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Original Research

Outcomes of pharmacist-led diabetes care intervention in Lao PDR: A randomized controlled trial

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Abstract

Background: Pharmaceutical care for diabetic patients has demonstrated benefits in many countries. Nevertheless, in Laos, diabetes care has been provided without pharmacists' involvement. This study aimed to evaluate the outcomes of pharmacist-led interventions in diabetes care in Laos. **Methods:** A single blinded randomized controlled trial with pre-test and post-test was designed. The study was undertaken in type 2 diabetes patients registered at a hospital from June 2019 to July 2020. Patients in the intervention group received pharmaceutical care in six months, while the control group received standard care. Primary outcomes were hemoglobin A1c (HbA1c) and fasting plasma glucose. Secondary outcomes included blood pressure, lipid profiles, renal function, 10-year risk, patient satisfaction, and quality of life. Intention-to-treat analysis was applied. **Results:** One hundred forty-four diabetes patients were recruited and randomly assigned to groups (73 intervention, 71 control); 121 included in the analysis (64 intervention, 57 control). Of the 67 pharmacist's interventions, adding statin/aspirin (doctor acceptance rate of 79.10%) was predominant. After six months, achievement of hemoglobin A1c and LDL goals showed improvement (OR 1.31, 95%CI .50- 3.43, p=.589; OR 1.35, 95%CI .61-3.01, p=.465), however, no statistically significant differences in clinical outcomes were found between groups. Compared to the pretest, the intervention group showed significant improvements in HbA1c, cholesterol, and low-density lipoprotein levels (p<.05). Nevertheless, the control group also showed significant improvement in HbA1c (p<.05). Patient satisfaction with pharmacists' competency was statistically significantly higher in the intervention group than the control group (p=.010). **Conclusion:** Pharmacist-led diabetes care could provide clinical benefits and improve patient satisfaction to pharmacists' competency. Although pharmacist's intervention did not yield statistically better clinical outcomes than usual care, there was a trend toward better HbA1c and cholesterol controls. Continuous pharmacists' contributions in diabetes care with advancing the collaborative protocol should be further supported. **Trial registration:** Thai Clinical Trials Registry: TCTR20200707003 on July 2, 2020—retrospectively registered, https://www.thaiclinicaltrials.org/show/TCTR20200707003.

Keywords: pharmacist, type 2 diabetes, pharmaceutical care, patient satisfaction, quality of life

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INTRODUCTION

Globally, more than one in 10 adults are now living with diabetes. The estimated prevalence of diabetes in adults aged 20-79 years has tripled from an estimated 151 million (4.6% of the global population in 2000) to 537 million (10.5%) in 2021. Without sufficient actions, the prediction of people who will have diabetes will be 643 million by 2023 (11.3% of the population) and continue to increase to 783 million (12.2%) by 2024.[1] Although the prevalence of diabetes in Lao PDR in 2021, 5.0%, was the lowest when compared with other countries in the Association of Southeast Asian Nations (ASEAN) (e.g. Malaysia 20.0%, Singapore 14.9%, Thailand 11.6%, Brunei 11.4%, Indonesia 10.8%, Vietnam 6.0%, Myanmar 6.6%,

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Philippines 6.5%, Cambodia 5.9%), Lao PDR has 214,800 adults with diabetes and 90,000 adults with undiagnosed diabetes.[2]

Despite the well-known long-term benefits of adequate glycemic control in reducing complications and death from any causes, patients' treatment adherence is suboptimal and falling short to achieve treatment goals. One study showed that 40% of diabetic patients had poor control as indicated by glycated hemoglobin (HbA1c > 7.5%).[3] Khan et al (2011) showed that reasons for poor glycemic control were poor concordance with lifestyle (26.5%), side effects (16.4%), infrequent attendance at clinic (16.4%), poor concordance with medications (14.0%), lack of knowledge of diabetes (14.0%), insulin refusal (11.7%), lack of titration of dose of tablets (7.8%) or titration of insulin (12.5%), social issue (10.9%).[4] In addition, diabetes management was related to various factors such as lack of coordination in referral system within the health care team, poor interaction between patients and healthcare providers, language barrier, lack of communication skill, and need for improving competency of healthcare providers.[5]

Many studies related to pharmacy practice in diabetes vary globally. Pharmacy-led interventions, comprehensive medication therapy management, improve clinical outcomes including blood glucose control,[6] HbA1c reduction,[7-9] systolic blood pressure reduction,[7, 8] medication adherence,[6] and low-density lipoprotein.[8, 10] Pharmacists' involvement with diabetic self-care is cost-effective.[11] In addition, pharmacists working in a home care agency identified numerous opportunities for improving patient care.[12] Home medication management review (HMMR) service by pharmacists decreased number of treatment-related problems with high physicians' acceptance of the pharmacist's recommendations (83%) and high satisfaction with the HMMR service.[13]

The Lao PDR healthcare system currently suffers from a lack of healthcare facilities, such as manual medical records, limited number of diabetes medications, limited healthcare coverage for diabetes medications. Although a diabetes management protocol in the hospital has been developed according to multiple guidelines such as the American Diabetes Association guideline, Thailand Clinical Practice Guideline, and International Diabetes Federation guideline, it has not yet been officially published or mentioned regarding their effect on achieving goals of diabetes care. Diabetes care in a hospital is routinely delivered by doctors, nurses and a nutritionist, without pharmacists' involvement. Moreover, primary care outreach to patients' homes has never been practiced as part of the regular care for diabetic patients. This study was conducted to evaluate the outcomes of pharmacists' interventions in diabetes care in Laos PDR.

METHODS

Ethical approvals were obtained from Mahasarakham University [023/2019] and ethical board for human from, Lao National Ethics Committee for Health Research [13/NECHR].

Study Design

The study design was single blinded randomized controlled trial with pretest and posttest. The trial protocol was designed, written, and executed by the investigators (Thai Clinical Trials Registry: TCTR20200707003). This trial report follows CONSORT trial guideline as shown in Supplementary Information 1. The study was undertaken in a hospital in Vientiane, Lao PDR. Enrollment began in June 2019 and was completed in July 2020.

