Outcomes of Pharmacist-led Diabetes Care Interventions in Lao PDR

Phoutsathaphone Sibounheuang

A Thesis Submitted in Partial Fulfillment of Requirements for
degree of Doctor of Philosophy in Pharmacy
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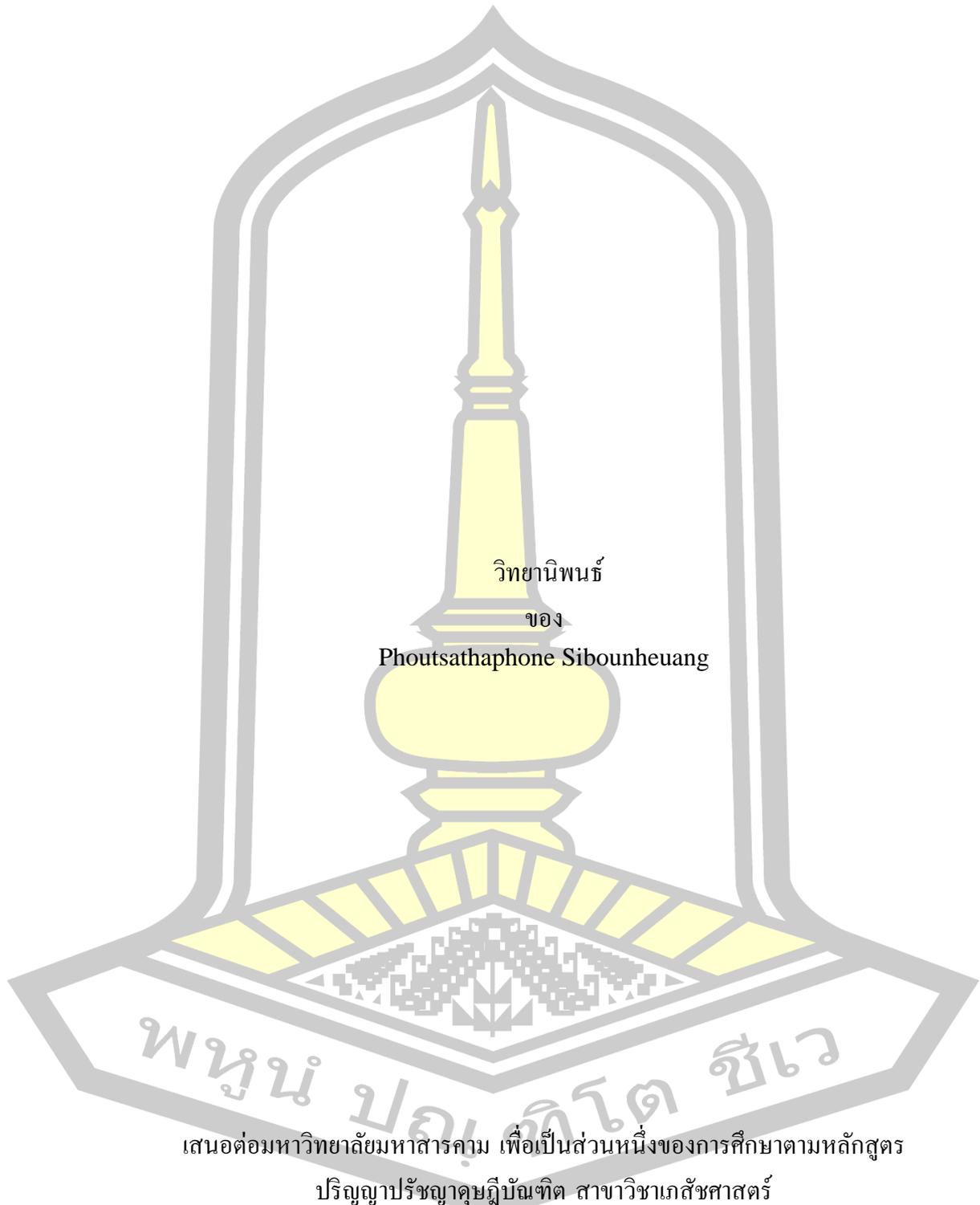
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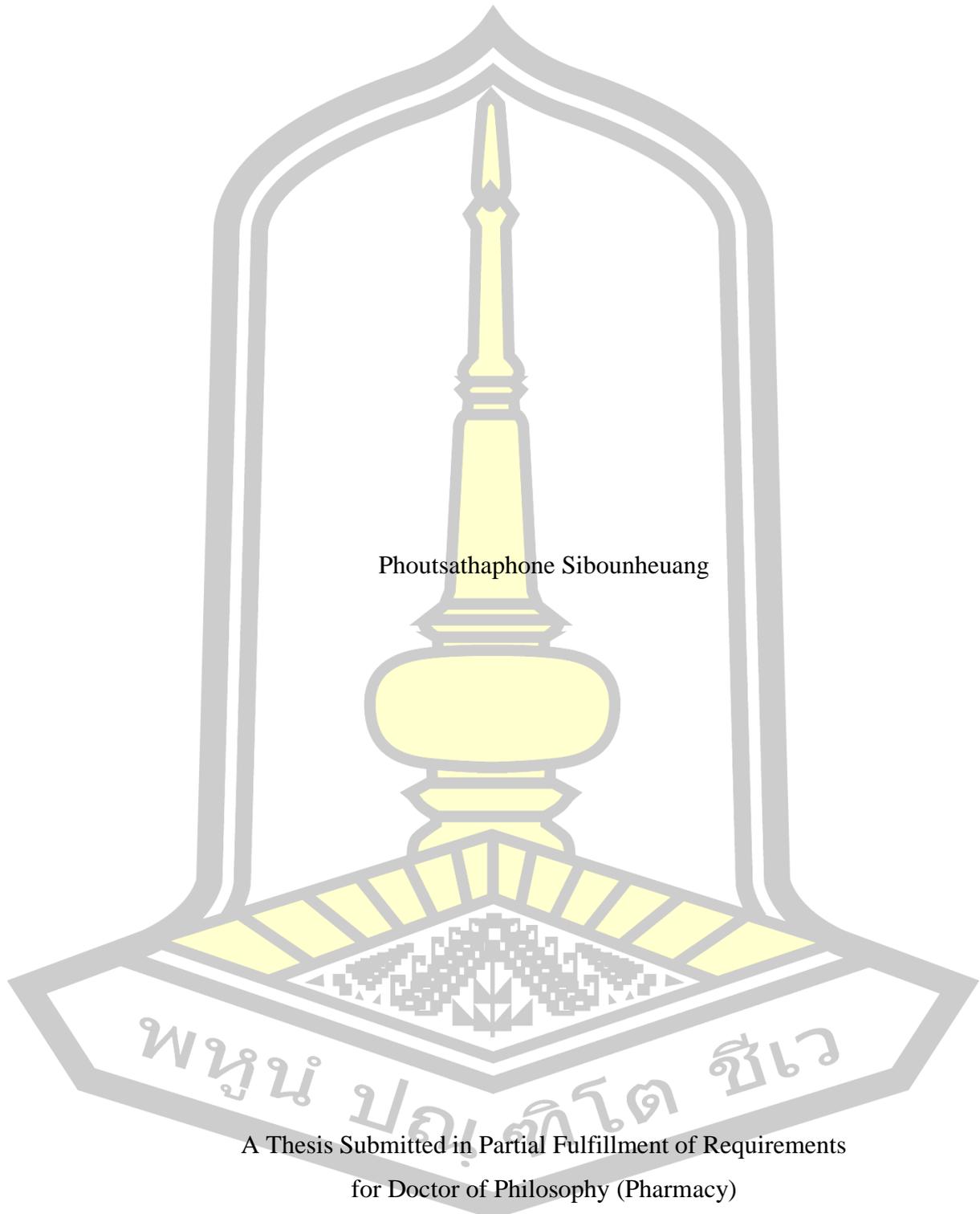
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The examining committee has unanimously approved this Thesis, submitted by Ms. Phoutsathaphone Sibounheuang , as a partial fulfillment of the requirements for the Doctor of Philosophy Pharmacy at Mahasarakham University

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ABSTRACT

Background: Diabetes is a major health problem worldwide. Despite the availability of evidence-based guidance to deliver effective diabetes care, many patients do not achieve treatment goals as per recommendations, including in Laos. Pharmaceutical care provided to diabetic patients by pharmacists together with other healthcare providers has shown to be effective in many countries. Diabetes care in Laos has been provided by doctors, nurses, and nutritionists, without the involvement of pharmacists. This study aimed to develop and validate standard tools of patient satisfaction and quality of life in Lao language and to evaluate the outcomes of pharmacists' interventions in diabetes care in Lao PDR.

Methods: Phase 1: Development and validation tools. Two questionnaires in Lao language were developed and validated in this study. They were related to patient satisfaction to diabetes management and quality of life for diabetes (D-39). Patient satisfaction questionnaire (PSQ) was developed by using systematic review of qualitative studies on patients' and healthcare providers' perspectives on diabetes management. Databases were searched including CINAHL, PubMed, Science Direct, and Web of Science from January 2001 to September 2017. Chronic care model framework was used to analyze the main themes and sub themes. The first PSQ was in the Thai language. The Thai version of Quality of life for diabetes (D-39) was used in this study. Both PSQ and D-39 were back-to-back-translated from the Thai version to Lao version. The properties of both tools were tested in 150 Type 2 diabetic patients in a university hospital in Thailand in November 2018, and in 150 Type 2 diabetic patients in a center hospital in Lao PDR in January 2019. Construct validity of both versions were tested by using factor analysis, Pearson correlation analysis, and reliability test.

Phase 2: Randomized controlled trial (RCT). The RCT with a control group was conducted to evaluate the outcomes of diabetes care led by a pharmacist in Lao PDR from June 2019 to July 2020. The mutual understanding protocol of this study was set by performing a focus group with healthcare providers in a hospital. The intervention group received pharmaceutical care from a pharmacist. The control

group received standard care from the hospital clinic. Patients were randomized by permuted block. Primary outcomes measurements were HbA1c and FPG. Secondary outcomes measurements were blood pressure, lipid profiles, GFR, ASCVD 10 years' risk score, scores of PSQ and D-39. Primary and secondary outcomes of patients of both groups were measured at month 0 (pre-test), month 3 (post-test 1) and 6 (post-test 2) except for HbA1c which was measured only at month 0 and 6. Independent t-test and Mann-Whitney U test were used to test the differences between two groups. Pair t-test and Wilcoxon Signed Rank tests were used to test the differences within the group. Subgroup analysis was performed in diabetes with hypertensive patients.

Result: Phase 1. Nine main themes from the systematic review of qualitative studies were used to develop the PSQ in this study. The PSQ of 45 items was constructed by three major-dimensions (attitudes to health, satisfaction to diabetes services, and attitudes to services achievement) and 11 sub-dimensions (attitude to knowledge on self-management, attitude to family, attitude to the community, satisfaction of the standard of services, satisfaction of the type of services, satisfaction of the competency of providers, satisfaction of the competency of pharmacists, satisfaction of the communication with providers, attitude to the accessibility of service, attitude to the health service system, attitude to goal setting). Kaiser-Meyer-Olkin (KMO) measure for sampling adequacy for both versions were 0.753 and 0.850, p-value < 0.001 for the Lao and Thai versions respectively. The Cronbach's alpha scores were 0.945 and 0.948 for the Lao and Thai versions respectively. Convergent and discriminant validity values of both versions were > 70%. Factor loadings for both versions were > 0.4 in all 45 items. Property test of Diabetes 39 (D-39) questionnaire showed KMO measure of 0.917, p-value < 0.001. The Cronbach's alpha score was 0.966. Convergent and discriminant validity values were >70%. Factor loadings were > 0.5 in all items.

Phase 2. Seventy-three diabetes patients were randomly allocated to the intervention group. Seventy-one patients were allocated to the control group. Thirteen patients of the intervention group (17.8%) and 20 patients of the control group (28.2%) were lost during follow-up. Sixty patients of the intervention group and 51 patients of the control group were analyzed. There was no significant difference between the groups for HbA1c, FPG, lipid profiles. There was a significant difference in systolic blood pressure between the groups for Month 6 (post-test). Both groups had well-controlled of HbA1c when comparing the mean of month 0 (pre-test) and month 6 (post-test), p-value < 0.001. The intervention group had well-controlled total cholesterol and the LDL-cholesterol when comparing the mean of month 0 (pre-test) and month 6 (post-test), p-value <0.001, and 0.001 respectively.

Conclusion: The PSQ and D-39 questionnaires are valid, reliable, and acceptable to use in further research in order to measure diabetic patients' satisfaction with diabetes management. Patients who received diabetes care interventions led by a pharmacist tend to have better control of HbA1c and LDL-cholesterol. However, patients in the intervention group had poor blood pressure control.

