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Review Article

Pharmacist-Led Interventions for Type 2 Diabetes Mellitus : A Systematic Review

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ABSTRACT

Background: Pharmacists can also contribute positively to diabetes management. The aim of this study to explore pharmacist interventions in the management of T2DM.

Methods: Article review was search of Pubmed, Embase and Science Direct during the period 2009-2019. A Combination of keys terms such as "pharmacists", "intervention", "type 2 diabetes mellitus" was used for the search. Trials were included if they were published in the English, evaluated any form of pharmacist interventions in the management of T2DM.

Results: There were 9 articles included and the studies evaluated the impact of several pharmacist interventions carried out in various countries and in community pharmacies. Pharmacist-led interventions had a positive effect on A1c with the difference in change between groups ranging from -0.3% to -1.0%; blood glucose (-1.43 mg/dL to -44 mg/dL); SBP (+0.6 mmHg to -23 mmHg); DBP (+1.3 mmHg to -22.3 mmHg); LDL (+0.18 mg/dL to -17.5 mg/dL); HDL (+0.31 mg/dL to +6.4 mg/dL); total cholesterol (+0,49 mg/dL to -7,5 mg/dL); triglycerides (-0.3 mg/dL to -28.3 mg/dL). A beneficial effect on BMI was also described in the intervention group. Pharmacist interventions had a positive impact on medication adherence and HRQoL in most studies.

Conclusion: Pharmacist interventions can have a positive influence on metabolic control, medication adherence and HRQoL of patients with T2DM.

Keywords: pharmacist, intervention, management, T2DM

INTRODUCTION

Type 2 diabetes mellitus (T2DM) is reaching epidemic proportions as its prevalence increases at an alarming rate in developed and developing countries (International Diabetes Federation, 2015). T2DM is chronic disease, if left uncontrolled, may cause microvascular and macrovascular complications in the long term, which are the main causes of increased morbidity and mortality and decreased high-related quality of life among patients (Stratton et al., 2000; Wu et al., 2014; Huang et al., 2007; Solli et al., 2010; Wexler et al., 2006).

Strict glycemic control with pharmacological agents, dietary modifications and physical activity could save healthcare costs by preventing the onset or progression of diabetes-related neuropathies and nephropathies (United Kingdom Prospective Diabetes Study, 1998; Shichiri et al., 2000; Lerman, 2005). Lack of adherence to treatment and other recommendations might explain these findings, given that more 50% of chronically treated patients do not follow the recommended lifestyle changes or do not take the prescribed pharmacotherapy (Debussche, X., 2014). The factors that contribute to low levels of adherence include complex treatments regimens, medication side effects, poor patient-provider communication, patient financial resources and beliefs, phychiatric disorders, and memory

impairment (Nam et al., 2011; Vermeire et al., 2001).

In order to address the current challenges of achieving therapeutic goals among the diabetes population, new models of health care delivery should be developed and implemented. Because of their expertise in pharmacotherapy and their accessibility in the community, pharmacists are able to build strong relationships with patients and become a reliable source of information. Thus, pharmacists are in an ideal position to provide patient education and monitor and promote adherence to self-care and therapeutic regimens, which have a positive impact on achieving therapeutic outcomes in diabetes (American College of Clinical Pharmacy et al., 2012; Nichols-English et al., 2002). In addition, because of their extended scientific and technical knowledge, pharmacists are especially alerted to certain aspects, such as the occurrence of adverse drug reactions and interactions, and specific features associated with aging and comorbidities.

The management of diabetes requires close collaboration between patient and a multidisciplinary health care team, in which pharmacists may also take a part by providing pharmaceutical care programs (Pousinho et al., 2016). In this context, pharmacists can also contribute positively to diabetes management by providing pharmaceutical care programs, which involve working closely with the patient and other health care professionals in designing, implementing, and monitoring therapeutic plans to achieve specific outcomes that will improve patient quality of life (Hepler & Strand, 1990). Because of the ongoing relationships with other health care professionals, pharmacists can also serve as a "bridge" between the patients and these health care professionals, thereby ensuring continuity of care, which is essential in the management of chronic diseases such as diabetes (Pousinho et al., 2016). The aim of this study to explore pharmacist intervention in the management of type 2 diabetes mellitus.