Study Setting and Sample

The trial was conducted in a diabetes clinic at a government hospital in Vientiane, Lao PDR. The inclusion criteria were 1) patient diagnosed with type 2 diabetes, 2) at least 18 years old, 3) did not participate in other studies within the past three months prior to the study, 4) HbA1c $\geq$ 7% and/or fasting blood glucose (FBS) $\geq$ 154 mg/dL with records of two in three time in the past three months, and 5) willingness to participate. Patients who lived outside of the urban area of Vientiane Capital were illiterate, and had severe co-morbidity such as cancer, kidney failure, were excluded. The study aimed to achieve a sufficient sample size with 80% power, and a 5% proportion of error. Based on a diabetes study of Lahavisavapanich et al.[14] which evaluated the impact of education and counseling intervention by a pharmacist compared with the control group, the standard deviation difference of 1.86 and estimated differences of means between groups of 0.93 were used. Thus, the estimated sample size for two independent groups with continuous outcomes[15] to require 63 participants per group. Adding a 20% drop-out rate, the estimated sample was adjusted to 76 participants per group.

Randomization and Study Arms

A researcher (PS) recruited patients at the Diabetes OPD clinic. If the patient met all the inclusion criteria the researcher asked for the patient's willingness to participate, if they agreed, the researcher gave the consent form for them to sign before starting the study. Participants were randomly allocated to the intervention and control groups by using permuted block randomization. The sampling table was prepared by PS according to permuted block size 4 prior to the allocation. Only pharmacist/researcher kept the random allocation paper in a separate file for personal use. Other healthcare providers did not know random allocation during the study period. Clinical outcomes were accessed by healthcare providers who were blinded to the intervention provided. Patient satisfaction and quality of life were assessed by a researcher (PS) and research assistants.

Intervention Group

Diabetes care protocol for pharmacists' interventions consisted of 10 conditions (five conditions related to diabetes management, and the other five related to complications) was developed and approved by the multidisciplinary team in diabetes care. Patients in the intervention group received pharmaceutical care for six months by a pharmacist. Pharmaceutical care for individual patients in the hospital was based on the problems they had while they were visiting the diabetes care service. If there were abnormalities in the results, the patients received more counselling and education on how to solve the problems. The pharmacist identified, resolved, and

prevented drug-related problems (DRPs) on each visit to the diabetes care service.

Patients were seen by the pharmacist at the diabetic clinic in a hospital in Month 0,1, 3, and 6. At month 0, routine laboratory tests (HbA1c, FBG, lipid profile, renal function), ASCVD risk factors were measured. In addition, after random allocation at month 0, the pharmacist and two research assistants made home visits to administer patient satisfaction and Diabetes-39 questionnaires and then provide more education on nutrition and proper medication use. At month 1, 3 and 6, the pharmacist provided prescription review, reviewed patients' system, and provided pharmaceutical care to identify, resolve, and prevent drug related problems at the hospital. At month 6 after the hospital visit, home visits were undertaken again to provide education and then administered the questionnaires. When home visits could not be possible because of the COVID pandemic, telephone calls were made by some patients (less than 5% of participants). A home visit took approximately 30-60 minutes. This pharmacy-led diabetes care was in addition to the usual care provided by doctors, nurses, and a nutritionist.

Control Group

The patients in the control group received the usual care provided by doctors, nurses, and a nutritionist. They were only seen by a pharmacist and two research assistants in Month 0 and 6 for assessment of patient satisfaction and quality of life at home. Such a home visit took around 20-30 minutes.

Study Outcomes

Primary outcomes, HbA1c and FBS, were assessed using laboratory results obtained as part of routine care. The secondary outcomes were blood pressure (BP), creatinine clearance, glomerular filtration rate (GFR), blood urea nitrogen (BUN), lipid profiles (total cholesterol, low-density lipoprotein (LDL), high-density lipoprotein (HDL), and triglyceride), body mass index (BMI), 10-year atherosclerotic cardiovascular disease (ASCVD) risk, patient satisfaction, and quality of life (D-39).

Study Tools and Administration

This study used three tools. First, a protocol was developed by a focus group consisting of seven healthcare providers (one diabetes doctor, two nutritionists, two pharmacists, and two nurses). Details of the diabetes care protocol for pharmacists' interventions are shown in Supplementary Information 2. The second tool, patient satisfaction questionnaire (PSQ), has 20 items, aimed at measuring satisfaction to diabetes management. The PSQ was developed using 5-Likert scale from 1 (unsatisfied) to 5 (very satisfied) and tested for reliability and validity.[16] The mean score of 1.00-1.80 is very low, 1.81-2.60 is low, 2.61-3.40 is average, 3.41-4.20 is high, and 4.21-5.00 is very high.[17]

The third tool, quality of life questionnaire in diabetes patients, the Diabetes-39 (D-39), was used. This D-39 was firstly developed by Boyer et al (1997)[18] and was translated into several languages including Thai language by Songraksa (2009).[19] The Thai version of D-39 was translated to Lao with back translation method. The reliability test was performed in 150 patients with Cronbach's alpha higher than 0.7. All five dimensions measured by seven scales of the effect to quality of life from (1) no affected to my quality of life (7) the most affected to my quality of life. The translation of D-39 quality of life score could be divided into 3 levels: 1.00-3.00 means those problems had little effect on patient's quality of life; 3.01-5.00 means those problems had moderate effect on patient's quality of life and 5.01-7.00 means those problems had high effect on patient's quality of life.[20] Administration of the two questionnaires was carried out at patients' homes. Ten research assistants attended 2-hour training by the researcher (PS) to standardize their understanding of the questionnaires. Two research assistants accompanied the pharmacist in each home visit to administer the questionnaires which took about 20 minutes.

Statistical Analysis

Statistical analyses were carried out using SPSS software version 29. After randomization, comparison between groups were carried out using multiple linear regression or multiple logistic regression with adjusting variables of age, and ASCVD risk score. A dummy variable of age using 55 years was used as a benchmark because of age-related changes in blood pressure from the Framingham Heart Study.[21] A variable of ASCVD risk was using high risk of 14.7% as defined by the American College of Cardiology.[22] Independent t-test was used in comparing between groups for demographic data. Within group comparison, paired t-test was used. For missing data, the missing pattern was analyzed, before the imputation using regression method. Intention-to-treat principles were used for the analysis as available data provided.