ACKNOWLEDGEMENTS

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Chapter 1

Introduction

1. Background

Type 2 diabetes mellitus (T2DM) is a chronic disease characterized by hyperglycemia and the body's inability to retain an optimal glucose level. (1) Diabetes is one of the largest global health challenges of the 21st century. Diabetes leads to macro-and micro-vascular complications. There is an urgency for greater action to improve diabetes outcomes and reduce the global burden of diabetes now affecting more than 425 million people, of which one-third are people older than 65 years. The number of people with diabetes may rise to 629 million in 2045, although the incidence has started to drop in some high-income countries. At the same time, a further 352 million people with impaired glucose tolerance are at high risk of developing diabetes.(2) In 2017 there were four million deaths as a result of diabetes and its complications. Diabetes is increasing markedly in the cities of low and middle-income countries. The International Diabetes Federation (IDF) Southeast Asia and Western Pacific regions reported that Southeast Asia regions are expected to face the highest upsurge in the next 28 years.(2) Over the lifetime, type 2 diabetes imposes a substantial economic burden on healthcare systems. The lifetime direct medical costs of treating type 2 diabetes and diabetic complications were $124,700 for patients 25–44 years old, $106,200 for patients 45–54 years old, $84,000 for patients 55–64 years old, and $54,700 for patients $\geq$ 65 years old. The cost of managing macrovascular complications accounted for 57% of the total complications cost. Effective interventions that prevent or delay type 2 diabetes and diabetic complications might result in substantial long-term savings in healthcare costs. (3)

Lao People's Democratic Republic is surrounded by five other countries: China, Cambodia, Myanmar, Thailand, and Vietnam, with an estimated population of 6.2 million; 32% of which live in urban areas. (4) Recent information from World Health Organization (WHO) – Diabetes Country Profiles, 2016, showed that the prevalence of diabetes in Laos was 5.5% in male and 5.7% in female. (5) WHO Country Cooperation Strategy for the Lao PDR during 2012-2015 reported that every year, non-communicable diseases (NCDs) was the cause of death of around 12,100 males, 60% of whom were under 70 years of age, and of about 11,700 females, 53% of whom were under 70 years old. Of all NCD-related deaths, cardiovascular diseases and diabetes were the highest age-standardized death rate per 100,000 (467.9 for males and 329.8 for females), followed by chronic respiratory diseases (122.8 for males and 111.1 for females). (4)

The core of T2DM treatment elements, which targets on an optimal glucose metabolism, consists of healthy lifestyle modification, e.g. increasing physical activity and improving healthy dietary patterns, and pharmacotherapy. (1). 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 a poor control measured by glycated hemoglobin (HbA1c > 7.5%). (6) The majority of T2DM patients did not meet the recommended levels of physical activity and did not adhere to dietary guidelines. Health care professionals also contribute to the problem and one common cause of treatment failure is unwillingness of health care providers to appropriately initiate or intensify therapy. Despite the existence of many well-defined targets and practice guidelines for the management of hyperglycemia, hypertension, and dyslipidemia in patients with T2DM, clinical inertia exists and makes health care providers confused as the data was periodically revised as new data emerges. (7) 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%). (8)

American Diabetes Association (ADA) stated that in order to gain the optimal outcomes, diabetes care or management must be individualized for each patient.(9) Thus, efforts to improve population health require both system-level and patient-level approaches. The ADA highlights the importance of patient-centered care, defined as care that is respectful and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions. Pharmacologic intervention has been updated every year toward ASCVD prevention benefit according to ADA guideline. The Thai diabetes guideline in 2017 also emphasizes that healthcare providers have to provide complete care such as diabetes education, treatment target and pharmacotherapy depending on individual comorbidity with available medications in the National Drug List. (10) The Chronic Care Model (CCM) is an integrated well-known care model used to improve outcomes for people with chronic condition including diabetes. (11) The systematic review of CCM and diabetes management showed positive outcomes for diabetes care in US primary care settings. (12)

A diabetes management program helps to manage diabetes patients to improve target goals. A meta-analysis of 41 randomized controlled trials of disease-management programs for diabetic patients that included patient education; coaching; treatment adjustment; monitoring; and care coordination resulted in a significant reduction in hemoglobin HbA1c levels (pooled standardized mean difference between intervention and control groups -0.38, 95% confidence interval -0.47 to -0.29). (13) Pharmacists are key persons who help to manage type 2 diabetes. Chen in 2016 found that a pharmacist intervention program providing pharmaceutical services improved long-term and safe control of blood sugar levels and did not increase medical expenses in ambulatory elderly patients with diabetes.(14) Many studies showed that pharmacist intervention improved HbA1c statistically (15) as well as low-density lipoprotein levels, total cholesterol, and blood pressure. (16) Several studies evaluated diabetes home care. Pharmacists working in a home care agency identified numerous opportunities for improving patient care.(17) In a study of pharmacists provided home medication management review (HMMR) service for Syrian refugees in Jordan, the number of treatment-related problems (TRPs) were significant decreased in the intervention group (p < 0.001) but not in the control group (p = 0.116). The physicians' acceptance of the pharmacist's recommendations was high (83 %). And more than 70

% of refugees in the intervention group reported high satisfaction with the HMMR service.(18)

Many studies of pharmacist-led diabetes care showed benefits to clinical outcomes, but none of these studies had evaluated clinical outcomes together with humanistic outcomes such as patient satisfaction and patient quality of life. None of aforementioned studies covered care for diabetic patients from hospital to home. The Lao PDR healthcare system remains currently with a lack of facilities. The diabetes care in the hospital is delivered by doctors, nurses and a nutritionist, but no pharmacists are involved in this care team. Furthermore, the diabetes protocol in the hospital was set according to multiple guidelines such as ADA, CPG Thailand and IDF, but it is not yet officially published and information on achieving goals of diabetes care is not mentioned. The primary care outreach to the homes of patients is not practiced as part of regular care for diabetes. Thus, this study aimed to develop standard tools of satisfaction to diabetes care, validate quality of life (Diabetes-39) in Lao language and evaluate outcomes of pharmacists' interventions in diabetes care in Lao P.D.R.

2. Objectives

Phase 1 (Questionnaire Development)
1) To conduct a systematic review of qualitative studies of patients' and healthcare providers' perspectives on diabetes management by using the concept of chronic care model.
2) To construct a patient satisfaction questionnaire by using the major themes from the systematic review of qualitative studies.
3) To prepare Diabetes-39 in Lao version by translating from the Thai version.
4) To validate the patient satisfaction questionnaire and Diabetes-39 Lao version.

Phase 2 (Randomized Controlled Trial, RCT)
1) To conduct focus group studies among healthcare providers for developing a protocol for diabetes care intervention led by a pharmacist.
2) To compare outcomes between two groups and to compare outcomes within each group:
   2.1. Clinical outcomes: BMI, FBS, HbA1C, BP, creatinine clearance, Lipid profile.
   2.2. Humanistic outcomes: patient satisfaction and quality of life (Diabetes-39).

3. Research Questions

1) What are the views of patients' and healthcare providers on current diabetes management?
2) Is patient satisfaction questionnaire validated and reliable in Thai and Lao version?
3) Is the Diabetes-39 questionnaire validated and reliable in Lao version?
4) Is a diabetes care intervention led by a pharmacist better than usual care in terms of clinical outcomes and humanistic outcomes?

4. Research Terminology

1) Usual care means diabetes care provided during regular service for diabetes patients in Mahosot hospital.
2) Diabetes care intervention led by a pharmacist means a pharmaceutical care plan, counselling and education for individual patients. Pharmaceutical care plan is to identify, resolve and prevent drug-related problems (DRPs). Self-management for lifestyle modification and home care by a pharmacist is also included.
3) Patient satisfaction means patients' opinion to diabetes care according to the patient satisfaction questionnaire developed by performing systematic review of other qualitative studies.
4) Quality of life was measured by Diabetes-39 in Lao language (which was translated from Diabetes-39 in the Thai language version) covering 5 dimensions 1) diabetes control, 2) anxiety and worry, 3) energy and morbidity, 4) social burden, and 5) sexual functioning.
5) Humanistic outcomes cover patient satisfaction questionnaire and quality of life (Diabetes-39).

5. Research Framework

Research framework of the randomized controlled trail is shown in Figure 1.

Diabetes care intervention including:

Pharmaceutical care:

1) Counselling
2) Identify, resolve and prevent drug-related problems (DRPs)
3) Education on self-management for lifestyle modification for individual patients.
4) Notify healthcare team in case of any DRPs

Home care:

1) Medication review
2) Patient education including their family

Outcomes:

1) Clinical outcomes: BMI, FPG, HbA1C, BP, creatinine clearance, Lipid profiles
2) Humanistic outcomes: patient satisfaction and quality of life (Diabetes-39)

Figure 1 Research Framework

6. Expected Benefits

1) This study may be a pilot for transforming the role of hospital pharmacists in Laos from dispensing to patient-oriented care.
2) As a source of information for hospital directors to enhance the diabetes care team by involving pharmacists and to work collaboratively to decrease mortality and/or comorbidities in the local regions.
3) This study will be a source of information for teaching pharmacy students about pharmacists' role in direct patient care.

Chapter 2

Literature Review

This literature review is divided into 4 main parts:

1. Pathophysiology of type 2 diabetes
2. Strategies to manage type 2 diabetes
    2.1. Standard of medical care in diabetes—2019 by American Diabetes Association (ADA)
    2.2. Clinical practice guideline for diabetes Thailand in 2017
    2.3. Diabetes medications
    2.4. Pharmaceutical care for type 2 diabetes
        2.4.1. Drug-related problems
    2.5. Chronic care model
    2.6. Home care pharmacist for type 2 diabetes
3. Health status and in Lao PDR
4. Related articles
    4.1. The perspectives on diabetes management
    4.2. Questionnaire development
        4.2.1. Satisfaction questionnaire
        4.2.2. Diabetes-39
    4.3. Inter disciplinary team as a strategy for diabetes management
    4.4. RCT, systematic review and meta-analysis (SR-MA) of diabetes care intervention
    4.5. Systematic Review of Qualitative Studies: Summary of included studies

1. Pathophysiology of type 2 diabetes

Diabetes mellitus is a heterogeneous disorder defined by the presence of hyperglycemia. Diagnostic criteria for diabetes include the following (any one of which establishes the diagnosis): (1) a fasting plasma glucose (FPG) of ≥126 mg/dL (7.0 mmol/L); (2) classic symptoms of hyperglycemia plus a random plasma glucose of ≥200 mg/dL (11.1 mmol/L); (3) a 2-hour plasma glucose level ≥200 mg/dL following a standard 75 grams oral glucose load (oral glucose tolerance test [OGTT]); or (4) a glycated hemoglobin (HbA1C) >6.5%. While HbA1C (A1C) values, which reflect average blood glucose levels during the previous 2–3 months (the predicted half-life of erythrocytes), have long been used to monitor therapeutic responses, their use for diagnosis is more recent now that assays are more standardized and evidence supports their correlation with risk of diabetic complications, analogous to FPG. The advantages of using A1C for screening (no need to fast, a reflection of glucose over time) are countered by its lower sensitivity, as it identifies one-third fewer cases of undiagnosed diabetes in large epidemiologic studies, leading to some controversy surrounding its appropriate use. (19)

Hyperglycemia in all cases is due to a functional deficiency of insulin action. Deficient insulin action can result from a decrease in insulin secretion by the β cells of the pancreas, a decreased response to insulin by target tissues (insulin resistance), and/or an increase in the counter-regulatory hormones that oppose the effects

of insulin. The relative contributions of these three factors form the basis for the classification of this disorder into subtypes and also help explain the characteristic clinical presentations of each subtype. (19) The pathophysiology of diabetes was shown in Figure 2 below.
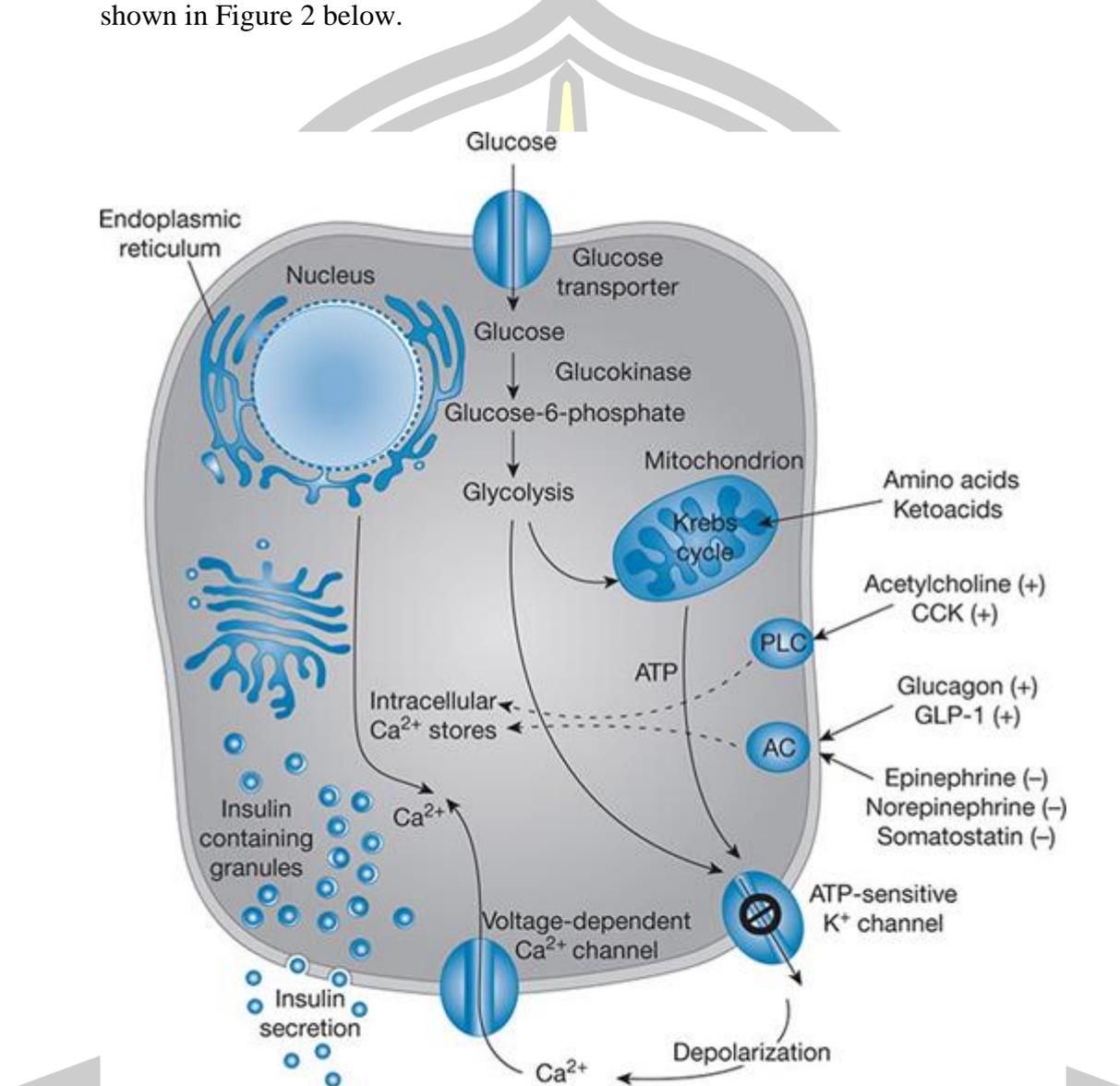
Figure 2 Pathophysiology of type 2 diabetes