METHODS

Studi identification

Publish articles written in the English language between 2009-2019 were identified using the Embase, Pubmed and Science Direct databases. The search terms used included pharmacists AND intervention or methods AND Type 2 Diabetes Mellitus. Evidence of research rigour was crucial to the inclusion or exclusion of studies, shown in Table 1.

Table 1: Inclusion and exclusion criteria

Inclusion Criteria	Exclusion Criteria
Published in the English language	Not available in full-text
Time frame year from 2009-2019	Did not mention the disease
Report pharmacist interventions in the management of T2DM	Not type 2 diabetes specific population Study protocol Conference abstracts Pharmacist as part of healthcare team Pharmacist in hospitals

Search strategy and extraction

Two investigators independently reviewed potentially relevant publications and abstracted necessary data. Non-agreement on the extracted data was resolved by discussion among the authors. Quality of studies were assessed by reviewers follow GRADE working group (GRADE Working Group, 2004). The search result showed a total 112 articles were initially retrieved and after further review only 9 studies were studies include. 103 articles could not be used because of the full text was inaccessible, did not mention the disease, not type 2 diabetes specific population, study protocol, conference abstracts, pharmacist as part of the healthcare team and pharmacist in hospitals. Full details of the search are presented in Figure 1.

RESULTS

Study selection

The initial literature review yielded 132 potential literature citations (Figure 1). Two independent reviewers assessed 112 full-text articles for eligibility. Articles were excluded because they were not available in full-text (n = 24), did not mention the disease (n = 3), not type 2 diabetes specific population (n = 1), study protocol (n = 8), conference abstracts (n = 27), pharmacist as part of healthcare team (n = 14) and pharmacist in hospitals (n = 26). In total, 9 studies met inclusion criteria and were included in this systematic review.