RESULTS

Patient Demographics

One hundred forty-four patients with diabetes were approached from a hospital in Vientiane, Lao PDR. As shown in Figure 1, a total of 144 patients, 73 were in the intervention group and 71 were in the control group. In the intervention group, 13 patients (17.8%) dropped out: nine patients declined to participate in the study and four were unable to contact after one visit. For the control group, 19 patients (26.8%) were dropped out because four patients declined to answer questionnaires, four patients changed a hospital, five patients were unable to contact, and one patient died. 64 and 57 patients had sufficient information in the intervention and control groups respectively to perform intention-to-treat analysis. Patients' characteristics showed significant differences between groups in age, and ASCVD risk score as shown in Table 1

Clinical Outcomes

After the 6-month study, there were no significant differences between groups in primary outcomes, while, unexpectedly, secondary outcomes showed a statistically significant difference between groups in body mass index (BMI) as shown in Table 2. The achievement of clinical goals was analyzed.

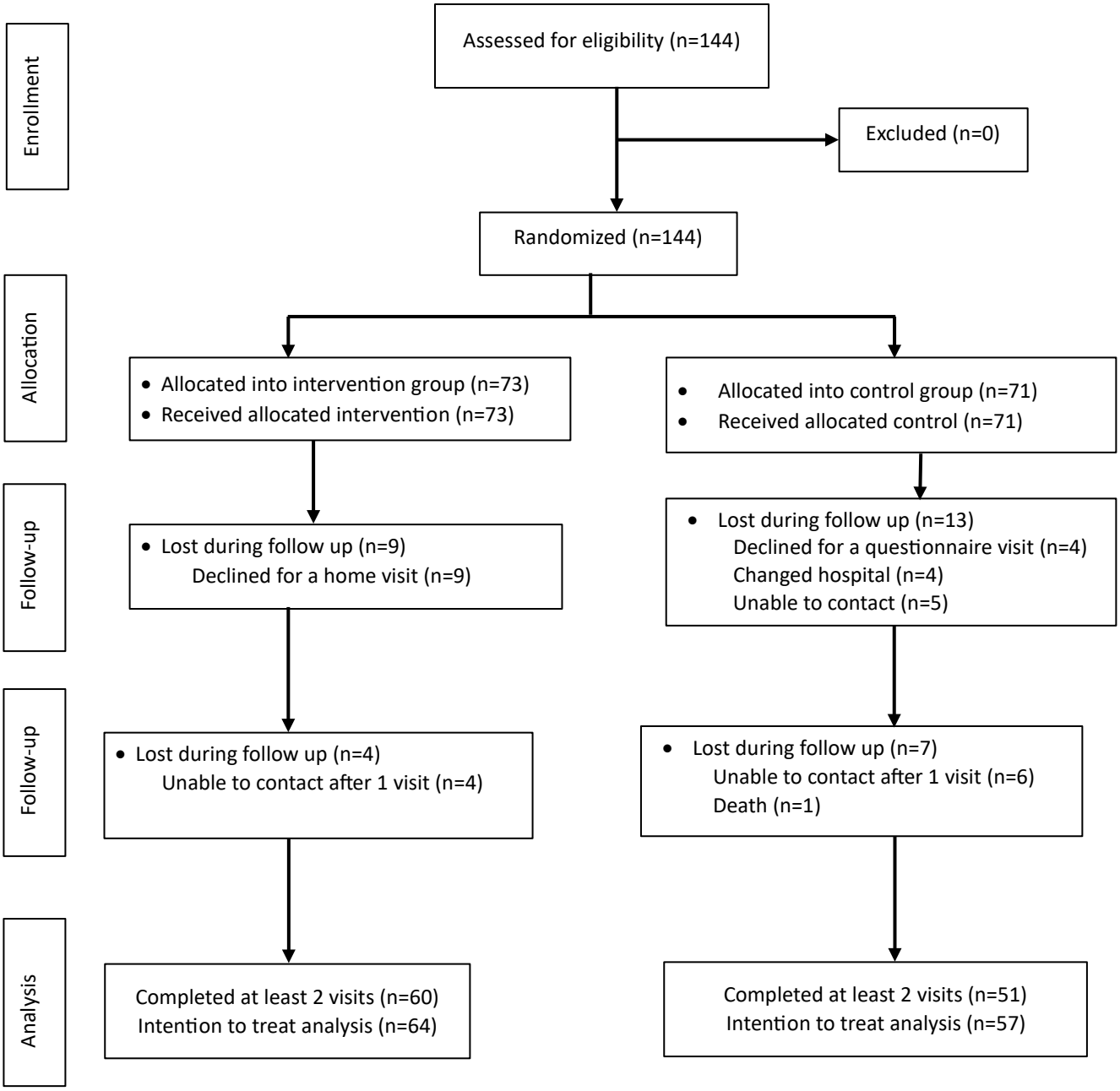

Figure 1. Consort Diagram 2010 for clinical trial

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Table 1. *Demographic data of participants in the intervention and control groups*

Characteristics	Intervention Group (n=64) n (%)	Control Group (n=57) n (%)	p-value
Sex: female	38 (59.4)	30 (52.6)	.455[a]
Age (mean SD)	60.2 ± 8.5	56.3 ± 9.8	**.022**[b]
Occupation			.143[a]
Civil servant	10 (15.6)	14 (24.6)	
Commercial	10 (15.6)	11 (19.3)	
Retired	27 (42.2)	13 (22.8)	
No job	17 (26.6)	19 (33.3)	
Education			.199[a]
Elementary School or lower	25 (39.1)	30 (52.6)	
Secondary School	25 (39.1)	14 (24.6)	
Bachelor and higher	14 (21.9)	13 (22.8)	
Having co-morbidity	50 (78.1)	40 (57.9)	.317[a]
Hypertension	44 (68.8)	33 (61.4)	.215[a]
Chronic kidney disease	8 (12.5)	5 (8.8)	.509[a]
Dyslipidemia	16 (25.0)	9 (15.8)	.212[a]
Cardiovascular diseases	6 (9.4)	4 (7.0)	.639[a]
Insurance			.500[a]
Civil servant insurance	30 (46.9)	26 (45.6)	
Social security insurance	13 (20.3)	11 (19.3)	
Community insurance	10 (15.6)	5 (8.8)	
No insurance	11 (17.2)	15 (26.3)	
Number of medicines	3.5 ± 1.5	3.0±1.4	.061[b]
ASCVD risk score (%)	20.9±16.1	13.6±10.3	**.004**[b]

