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Original Article

Effectiveness of family pharmacist intervention on drug use problems, quality of life and cardiovascular risk factors in patients with diabetic kidney disease at a primary care unit: A randomized controlled trial

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Abstract

Patients with diabetic kidney disease have high cardiovascular risk (CV risk). Many patients also have drug-related problems (DRP) leading to negative quality of life (QOL). Family pharmacist intervention (FPI) is a family medicine concept that emphasizes patient-centered care with effective communication. This study assessed the effectiveness of FPI compared with usual care (UC) on outcomes of drug use, QOL and CV risk factors. This randomized controlled trial was conducted with 48 patients in each group in a primary care unit. Results showed that 157 DRP were found in the FPI group (75.8% were resolved) with 43 in the UC group (41.9% were resolved). There were 84 incidents of drug-related suffering (DRS) and 34 drug system problems (DSP) in primary care in the FPI group. For QOL, the FPI group had significantly different utility scores than the UC group. Clinical outcomes, blood pressure and total cholesterol were significantly different between the two groups, while CV risk of the FPI group decreased. FPI proved to be effective for pharmacists to resolve problems with patients and multidisciplinary teams. FPI was also more effective than UC for patient QOL and some CV risk factors.

Keywords: family pharmacist intervention, cardiovascular risk, drug-related problems, drug-related suffering, primary care

1. Introduction

Diabetic kidney disease (DKD) is a complication in patients with long-term diabetes and its global incidence has increased (Hussaina *et al.*, 2021). DKD is the main cause of end-stage renal disease (ESRD), but the highest causes of mortality in DKD patients are cardiovascular (CV) events and CV death (Alicic, Rooney, & Tuttle, 2017; Selby & Taal, 2020). Therefore, reducing CV risk is one of the treatment aims for DKD patients (Selby & Taal, 2020). In the DKD treatment process, patients are prescribed many medications. Polypharmacy patients, meaning those following regular use of at least five medications, require special attention from multidisciplinary teams, especially pharmacists, because polypharmacy leads to drug-related problems and affects the quality of life (QOL) (Preetha, Manoj, Thomas, John, & Shabaraya, 2021).

In primary care units, multidisciplinary teams continuously treat patients with chronic diseases. The type of intervention depends on the context, for example, clinic-based intensive primary care, home-based models, and primary care augmentation (Edwards, 2017). Interventions in primary care have improved various outcomes without specific focus only on clinical outcomes, as mental health outcomes, QOL outcomes and medication use are also important concerns (Smith, Wallace, O'Dowd, & Fortin, 2016). The team composition for providing healthcare services differs by community. Pharmacists were among the professionals that collaborated with the team to provide effective medication management (Schepman, Hansen, De Putter, Batenburg, & De Bakker, 2015). The role of the pharmacist in improving outcomes in primary care has been shown in many studies but

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is highlighted in the clinical outcomes (AI Hamarneh *et al.*, 2018; Chiazor, Evans, Woerden, & Oparah, 2015).

Family pharmacist intervention (FPI) allows pharmacists to deal with patients with chronic diseases. FPI was developed from a family medicine concept that emphasized patient-centered care (PCC) (Thavorn wattanayong & Sribundit, 2017). The PCC concept is applied in many pharmacist interventions in various settings of primary care and community pharmacy (Williams, Walker, Smalls, Hill, & Egede, 2016; Reddy *et al.*, 2019). In FPI, pharmacists have found more drug-related problems (DRP) through effective communication within a private room in the primary care unit for 15 minutes. After identification, drug use problems were resolved using common ground between patients, pharmacists, and the team, based on reality (Naughton, 2018). In Thailand, an FPI study showed improved clinical outcomes in blood pressure control and glycemic control compared to the usual primary care (Thavornwattanayong & Sribundit, 2017). A study regarding humanistic outcomes including health QOL and drug use as a consequence of FPI is required. As well as achieving clinical outcomes, the goals of treating patients suffering from medicine or the prescribed treatment should also be assessed. This study investigated the effectiveness of FPI compared with usual care for drug use outcomes (DRP, DRS and DSP), health QOL (EQ-5D-5L) and clinical outcomes regarding CV risk factors.