2. Strategies to manage type 2 diabetes

    2.1. Standard of medical care in diabetes in 2019 by ADA

        There are 16 sections of strategy in the new ADA's recommendation (9) as follows:

        2.1.1. Improving care and promoting health in populations. Because telemedicine is a growing field that may increase access to care for patients with

diabetes, discussion was added on its use to facilitate remote delivery of health-related services and clinical information.

2.1.2. Classification and diagnosis of diabetes. The criteria for the diagnosis of diabetes was changed to include two abnormal test results from the same sample (i.e., fasting plasma glucose and A1C from same sample).

2.1.3. Prevention or delay of type 2 Diabetes. Nutrition and smoking cessation are recognized for weight control in order to prevent and delay of T2DM.

2.1.4. Comprehensive medical evaluation and assessment of comorbidities. To explicitly call out the importance of the diabetes care team and to list the professionals that make up team.

2.1.5. Lifestyle management. To encourage people with diabetes to decrease consumption of both sugar sweetened and nonnutritive-sweetened beverages and use other alternatives, with an emphasis on water intake as well as emphasizing the benefit of physical activity such as a variety of leisure-time physical activities and flexibility and balance exercises.

2.1.6. Glycemic targets. To emphasize that the risks and benefits of glycemic targets can change as diabetes progresses and patients age, a recommendation was added to reevaluate glycemic targets over time. Generally accepted glycemic target is lower than 7%.

2.1.7. Diabetes technology. The recommendation to use self- monitoring of blood glucose in people who are not using insulin was changed to acknowledge that routine glucose monitoring is of limited additional clinical benefit in this population.

2.1.8. Obesity management for the treatment of type 2 diabetes. A recommendation was modified to acknowledge the benefits of tracking weight, activity, etc., in the context of achieving and maintaining a healthy weight.

2.1.9. Pharmacologic approaches to glycemic treatment. Consideration of key patient factors: 1) important comorbidities such as ASCVD, chronic kidney disease, and heart failure, 2) hypoglycemia risk, 3) effects on body weight, 4) side effects, 5) costs, and 6) patient preferences.

2.1.10. Cardiovascular disease and risk management. Recommendations were modified to include assessment of 10-year ASCVD risk as part of overall risk assessment and in determining optimal treatment approaches. The recommendation and text regarding the use of aspirin in primary prevention was updated with new data.

2.1.11. Microvascular complications and foot care. The recommendation was added for people with type 2 diabetes and chronic kidney disease to consider agents with proven benefit with regard to renal outcomes. Gabapentin was added to the list of agents to be considered for the treatment of neuropathic pain in people with diabetes based on data on efficacy and the potential for cost savings.

2.1.12. Older adults. A new section and recommendation on lifestyle management was added to address the unique nutritional and physical activity needs and considerations for older adults.

2.1.13. Children and adolescents. A recommendation was added to emphasize the need for disordered eating screening in youth with type 1

diabetes beginning at 10–12 years of age. The discussion of type 2 diabetes in children and adolescents was significantly expanded, with new recommendations in a number of areas, including screening and diagnosis, lifestyle management, pharmacologic management, and transition of care to adult providers.

2.1.14. Management of diabetes in pregnancy. Greater emphasis has been placed on the use of insulin as the preferred medication for treating hyperglycemia in gestational diabetes mellitus as it does not cross the placenta to a measurable extent and how metformin and glyburide should not be used as first line agents as both cross the placenta to the fetus.

2.1.15. Diabetes care in a hospital. Because of their ability to improve hospital readmission rates and cost of care, a new recommendation was added calling for providers to consider consulting with a specialized diabetes or glucose management team where possible when caring for hospitalized patients with diabetes.

2.1.16. Diabetes advocacy. The "Insulin Access and Affordability Working Group: Conclusions and Recommendations" ADA statement was added to this section. Published in 2018, this statement compiled public information and convened a series of meetings with stakeholders throughout the insulin supply chain to learn how each entity affects the cost of insulin for the consumer, an important topic for the ADA and people living with diabetes.

2.2. Clinical Practice Guideline for Diabetes in Thailand in 2017

The clinical practice guideline for diabetes in Thailand (10) has emphasized the recommendation to clarify the objective or the treatment goal which is highly beneficial for diabetes patient in order to prevent or delay diabetes related complications. The key to facilitate the benefit of diabetes care is an inter-disciplinary team of healthcare providers who are able to provide complete diabetes care such as diabetes education on self-management, treatment goal, lifestyle modification which is the real evidence of patient motivation.

2.3. Diabetes medications

ADA guideline (9) stated that for initial therapy metformin should be started at the time type 2 diabetes is diagnosed unless there are contraindications; for most patients this will be monotherapy in combination with lifestyle modifications. Metformin is effective and safe, is inexpensive, and may reduce risk of cardiovascular events and death. The summary of hypoglycemic agents of ADA is in the Figure 3, 4, and 5
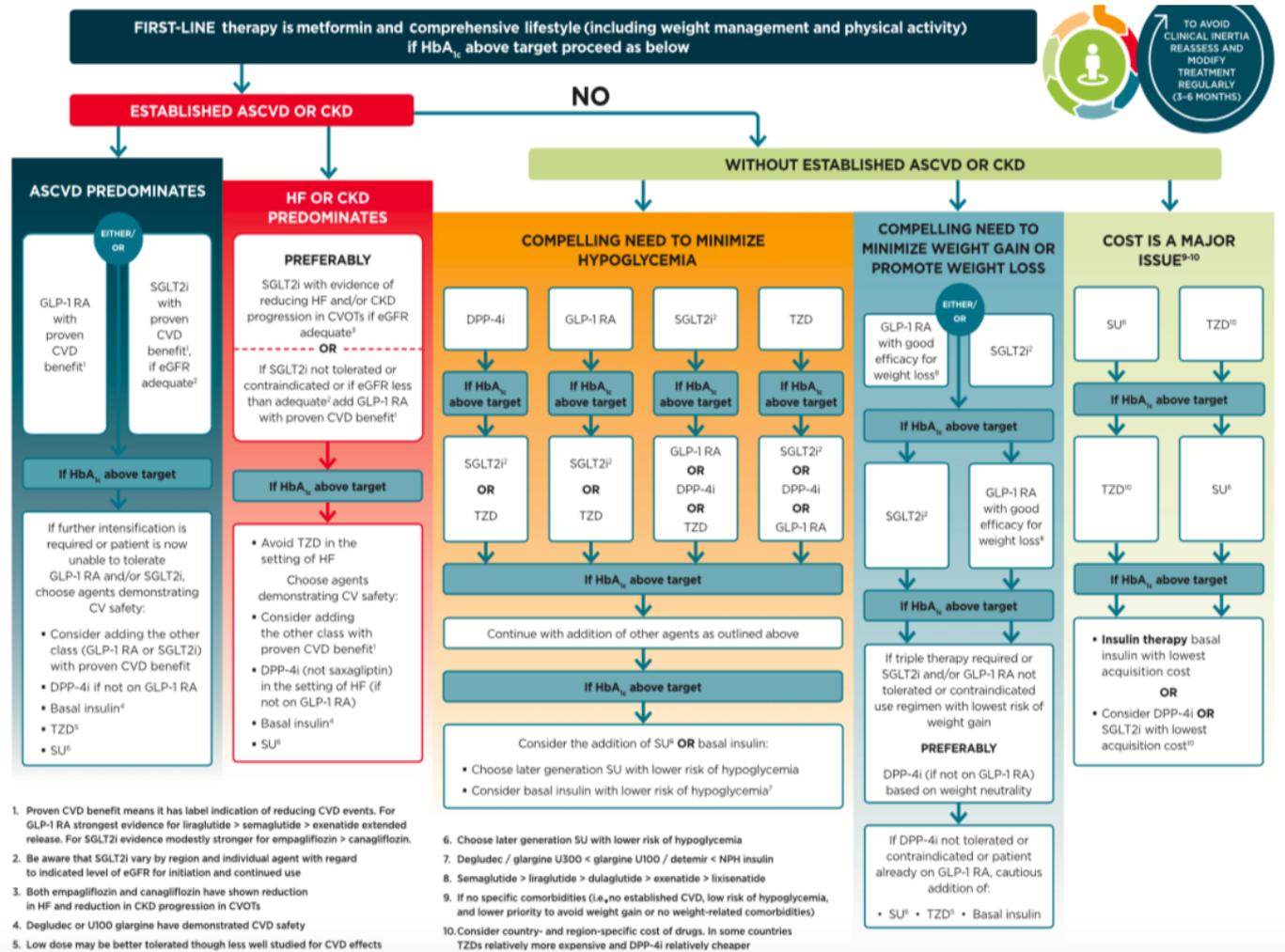
Figure 3 General recommendation of anti-hyperglycemic therapy in type 2 diabetes by ADA 2019 (9)
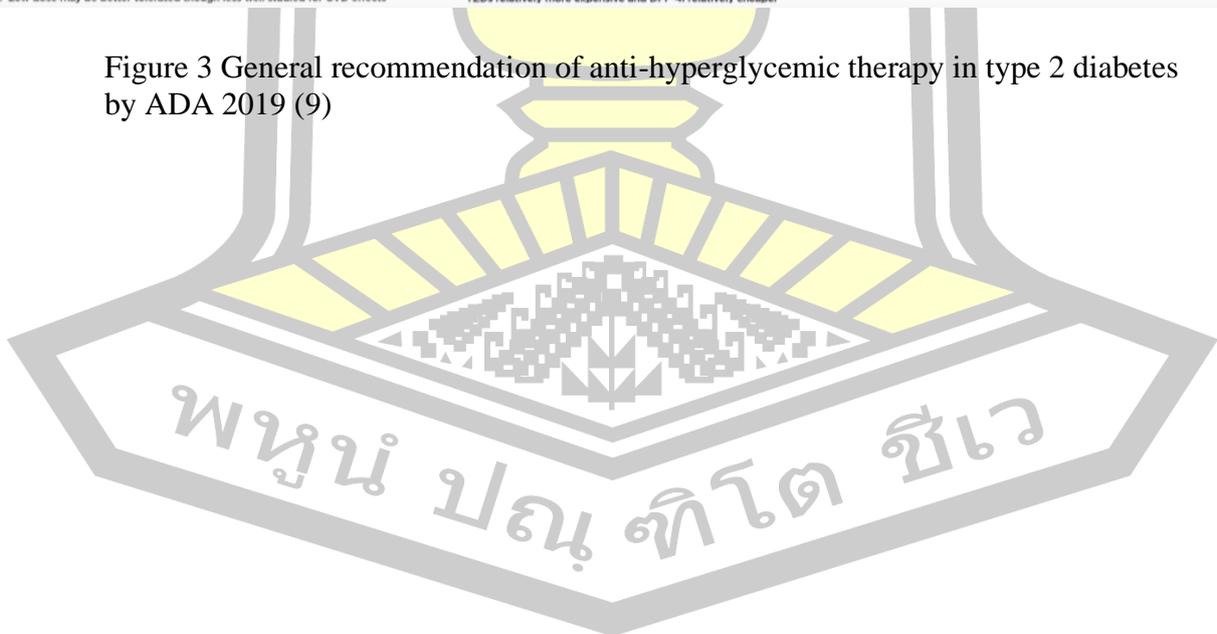
Class	Compound(s)	Dosage strength/product (if applicable)	Median AWP (min, max)†	Median NADAC (min, max)†	Maximum approved daily dose*
Biguanides	• Metformin	500 mg (IR)	$84 ($4, $93)	$2	2,000 mg
		850 mg (IR)	$108 ($6, $109)	$3	2,550 mg
		1,000 mg (IR)	$87 ($4, $88)	$2	2,000 mg
		500 mg (ER)	$89 ($82, $6,671)	$4 ($4, $1,267)	2,000 mg
		750 mg (ER)	$72 ($65, $92)	$4	1,500 mg
		1,000 mg (ER)	$1,028 ($1,028, $7,214)	$311 ($311, $1,321)	2,000 mg
Sulfonylureas (2nd generation)	• Glimepiride	4 mg	$71 ($71, $198)	$4	8 mg
	• Glipizide	10 mg (IR)	$75 ($67, $97)	$5	40 mg (IR)
		10 mg (XL)	$48	$15	20 mg (XL)
	• Glyburide	6 mg (micronized)	$50 ($48, $71)	$10	12 mg (micronized)
		5 mg	$93 ($63, $103)	$13	20 mg
Thiazolidinediones	• Pioglitazone	45 mg	$348 ($283, $349)	$4	45 mg
	• Rosiglitazone	4 mg	$407	$329	8 mg
α-Glucosidase inhibitors	• Acarbose	100 mg	$106 ($104, $106)	$23	300 mg
	• Miglitol	100 mg	$241	$311	300 mg
Meglitinides (glinides)	• Nateglinide	120 mg	$155	$46	360 mg
	• Repaglinide	2 mg	$878 ($162, $898)	$48	16 mg
DPP-4 inhibitors	• Alogliptin	25 mg	$234	$170	25 mg
	• Saxagliptin	5 mg	$490 ($462, $490)	$392	5 mg
	• Linagliptin	5 mg	$494	$395	5 mg
	• Sitagliptin	100 mg	$516	$413	100 mg
SGLT2 inhibitors	• Ertugliflozin	15 mg	$322	$257	15 mg
	• Dapagliflozin	10 mg	$557	$446	10 mg
	• Canagliflozin	300 mg	$558	$446	300 mg
	• Empagliflozin	25 mg	$558	$448	25 mg
GLP-1 receptor agonists	• Exenatide (extended release)	2 mg powder for suspension or pen	$792	$634	2 mg**
	• Exenatide	10 μg pen	$850	$680	20 μg
	• Dulaglutide	1.5/0.5 mL pen	$876	$702	1.5 mg**
	• Semaglutide	1 mg pen	$875	$704	1 mg**
	• Liraglutide	18 mg/3 mL pen	$1,044	$835	1.8 mg
Bile acid sequestrants	• Colesevelam	625 mg tabs	$712 ($674, $712)	$354	3.75 g
		3.75 g suspension	$674	$598	3.75 g
Dopamine-2 agonists	• Bromocriptine	0.8 mg	$855	$685	4.8 mg
Amylin mimetics	• Pramlintide	120 μg pen	$2,547	$2,036	120 μg/injection†††