[a] Chi-square test; [b] independent t-test; Bold numbers show statistically significant differences. *ACEIs/ARBs* stand for angiotensin converting enzyme inhibitors/ angiotensin receptor blockers. *ASCVD* atherosclerotic cardiovascular diseases

Table 2. Comparison of clinical outcomes between the intervention and control groups

Clinical Outcomes	Intervention Group (n=64) Mean SD		Control Group (n=57) Mean SD		p-value Month 0 [b]	p-value Month 6[c]
	Month 0	Month 6	Month 0	Month 6		
Primary Outcomes						
HbA1c (mg%)	9.6 2.2	**8.6 2.0**[**]	9.4 1.9	**8. 8 2.0**[*]	.671	.414
FPG (mg/dL)	179.6 83.0	169.4 64.5	178.1 59.4	169.0 58.1	.835	.695
Secondary outcomes						
SBP	142.7±22.1	144.7±22.7	137.0±20.7	134.4±21.7	.676	.090
DBP	78.9±12.3	78.3±11.5	80.6±10.0	78.7±12.3	.336	.899
Total cholesterol (mg/dL)	213.7±41.8	**187.0±42.4**[**]	197.9±47.7	196.4±41.3	.099	.332
HDL-C (mg/dL)	50.5±18.1	48.7±17.4	45.6±11.0	46.8±12.2	.052	.202
LDL-C (mg/dL)	130.8±41.5	**113.2±31.7**[*]	116.9±39.7	120.2±32.2	.149	.347
Triglyceride (mg/dL)	180.2±100.0	184.3±142.6	212.1±119.7	220.7±139.1	.154	.278
BMI (kg/m^2)	26.0±3.2	26.0±3.1	25.2±3.1	**25.0±2.9**[*]	.169	**.040**
GFR (mL/min)	59.5±21.8	57.2±21.4	61.9±22.7	59.9±21.8	.247	.528
ASCVD risk score (%)	20.9±16.1	18.8±14.6	13.6±10.3	13.7±13.0	**.004**	.603
Number of Medications	3.5±1.5	3.9±1.5	3.0±1.4	3.2±1.4	.061	.103
Insulin	29 (45.3)	30 (46.9)	18 (31.6)	19 (33.3)	.122 [a]	.190
Metformin	40 (62.5)	37 (57.8)	41 (71.9)	39 (68.4)	.271[a]	.347
Diabetes combinations	38 (59.4)	33 (51.6)	32 (56.1)	30 (52.6)	.719	.983
Statins	10 (15.6)	**33 (51.6)** [#]	5 (8.8)	**11 (19.3)** [#]	.254 [a]	**.001**

Table 2. Comparison of clinical outcomes between the intervention and control groups

Clinical Outcomes	Intervention Group (n=64) Mean SD		Control Group (n=57) Mean SD		p-value Month 0 [b]	p-value Month 6 [c]
	Month 0	Month 6	Month 0	Month 6		
Aspirin	5 (7.8)	**24 (37.5)** [#]	7 (12.3)	7 (12.3)	.412 [a]	**.006**
Antihypertensives	44 (68.8)	48 (75.0)	33 (57.9)	35 (61.4)	.215 [a]	.272
ACEIs/ARBs	28 (43.9)	29 (45.3)	19 (33.3)	16 (28.1)	.241 [a]	.079
Hypertension Combinations	17 (26.6)	15 (23.4)	8 (14.0)	11 (19.3)	.089 [a]	**.041**
Adherence to the study program	n/a	2.7±.6	n/a	2.2±0.6	n/a	**<.001**

[a] Chi-square test, [b] independent t test [c] Linear regression by adjusted variables: age, ASCVD; [*]paired-t test with p<0.05; [**] paired-t test with p<0.001; [#] McNemar test with p<0.05. Bold numbers show statistically significant differences. Bold letters show significant differences.

The intervention group showed higher achievement of HbA1c and LDL goals than the control group, however, there were no statistically significant differences between groups (Table 3). Comparison within groups between the pretest and the posttest, the intervention group showed significant improvements in HbA1c (p<.001), total cholesterol (p<.001), and LDL-C (p=.002). Whereas the control group showed significant improvement in HbA1c (p=.002), and BMI (p=.006) as shown in Table 2.

At month 6, the adherence to the treatment, number of medications prescribed including statins, aspirin, combinations of hypertensive medications, and adherence to the study program showed statistically significant differences between both groups (p<.05). Within group comparison, the intervention group statistically significantly received more statins and aspirin, whereas the control group also received more statins with a statistically significant difference as shown in Table 2.

In the intervention group, the pharmacist provided pharmaceutical care for individuals at month 1, 3, and 6. Identified drug-related problems (DRPs) were shown in Table 4. Of 67 DRPs events, the highest was untreated indications (74.6%) especially primary prevention medicines of aspirin and statin in high-risk patients estimated by ASCVD risk score (n=44). Pharmacist's interventions were accepted, 79.10%.

Patient Satisfaction

At Month 6, high satisfaction scores (3.41-4.20) were observed in the intervention group for Competency of Providers (SC), Competency of Pharmacists (SCP), and Communication with Providers (SCM). In the control group, high scores were found in Standard of Services (SS), SC, and SCM. A significant difference between the intervention and control groups was observed in SCP (p=.036). Within group comparisons, both groups showed significant higher satisfaction for Type of Services (ST), and SCP, p<.05. Interestingly, SCP scores at Month 0 were very low in both groups as shown in Table 5.