2. Materials and Methods

2.1. Study design

This randomized controlled trial was conducted in a primary care unit from June 2019 to March 2020 by comparing patients who received FPI with patients who received usual care (UC). Based on a previous study (power of the study = 80%, significance = 5%) (AI Hamarneh *et al.*, 2018), sample size was selected as 48 patients for each group and it included DKD patients who were diagnosed by the internal medicine doctor, spoke Thai fluently for communication purposes and were willing to participate. Exclusion criteria were 1) patients who had estimated glomerulus filtration rate (eGFR) <30 ml/min/1.73 m^2; these patients were referred for treatment in the renal department at the hospital, 2) patients who had a previous diagnosis of cardiovascular disease and 3) patients who were bedridden. Stratified block randomization was used to sample the study participants. Patients were categorized into strata with four factors including the stage of chronic kidney disease (CKD) (stage 1, 2, 3a and 3b), gender (male and female), age (<60 and ≥60 years olds) and %Thai CV risk (<20% and ≥20%). The categorization gave 32 blocks of patients. We calculated the sample and population ratio in each block and randomly selected the patients for sampling. Then, we randomly divided the samples into two groups with a 1:1 ratio in each block giving an FPI group and a UC group. This study was approved by the Research Ethics Board of Angthong Province (project number ATGEC54-2562) and all patients provided signed consent to participate.

2.2. Interventions

2.2.1. Usual care (UC)

UC is the standard for DKD patients. The process of UC is as follows: 1) patient assessment and BP measurement, 2) laboratory assessment (3-6 months), 3) nurse screening, 4) patient-physician meetings, and 5) medicine dispensing by the pharmacist.

2.2.2. Family pharmacist intervention (FPI)

FPI was added to UC before patient-physician meetings. FPI was provided by a pharmacist trained in intensive FPI, and to reduce intervention bias this was not the same person as the dispensing pharmacist. FPI is a patient-centered care concept that involves understanding the whole person, exploring the disease and illness, finding common ground, incorporating prevention and promotion, enhancing the pharmacist-patient relationship and being realistic. FPI consists of two components namely effective communication and family medicine tools (IFFE technique: idea, feeling, function and expectation; BATHE technique: background, affect, trouble, handle and empathy) to explore DRP, DRS and DSP and find solutions to problems. Patients assigned to the FPI group received FPI once a month for 6 months from the same pharmacist. Each FPI lasted for 15-20 minutes before the patient-physician meeting process took place. All the FPI procedures were approved by a family physician, a nephrologist, and a nurse in the primary care unit.

2.3. Data collection

Data were collected from the hospital database, medical record profiles and by talking directly to the patients. The data comprised the four parts demographics, FPI counseling records (only FPI group), clinical data at baseline and 6 months, and drug use data of DRP for both groups; and DRS and DSP, especially in the FPI group.

Drug-related problems (DRP) were classified into seven types (Cipolle, Strand & Morley, 2012): 1) unnecessary drug therapy, 2) need additional therapy, 3) ineffective drug, 4) dosage is too low, 5) dosage is too high, 6) adverse drug reaction and 7) adherence problem.

DRS relates to patient discomfort from taking prescribed medicines. No previous studies have classified DRS. Drug-related suffering (DRS) was categorized into six types: 1) patient has lost some living capacity, 2) patient becomes stressed and anxious about drug use, 3) patient lacks confidence in using the medicine, 4) patient feels dependent on others, 5) medications affect relationships between family members and 6) medications make caregivers stressful or worried about taking care of the patient's medication.