AWP, average wholesale price; DPP-4, dipeptidyl peptidase 4; ER and XL, extended release; GLP-1, glucagon-like peptide 1; IR, immediate release; NADAC, National Average Drug Acquisition Cost; SGLT2, sodium–glucose cotransporter 2. †Calculated for 30-day supply (AWP [44] or NADAC [45] unit price × number of doses required to provide maximum approved daily dose × 30 days); median AWP or NADAC listed alone when only one product and/or price. *Utilized to calculate median AWP and NADAC (min, max); generic prices used, if available commercially. **Administered once weekly. †††AWP and NADAC calculated based on 120 μg three times daily.

Figure 4 ADA guidelines for hypoglycemic agents, dose recommended, and cost (9)
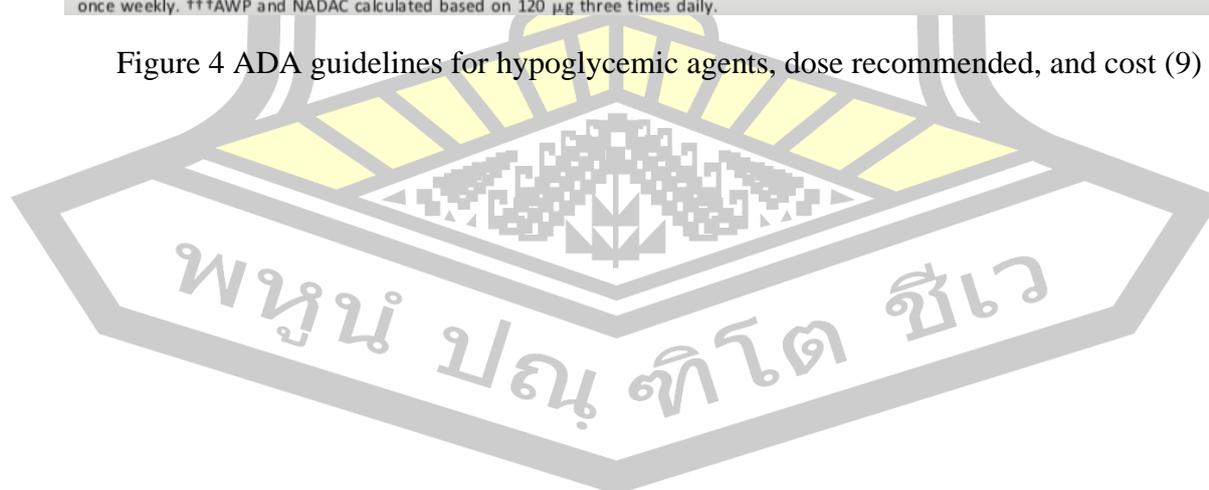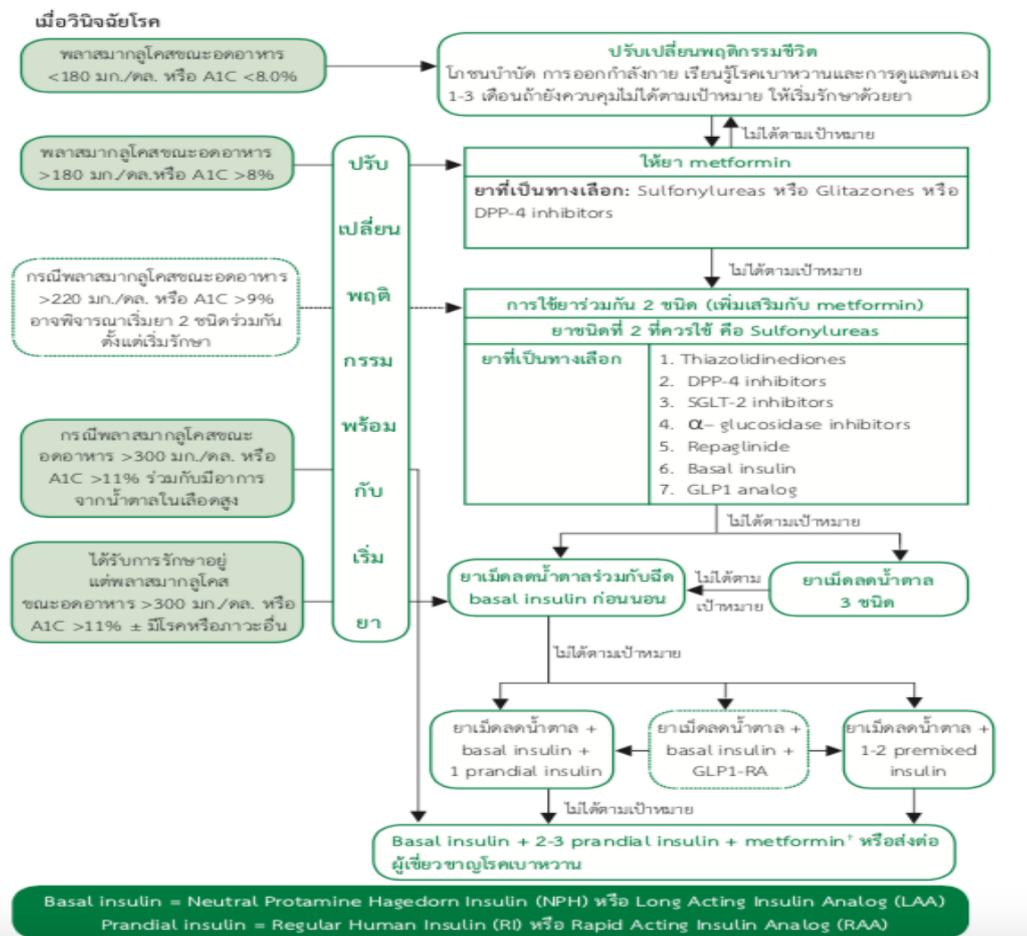
Figure 5 General recommendation of anti-hyperglycemic therapy in type 2 diabetes
by the clinical practice guideline for diabetes in Thailand in 2017 (10)

2.4. Pharmaceutical care

2.4.1. Diabetes care

According to ADA guidelines 2017, an inter-disciplinary team of
health professional including pharmacists who play a very important role
for improving diabetes care. Optimal diabetes management requires an
organized, systematic approach and the involvement of a coordinated
team of dedicated health care professionals working in an environment
where patient-centered high-quality care is a priority. The National
Diabetes Education Program (NDEP) maintains an online resource
(www.betterdiabetescare.nih.gov) to help health care professionals to
design and implement more effective health care delivery systems for
those with diabetes. (20)

The concept of pharmaceutical care was first conceived by Hepler
and Strand and is defined as the responsible provision of drug therapy for
the purpose of achieving definite outcomes that improve a patient's quality
of life.(21) Pharmacists must abandon factionalism and adopt patient-

centered pharmaceutical care as their philosophy of practice. Changing the focus of practice from products and biological systems to ensuring the best drug therapy and patient safety will raise the pharmacist's level of responsibility and require philosophical, organizational, and functional changes. It will be necessary to set new practice standards, establish cooperative relationships with other health-care professions, and determine strategies for marketing pharmaceutical care. Pharmacy's re-professionalization will be completed only when all pharmacists accept their social mandate to ensure the safe and effective drug therapy of the individual patient.(21) Well-trained clinical pharmacists and a medical system utilizing active pharmacist-driven patient care can improve the quality, outcomes, and efficiency of patient management.(22)

Pharmaceutical care involves three major functions: identifying potential and actual drug-related problems; resolving actual drug-related problems; and preventing drug-related problems. Although there are different trends, such as clinical pharmacy services, cognitive services, medication management, medication review, they all share the same philosophy and objectives, namely ''the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life.''(23)

A review of Hughes et al (2017) revealed the extensive studies worldwide have evaluated the effectiveness of pharmacy-based interventions in supporting people with T2DM. Most of the studies have been conducted in developed western countries, particularly the United States of America, although examples can be found around the globe including the United Arab Emirates and Hong Kong. Fewer studies however have been conducted in low-income and middle-income countries such as Nigeria, Iran, India, Brazil, Thailand, Jordon, Iraq, and Malaysia. The interventions were measured for their effectiveness using the following: clinical outcomes, such as glycemic control, reduction of risk factors (such as blood pressure, lipids, and body mass index [BMI]), medication adherence, screening for complications, and drug-related problems identified/solved; humanistic/social outcomes, such as quality of life, satisfaction, belief, knowledge, lifestyle changes, and self-care activity; economic outcomes, such as health costs. Mostly of studies review supported the role of pharmacist involved with diabetes care. (11)

2.4.2. Drug-related problem

Drug-related problems (DRPs) include medication errors (involving an error in the process of prescribing, dispensing, or administering a drug, whether there are adverse consequences or not) and adverse drug reactions (any response to a drug which is noxious and unintended, and which occurs at doses normally used in humans for prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function). Furthermore, adverse drug events can be defined as an injury – whether or not causally–related to the use of a drug.(24) Medication review by pharmacist seem to reduce DRPs from the literature

review of Wilmer et al (2015). The Preventing Hospital Admissions by Reviewing Medication (PHARM) study demonstrated that a pharmaceutical care process seems to reduce the number of medication-related (often costly) hospital admissions, and the authors stated that a pharmaceutical care process like PHARM is unlikely to be cost saving in its present form.(25) Another study showed that medication review by a pharmacist decreases the risk of drug interaction by 20%.(26)

Brandt et al (2014) described seven steps of medication review for pharmacists. The first three steps focus on collecting information about the patient, while the fourth and fifth steps identify drug-related problems. The sixth and seventh steps concern the reporting of interventions and the GP's consideration. The model was tested and found to be workable to deliver a medication review with high acceptance rates.(27)

2.5. Chronic Care Model

The Chronic Care Model (CCM) is a multifaceted, evidence-based framework for enhancing care delivery by identifying essential components of the health care system that can be modified to support high-quality, patient-centered chronic disease management.(28) The CCM provides a systematic approach to initiate transformation. Interrelated elements of the CCM, Figure 6, include:

1) Health systems, including culture, organizations, and mechanisms to promote safe, high-quality care
2) Decision support based on evidence and patients' preferences and needs
3) Clinical information systems to organize patient and population data
4) Patient self-management support to enable patients to manage their health and health care
5) Community resources to mobilize patient resources
6) Delivery system design for clinical care and self-management support, including team care

The CCM has been used in a variety of health care settings to guide systematic and individual improvement in chronic illness care, including diabetes. Previous studies demonstrate the effectiveness of interventions for patients and diabetes-related outcomes based on specific components of the CCM.(28)