Quality of Life

After intervention, scores in each dimension ranged between 1.00 and 3.00, indicating that little effect on quality of life in the intervention group. In the control group, most dimensions also showed little effect on patients' quality of life except for Diabetes Control which showed moderate effect (3.01-5.00). The mean scores in all five dimensions showed higher scores in the control group than the intervention group, however, these differences were not statistically significant. In addition, no significant differences were observed when compared with the pretest for either group, as shown in Table 5.

DISCUSSION

In this study, there was no significant difference between groups in primary outcomes, however, the secondary outcome of BMI showed a significant difference between groups. Compared to the pretest, the intervention group demonstrated statistically significant improvements in HbA1c, total cholesterol, and LDL-cholesterol, while the control group had significant improvements in HbA1c and BMI. Over 80%

Table 3. Comparison of achievements of clinical outcome goals between the intervention and control groups

Clinical Outcomes	Intervention Group (n=64) (n, %)		Control Group (n=57) (n, %)		Odds Ratio	95% CI	p-value [a]
	Month 0	Month 6	Month 0	Month 6			
HbA1c (<7%)	0 (0.0)	12 (18.9)	0 (0.0)	9 (15.8)	1.31	.50-3.43	0.589
FPG (80-130 mg/dL)	22 (34.4)	17 (26.6)	11 (19.3)	17 (29.8)	0.74	.32-1.71	0.485
GFR > 30 ml/min	57 (89.1)	59 (92.2)	53 (93.0)	53 (93.0)	0.97	.24-3.92	0.968
BP <140/90 mm Hg	32 (50.0)	29 (45.3)	35 (61.4)	38 (66.7)	0.48	.22-1.05	0.065
LDL <100 mg/dL	13 (20.3)	21 (32.8)	19 (33.3)	15 (26.3)	1.35	.61-3.01	0.465

[a] Logistic regression by adjusted variables: age (dummy variable of lower and at least 55 years) and ASCVD (dummy variable of lower and at least 14.7)

Table 4. Drug-related problems identified, resolved by a pharmacist in the intervention group (n=60)

Drug-related problems (DRPs)	Explanation	Pharmacist's intervention No (%)	Total events No (%)	Doctor acceptance
Untreated indications	• No statin and/or aspirin in high ASCVD risk score (44 events)	• Added statin/ASA	50 (74.6)	39 (78.0)
	• Need more BP medications (6 events)	• Added BP medications		
Too low dose	• Too low dose of metformin (1 event)	• Consult to increase dose	4 (6.0)	4 (100.0)
	• Too low dose of losartan according to high BP (1 event)			
	• Too low dose of statins (2 events)			
Drug-Drug interaction	• Nifedipine and simvastatin	• Consults to change	1(1.5)	1 (100.0)
Adverse drug reaction	• GI disorder from metformin (5 events)	• Change medication	7 (10.5)	7 (100.0)
	• Patient's report of swelling on patient's legs, feet, and hands due to pioglitazone (1 event)	• Stopped medication		
	• Gout from furosemide (stopped) (1 event)	• Stopped medication		
Prescription error	• Detecting a patient received regular insulin of mixtard, but the prescription was NPH (1 event)	• Intervention to change	1 (1.5)	1 (100.0)
Nonadherence	• Double dose of medication because of misunderstanding (1 event)	• Patient education	1 (1.5)	N/A
Use of other supplements	• Due to supplements, one patient had elevated of creatinine level, and one had elevated fasting plasma glucose (2 events)	• Patient education	2 (3. 0)	N/A
Unable to access to the medication	• covid-19 limited access to medication (glimepiride) which was not available at community pharmacy (1 event).	• Intervention to change to another sulfonylurea	1 (1.5)	1 (100.0)
Total of DRPs Events			67 (100.0)	53 (79.1) [a]

[a] The denominator was 64 by excluding 3 interventions to patients from 67 events; *ASA* aspirin; *ADR* adverse drug reactions; *DDI* drug-drug interaction; *DRPs* drug related problems; *N/A* not applicable.

Table 5. Comparisons of patient satisfaction and quality of life at Month 0 and 6

Dimensions	Intervention Group Mean SD (n=60)			Control Group Mean SD (n=51)			p-value month 0*	p-value month 6*
	Month 0	Month 6	p-value[$]	Month 0	Month 6	p-value[$]		
Satisfaction [a]								
Standard of Services (SS)	3.50 .62	3.36 .43	.061	3.46 .61	3.47 .72	.919	.732	.465
Type of services (ST)	2.67 .54	3.28 .50	**<.001**	2.75 .58	3.23 .73	**<.001**	.604	.376
Competency of Providers (SC)	3.96 .52	3.95 .31	.927	3.97 .40	3.92 .54	.485	.283	.709
Competency of Pharmacists (SCP)	1.18 .61	3.67 .99	**<.001**	1.36 .91	3.11 1.31	**<.001**	.234	**.036**
Communication with Providers (SCM)	3.94 .56	3.96 .31	.771	3.97 .44	4.00 .52	.656	.610	.638
Quality of life [b]								
Diabetes Control (DC)	2.60 1.14	2.69 1.19	.412	2.85 1.36	3.14 1.53	.074	.378	.212
Anxiety and Worry (AW)	2.66 1.62	2.72 1.36	.693	2.65 1.68	2.91 1.67	.137	.625	.788
Energy and Morbidity (EM)	2.65 1.19	2.71 1.22	.609	2.64 1.28	2.86 1.37	.072	.767	.475
Social Burden (SB)	2.26 1.37	2.20 1.20	.615	2.24 1.44	2.48 1.54	.081	.879	.377
Sexual Functioning (SF)	2.20 1.77	2.09 1.67	.488	2.10 1.58	2.44 1.85	.092	.958	.292

[$] Paired t test; * Linear regression by adjusted variables: age, ASCVD; [a] 5-likert scales used, ranging from (1) unsatisfied to (5) very satisfied; [b] 7 scales used, ranging from (1) no affected to my quality of life (7) the most affected to my quality of life. Bold numbers show statistically significant differences.

of pharmacist's interventions were accepted by doctors. In addition, the intervention group showed more satisfaction with the Competency of Pharmacist (SCP) than the control group.