Drug system problems (DSP) in primary care affect drug therapy including access to medicine, holistic care, continuity of care, community empowerment and coordination (Thavornwattanayong & Sribundit, 2017). DSP cases were classified into four types: 1) pharmaceutical management problems that affect the accessibility of medicines, for

example, problems with inventory management or logistic problems, 2) pharmaceutical service problems in primary care units caused by faulty service management systems, for example, medication error management, 3) problems related to continuous care for medicines in the community, for example, medication reconciliation processes with other health settings such as hospitals and pharmacies or public transport not conducive to a medical visit, and 4) problems with consumer protection and reasonable use of healthcare products, for example, problems with inappropriate drug use in the community, such as the use of traditional medicines and herbal medicines. All patients assessed their QOL using the Thai version of EQ-5D-5L (Euroqol approved our request in 2019) at the baseline. At 6 months, computer programs were used to calculate EQ-5D-5L scores, with results shown as utility scores (Pattanaphesaj, 2014).

2.4. Statistical analysis

Descriptive statistics were used to classify demographic data, DRP, DRS and DSP numbers. The Chi-square test or Fisher's exact test was used for nominal or ordinal variables, with the independent t-test or Mann-Whitney U test used to compare continuous variables between the FPI and UC groups at p-value <0.05. Differences within groups (pre and post intervention) were analyzed by paired t-test statistics or the Wilcoxon signed rank test at p-value < 0.05. All continuous variables were first tested for normality by the Shapiro-Wilk test.

3. Results and Discussion

3.1 Results

Demographic and clinical parameters are shown in Table 1. No differences were recorded between the two groups except for fasting blood sugar, which was higher in the FPI group. Number of drugs per patient did not differ between the groups but number of patients with drug change differed significantly. Table 2 shows drug use and prescribed drug change data.

Table 1. Demographic characteristics and baseline clinical data

Baseline data	FPI (n=48)	UC (n=48)	*p*-value
Age, years	66.0 [8.0]	65.5 [11.0]	0.936[1]
Female	32 (66.7%)	31 (64.6%)	0.830[2]
Smokers	3 (6.3%)	6 (12.5%)	0.486[3]
Duration of Diabetes, years	8.4±7.4	10.1±7.7	0.071[4]
History of CVD in family members	6 (12.5%)	5 (10.4%)	0.749[2]
Comorbidity			
Hypertension (HT)	45 (93.8%)	44 (91.7%)	1.000[3]
Dyslipidemia (DLP)	42 (87.5%)	42 (87.5%)	1.000[2]
HT and DLP	34 (70.8%)	39 (81.3%)	0.064[2]
Others	5 (10.5%)	6 (12.5%)	1.000[3]
Stage of chronic kidney disease (CKD)			
CKD stage 1	8 (16.7%)	6 (12.5%)	0.563[2]
CKD stage 2	20 (41.7%)	18 (37.5%)	0.529[2]
CKD stage 3a	14 (29.2%)	14 (29.2%)	0.824[2]
CKD stage 3b	6 (12.5%)	10 (20.8%)	0.273[2]
Estimates glomerular filtration rate (eGFR), ml/min/1.73m^2	66.3 [24.8]	59.7 [24.6]	0.204[1]
Systolic blood pressure, mmHg	135.0 [14.0]	134.0 [13.0]	0.668[1]
Diastolic blood pressure, mmHg	76.9±10.3	74.4±9.2	0.202[4]
Glycated hemoglobin (HbA1C), %	6.5 [1.6]	6.6 [1.6]	0.536[1]
Fasting blood sugar, mg/dl	142.0 [44.0]	125.0 [24.0]	0.002[1]
Total cholesterol, mg/dl	174.6±40.2	176.5±32.3	0.795[4]
Low-density lipoprotein (LDL), mg/dl	92.0 [43.0]	95.5 [34.0]	0.655[1]
High-density lipoprotein (HDL), mg/dl	43.0 [16.0]	47.0 [15.0]	0.116[1]
%Thai cardiovascular risk (%Thai CV risk)	21.9 [16.2]	20.2 [15.2]	0.535[1]

Footnote: Values for continuous variables are presented as mean ± standard deviation (normal distribution) or median [interquartile range] (non-normal distribution), values for categorical variables are given as frequency (percentage), statistical comparisons: [1]Mann-Whitney U test, [2]Chi-square test, [3]Fisher's exact test, and [4]independent t-test.