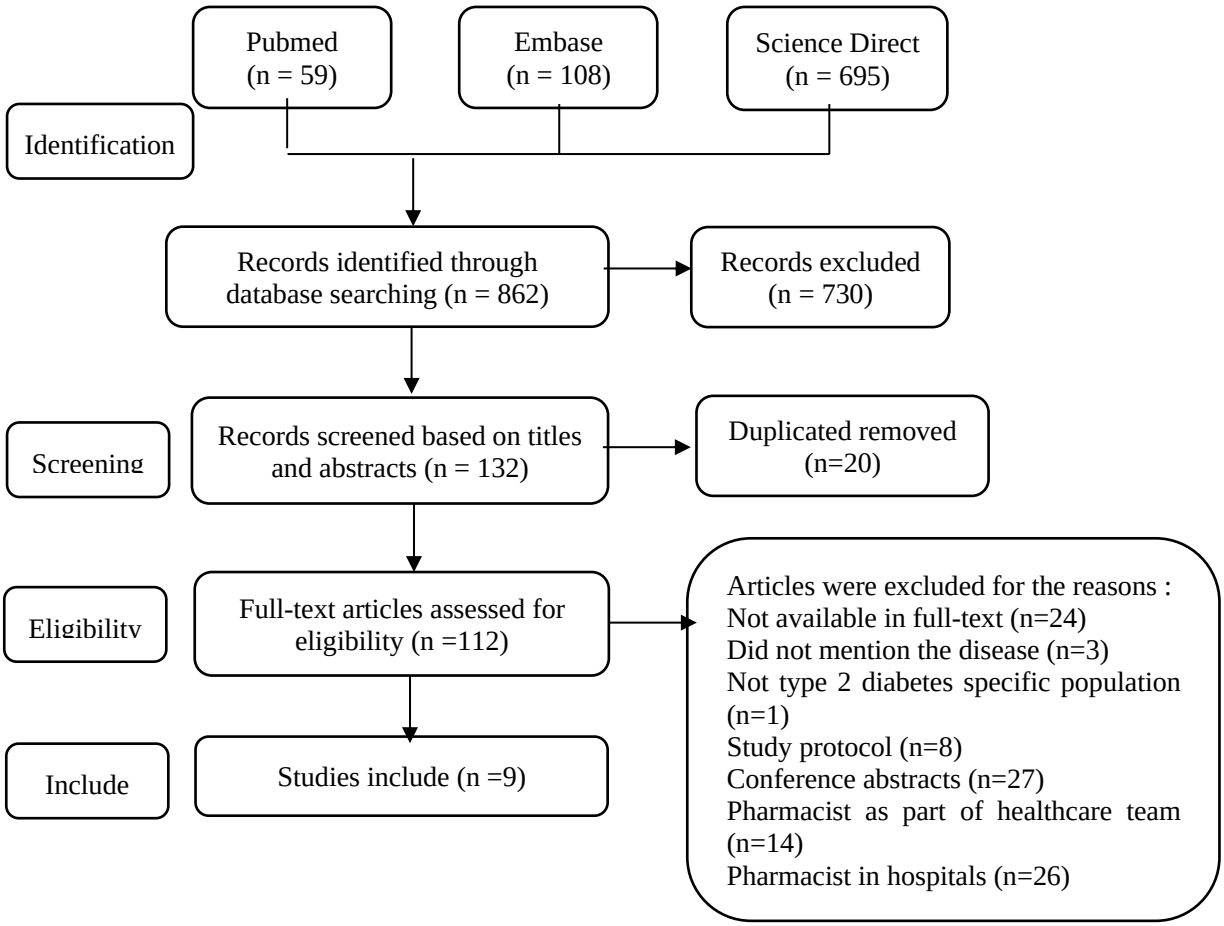

Fig.1: Flowchart of study selection process

Study characteristics

Among the included studies, almost trials in which the participating pharmacies were randomly assigned to either the intervention group or the control group. Two studies were conducted in USA (Castejon et al., 2013; Odegard et al., 2012), 2 in Iran (Jahangard-Rafsanjani et al., 2015; Sarayani et al., 2018), UK (Ali et al., 2012; Lyons et al., 2016), 1 in Denmark (Kjeldsen et al., 2015), Belgium (Mehuys et al., 2011), and France (Michiels et al., 2019). The settings in which studies took place in community pharmacies. Pharmacist interventions varied across the included studies and encompassed 1 or more of the following: counseling and education on diabetes, medication, lifestyle modification, and self-monitoring; reinforcement of medication adherence or complications screening; provision of materials such as educational leaflets, brochure, booklet and pill boxes; medication review; identification and resolution of drug-related problems; discussions with the primary care provider regarding pharmacotherapy; adjustment of pharmacotherapy; and referrals to other health care professionals. One studies mentioned motivational interviews as a technique used to deliver advice to patients (Lyons et al., 2016). In most studies, the control group received usual care from medical and nursing staff and/or community pharmacists, depending on the study setting. Globally, the included studies involved 2051 participants. The duration of follow-up ranged from 3 to 21 months. A detailed description of the characteristics of included studies is presented in Table 2.

Table 2: Characteristics of included studies

Author,Year	Country	Follow up Duration	Number of Respondent	Pharmacist Intervention	Control	Outcome Measures
Ali et al., 2012	UK	12 months	46	Pharmaceutical care for patients with T2DM, regular monitoring and consultations	Usual Care	A1c, FBG, BMI, BP, LDL, HDL, TC, TG, HRQoL, diabetes knowledge, diabetes treatment satisfaction, beliefs about medicines, others
Castejon et al., 2013	Florida	3 months	43	The Pharmacist-centered Assessment and Reinforcement of Diabetes Self-efficacy (PARDS) including medication, nutrition, exercise, self-care	Usual Care	A1c, BG, BP, TC, TG, LDL, HDL, BMI
Jahangard-Rafsanjani et al., 2015	Iran	5 months	101	Diabetes education program: treatment adherence, diet management, physical activity, and diabetes complications, therapy-related problems, blood glucose self-monitoring	Usual Care	A1C, BP, BMI, self-care activities, medication adherence
Kjeldsen et al., 2015	Denmark	6 months	205	Educational materials and counseling	Usual Care	BP, medication adherence, self-management, knowledge, self-efficacy, HRQoL, perceived competence for diabetes scale
Lyons et al., 2016	UK	21 months	677	Medicines advice service intervention focused on lipid-lowering and antidiabetic medications	Usual Care	A1c, medication adherence