The strength of this study was a single blinded randomized controlled trial design. The assigned intervention was blinded to healthcare providers and patients to ensure that the usual care was similar in both groups. The same measurement was performed in both groups with the standardized questionnaires (PSQ[16] and DM-39)[18] and standardized interviewers. Moreover, the questionnaires were administered at patients' homes to reduce response bias.[23] Nevertheless, only the research pharmacist was aware of this assigned intervention, the assessment of the outcomes could have been influenced by knowledge of intervention received.

There were no significant differences of HbA1c between groups after six months, however, the intervention group showed statistically significant improvement in HbA1c compared to the pretest. Our results were not consistent to other studies which found that patients receiving pharmacist interventions in diabetes care exhibited statistically significant differences in mean HbA1c levels.[24-26] Nevertheless, the effect of pharmacists' intervention tends to become more pronounced in a longer period of time, more than six month is needed.[26] Stading et al (2019) found a statistically significant reductions in HbA1c over a 2-year period after initiating insulin therapy by a clinical pharmacist within a multidisciplinary team, compared to control patients ($p = .025$).[24] Similarly, Meade et al (2018) reported that the education and interventions provided by a pharmacist for 12 months significantly decreased mean HbA1c, $p < .001$.[25] Moreover, a systematic review and meta-analysis of 37 studies indicated that interventions less than six months did not significantly affect clinical outcomes.[26] In contrast, the pharmacist's interventions in this study did not use HbA1c to adjust medication dosages like other studies[24, 25] due to the high cost of the HbA1c and the routine practice of ordering this lab test only once a year.

One main role of pharmacist's interventions was suggesting adding statins, thus, the intervention group showed significant improvement in total cholesterol and LDL after six months when compared with the pretest. These positive outcomes could be explained by the intervention of adding statins for primary prevention in 44 out of 64 patients (68.8%). The results were consistent with a study in Jordan which showed that dyslipidemia patients in the clinical pharmacy service intervention group and 71.2% of control group reached their goal of low-density lipoprotein cholesterol (LDL) level, after six months ($p<.001$) compared to 24.7 and 28.8% respectively at baseline.[10]

Unexpectedly, positive outcomes favored the control group, with BMI and HbA1c. A possible explanation was patients in the control group who were younger and had less ASCVD risk, which may have allowed them to benefit more from usual care. Moreover, the collaborative protocol for the pharmacist interventions did not specifically target weight reduction. Another possible explanation could be from diabetic medications. Although the use of insulin, metformin did not show statistical differences, the intervention group had higher percentage of insulin use (46.9% vs 33.3%, respectively), and lower percentage of metformin use (57.8% vs 68.4%, respectively) when compared with the control group. Insulin can affect weight increase[27] and metformin has efficacy in mild weight loss.[28] Nevertheless, lifestyle modification was not assessed in this study, this could also have influenced these outcomes.

Patient satisfaction with diabetes care at six months in the intervention group showed a statistically significantly higher satisfaction to the Competency of Pharmacists (SCP) than the control group. This result indicated the quality of pharmacy service. One example, during the follow-ups at Month 3 and 6, the covid-19 pandemic affected the availability of glimepiride, which was not accessible from any community pharmacy. The pharmacist/research consulted a doctor to switch the patient to an available medication in the same pharmacological group. Another example, one patient made a phone call to the research pharmacist due to swellings in his legs, feet, and hands. Following the pharmacist's suggestion, the patient visited the study hospital, where a medication review and adverse drug reaction assessment identified pioglitazone as the suspected cause after a week of exposure. The pharmacist's intervention was accepted, and the doctor stopped this medication, with a follow-up schedule in two weeks. The patient's swelling symptoms had been resolved.

The study results align with several studies showing that pharmacist services in diabetes care improved patient satisfaction.[29, 30] One study presented the most significant improvement for the patients who received community pharmacist patient care services using scheduled consultations, clinical goal setting, monitoring, and collaborative drug therapy management with physicians and referrals to diabetes educators.[29] Another study showed 95.7% of patients reported being very satisfied or satisfied with the diabetes care provided by their pharmacists after six months.[30] Nevertheless, satisfaction in the control group also improved when compared with the pretest. This could have been influenced by the presence of the research pharmacist who provided care in the same room with doctors and visited patients' homes to administer questionnaires. However, the intervention group reported significantly higher satisfaction than the control group.

People with diabetes have a worse quality of life than people with no chronic illness.[31] The only dimension that showed moderate effect on quality of life in the control group was Diabetes Control. In order to improve the patients' quality of life, counseling on medication use and glycemic control is recommended. In addition, counselling patients about diabetes care and ways to manage stress will promote treatment adherence and lifestyle modifications.[32]

This study had several limitations. First, the participants' characteristics were not equal, with differences in age and ASCVD risk between groups required statistical adjustment. Thus, linear and logistic regression were applied based on the types of variables, adjusting these two factors, to test

differences between groups. However, a larger stratified sample might help balance baseline characteristics more effectively. Second, the drop-out rate exceeded the estimation, and the control group ended up smaller than planned. When compared with other similar studies, one study estimated sample size of 30 participants per group (using a difference of 1% reduction with 1.2% standard deviation in HbA1c, power of study= 80%, significance =5%). This study showed a statistically significant difference in HbA1c between groups.[33] Another two studies did provide details on sample estimation but recruited 36/34 patients,[34] and 51/54 patients[35] in the intervention/ control groups, respectively. Both studies showed statistical differences in HbA1c between groups after six and nine months of follow-up. If this study had estimated its sample using a 1% reduction difference, it would have required 54 participants in each group instead of 63. Therefore, the final sample of 57 participants in the control group should not significantly affect the true difference or statistical power. The explanations for drop out were because some patients refused to participate in the pretest after recruitment. Although additional recruitment was discussed during the study, it was difficult in the context at that time. Patient information records were retrievable only manually, and some laboratory data could only be accessed from individual booklets. Moreover, the high costs of lab tests and the effort to administer questionnaires at home limited further recruitment.