The Chronic Care Model
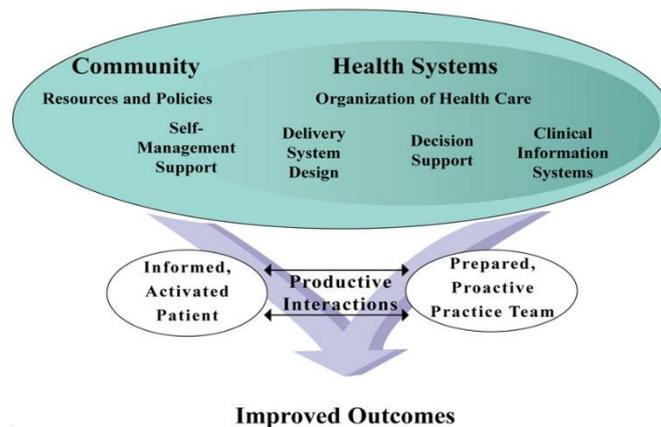
Figure 6 Chronic Care Model (28)

2.6. Home care pharmacist

Initiatives such as the Patient-Centered Medical Home show promise for improving outcomes by coordinating primary care and offering new opportunities for team-based chronic disease management. Additional strategies to improve diabetes care include reimbursement structures that, in contrast to visit- based billing, reward the provision of appropriate and high-quality care to achieve metabolic goals, and incentives that accommodate personalized care goals.(20)

Over the years, pharmacists have proved to be effective in delivering different pharmaceutical care services, such as the Home Medication Management Review (HMMR) service, to better manage chronic diseases. Similar services are being conducted by accredited pharmacists all around the world, including the Medication Therapy Management in the USA, the Home Medication Review in Australia, the Medicines Use Reviews' in England and Wales and the Chronic Medication Service in Scotland. The positive impact of such pharmacist-delivered services on patients' primary outcomes has been proven through several studies.(18)

There is a growing body of literature supporting the role of the pharmacist in diabetes care, as pharmacists can provide "continuity of care" by following patient care progress between physician visits, utilizing their clinical expertise to monitor and manage diabetes medication plans, and educating patients on disease, lifestyle, and adherence issues. In January 2008, new current procedural terminology codes have been established to allow pharmacists to bill for medication therapy management services. Pharmacists in community and primary care settings can be a key resource working in an interdisciplinary model for improved medication management of patients with diabetes. This is consistent with the "medical home" concept of care that promotes health care providers working collaboratively to coordinate patient-centered care. In such a model, pharmacists can focus on managing medications to positively impact health outcomes, reduce overall healthcare system costs, and empower patients and consumers to actively manage their health.(29)

3. Health status in Lao PDR

The Lao People's Democratic Republic is surrounded by five other countries in the Greater Mekong Region (all provinces have an international border): China, Cambodia, Myanmar, Thailand, and Vietnam, with an estimated population of 6.2 million. (4)

The national health indicators of the Lao People's Democratic Republic have been improving steadily over the past three decades. The crude death rate declined from 15.1 to 8.0 deaths per 1000 inhabitants between 1995 and 2010, with probability of children under 5 dying estimated to be 59 in 1000 live births. The crude birth rate fell from 41.3 to 29.9 in the same period. At the same time, life expectancy at birth rose by more than 10 years in a decade, from 51 years in 1995 to 65 in 2010. The main cause of mortality and morbidity are communicable diseases where lower respiratory infection and diarrhea are the leading causes, and main cause of death for children under 5 years old is pneumonia (27%). (4)

Every year, non-communicable diseases (NCDs) cause the deaths of around 12 100 males, 60% of whom are under 70 years of age, and about 11 700 females, 53% of whom are under 70 years old. Of all NCD-related deaths, cardiovascular diseases and diabetes have the highest age-standardized death rate per 100 000 (467.9 for males and 329.8 for females), followed by chronic respiratory diseases (122.8 for males and 111.1 for females). Cancer kills 145.4 males and 89.0 females per 100 000 population. According to the recently published global NCD status report by WHO, 17% of the Lao population are not physically active enough, 13.3% are overweight and 32.1% have raised blood pressure. With the current speed of socioeconomic development in the Lao People's Democratic Republic, the incidence of NCDs is expected to continue to rise. (4)

Tobacco and alcohol abuse remain the main risk factors of NCDs in the Lao People's Democratic Republic. In 2008, smoking rate recorded among the Lao population was 21.6%, with a higher rate among males (41.1%) than females (2.5%). Estimates in 2008 showed that adult per capita consumption of alcohol is seven litres per year. These risk factors put an additional strain on health services in the Lao People's Democratic Republic. (4)

In the point of human resources for health care, the health system review in 2014 stated that compared to its neighboring countries, the Lao People's Democratic Republic has a relatively low ratio of qualified health workers per 1000 population. The number of qualified HCPs (i.e. medical doctors, nurses and midwives with high- and mid-level professional qualifications) was 3873 (MOH, 2010), equivalent to 0.69 per 1000 this is significantly lower than the WHO recommended standard of 2.5 HCPs per 1000 population.(30)

4. Related articles

4.1. The perspectives on diabetes management

Despite the well-known long-term benefits of adequate glycemic control on reducing complications and death from any causes, many diabetic patients

still fail to achieve treatment targets, adhere poorly to the treatment, and thus remain at risk of complications. With the increasing demand of chronic diabetes care due to the increasing disease prevalence, a shift from secondary diabetes care to a primary type was found to improve the quality of care provided by both general practitioners and nurses in the United Kingdom.(31) Furthermore, with the philosophical shift to address the needs of patients with complex chronic medical conditions such as diabetes, the Chronic Care Model (CCM) has been developed to guide for service quality improvements.(32) The CCM focuses on improving and optimizing six main domains of health care system including health care organization, delivery system design, clinical information system, decision support, self-management support, and community resources. (11) The strategies are centered on patients' needs,(33) focusing on an individual patient to address specific societal, cultural, and religious factors. (34) Strickland et al (2010) revealed that CCM implementation in primary care practice improved service care for diabetic patients and increased rates in the conduct of behavioral counseling. (35)

A systematic review revealed that some of the barriers in diabetes management include language and communication discordance with health care providers, inconsistent willingness to partake in self-management, failure to adopt a diabetic diet due to lack of specific information, misunderstandings and misconceptions, and concerns on the long-term safety of diabetes medications .(36) Despite the existence of many well-defined targets and practice guidelines for the management of hyperglycemia, hypertension, and dyslipidemia in patients with T2DM, clinical inertia exists due to periodic revisions of guidelines resulting with confusion among healthcare providers. (7)

Previous systematic reviews have identified more focused specific interests covering self-management interactions between patients and healthcare providers, (37) strategies to improve primary care,(38) experiences in taking oral medication, (39) and population groups such as East Asian Immigrants (40), South Asian (36), and Ethnic Minorities. (41) These data, however, might not be relatable to developing countries which have never established diabetes clinics in their health care system. Thus, it is imperative that insight details from the perspectives of patients and providers be synthesized through a systematic review utilizing the CCM framework to provide more information on factors related to diabetes management.

4.2. Questionnaire Development

4.2.1. Satisfaction questionnaire

Patient satisfaction is one important indicator for evaluation and development of diabetes management or care. Some studies used satisfaction as the primary outcomes. (42) Satisfaction of service can be assessed in several perspectives such as healthcare providers' perspectives, patients' perspectives, however, perspectives from patients are an important indicator which reflects the quality of service.(43) Patients' perspectives analysis lead to good understanding of developing the quality of service.(44) Several studies have been done for validity and

reliability of the tool,(45, 46) however, each study has different aspects of satisfaction depending on framework, essential need for service, culture and needs of healthcare system in each country.

According to the information service of diabetes clinic, the perspective of patients' trends to promote the quality of service. Previous studies have developed the validity and reliability of the tools for satisfaction assessment of diabetes care service, including diabetes management.(47, 48) Paddock et al (2000) also developed the 73 items of the questionnaire tool in order to evaluate a Diabetes Disease Management Program (DDMP), the validated 73-item mailed satisfaction survey had a 34.1% response rate. Principal components analysis yielded 13 components with eigenvalues 1.0. The Scree test proposed a 6-component solution (39 items), which explained 59% of the total variation. Internal consistency reliabilities computed for the first 6 components (Cronbach's alpha = 0.79–0.95) were acceptable. (49) The development and test a reliable and practical self-administrated questionnaire in Chinese to evaluate outpatient satisfaction in China found that factor analysis generated six dimensions, and all item-total coefficients were >0.8. Cronbach's alpha exceeded 0.7 for all dimensions, and the inter-subscale correlation coefficients were all lower than the Cronbach's alpha coefficients of the corresponding scale. According to the results, outpatients were least satisfied with waiting time (86.8%) and most satisfied with the quality of medical care (90.1%). (50)

4.2.2. Diabetes-39

Boyer et al (1997) firstly developed the Diabetes-39 (DM-39) questionnaire. This tool was developed in two phases and the final result consisted 39 item that covered five dimensions of patients' lives: energy and mobility; diabetes control; anxiety and worry; social burden and sexual functioning. The results showed that Diabetes-39 was as a valid discriminative instrument, one which showed significant correlations with an overall quality-of-life assessment, the pattern of diabetes severity, and comorbidity. Further, the results from Diabetes-39 correlated well with the results from the established generic quality-of-life instrument, the medical outcomes study 36-Item Short-Form Health Survey.(51)

This tool had been used and translated in various countries. Songraksa and Lerkiatbundit (2009) translated Diabetes-39 from English into Thai language and conducted the factor analysis, and the result revealed that a six-factor structure underlying the DM-39. The newly identified factor was other health problems and diabetic complications, comprising of 3 items. Thirty-one items from the 36 remaining items clustered into 5 factors identified by the previous studies. The size of nearly all factor loadings were about 0.40 or greater than 0.40. All six dimensions of the DM-39 showed reliability indices greater than 0.70. The patterns of the relationship between the D-39 and the SF-36 or self-perception of disease severity were consistent with those hypothesized. All dimensions of the DM-39 could reliably discriminate among subjects

with/without comorbidities or those with/without insulin injection or those with/without complications. However, the effect size was rather small, less than 0.50.(52)

The study of Chen et al (2015) aimed to compare the Diabetes-39 (DM-39) with six multi-attribute utility (MAU) instruments (15D, AQoL-8D, EQ-5D, HUI3, QWB, and SF-6D), and to develop mapping algorithms which could be used to transform the DM-39 scores into the MAU scores. The results showed that MAU instruments discriminated between diabetes patients and the healthy public; however, utilities varied between instruments. The 15D, SF-6D, AQoL-8D had the strongest correlations with the DM-39. Except for the HUI3, there were significant differences by gender. Mapping algorithms based on the ordinary least squares (OLS) estimator consistently gave better goodness-of-fit results. The mean absolute error (MAE) values ranged from 0.061 to 0.147, the root mean square error (RMSE) values 0.083 to 0.198, and the R-square statistics 0.428 and 0.610. Based on MAE and RMSE values the preferred mapping is D-39 into 15D. R-square statistics and the range of predicted utilities indicate the preferred mapping is DM-39 into AQoL-8D. The result supported that DM-39 could also be used for conducting the cost utility analysis.(53)

4.3. Inter disciplinary team as a strategy for diabetes management.

A study of Doherty et al (2000) stated that the six core team members included; one consultant physician, four diabetes nurse specialists and one dietician who participated throughout the duration of the project. They conducted the qualitative interview with T2DM patients who had been treated with this core team. In semi-structured interviews, patients were asked to consider the possibility of being offered extra appointments to focus specifically upon improving their diabetes control. They stated the benefit of being seen by the same person, obtaining reassurance, getting help with hypos and increased knowledge.(54)

A review by McGill et al (2017) stated that an interdisciplinary team (IDT) approach to type 2 diabetes (T2DM) management as one of 10 practical steps for health care professionals to help more people achieve their glycemic goal. The IDT, including a diabetes nurse educator, psychologist, pharmacist and nutritionist, approach can be effective in delivering care to people who have chronic conditions, such as T2DM, that require both self-management and major lifestyle alterations significantly reduced HbA1c levels compared with usual diabetes care provided by PCPs (−1.3% vs. −0.2%, respectively, $p < 0.0001$).(55)

4.4. RCT, SR-MA of diabetes care intervention

The systematic review and meta-analysis included five English and 48 Chinese publications of Choi et al (2016) which aimed to determine the size of glycemic effect of different diabetes education approaches for Chinese patients. The Chinese studies found that glycemic improvement for Chinese patients was

particularly effective when an ongoing regular education was employed; and resulted in the overall weighted mean difference (WMD) in glycated hemoglobin (HbA1c) was −1.19% (−13 mmol/mol). Ongoing regular education was most-commonly employed, with a reported WMD of −2.02% (−22 mmol/mol).(56)

The meta-analysis of Huang et al (2016) aimed to evaluate the outcomes of various lifestyle interventions, including diet modifications (DIET), physical activity (PA), and patient education (EDU) in reducing the risk of cardiovascular disease in patients with type 2 diabetes. The study found that DIET intervention showed an improvement in HbA1c, systolic/diastolic blood pressure and HDL-c, with an exception of LDL-c and BMI, suggesting that nutritional intervention had a significant impact on the quality of life by reducing the cardiovascular risk in type 2 diabetes patients.(57)