Table 2. Drug use and prescription changes

Drugs	FPI group (n=48)	UC group (n=48)	p-value
Number of drugs per patient			
At baseline	6 [3]	5 [3]	0.446[1]
Final intervention	6 [2]	5 [3]	0.500[1]
Patients with any drug change	35 (72.9%)	25 (52.1%)	0.035[2]
Patients with hypertension (HT) medications change			
Change type of HT drug	6 (12.5%)	1 (2.1%)	0.111[3]

Table 2. Continued.

Drugs	FPI group (n=48)	UC group (n=48)	p-value
Increase HT drug dose	6 (12.5%)	4 (8.3%)	0.504[2]
Decrease HT drug dose	9 (18.8%)	3 (6.3%)	0.064[2]
Patients with hypoglycemia medications change			
Change type of hypoglycemia drug	-	-	-
Increase hypoglycemia drug dose	9 (18.8%)	10 (20.8%)	0.798[2]
Decrease hypoglycemia drug dose	9 (18.8%)	11 (22.9%)	0.615[2]
Patients with dyslipidemia (DLP) medications change			
Change type of DLP drug	1 (2.1%)	1 (2.1%)	1.000[3]
Increase DLP drug dosing	3 (6.3%)	1 (2.1%)	0.617[3]
Decrease DLP drug dosing	2 (4.2%)	1 (2.1%)	1.000[3]

Footnote: Values for continuous variables were presented in median [interquartile range], values for categorical variables are given as frequency (percentage), p-value: [1] compared with Mann-Whitney U test, [2]Chi-square test, and [3]Fisher's exact test.

Drug use outcomes were resolved in 75.8% (157) of DRP cases in the FPI group, and 41.9% (43) in the UC group. Mean of DRP per patient in the FPI group was 3.3±1.9, while the UC group had 0.9±0.9 problems ($p<0.001$) (Table 3). The FPI group had 84 DRS cases with 65.5% mitigated. Types of DRS are shown in Table 4. “The patient gets stressed and anxious about drug use” was the most frequent type of DRS (50% of patients in the FPI group). Furthermore, 34 DSP were explored in the FPI group; 61.8% of the problems were mitigated while 58.9% related to continuous care for medicines in the community (Table 5). For health outcomes, QOL was interpreted as a utility score. No baseline differences were initially seen between the two groups but there were significant differences after the intervention (Table 6).

Clinical outcomes regarding CV risk factors after the final intervention, systolic blood pressure (SBP), diastolic blood pressure (DBP) and total cholesterol (TC) were significantly different between the groups. The FPI group had lower values than the UC group for CV risk factors, while other clinical outcomes: HbA1C, FBS, LDL, HDL and eGFR were not significantly different. Details are shown in Table 7. Percentage CV risk within the FPI group was significantly different from the baseline at 21.9% [IQR16.2] to 18.1% [IQR16.0] at 6 months ($p=0.002$), while the UC group was not different from the baseline. Clinical outcome results between the two groups and within each group are presented in Figure 1.

Table 3. Drug-related problems (DRPs) found in the FPI and the UC groups

Type of DRP	Number of DRP (% of DRPs found in each group)	
	FPI group	UC group
1. Unnecessary drug therapy	9 (5.7%)	4 (9.3%)
2. Need additional therapy	43 (27.4%)	17 (39.5%)
3. An ineffective drug	7 (4.5%)	3 (7.0%)
4. The dosage is too low	10 (6.4%)	3 (7.0%)
5. The dosage is too high	1 (0.6%)	2 (4.7%)
6. Adverse drug reaction	18 (11.5%)	6 (14.0%)
7. Adherence problems	69 (43.9%)	8 (18.6%)
Total DRP	157 (100.0%)	43 (100.0%)
Number of resolved DRP	119 (75.8%)	18 (41.9%)