Third, the following-up process for patients at the diabetes care service in the hospital was conducted by one researcher. Because of time constraints in the service and data collection, some patients in the invention group did not meet face-to-face with the researcher pharmacist at every visit. However, all patients in the intervention group received pharmaceutical care at least twice during the study which may have diminished the effect of intervention in changing outcomes at the end of the study. Fourth, this study was the first pharmaceutical care intervention for diabetic patients in Lao PDR, the intervention process did not go smoothly because only a few diabetic doctors participated in the focus group meeting before starting the intervention, so the rest of the doctors in the clinical setting were lack of understanding on the role of pharmacist in providing pharmaceutical care. Lastly, medication adherence was originally intended to be measured by counting pills, but it was not feasible in practice. Nevertheless, the study assessed the adherence based on the frequency of visits to the diabetes clinic.

In Lao PDR context, this study was an initiative to enhance pharmacists' contributions to diabetes care with an interdisciplinary team, generalizability to other countries may be limited. Further studies should be designed for extending the intervention period to at least 12 months for stronger clinical outcome assessment, incorporating assessments of lifestyle modification. Moreover, enhancing the collaborative protocols between pharmacists and physicians for better medication therapy management could lead to a key success in achieving treatment goals, enhancing patient satisfaction, and improving quality of life.

CONCLUSION

Patients who received diabetes care led by a pharmacist received benefits from the pharmacist's contributions, with significantly higher satisfaction in pharmacist's competency. Although pharmacist's intervention did not yield better clinical outcomes than the usual care, there was a trend of having better control of HbA1c, total cholesterol, and LDL-Cholesterol.

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AUTHOR CONTRIBUTIONS

All authors contributed to the conceptualization. Sibounheuang P, Olson PS, Ploylearmsang C, Kittiboonyakun P, Sookaneknun S, and Vongvandy V contributed to study design and methodology. Sibounheuang P contributed to project administration, investigation, data collection, and writing the original draft. Olson PS contributed to formal analysis and validation. Ploylearmsang C contributed to validation and funding acquisition. Olson PS, Lau AH, and Ploylearmsang C contributed to critical revising and editing the original draft. All authors contributed to reviewing and editing of the final manuscript.

CONFLICT OF INTEREST

The authors declare no competing interests.

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References

1. Vluggen S, Hoving C, Schaper NC, de Vries H. Exploring beliefs on diabetes treatment adherence among Dutch type 2 diabetes patients and healthcare providers. Patient Educ Couns. 2018;101(1):92-8. https://doi.org/10.1016/j.pec.2017.07.009.
2. IDF. IDF Diabetes Atlas 10th edition 2021 [Internet]. 2021 cited [2024 December 11]. Available from: https://diabetesatlas.org/atlas/tenth-edition/?dlmodal=active&dlsrc=https%3A%2F%2Fdiabetesatlas.org%2Fidfawp%2Fresource-files%2F2021%2F07%2FIDF_Atlas_10th_Edition_2021.pdf.
3. Low WY, Lee YK, Samy AL. Non-communicable diseases in the Asia-Pacific region: Prevalence, risk factors and community-based prevention. Int J Occup Med Environ Health. 2015;28(1):20-6. https://doi.org/10.2478/s13382-014-0326-0.
4. Khan H, Lasker SS, Chowdhury TA. Exploring reasons for very poor glycaemic control in patients with Type 2 diabetes. Prim Care Diabetes. 2011;5(4):251-5. https://doi.org/10.1016/j.pcd.2011.07.001.
5. Sibounheuang P, Olson PS, Kittiboonyakun P. Patients' and healthcare providers' perspectives on diabetes management: A systematic review of qualitative studies. Res Social Adm Pharm. 2020;16(7):854-74. https://doi.org/10.1016/j.sapharm.2019.09.001.
6. Presley B, Groot W, Pavlova M. Pharmacy-led interventions to improve medication adherence among adults with diabetes: A systematic review and meta-analysis. Res Social Adm Pharm. 2019;15(9):1057-67. https://doi.org/10.1016/j.sapharm.2018.09.021.
7. Alabkal RM, Medlinskiene K, Silcock J, Graham A. Impact of Pharmacist-Led Interventions to Improve Clinical Outcomes for Adults With Type 2 Diabetes at Risk of Developing Cardiovascular Disease: A Systematic Review and Meta-analysis. J Pharm Pract. 2023;36(4):888-99. https://doi.org/10.1177/08971900211064459.
8. Rodriguez de Bittner M, Chirikov VV, Breunig IM, Zaghab RW, Shaya FT. Clinical effectiveness and cost savings in diabetes care, supported by pharmacist counselling. J Am Pharm Assoc (2003). 2017;57(1):102-8.e4. https://doi.org/10.1016/j.japh.2016.08.010.
9. Stading J, Herrmann J, Walters R, Destache C, Chock A. Impact of Pharmacist Intervention on Diabetes Patients in an Ambulatory Setting. Diabetes Spectrum. 2009;22(4):241-6. https://doi.org/10.2337/diaspect.22.4.241.
10. Tahaineh L, Albsoul-Younes A, Al-Ashqar E, Habeb A. The role of clinical pharmacist on lipid control in dyslipidemic patients in North of Jordan. Int J Clin Pharm. 2011;33(2):229-36. https://doi.org/10.1007/s11096-011-9479-0.
11. Jamshed SQ, Siddiqui MJ, Rana B, Bhagavathula AS. Evaluation of the Involvement of Pharmacists in Diabetes Self-Care: A Review From the Economic Perspective. Front Public Health. 2018;6:244. https://doi.org/10.3389/fpubh.2018.00244.
12. Triller DM, Hamilton RA, Briceland LL, Waite NM, Audette CM, Furman CA. Home care pharmacy: extending clinical pharmacy services beyond infusion therapy. Am J Health Syst Pharm. 2000;57(14):1326-31. https://doi.org/10.1093/ajhp/57.14.1326.
13. Al Alawneh M, Nuaimi N, Basheti IA. Pharmacists in humanitarian crisis settings: Assessing the impact of pharmacist-delivered home medication management review service to Syrian refugees in Jordan. Res Social Adm Pharm. 2019;15(2):164-72. https://doi.org/10.1016/j.sapharm.2018.04.008.
14. Lahavisavapanich R, Wongwiwatthananukit,S, Wongthawarawat, W. Impact of education and counseling provided by clinical pharmacist on diabetic outpatients. Thai J Health Res. 2006;20(1):19-40.
15. Allen Jr J. Sample size calculation for two independent groups: a useful rule of thumb. PoSH. 2011;20(2):138-40.
16. Olson PS, Ploylearmsang C, Sibounheuang P, Sookaneknun S, Manithip C, Watcharadamrongkun S, Jungnickel PW, Kittiboonyakun P. Development of a patient satisfaction questionnaire (PSQ) for diabetes management in Thailand and Lao PDR. PLoS One. 2024;19(3):e0300052. https://doi.org/10.1371/journal.pone.0300052.
17. Issam Khalil Abu-Baker M, Khair Saleem Abu-Zaid M, Alsawalqah H, Al Shamayleh Y, Al Shboul B. The Impact of the Implementation of Capability Maturity Model Integration on User Satisfaction: Case Study on Software Companies in Jordan. J Softw. 2019;14(7):293-311.
18. Boyer JG, Earp JA. The development of an instrument for assessing the quality of life of people with diabetes. Diabetes-39. Med Care. 1997;35(5):440-53. https://doi.org/10.1097/00005650-199705000-00003.
19. Songraksa K, Lerkiatbundit, S. Development of a disease specific quality of life instrument: Thai version of the Diabetic-39. Songkla Med J. 2009;27(1):35-49.
20. Sroisong S. Quality of Life among Clients with Type 2 Diabetes Mellitus. Journal of Disease and Health Risk DPC3. 2019;13(2):37-49.
21. Franklin SS, Gustin Wt, Wong ND, Larson MG, Weber MA, Kannel WB, Levy D. Hemodynamic patterns of age-related changes in blood pressure. The Framingham Heart Study. Circulation. 1997;96(1):308-15. https://doi.org/10.1161/01.cir.96.1.308.
22. American College of Cardiology. ASCVD risk estimator plus [Internet]. 2023 cited [2024 December 11]. Available from: https://tools.acc.org/ascvd-risk-estimator-plus/#!/calculate/estimate/.
23. Mazor KM, Clauser BE, Field T, Yood RA, Gurwitz JH. A demonstration of the impact of response bias on the results of patient satisfaction surveys. Health Serv Res. 2002;37(5):1403-17. https://doi.org/10.1111/1475-6773.11194.
24. Stading JA, Herrmann J, Walters RW, Destache CJ, Chock A. Impact of Pharmacist Intervention on Diabetes Patients in an