Mehuys et al., 2011	Belgium	6 months	288	Educational material : T2DM, complications; oral hypoglycaemic agents (timing in relation to food); medication adherence; healthy lifestyle education (diet, physical exercise and smoking cessation); reminders about annual eye and foot examinations	Usual Care	A1c, FPG, medication adherence, diabetes knowledge, self-management
Michiels et al., 2019	France	12 months	377	Educational materials : diabetes diet, medication management, diabetes complications, dispensed the medication boxes prescribed for a 1-month period	Usual Care	A1c, LDL, BP, medication adherence, self-manage, diabetes knowledge
Odegard et al., 2012	USA	12 months	208	Educational materials and counseling about the medication adherence program (MAP)	Usual Care	medication adherence, self-management
Sarayani et al., 2018	Iran	9 months	106	Education material : diabetes, diabetes management, self-care (diet, exercise, blood sugar monitoring, foot examination, smoking), drug therapy, training blood glucose self-monitoring devices	Usual Care	A1c, LDL, HDL, TG, TC, medication adherence, self-care practise

Study outcomes

A1c. A1c was considered as an primary outcome measure in 5 studies (Table 3). A1 mean decreased in the intervention group during the follow-up period in all studies. The difference in A1c change from baseline to final follow-up between the intervention group and the control group range from -0.3% to -1.0% (Ali et al., 2012; Castejon et al., 2013; Jahangard-Rafsanjani et al., 2015; Mehuys et al., 2011; Michiels et al., 2019).

Blood glucose. Regarding blood glucose, 3 studies reported this parameter as an outcome measure (Table 3). In all studies, there was a decrease in blood glucose (fasting or random blood glucose) in the intervention group from baseline to final follow-up. Nevertheless, the difference in change ranged from -1.43 to -44 mg/dL between the intervention group and the control group (Ali et al., 2012; Castejon et al., 2013; Mehuys et al., 2011).

Blood pressure. Five studies evaluated the change in systolic blood pressure during the course of the study (Table 3). Two of them described a reduction in mean systolic blood pressure in the intervention group from baseline to final follow-up (Ali et al., 2012; Kjeldsen et al., 2015) and 3 studies observed a increased in mean systolic blood pressure in the intervention group from baseline to final follow-up (Castejon

et al., 2013; Jahangard-Rafsanjani et al., 2015; Michiels et al., 2019). For systolic blood pressure, the difference in change between the groups ranged from +0.6 mmHg to -23 mmHg. As for diastolic blood pressure, 4 studies reported data on this outcome (Table 3). Two of them described a reduction in mean diastolic blood pressure in the intervention group from baseline to final follow-up (Ali et al., 2012; Castejon et al., 2013) and 2 studies observed a increased in mean diastolic blood pressure in the intervention group from baseline to final follow-up (Jahangard-Rafsanjani et al., 2015; Michiels et al., 2019). The difference in change between the 2 groups ranged from +1.3 mmHg to -22.3 mmHg.