Table 4. Types of drug-related suffering (DRS) found in the FPI group

Types of drug-related suffering (DRS)	Number of DRS (% of all DRS)
1. The patient has reduced living capacity.	29 (34.5%)
1.1 Suffering from side effects	9 (10.7%)
1.2 Administration of the drug is inconsistent with work or daily life	20 (23.8%)
2. The patient gets stressed and anxious about drug use.	42 (50.0%)
2.1 Stress or anxiety from past experiences	13 (15.5%)
2.2 Stress or anxiety caused by taking many pills per dose and worried about kidney failure, liver damage, or stomach perforation.	29 (34.5%)
3. The patient lacks confidence in using medicine and the feeling of self-esteem decreases from the use of medicine which could be a stigma.	0 (0.0%)
4. Patients felt that they were dependent on others.	5 (6.0%)
5. Medications affected relationships between family members.	7 (8.3%)
6. Caregivers were stressed or worried about taking care of the patient's medication.	1 (1.2%)
Total DRS	84 (100.0%)
Number of mitigated DRS	55 (65.5%)

Table 5. Types of drug system problems in a primary setting (DSP) found in the FPI group

Type of drug system problems (DSP)	Number of DSP (%)
1. Pharmaceutical management problems	1 (2.9%)
2. Pharmacy service problems	1 (2.9%)
3. Problems related to continuous care for medicines in the community	20 (58.9%)
3.1 Service providers' problems, for example, medication errors from the service system or medication reconciliation between hospitals.	11 (32.4%)
3.2 Patient problems, for example, traveling to the primary care unit was difficult because of the lack of public transportation.	9 (26.5%)
4. Problems concerning protection and reasonable use of healthcare products.	12 (35.3%)
Total DSP	34 (100.0%)
Number of mitigated DSP	61.8%

Table 6. Utility scores in the FPI and the UC groups at baseline and 6 months

Utility scores	Baseline	6 months	*p*-value (compared within the group)
The FPI group	0.868 [0.201]	0.952 [0.096]	<0.001[1]
The UC group	0.829 [0.164]	0.904 [0.118]	<0.001[1]
p-value (compared between groups)	0.226[2]	0.044[2]	

Footnote: Values presented in median [interquartile range], p-value: [1]compared with Wilcoxon signed ranks test, [2]compared with Mann-Whitney U test.

Table 7. Clinical outcomes in the FPI and the UC groups at 6 months

Clinical outcomes	FPI (n=48)	UC (n=48)	p-value
Systolic blood pressure, mmHg	125.2±10.4	134.3±11.1	<0.001[1]
Diastolic blood pressure, mmHg	67.2±10.8	71.8±10.2	0.035[1]
Glycated hemoglobin (HbA1C), %	7.5 [2.0]	7.7 [1.9]	0.326[2]
Fasting blood sugar, mg/dl	139.5 [41.0]	137.5 [28.0]	0.517[2]
Total cholesterol, mg/dl	164.0 [54.0]	188.5 [42.0]	0.030[2]
Low-density lipoprotein (LDL), mg/dl	89.5 [45.0]	104.0 [36.0]	0.053[2]
High-density lipoprotein (HDL), mg/dl	44.5 [13.0]	47.0 [12.0]	0.172[2]
Estimates glomerular filtration rate (eGFR), ml/min/1.73m^2	64.4±20.8	63.3±23.7	0.796[1]
%Thai cardiovascular risk (%Thai CV risk)	18.1 [16.0]	22.0 [18.6]	0.438[2]

Footnote: Values shown as mean ± standard deviation or median [interquartile range] and statistical comparisons: [1]independent t-test and [2]Mann-Whitney U test.