Another meta-analysis for lifestyle change by Chen et al (2015) aimed to evaluate the effects of comprehensive lifestyle change, such as diet, exercise, and education, on clinical markers that were risk-factors for cardiovascular disease in patients with type 2 diabetes, also found that lifestyle intervention showed significant benefit in risk factors that are known to be associated with development of cardiovascular disease in patients with type 2 diabetes; and resulted in standardized difference in means of change from baseline significantly favored the intervention compared with the control group in BMI (− 0.29; 95% CI, − 0.52 to − 0.06, p = 0.014), HbA1c (− 0.37; 95% CI, − 0.59 to − 0.14, p = 0.001), SBP (− 0.16: 95% CI, − 0.29 to − 0.03, p = 0.016), DBP (− 0.27, 95% CI = − 0.41 to − 0.12, p < 0.001). (58)

In Canada they conducted a systematic review of interventions that aimed at improving screening, treatment, prevention and management of type 2 diabetes and obesity-related chronic disease in Indigenous communities from 2008 to 2014, with the aim of identifying current best practices. Interventions focused on improving fitness were more effective than those aimed at dietary change. Overall, they found a range of successes among these interventions. Those that met with limited success reported that complex social issues and poverty presented challenges to effective intervention work in these communities. Participatory action research methods and community ownership of the intervention were found to be essential for project success.(59)

Regular physical activity is an important goal for elders with chronic health conditions. The study in Southeast Seattle gave Physical Activity for a Lifetime of Success (PALS) has been used with people with diabetes aged 65 years or older, the main intended outcome measure was physical activity level; the secondary outcome measure was mean hemoglobin A1c. A community-based referral and support program found that to increase physical activity among elderly, ethnically diverse, low-income people with diabetes, many of whom are not English-speaking, may be thwarted by unforeseen barriers. Those who enrolled and participated in the PALS program appeared to increase their level of physical activity. (60)

In Thailand, the study gave family-oriented intervention to improve self-efficacy, self-management, glycemic control and quality of life in individuals living with type 2 diabetes with a design of single-blinded randomized

controlled trial found that the intervention arm had significantly better self-efficacy, self-management, outcome expectations, and diabetes knowledge (p < 0.001, in each). Participation in the intervention increased the diabetes self-management score by 14.3 points (b=14.3, 95% CI 10.7–17.9, p<0.001). Self-management was better in leaner patients and in females. No between-group differences were seen in quality of life or glycemic control, however, in the risk-adjusted multivariable models, higher self-management scores were associated with significantly.(61)

4.5. Systematic Review of Qualitative Studies: Summary of included studies

This study had reviewed qualitative studies which showed the results of 23 studies with CASP scores as shown in Table 1.

Table 1 Overview of included studies and CASP scores for systematic review

Coding article	Authors/year/ Country/setting	Aims	Study design	Sampling/ participants	Analysis method	Finding	CASP score
1	Beverly et al .2012 (62) USA Primary Care	To explore physicians' and T2DM patients' perceptions, attitudes, and behaviors that support or impeded the physician-patient relationship T2DM treatment.	In-depth face-to-face interviews	Purposive sampling of 19 endocrinologists and primary care physicians and 34 patients diagnosed with T2DM at least two years prior	Content analysis by independently marking and categorizing key words, phrases, and texts to identify themes	Two themes of physician perspectives are 1) responsibility for patients' difficulty achieving treatment goals and 2) patients' reactions. Two themes of patient perspectives are 1) patients' self-blame for difficulty achieving treatment goals and 2) physicians' reactions to unmet goals.	8
2	Goetz et al. 2012(63) Germany Primary Care	To explore general practitioners', nurses' and T2DM patients' views, experiences, and perspectives on the importance of social support in caring for people with T2DM and their roles in providing social support.	Focus groups	General practitioners (n=10), practice nurses (N=10), and people with diabetes (n=9)	Thematic analysis using qualitative content analysis	Three main themes of social support are 1) current situation, 2) barriers and problems, and 3) future perspectives.	10
3	Längst et al. 2015 Netherlands	To investigate which factors participants perceived to enhance	Semi-structured focus groups	T2DM patients (n=25), general practitioners	Transcribed verbatim, content analysis	Two main themes are 1) factors perceived to enhance medication	8

Coding article	Authors/year/ Country/setting	Aims	Study design	Sampling/ participants	Analysis method	Finding	CASP score
	Primary Care	or impede medication information provision in primary care.		(n=13), and health care assistants (n=10) (four patients had both a general practitioner and a health care assistant)		information provision (including tailored, adequate information, trusting patient–provider relationship, medication reconciliation, tools for medication management, team approach to medication communication), 2) factors perceived to impede medication information provision (including inadequate information, lack/overload of information on potential adverse effects, medication reconciliation impeded, lack of support for medication self-management, and system-related barriers).	
4	Brez et al. 2009(64) Canada Hospital	To explore PCPs' perspectives and concerns related to reassuming responsibility for diabetes care after referral to a	Focus groups	Participants included 22 primary care physicians representing a variety of referral frequencies,	Themes identified using a constant comparison method.	Three main themes are 1) primary care physician readiness for transition of care from specialist, 2) patient readiness for discharge, and 3) systems factors and transition of	9

Coding article	Authors/year/ Country/setting	Aims	Study design	Sampling/ participants	Analysis method	Finding	CASP score
		specialized diabetes center.		practice types, and settings.		care from specialist.	
5	Noor et al. 2012 (65) Oman Primary Care	To explore the experiences of primary health-care providers' encounters with patients with T2DM, and their preferences and suggestions for future improvement of diabetes care.	Semi-structured interviews	Nineteen doctors and seven nurses who worked in primary health care in Oman.	Content analysis	Four main themes are 1) organizational factors, 2) patient factors, 3) factors related to health-care providers, and 4) suggestions to improve diabetes care.	8
6	Kern et al. 2001 (66) USA Primary Care	The study captured the PCPs' perceived barriers on the delivery of diabetes care, how diabetes care was delivered, how PCPs preferred to deliver diabetes care, and how they reconciled any inconsistencies.	In-depth interviews, using a semi-structured interview tool.	Twelve PCPs: both family physicians and internists	Interpretive form of qualitative data analysis known as the editing style.	Three main themes are 1) planned care, 2) time constraint, and 3) quality assurance system.	9
7	Raaijmakers et al. 2013 (67) Netherlands Primary Care	To investigate the facilitating and impedeing factors among HCPs (Health Care Professionals) using a qualitative research design.	Semi-structured interviews	Eightteen health care professionals in Netherlands	Data were analyzed using the NVivo qualitative research software package. The	Seven main themes are 1) community resources and policies, 2) organization of health care, 3) self-management support, 4) delivery system design, 5) decision support, 6)	8

Coding article	Authors/year/ Country/setting	Aims	Study design	Sampling/ participants	Analysis method	Finding	CASP score
					Chronic Care Model (CCM) was used to classify the facilitating factors and barriers	clinical information systems, and 7) HCP-related factors.	
8	Brown et al. 2002(68) Canada Primary Care	To explore family physicians' issues and perceptions regarding the barriers and facilitating factors of the management of patients with T2DM.	Focus groups	Physician participants included 16 males and 14 females who attended one of four focus groups with an average of seven physicians per group	The researchers compared field notes and discussed the group process. The strategy of constant comparison analysis was used. Central themes were identified across all focus groups.	Three main themes are 1) patient facilitating factors and barriers, 2) physician facilitating factors and barriers, and 3) system facilitating factors and barriers.	8.5
9	Matthews et al . 2008 (69) USA Primary Care	To explore the experiences, attitudes, and beliefs of adult women living with diabetes and how they managed their diabetes.	Focus groups	Five females who have T2DM	Thematic analysis	Three major themes affecting adherence to treatment regimens are 1) communication with the healthcare providers, 2) knowledge of diabetes, and 3) the consequences of poor glycemic control.	8
10	Carbon et al 2006 (70)	To inform the refinement of self-	Focus groups	Twenty patients were invited to	A structured framework to	Five main themes are 1) diabetes-related	7

Coding article	Authors/year/ Country/setting	Aims	Study design	Sampling/ participants	Analysis method	Finding	CASP score
	USA Health Center	management interventions tailored to Latino patients with T2DM.		participate in each group	systematically review the findings	knowledge, 2) beliefs and attitudes regarding diabetes self-management, 3) self-management practices, 4) perceived barriers, and 5) perceived facilitating factors.	
11	Dutton et al . 2014 (71) Canada Specialist Clinic	To explore patients' expectations and experiences concerning discharge from a specialized diabetes centre back to primary care.	One-on-one semi-structured interviews	Twelve of T2DM patients who have been discharged from the Tertiary Care Diabetes Referral Centre in Ottawa, Canada.	Grounded theory techniques where NVivo 9 was used to organize the coding process	Four main themes are 1) expectations at initial referral, 2) specialist care, 3) discharge from specialist care, and 4) primary care physicians' (PCP) care after discharge.	8
12	Al-Qazaz et al. 2011 (72) Malaysia University Health Clinic	(1) To explore T2DM patients 'experience and knowledge about diabetes. (2) To explore the experiences of diabetic patients in terms of their medications, and (3) To understand the factors contributing to medication adherence in	Semi-structured interview guide	Twelve patients diagnosed with T2DM who attended the USM clinic and received their medications and health care from the same clinic.	Thematic content analysis. The transcripts were analyzed line by line for relevant content and to identify categories of emerging themes for coding.	Four themes are 1) knowledge about diabetes and its medication, 2) experiences of adverse effects of medication, 3) issues related to adherence, and 4) the impact of medical and family relationships on well-being.	9

Coding article	Authors/year/ Country/setting	Aims	Study design	Sampling/ participants	Analysis method	Finding	CASP score
		Malaysia.					
13	Karimi et al. 2014 (73) Iran Primary Care	To explore the facilitating factors and barriers in adaptation among T2DM Iranian patients using qualitative research methods.	In-depth, semi-structured and face- to- face interviews	Purposive samples of 15 T2DM patients	Content analysis focusing on contextual meaning to "provide knowledge and understanding of the phenomenon under study"	Three themes are 1) individual context with subthemes of beliefs, personal background, and previous experience, 2) supportive system with subthemes of family, society and health organizations, and 3) self-comparison with other disease and other diabetes patients. .	8
14	Lewis et al. 2014 (34) Bangladesh Primary Care	To understand patients 'experiences in the treatment of their T2DM.	In-depth interviews	Twenty-three participants with T2DM in five sites across two administrative districts of Bangladesh	Interview transcripts were coded and emergent themes identified	Two main themes are 1) awareness and understanding of diabetes and its effective management, and 2) availability and costs of diagnosis and care.	6
15	Held et al. 2010 (74) America Samoa Health Center	To identify agenda items related to depressive symptoms and its relationship to diabetes.	Focus groups	Thirty-nine American Samoan adults with diabetes	Thematic analysis with NVivo 8	Four main themes are 1) the relationship of depressive symptoms and diabetes, 2) managing depressive symptoms, 3) frequency of seeing depressed patients and 4) stigma and cultural differences.	8

Coding article	Authors/year/ Country/setting	Aims	Study design	Sampling/ participants	Analysis method	Finding	CASP score
16	Lai et al. 2006 (75) Taiwan Rural Area	To gain insight into the perceptions of patients with diabetes, especially ideas of the illness course and perceived severity, and their impacts on self-care behavior.	In-depth patient interviews and focus groups	A purposive sampling strategy for 22 patients (in-depth interview) and 53 patients in seven focus groups	The transcripts of the interviews were analyzed with editing and immersion/cryst allization styles	Three main themes are 1) diagnosis of diabetes and the main features of its course, 2) perceived severity and its assessment, and 3) unidimensionality and its impact on health behaviors.	7
17	Alazri, et al. 2010 (76) UK Rural vs Urban	To explore perceptions and experiences of continuity of care in general practice from the perspectives of patients with T2DM, focusing on the advantages and disadvantages of different types of continuity.	Focus groups	Seventy-nine patients with T2DM from seven practices in Leeds, UK	Framework approach	Three main themes are 1) relational or longitudinal continuity, 2) cross-boundary or team continuity, and 3) continuity of information.	7
18	Kato et al. 2016 Japan(77) Tertiary Hospital	To explore how patients with T2DM psychologically and behaviorally respond to social stigma.	Semi-structured interviews	Participants were adults aged 30–64 diagnosed with T2DM. A total of 26 patients participated.	Transcribed verbatim and analyzed using a grounded theory approach	Four main themes are 1) encountering negative experiences, 2) re-evaluating self with T2DM, 3) reconstructing a sense of identity, and 4) maintaining a balance between managing T2DM and social roles.	8.5