Ambulatory Setting. Diabetes Spectrum. 2009;22:241 - 6.
25. Meade LT, Tart RC, Buzby HL. Evaluation of Diabetes Education and Pharmacist Interventions in a Rural, Primary Care Setting. Diabetes Spectr. 2018;31(1):90-5. https://doi.org/10.2337/ds16-0064.
26. Jeong S, Lee M, Ji E. Effect of pharmaceutical care interventions on glycemic control in patients with diabetes: a systematic review and meta-analysis. Ther Clin Risk Manag. 2018;14:1813-29. https://doi.org/10.2147/tcrm.S169748.
27. Edens MA, van Dijk PR, Hak E, Bilo HJG. Course of body weight before and after the initiation of insulin therapy in type 2 diabetes mellitus: Retrospective inception cohort study (ZODIAC 58). Endocrinol Diabetes Metab. 2021;4(2):e00212. https://doi.org/10.1002/edm2.212.
28. Lazzaroni E, Ben Nasr M, Loretelli C, Pastore I, Plebani L, Lunati ME, Vallone L, Bolla AM, Rossi A, Montefusco L, Ippolito E, Berra C, D'Addio F, Zuccotti GV, Fiorina P. Anti-diabetic drugs and weight loss in patients with type 2 diabetes. Pharmacol Res. 2021;171:105782. https://doi.org/10.1016/j.phrs.2021.105782.
29. Correr CJ, Pontarolo R, Souza RADPE, Venson R, Melchiors AC, Wiens A. Effect of a Pharmaceutical Care Program on quality of life and satisfaction with pharmacy services in patients with type 2 diabetes mellitus. Brazilian Journal of Pharmaceutical Sciences. 2009;45(4):809-17. https://doi.org/10.1590/s1984-82502009000400027.
30. Garrett DG, Bluml BM. Patient self-management program for diabetes: first-year clinical, humanistic, and economic outcomes. J Am Pharm Assoc (2003). 2005;45(2):130-7. https://doi.org/10.1331/1544345053623492.
31. Rubin RR, Peyrot M. Quality of life and diabetes. Diabetes Metab Res Rev. 1999;15(3):205-18. https://doi.org/10.1002/(sici)1520-7560(199905/06)15:3<205::aid-dmrr29>3.0.co;2-o.
32. Natarajan J, Mokoboto-Zwane S. Health-related Quality of Life and Domain-specific Associated Factors among Patients with Type2 Diabetes Mellitus in South India. Rev Diabet Stud. 2022;18(1):34-41. https://doi.org/10.1900/rds.2022.18.34.
33. Butt M, Mhd Ali A, Bakry MM, Mustafa N. Impact of a pharmacist led diabetes mellitus intervention on HbA1c, medication adherence and quality of life: A randomised controlled study. Saudi Pharm J. 2016;24(1):40-8. https://doi.org/10.1016/j.jsps.2015.02.023.
34. Cani CG, Lopes Lda S, Queiroz M, Nery M. Improvement in medication adherence and self-management of diabetes with a clinical pharmacy program: a randomized controlled trial in patients with type 2 diabetes undergoing insulin therapy at a teaching hospital. Clinics (Sao Paulo). 2015;70(2):102-6. https://doi.org/10.6061/clinics/2015(02)06.
35. Chan CW, Siu SC, Wong CK, Lee VW. A pharmacist care program: positive impact on cardiac risk in patients with type 2 diabetes. J Cardiovasc Pharmacol Ther. 2012;17(1):57-64. https://doi.org/10.1177/1074248410396216.