Table 3: Studies with results for A1c, blood glucose and blood pressure

Author, Year	A1c (%)		Blood Glucose (mg/dL)/(mmol/L)		Blood Pressure (mmHg)		
	Change from Baseline to Final Follow-up	Difference in Change Between Groups	Change from Baseline to Final Follow-up	Difference in Change Between Groups	Change from Baseline to Final Follow-up		Difference in Change Between Groups
Ali et al., 2012	IG : 8.2 – 6.6 CG : 8.1 – 7.5	-1.0	Fasting blood glucose IG : 8.80 – 6.88 CG : 9.53 – 9.04	-1.43	SBP	IG : 146 – 126 CG : 136 – 139	-23
					DBP	IG : 87 – 81 CG : 86 – 82	-2
Castejon et al., 2013	IG : 8.3 – 7.3 CG : 8.2 – 8.0	-0.8	Random blood glucose IG : 190 – 165 CG : 183 – 202	-44	SBP	IG : 129 – 126 CG : 131 – 126	2
					DBP	IG : 82.2 – 9.8 CG : 81.8 – 0.1	-22.3
Jahangard-Rafsanjani et al., 2015	IG : 7.6 – 6.6 CG : 7.5 – 7.0	-0.5	NR	-	SBP	IG : 132.0 – 32.8 CG : 136.4 – 34.2	3
					DBP	IG : 81.7 – 82.2 CG : 83.3 – 82.0	1.8
Kjeldsen et al., 2015	NR	-	NR	-	SBP	IG: 138 – 31.3	-5.3

						CG: 139 – 37.6	
Mehuys et al., 2011	IG : 7.7 – 7.3 CG : 7.7 – 7.6	-0.3	Fasting blood glucose IG: 154.1 – 138.8 CG : 153.9 – 45.8	-7.2	NR		-
Michiels et al., 2019	IG : 7.9 – 7.3 CG : 7.7 – 7.6	-0.5	NR	-	SBP	IG : 134.4 – 134.9 CG: 137.0 – 136.9	0.6
					DBP	IG : 78.5 – 79.8 CG : 79.9 – 79.9	1.3

Negative values indicate indicate IG had greater decrease; positive values indicate CG had greater decrease. A1c = glycosylated hemoglobin; IG = intervention group; CG = control group; SBP = systolic blood pressure; DBP = diastolic blood pressure; NR = not reported.

Lipid profile. Four studies described LDL cholesterol as an outcome measure (Table 4). Two studies described an decreased in the intervention group from baseline to final follow-up (Castejon et al., 2013; Sarayani et al., 2018). Nevertheless, the difference in change between both of groups range from +0.18 mg/dL to -17.5 mg/dL. Regarding HDL cholesterol, 3 studies reported data on this outcome (Table 4). All studies described an increase in the intervention group from baseline to final follow-up (Ali et al, 2012; Castejon et al, 2013; Sarayani et al, 2018). The difference in change between the 2 groups ranged from +0.31 mg/dL to +6.4 mg/dL. Among the 3 studies that reported total cholesterol as an outcome measure (Table 4). Two studies described an decreased in the intervention group from baseline to final follow-up (Castejon et al, 2013; Sarayani et al, 2018). For this parameter, the difference in change between the groups ranged from +0.49 mg/dL to -7.5 mg/dL. Finally, 3 studies reported data on triglycerides (Table 4). All of them described a reduction in the intervention group from baseline to final follow-up (Ali et al, 2012; Castejon et al, 2013; Sarayani et al, 2018). The difference in change between both of groups range from -0.3 mg/dL to -28.3 mg/dL.

Body Mass Index (BMI). Four studies described BMI as an outcome measure (Table 4). Three studies, mean BMI decreased in the intervention group from baseline to final follow-up (Ali et al, 2012; Castejon et al, 2013; Jahangard-Rafsanjani et al, 2015). The difference in change between the 2 groups ranged from -0.5 kg/m^2 to -2.77 kg/m^2.

Table 4: Studies with results for lipid profile and body mass index

Author, Year	Lipid Profile (mg/dL)/(mmol/L)			Body Mass Index (kg/m^2)	
	Change from Baseline to Final Follow-up		Difference in Change Between Groups	Change from Baseline to Final Follow-up	Difference in Change Between Groups
Ali et al., 2012	LDL	IG : 2.35 – 1.97 CG :	0.18	IG : 30.84 – 26.98 CG : 29.82 –	-2.77