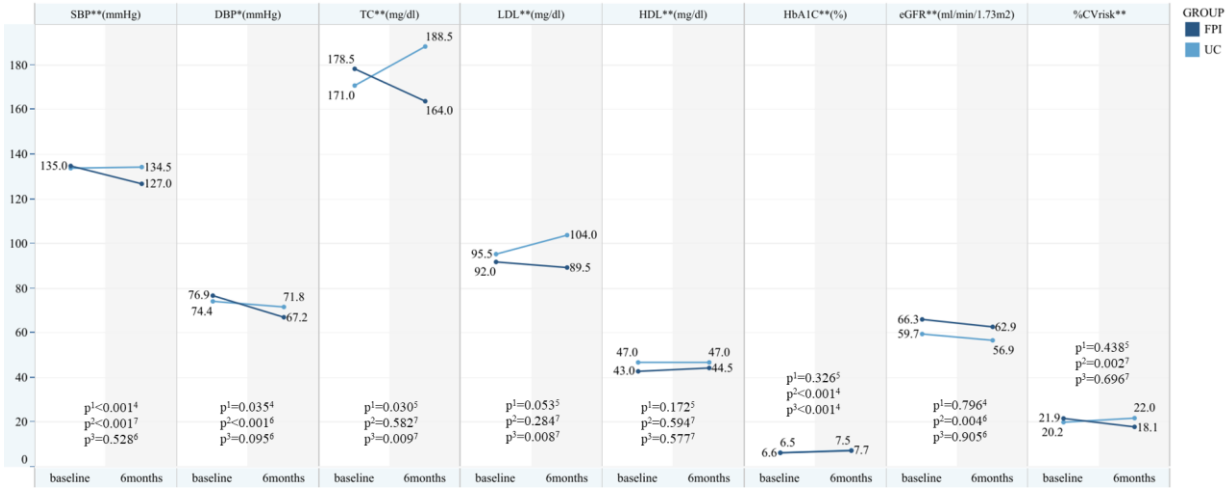

Figure 1. Clinical outcomes were compared for the FPI group and UC group at baseline and 6 months.
Footnote: *Values presented in mean and **Values presented in median, p-value; [1]compared between groups at 6 months, [2]compared within FPI group (baseline and at 6 months) and [3]compared within UC group (baseline and at 6 months), statistical comparison; [4]independent t-test, [5]Mann-Whitney U test, [6]Paired T-test, and [7]Wilcoxon Signed Ranks test.

3.2 Discussion

This is the first study to address the impacts of family pharmacist intervention (FPI) as a family medicine concept in pharmaceutical care compared with usual care in three aspects: 1) drug use outcomes: drug-related problems (DRP), drug-related suffering (DRS) and drug system problems (DSP), 2) quality of life (QOL) and 3) clinical outcomes as CV risk factors in patients with diabetic kidney disease.

FPI is different from pharmacist interventions that were previously conducted (AI Hamarneh *et al.*, 2018; Chiazor, Evans, Woerden, & Oparah, 2015). FPI enhances the relationship between the patient and the pharmacist and increases patient trust. Patients are more willing to share problems or their suffering regarding drug use with the pharmacist. A higher number of DRP was recorded in the FPI group but the percentage of resolved DRP was higher than in the UC group (75.8% in the FPI group and 41.9% in the UC group). Most DRP in the FPI group were related to adherence and differed from the UC group. Another study found that most patients with DRP needed additional therapy (Yimama, Jarso, & Desse, 2018).

FPI displayed information about DRS and DSP for the first time in this study. Half the members of the FPI group became stressed and anxious about drug use. For instance, taking many pills per dose made them worried about renal, liver or stomach side effects (34.5% of DRS) and they were also concerned about side effects from past experiences (15.5% of DRS) such as hypoglycemia from sulfonylureas. As a consequence, many patients preferred not to take medicine (non-adherence problem). By contrast, pharmacists using FPI were able to alleviate the suffering from drug use in 65.5% of all DRS cases. Most DSP concurred with a previous study in a primary care setting (Angkanavisul & Musikachai, 2019; Chalongsuk, Lochid-amnuay, Sribundit, & Tangtrakultham, 2015), with continuous care management in community problems consisting of a provider and patient issues. These data can be used to improve drug system control in primary care in the future.

