutes, which was considered

sufficient by the patients (question 1 and 10). All five individuals (11%) who answered that time was insufficient (question 7) had personal and family problems and were referred to a psychologist: "Doctor, I don't need a doctor; I need a priest" (UFC, 57-year-old man).

In the healthcare context, the commitment of both parties and the use of communication and humanization resources mediate the process that leads to the construction of therapeutic relationships, co-responsibility for health and in obtaining positive results (Zhang, 2012). As our participants stated "My diabetes is only under control when I'm here with you" (AJL, 68-year-old man) and "Now, after participating in this study, I understand the importance of pharmacists" (VPM, 66-year-old woman). Building good therapeutic relationships is important for successful pharmaceutical care.

Scores in the professional competence and pharmacotherapy management domains (questions 2 and 9) were excellent. Pharmacists correctly explained the possible side effects that new medication could entail. However, two (4%) participants answered that the professional was not clear enough (question 5), which may have compromised understanding the safe and rational use of medication.

The availability of an exclusive room for pharmaceutical care in the community pharmacies was an important point for patient follow-up visits. On this issue, 3 (6%) participants reported that there were distractions in the room that hindered good understanding, confidentiality, and privacy (question 13). For example, a 59-year-old woman (MFLC) came to the pharmacy with her son and preferred to talk about her family history rather than her diabetes. In this environment, patients received the necessary information: "You explain the exams better; the doctor doesn't explain anything, he says everything is fine" (MGGP, 60-year-old woman). Another 65-year-old patient (SG) arrived feeling unwell and the pharmacist discovered that she was taking the wrong drug (hydrochlorothiazide instead of digoxin), which had been erroneously sold to her; the problem was solved. Pharmaceutical care is important in preventing medication errors, as well as in promoting humanized and social activities, fulfilling its role and collaborating with other health professionals (Carter, 2016).

All 47 participants (100%) answered that they were completely satisfied, with the overall care provided by the research pharmacist (question 14). On their last visit, several participants made spontaneous comments about their satisfaction: “We won’t see each other again. My wife died and I am managing to survive. I will manage to live without your care. But please don’t change your cell phone number.” (ATS, 76-year-old man); “I want to pay for the treatment. How much do I owe you?” (JMS, 58-year-old man). Our results indicate that this follow-up model was effective, that it was associated with a high degree of patient satisfaction, and that it produced a significant improvement in the quality of life of the participants.

LIMITATIONS

Our study had several limitations, starting with its sample size. Although statistically grounded, our sample size of 100 patients is small when compared with other studies that enrolled thousands of participants. However, our results show what can occur with diabetics who are accompanied by pharmacists. Another possible study limitation is that each pharmacy included participants from both groups. This could have led to an exchange of information between the participants of each group because the pharmacist interviewed sequentially patients in the intervention and in the control groups. However, we think that this did not produce significant effects because each patient was treated according to a specific standardized protocol that was different for each group.

CONCLUSIONS

The provision of pharmaceutical care by pharmacists at community pharmacies improved the quality of life of T2DM patients and was associated with a high degree of patient satisfaction. These results should encourage other pharmacists to carry out pharmaceutical care with their patients because this important practice can help to promote and restore health. However, to put this practice into place, it is necessary to overcome challenges, barriers, and difficulties. This model can also be used

in other settings such as family health programs and outpatient clinics in hospitals.

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