		1.81 – 1.25		28.73	
	HDL	IG : 1.10 – 1.46 CG : 1.20 – 1.25	0.31		
	TC	IG : 4.15 – 4.12 CG : 3.66 – 3.14	0.49		
	TG	IG : 1.35 – 1.52 CG : 1.44 – 1.78	-0.17		
Castejon et al., 2013	LDL	IG : 99.9 – 91.0 CG : 88.2 – 96.8	-17.5	IG : 31.2 – 30.5 CG : 31.5 – 31.9	-1.1
	HDL	IG : 34.8 – 37,3 CG : 37.1 – 38.3	1.3		
	TC	IG : 179 – 169 CG : 180 – 175	-5		
	TG	IG : 211 – 198 CG : 212.7 – 228	-28.3		
Jahangard-Rafsanjani et al., 2015	NR		-	IG : 29.3 – 29.1 CG : 29.4 – 29.7	-0.5
Michiels et al., 2019	LDL	IG : 110 – 110 CG : 120 – 110	10	NR	-
Sarayani et al., 2018	LDL	IG : 94.7 – 82.4 CG : 87.0 – 83.8	-9.1	IG : 29.2 – NR CG : 29.9 – NR	-
	HDL	IG : 41.5 – 49.7 CG : 44.5 – 46.3	6.4		
	TC	IG : 171.2 – 162.9 CG : 159.0 – 158.2	-7.5		
	TG	IG : 159.8 – 164.1 CG : 156.3 – 160.9	-0.3		

Negative values indicate indicate IG had greater decrease; positive values indicate CG had greater decrease. For HDL positive values indicate IG had greater increase, negative values indicate CG had greater increase. HDL = high-density lipoprotein cholesterol; LDL = low-density lipoprotein cholesterol; TC = total cholesterol; TG = triglycerides. NR = not reported.

Medication adherence. Medication adherence was evaluated in 4 studies (Table 5). The methods used to measure this outcome among participants varied between studies. Self-reported adherence was used as the only method in almost all studies, while 1 studied used prescription refill rate in combination with self-reported adherence (Mehuys et al, 2011).

One studied revealed an improvement in medication adherence in the intervention group from baseline to final follow-up (Sarayani et al., 2018).

Health-Related Quality of Life (HRQoL). Two studies considered HRQoL as an outcome measure (Table 5). Various tools were used to asses this outcome. All study used generic tools (e.g, the 36-Item Short Form Health Survey and the EuroQoL-Dimension questionaire). One studied reported an improvement in HRQoL in the intervention group from baseline to final follow-up, which was greater than that observed in the control group (Ali et al., 2012).

Table 5: Studies with results for medication adherence and health-related quality of life

Author, Year	Medication Adherence		Health-Related Quality of Life	
	Change from Baseline to Final Follow-up	Difference in Change Between Groups	Change from Baseline to Final Follow-up	Difference in Change Between Groups
Ali et al., 2012	NR	-	SF 36 total score IC : 65.61 – 79.09 CG : 70.04 – 66.53 DQoL IC : 29.81 – 23.48 CG : 30.52 – 27.87	16.99 -3.68
Jahangard-Rafsanjani et al., 2015	Low adherence IG : 51% – 24% CG : 46% – 49% High adherence IG : 49% – 76% CG : 54% - 51%	24 30	NR	-
Kjeldsen et al., 2015	Three self-reported adherence measures: Behavior-related nonadherence (nonintentional) IG : 68.3% - NR CG : 61.1% - NR Behavior-related nonadherence (intentional, self-regulation) IG : 22.5% - NR CG : 26.8% - NR Behavior-related non adherence (intentional, effect-related) IG : 19.5% - NR CG : 16.5% - NR	-	EQ-5D total score IG : 0.782 – 0.842 CG : 0.812 – 0.815	0.057
Mehuys et al., 2011	Prescription refill rate IG : 99.7% CG : 94.7%		NR	-

	Self-reported adherence IG : 59.9% - 61.9% CG : 64.2% - 61.1%	5.2		
Sarayani et al., 2018	Low adherence IC : 46% - 17.4% CG : 44% - 52.1% Medium adherence IG : 38% - 19.6% CG : 38% - 25% High adherence IG : 16% - 63% CG: 18% - 22.9%	-36.7 -5.4 42.1	NR	-

Negative values indicate IG had greater increase in medication adherence, positive values indicate CG had greater increase in medication adherence. Negative values indicate IG had greater increase in HRQoL, positive values indicate CG had greater increase in HRQoL. CG = control group; IG = intervention group; DQoL = diabetes quality of life; SF-36 = Short Form 36; EQ-5D = EuroQoL-5 dimension.