Quality outcomes after 6 months showed that utility scores significantly increased in both groups, with the FPI group showing significantly higher utility scores than the UC group. Patients in the FPI group were more satisfied with their health, possibly because FPI was always administered by the same pharmacist. Previous patient-centered care study interventions found similar QOL results between the intervention group and the control group because they changed pharmacists for each visit (Abbott *et al.*, 2020, Salisbury *et al.*, 2018). Therefore, keeping the same pharmacist at every intervention is the key to increasing patient trust in FPI. When confiding in the same pharmacist, patients gave more information about their suffering or health problems and also found common ground to resolve problems (Patike *et al.*, 2019; Williams *et al.*, 2016).

In clinical outcomes, the FPI group showed decreased %Thai CV risk, while the UC group remained unchanged. This result concurred with a study on the effect of community pharmacist care (AI Hamarneh *et al.*, 2018). In our study, reducing CV risk in the FPI group may be mainly the result of reduction in SBP. The FPI group showed significantly lower SBP and DBP than the UC group at the final intervention. Blood pressure reduction in the FPI group was consistent with a previous study on the impact of FPI in primary care units for patients with uncontrolled BP and blood sugar levels (Thavornwattanayong & Sribundit, 2017). Furthermore, the effect of pharmaceutical care in primary care CKD patients or high CV risk patients was similar to our study (AI Hamarneh *et al.*, 2018; Chiazor, Evans, Woerden & Oparah, 2015). Lipid profile results showed that only total cholesterol (TC) of the FPI group was different from the UC group. In an intragroup comparison, TC and LDL were not different in the FPI group but significantly increased in the UC group. A previous study of pharmacist-centered processes with 3 years of follow-up demonstrated clinical outcomes with improvements in lipid levels after years 1 and 2. These results require further evaluation with longer follow-up studies (Berdine & Skomo, 2012).

Patients in the FPI group did not show lower glycated hemoglobin (HbA1C) because these patients experienced a long duration of diabetes and had renal complications similar to previous studies (Abbott, 2020; Fahs *et al.*, 2018). Six months may not be sufficient to cause changes in HbA1levels. The FPI group recorded greater reduction in FBS, probably because they better understood the importance of controlling their sugar levels and were in the process of finding solutions to drug use.

In the renal outcomes, estimated glomerulus filtration rate (eGFR) was not different between the two groups after 6 months. This outcome was different from previous multidisciplinary team intervention studies that showed slow progression of CKD (Al Raiisi *et al.*, 2019; Nicoll *et al.*, 2018). However, long-term renal outcomes should be studied because patients with DKD have multiple mechanisms contributing to decline of renal function, for instance, glomerular hemodynamics, inflammation, oxidative stress, and fibrosis. One limitation of this study was that hypotension drugs that preserve renal function such as angiotensin-converting enzyme inhibitors (ACEI) and angiotensin II receptor antagonists (ARB) were not controlled in the study (Pelle, 2022; Thomas *et al.*, 2015).

This study had non-independent selection due to the small number of samples. However, no statistical differences for important parameters were recorded at the baseline. Only one primary care unit setting was investigated but bias about the reception of the intervention was reduced by using a multidisciplinary team including a physician, nurses, and a dispensing pharmacist who remained in the same team for each week of the intervention and were blinded about the intervention groups, except for the pharmacist who provided FPI.

4. Conclusions

The advantages of FPI were highlighted regarding resolving DRP and clarifying and alleviating DRS and DSP. FPI is an excellent practice and appropriate to apply in pharmaceutical care services. The process of FPI should also be provided for patients collaborating with a multidisciplinary team, leading to a better quality of life and improved clinical outcomes.

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