Coding article	Authors/year/ Country/setting	Aims	Study design	Sampling/ participants	Analysis method	Finding	CASP score
19	Al-Azri et al. 2011 (78) Oman Primary Care Health Center	To explore diabetic patients views of factors affecting the quality of services delivered in primary care in Oman-- a developing country with a high incidence of diabetes.	Semi-structured face to face interviews	Nineteen type 2 diabetic patients recruited from four primary healthcare centers (PCHs) in Muscat region, the capital city of Oman.	Framework approach	Two main themes are 1) communication and continuity of care with healthcare professionals, and 2) provision of services at the right time and place.	7
20	Beverly et al. 2011 (79) USA Primary Care	To explore older patients 'perceived impact of chronic co-morbid conditions on T2DM self-management.	Focus groups	Purposive sampling to select 32 T2DM patients aged 60 and older with at least one other chronic health condition.	Identified codes to describe the overarching themes	Three themes are 1) diabetes complications as a motivator, 2) prioritizing health conditions, and 3) emotional impact of co-morbidity management.	6.5
21	Dhippayom et al. 2015 (80) Australia Pharmacy	To identify potential unmet needs and explore preferences for pharmacist-delivered support for T2DM.	Focus groups	Thirty-two consumers with T2DM	Thematic analysis	The key three themes are 1) the experiences of diabetes services received, 2) the potential to deliver self-management services, and 3) the suggested role of the pharmacist in supporting diabetes management.	7
22	Huang et al. 2005 (81) USA Primary Care	To specifically examine how older patients defined their healthcare goals,	In-depth one-on-one semi-structured interviews	Patients aged 65 and older with T2DM (n=28).	Developed a scheme for systematically coding by a	Three main themes are 1) healthcare goals, 2) external influences of healthcare goals, and 3)	9

Coding article	Authors/year/ Country/setting	Aims	Study design	Sampling/ participants	Analysis method	Finding	CASP score
		what factors shaped their goals, and the extent to which their goals related to self-care behavior.			two-step process: first is face-sheet summary of themes for each transcript, and second is comparing interview notes and reconciling any differences between them	self-care practices.	
23	Halkoaho et al 2013(82) Finland Public Health Organization	To understand how health-promoting aspects are realized in counseling according to T2DM	Semi-structured interview	Participants (9 males and 6 females) with T2DM, who were Finnish, living in Eastern Finland, aged 58–81.	Inductive content analysis described by Graneheim and Lundman, guided by interview themes	Three main themes are 1) coping resources of patients with diabetes, 2) the content of the counseling, and 3) the form of the counseling.	9

Chapter 3

Research Methodology

This research plan was carried out in two phases: Phase 1 was to develop patient satisfaction questionnaire according to systematic review of patient and healthcare provider perspective on diabetes management, and to translate Diabetes-39 (quality of life) questionnaire Thai version into Lao version. Phase 2 was to conduct randomized controlled trial of pharmacists' interventions in diabetes care to find out the outcomes compared with usual care as in Figure 7
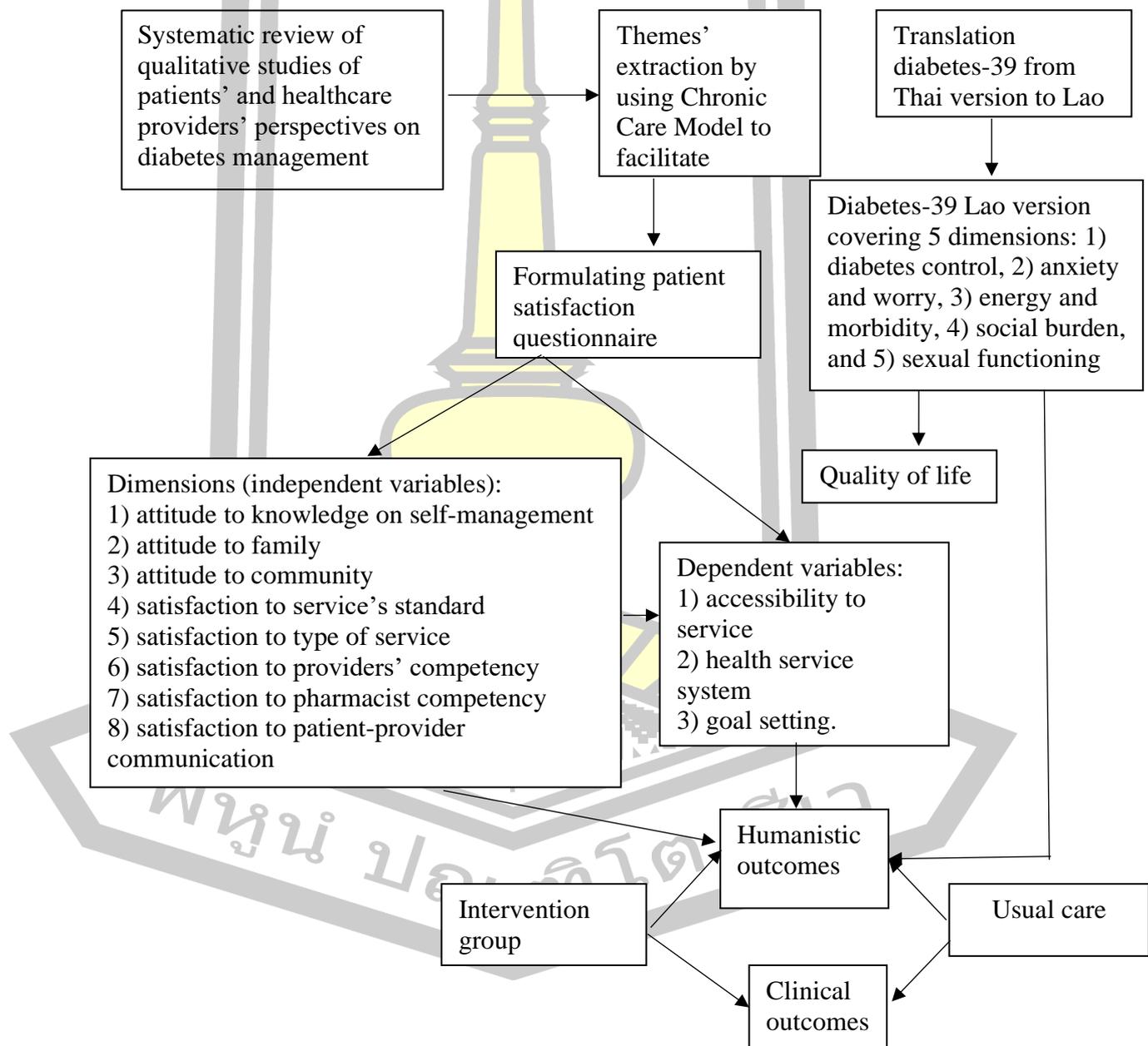
Figure 7 Research flow diagram

Ethical review

This study obtained ethical approvals from Mahasarakham University and ethical board for human and Lao National Ethics Committee for Health Research

1. Phase 1: Questionnaire Development

This study phase was designed to develop two questionnaires including patient satisfaction questionnaire by using themes from systematic review of qualitative studies and diabetes-39 by translating Thai version to Lao version. This phase of the research design was a descriptive study.

1) Patient Satisfaction questionnaire Development

1.1 Systematic review of patient and healthcare provider perspectives on

diabetes management

1.1.1 Search strategies

Four electronic databases were included for searching: PubMed (Medline), Science Direct, Web of Science, and CINAHL. The search was restricted to peer-reviewed studies published in English between the period of January 2001 and September 2017. A hand-search was also performed in which all the references cited in previous reviews were screened for studies that met the inclusion criteria. All identified titles and abstracts were independently screened and selected by two researchers

. Any discrepancies were discussed and resolved by consensus. A combination of search terms was used for this review to identify articles in original qualitative studies related to patients' and providers' perspectives and diabetes management. Keywords and strategies were 'Type 2 Diabetes Management' used with a Boolean 'AND' to conjugate with the following words 'Patient needs,' 'Patient perceptions,' 'Patient opinions,' 'Patient perspectives,' 'Provider needs,' 'Provider perceptions,' 'Provider opinions,' and 'Provider perspectives.'

1.1.2 Eligibility

The articles were included if they were 1) qualitative studies involving T2DM patients, 2) studies which met two screening questions in Critical Appraisal Skills Program (CASP) in Appendix 1. (83) 3) studies which aimed to evaluate patients' and providers' perspectives on diabetes management, and 4) studies available in full-text format with report scripts from interviews.

The articles were excluded if they were at least characterized by one of the following: 1) trialed an intervention in the study (e.g. technology, program, training, education), 2) studied in special groups of patients such as immigrants or disabled patients, or during an event such as that of Ramadan,

or travels, and 3) described other perspectives such as family members, or people who were only at risk for having T2DM.

1.1.3. Critical appraisal of studies

A checklist for assessing methodological quality of a qualitative research followed CASP 2006 (See Appendix 1 Table 1). (83) The checklist covered two screening criteria for a clear statement of the research aims and appropriate methodology, and eight detailed criteria involving appropriate research design, appropriate recruitment, proper data collection, relationship between researcher and participants, ethical issues, rigorous data analysis, a clear finding statement, and research value.

1.1.4. Data extraction

A data extraction form was developed as a modification of the form used by Zaza et al (84). Microsoft Excel was used to sort retrieved articles by authors, publication year, aims, study design, sampling and participants, method of analysis, and finding.

1.1.5. Data analysis

Content analysis for identifying main themes and sub-themes was performed by three researchers. The CCM and all themes from the included articles were used to facilitate thematic framework development. (11) Researchers focused on major themes and sub-themes of all included papers by comparing with Chronic Care Model, and then looked for quotations related to each theme. When identified themes were not consistent with the CCM, they were grouped as additional themes and subthemes as necessary. Disagreements in content analysis were resolved through consensus building.

1.2 Formulation of Patient Satisfaction Questionnaire (PSQ)

1.2.1. Questionnaire dimensions and items formulation

The dimensions and items of patient satisfaction questionnaire were constructed according to main themes and sub-themes of systematic review. The results showed 9 main themes; 1) community linkage (CL), 2) health service systems (HSS), 3) continuity of care (CC), 4) self-management (SM), 5) providers' support (PS), 6) referral system (RS), 7) patient-provider interaction (PPI), 8) increased competency of healthcare providers (ICP) and 9) family involvement (FI). These 9 main themes of the systematic review were used as the main idea for formulating the PSQ as follows:

1) Attitude to knowledge on self-management: there are 5 items in this dimension, measured by 5-likert scales.
2) Attitude to family: there are 4 items in this dimension, measured by 5-likert scales.
3) Attitude to community: there are 4 items in this dimension, measured by 5-likert scales.

4) Satisfaction to service's standard: there are 4 items in this dimension, measured by 5-likert scales.

5) Satisfaction to type of service: there are 4 items in this dimension, measured by 5-likert scales.

6) Satisfaction to providers' competency: there are 4 items in this dimension, measured by 5-likert scales.

7) Satisfaction to pharmacist competency: there are 4 items in this dimension, measured by 5-likert scales.

8) Satisfaction to patient-provider communication: there are 4 items in this dimension, measured by 5-likert scales.

9) Service achievement including: accessibility to service, health service system and goal setting each dimension contains 4 items, measured by 5-likert scale.

1.2.2. Content validity

The content validity was approved by four experts which consisted of two clinical pharmacists, one social and administrative pharmacist and one specialist in management who was non-pharmacist. The expert who was a non-pharmacist approved the final content for using in diabetes patients in order to make the content intelligible for general population.

1.2.3. Construct validity

Face validity test and reliability test were conducted with 30 of diabetes patients in Thailand for Thai version and in Laos for Lao version.

1.2.4 Translation process

The following was the procedure of translation from Thai language into Lao language:

1) Translated by Lao translator who could read Thai fluently, got questionnaire in Lao version, issue 1.

2) Compared Lao version, issue 1 with Thai original version and making mutual adjustment with experts, got Lao version, issue 2.

3) Lao version, issue 2 was translated back into Thai language by number two Lao translator who could read Thai fluently.

4) Compared Lao questionnaire from number 3 with Thai language original version and made mutual adjustment with experts, got Lao version, issue 3 which was the final version and could be used in the next step.

1.2.5 Pilot test

Patient satisfaction questionnaire was tested with 30 patients in Thailand and 30 patients in Lao P.D.R.

2) Diabetes-39 questionnaire

    2.1. Translation process

        This procedure for the translation from Diabetes-39 Thai version of Songraksa et al (2009) (52) into Lao language was by following procedure:

1) Translated by number one Lao translator who could read Thai fluently, got questionnaire in Lao version, issue 1.
2) Compared Lao version, issue 1 with Thai original version and making mutual adjustment with experts, got Lao version, issue 2.
3) Lao version, issue 2 was translated back into Thai language by number two Lao translator who could read Thai fluently.
4) Compared Lao questionnaire from number 3 with Thai language original version and making mutual adjustment with experts, got Lao version, issue 3 which was the final version and could be used in the next step.

    2.2 Pilot test

        Diabetes-39 was tested with 30 patients in Lao P.D.R.

3) Psychometric properties test for patient satisfaction questionnaire and Diabetes-39 questionnaire

    3.1 Sample

        Diabetes patients of 150 who registered at Mahosot and Setthathirath Hospital, Lao PDR and diabetes patients of 150 who registered at Suddhavej hospital, Maha Sarakham Thailand.

    3.2 Inclusion criteria

- Patients who were diagnosed as diabetes patients.
- Patients who were treated in the hospital.
- Patients who were willing to participate.

    3.3 Exclusion criteria

        Patients who didn't receive medications and/or insulin for treating diabetes.

4) Statistical analysis used for patient satisfaction questionnaire and Diabetes-39 questionnaire

1) Reliability test for both questionnaires was performed by Cronbach's alpha with the score at least 0.7. Each dimension was evaluated for relationship by inter-subscale correlation and should be lower than corresponding Cronbach's alpha. (48)
2) Analyzing the correlation coefficient between dimensions of Patient Satisfaction Questionnaire by using Pearson correlation coefficients.
3) Factor analysis for both questionnaires in order to adjust the item by enter for factor loading at 0.5.
4) The research employed regression analysis between independent and dependent variables.