DISCUSSION

The review evaluating the effectiveness of pharmacist interventions in the management of patients with type 2 diabetes. Nine studies were conducted in various countries and took place in community pharmacies. Evidence from the included studies suggests that pharmacist interventions directed at patients with type 2 diabetes can have a positive impact on clinical outcomes, as demonstrated by the reduction in A1c, blood glucose, blood pressure, and Body Mass Index and by the improvement in the lipid profile observed in the intervention group during the follow-up period in almost all studies. When compared with the control group, the effect of pharmacist interventions on these outcomes was shown to be greater in the intervention group in most studies.

The failure results in this studies may be explained by several factors, such as small sample size, short follow-up duration, cross-contamination between patients in the intervention group and those in the control group, difference in the statistical tests used to perform the statistical analysis (paired-samples or independent-samples tests), and presence of a statistical difference between the baseline values of both study groups (Pousinho et al., 2016). Collins et al., (2011) showed that in 14 studies there was greater improvement in A1c in the intervention in change between groups ranged from -1,06 to -0,47 this range is almost identical to the range defined for A1c in the present review. Regarding blood pressure, the systematic review conducted by Santschi et al., (2012) revealed that in comparison with the control group, 7 out of 12 (58.3%) studies demonstrated a greater reduction in systolic blood pressure in the intervention group, and 3 out of 9 (33.3%) studies reported a greater decrease in diastolic blood pressure these proportions are also similar to those found in the present review. As for lipid profiles, Wubben et al., (2008) reported that most studies found decreases in LDL cholesterol and triglycerides, which is in accordance with what is reported in the present review.

These findings suggest that pharmacists, through their interventions, may play an essential role in enhancing adherence to prescribed medications among patients with type 2 diabetes, which, in turn, may have a beneficial effect on treatment outcomes. In fact, in some studies that evaluated this outcome, the increase in medication adherence observed in the intervention group during the follow-up period was accompanied by an improvement in other outcomes, such as A1c, blood pressure, and lipid profile. Medication adherence is a health issue that needs to be addressed. Medication adherence to therapy of chronic disease include type 2 diabetes is very useful to improve the quality of life of patients (Kristina & Wulandari, 2020). However, it should be borne in mind that the method most frequently used to measure this outcome (self-reported adherence) might overestimate adherence (Gonzalez et al., 2013; Osterberg et al., 2005). As for HRQoL, most of the included studies demonstrated an improvement in overall or subdomain scores among the patients of the intervention groups. The lack of significant improvements observed in some studies might be because there is no tool for measuring quality of life that is specifically designed for use in pharmaceutical care, and the existing tools might not have enough sensitivity to detect the subtle changes on HRQoL that may result from pharmaceutical care (Kheir et al., 2004).

CONCLUSION

T2DM is a chronic metabolic disease often associated with increasing levels of morbidity and mortality (Levitt, 2008). Full adherence to treatment recommendation, such as: pharmacological agents, dietary changes, physical activities, regular self monitoring blood glucose and medication adherence is essential in the achievement of sustainable metabolic control (Department of Health, 2002; American Diabetes Association, 2008). Our review provides evidence that pharmacist interventions can have a positive influence on metabolic control, medication adherence and HRQoL of patients with type 2 diabetes mellitus. These promising findings support the involvement of pharmacist as members of health care team in the management of patients with type 2 diabetes mellitus.

DECLARATION OF CONFLICTING INTERESTS

The authors declared that are no competing or potential conflicts of interest with respect to the research and publication of this article.

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