2. Phase 2: Outcomes of patients with type 2 diabetes who receive diabetes care intervention led by a pharmacist compare with usual care.

2.1. Develop diabetes care intervention led by a pharmacist.

Conducted a focus group with healthcare providers who were in charge of diabetes clinic in Mahosot hospital (2 doctors, 2 nurses, 2 nutritionists and 2 pharmacists) according to Mary Marczak concept.(85) These included

1) Searching for international and region diabetes management guidelines by the main researcher that similar to Laos in order to be able to use in Laos.
2) Summarizing and synthetizing the concept of guideline review from Clinical Practice Guideline for Diabetes Thailand, 2017 and ADA, 2019 to formulate the practice protocol for Mahosot hospital by two researchers.
3) Presenting diabetes care intervention led by a pharmacist of this research in the focus group and ask for the recommendations.
4) Giving the first draft practice protocol to healthcare providers one week before conducting the focus group.
5) Focus group interview was conducted by the main researcher. The interview guide by using these following questions:
   - What do you think about the pharmacist role in OPD (diabetes clinic) and home care?
   - What would you like to add or recommend about pharmacist role?
6) The facilitators (researcher and research assistant) recorded the interview by using the audio recorder, and also made notes of discussion in the focus group.
7) Familiarizing by listening the audio record, transcript verbatim and review transcript note.
8) Identifying any changes and adjusted the practice protocol.

2.2. Evaluation outcomes of diabetes care intervention led by a pharmacist.

2.2.1. Study Design

This study was experimental study using Randomized Controlled Trial. Registration number was TCTR20200707003

2.2.2. Population Sample and Setting

Patients with type 2 diabetes who currently receiving care in diabetes clinic (OPD), Mahosot hospital.

Inclusion criteria
1) Patient diagnosed having type 2 diabetes
2) Aged at least 18 years old
3) Did not participate in other studies in the past 3 months
4) HbA1c $\geq$ 7% and/or FBS $\geq$ 154 mg/dL and record two in three time in past three months.
5) Willingness to participate

Exclusion criteria
1) Patient who lived outside urban area of Vientiane Capital.
2) Patient who were illiterate.
3) Patient who had severe co-morbidity such as cancer, kidney failure.

Sample calculation

The sample calculation following by formula of comparison between group and continuous variable

$$n/group = \frac{(Z_a + Z_b)^2\, 2S_p^2}{D^2}$$

$$S_p = \frac{(n1-1)S_1^2 + (n2-1)\, S_2^2}{(n1+n2)-2}$$

According to the research on impact of education and counseling provided by a clinical pharmacist on diabetic outpatients at King Chulalongkorn Memorial Hospital, by Lohavisavapanich et al (2549), 2006 (86), found that in 97 of diabetic patients. Patients in control group had average of HbA1c 7.94 ± 1.59 and patients in intervention group had average of HbA1c 7.01 ± 1.09 with statistically significant.

Alpha = 0.05, Z_{alpha} = 1.96 (two-tailed)
Beta = 0.02, Z_{beta} = 0.84 (two-tailed)
S_1 = 1.59, n1=49
S_2 = 1.09, n2=48
D = 0.93 (differential between average of HbA1c in 2 groups not greater than 0.93

$$S_p = \frac{(49-1)(1.59^2) + (48-1)(1.09^2)}{(49+48)-2} = 1.86$$

$$n/group = \frac{(1.96 + 0.84)^2\, 2(1.86)^2}{(0.93)^2} = 62.72 = 63$$

Dropout rate of 20%; n=63/(1-0.2) = 79. This research contained participants in each group of at least 79 participants.

2.2.3. Randomization strategy

Systematic random sampling was designed using permuted block size 4. Table of randomization divided patients into 2 groups, intervention groups (group A) and control groups (group B). The permuted block size 4 was collated according to the 6 types shown below and the patients who were allocated into groups were generated according to 6 types in the Table 2 below:

Table 2 Sampling table by permuted block

Type 1 AABB; Type 2 BBAA; Type 3 ABAB; Type 4 BABA; Type 5 ABBA; Type 6 BAAB

Sample number	Block 4	Sample number	Block 4	Sample number	Block 4	Sample number	Block 4
1	A	41	A	81	A	121	A
2	A	42	B	82	B	122	A
3	B	43	A	83	A	123	B
4	B	44	B	84	B	124	B
5	B	45	B	85	B	125	B
6	B	46	A	86	A	126	B
7	A	47	A	87	B	127	A
8	A	48	B	88	A	128	A
9	A	49	A	89	A	129	A
10	B	50	A	90	B	130	B
11	A	51	B	91	B	131	A
12	B	52	B	92	A	132	B
13	B	53	B	93	B	133	B
14	A	54	B	94	A	134	A
15	B	55	A	95	A	135	B
16	A	56	A	96	B	136	A
17	A	57	A	97	A	137	A
18	B	58	B	98	A	138	B
19	B	59	A	99	B	139	B
20	A	60	B	100	B	140	A
21	B	61	B	101	B	141	B
22	A	62	A	102	B	142	A
23	A	63	B	103	A	143	A
24	B	64	A	104	A	144	B
25	A	65	A	105	A	145	A
26	A	66	B	106	B	146	A
27	B	67	B	107	A	147	B
28	B	68	A	108	B	148	B
29	B	69	B	109	B	149	B

Sample number	Block 4	Sample number	Block 4	Sample number	Block 4	Sample number	Block 4
30	B	70	A	110	A	150	B
31	A	71	A	111	B	151	A
32	A	72	B	112	A	152	A
33	A	73	A	113	A	153	A
34	B	74	A	114	B	154	B
35	A	75	B	115	B	155	A
36	B	76	B	116	A	156	B
37	B	77	B	117	B	157	B
38	A	78	B	118	A	158	A
39	B	79	A	119	A		
40	A	80	A	120	B		

2.2.4. Setting

Diabetes clinic in Mahosot hospital, and patients' house in Vientiane, Lao PDR.

2.2.5. Outcomes of the study

Primary outcomes: HbA1C, FBS
Secondary outcomes: BP, creatinine clearance, GFR, BUN, Lipid profiles (cholesterol, LDL, HDL, Triglyceride), BMI, patient satisfaction and quality of life (D-39)

2.2.6. Research tools

1) Practice protocol for diabetes care developed in this study is shown in Table 24. Guideline protocol
2) Participant record form (Appendix 2. Table 44), Laboratory record form (Appendix 2. Table 45), Participant evaluation form (Appendix 2. Table 46), Drug-related problem evaluation form (Appendix 2. Table 47), Medication counseling form (Appendix 2. Table 48), Home visit record form (Appendix 2. Table 49), Diabetes 39 questionnaire original version (Appendix 2. Table 50), Questionnaire for satisfaction's assessment Thai version (Appendix 2. Table 51)

2.2.7. Research procedure

The process of pharmaceutical care intervention and usual care during the research is shown in Table 3 work flow for RCT and Figure 8 intervention flow

Table 3 Work Flow of RCT

Timing	Usual Care (Control)	Pharmaceutical Care (Intervention)
Day 0/ Month 0	- Receive Blind OPD* card from the researcher	- Receive Blind OPD* card from the researcher
Month 0	- Home visit for answering the questionnaires. - Make an appointment for following in the next month	- Home visit for answering the questionnaires. - Make an appointment for following in the next month
Month 1	- Receive usual care from nurse and doctor as following steps: 1) Meet with nurse for vital sign check-up. 2) Meet with doctor for follow-up. 3) Take medications from doctor order in the pharmacy of hospital 4) Meet the researcher for marking the OPD card for the next appointment.	1) Meet with nurse for vital sign check-up. 2) Meet with doctor for follow-up. 3) Meet with the researcher for medication review and lifestyle modification counselling such as dietary intake for diabetes patient, physical activity in verbal and leaflet base on individual problem 4) In case of any DRPs, notify doctor with drug-related problem evaluation form. 5) Record the change in medication counseling form and appoint patient for the next visit.
Month 3	- Receive usual care from nurse and doctor as following steps: 1) Meet with nurse for vital sign check-up. 2) Meet with doctor for follow-up. 3) Take medications from doctor order in the pharmacy of hospital 4) Meet the researcher for marking the OPD card for the next appointment.	1) Meet with nurse for vital sign check-up. 2) Meet with doctor for follow-up. 3) Meet with the researcher for medication review and lifestyle modification counselling such as dietary intake for diabetes patient, physical activity in verbal and leaflet base on individual problem 4) In case of any DRPs, notify doctor with drug-related problem evaluation form. 5) Record the change in medication counseling form and appoint patient for the next visit.
Month 6	- Home visit/telephone for answering the questionnaires. - Receive usual care from nurse and doctor as following steps: 1) Meet with nurse for vital sign check-up. 2) Meet with doctor for follow-up.	- Home visit/telephone by researcher for answering the questionnaire. - Follow-up at the hospital by following step: 1) Meet with nurse for vital sign check-up. 2) Meet with doctor for follow-up.

Timing	Usual Care (Control)	Pharmaceutical Care (Intervention)
	3) Take medications from doctor order in the pharmacy of hospital 4) Meet the researcher for marking the OPD card for the next appointment.	3) Meet with the researcher for medication review and lifestyle modification counselling such as dietary intake for diabetes patient, physical activity in verbal and leaflet base on individual problem 4) In case of any DRPs, notify doctor with drug-related problem evaluation form. 5) Record the change in medication counseling form and appoint patient for the next visit.

* Blind OPD card is only for the researcher know the code which define the groups.
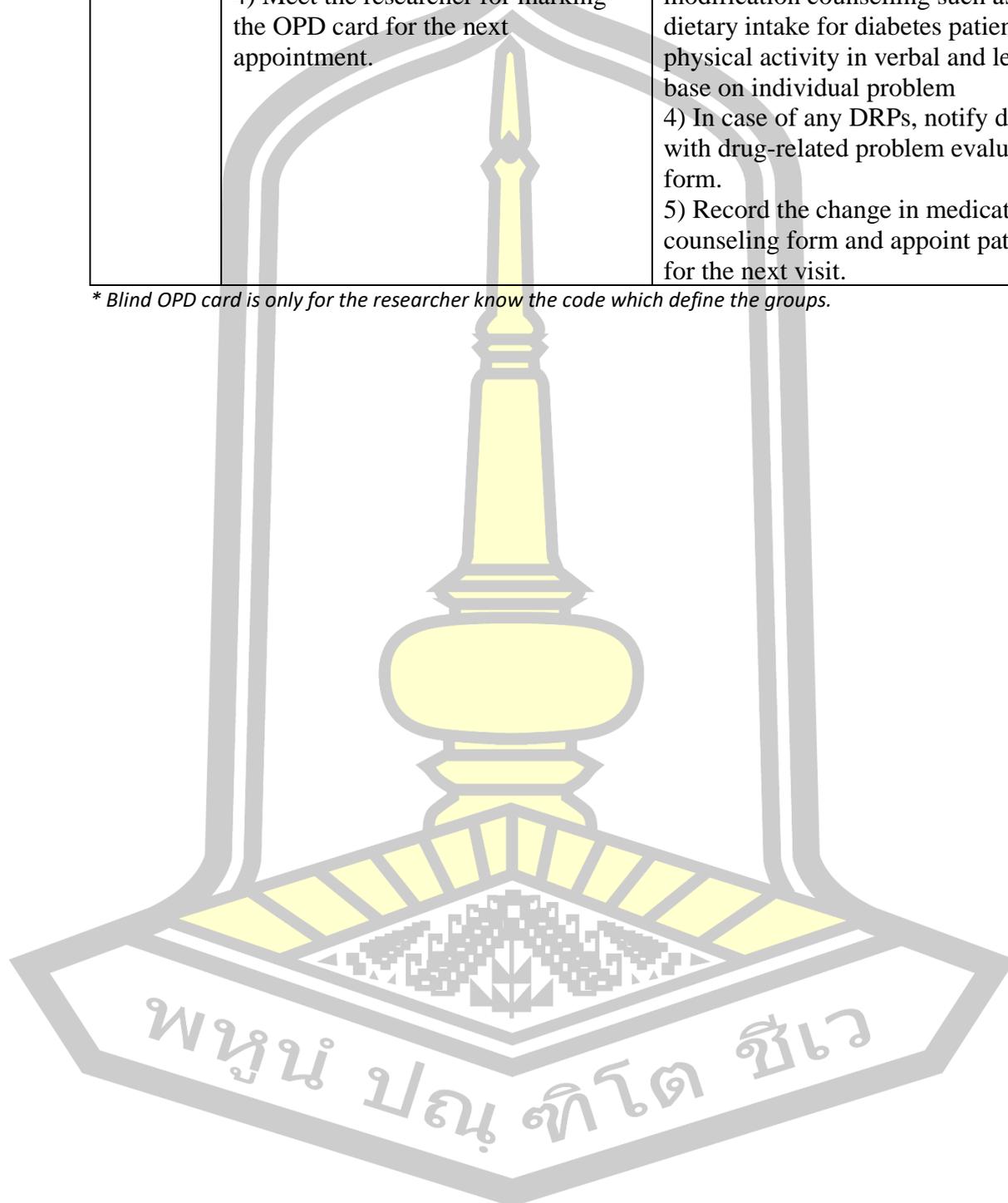
2.2.8. Intervention Flow
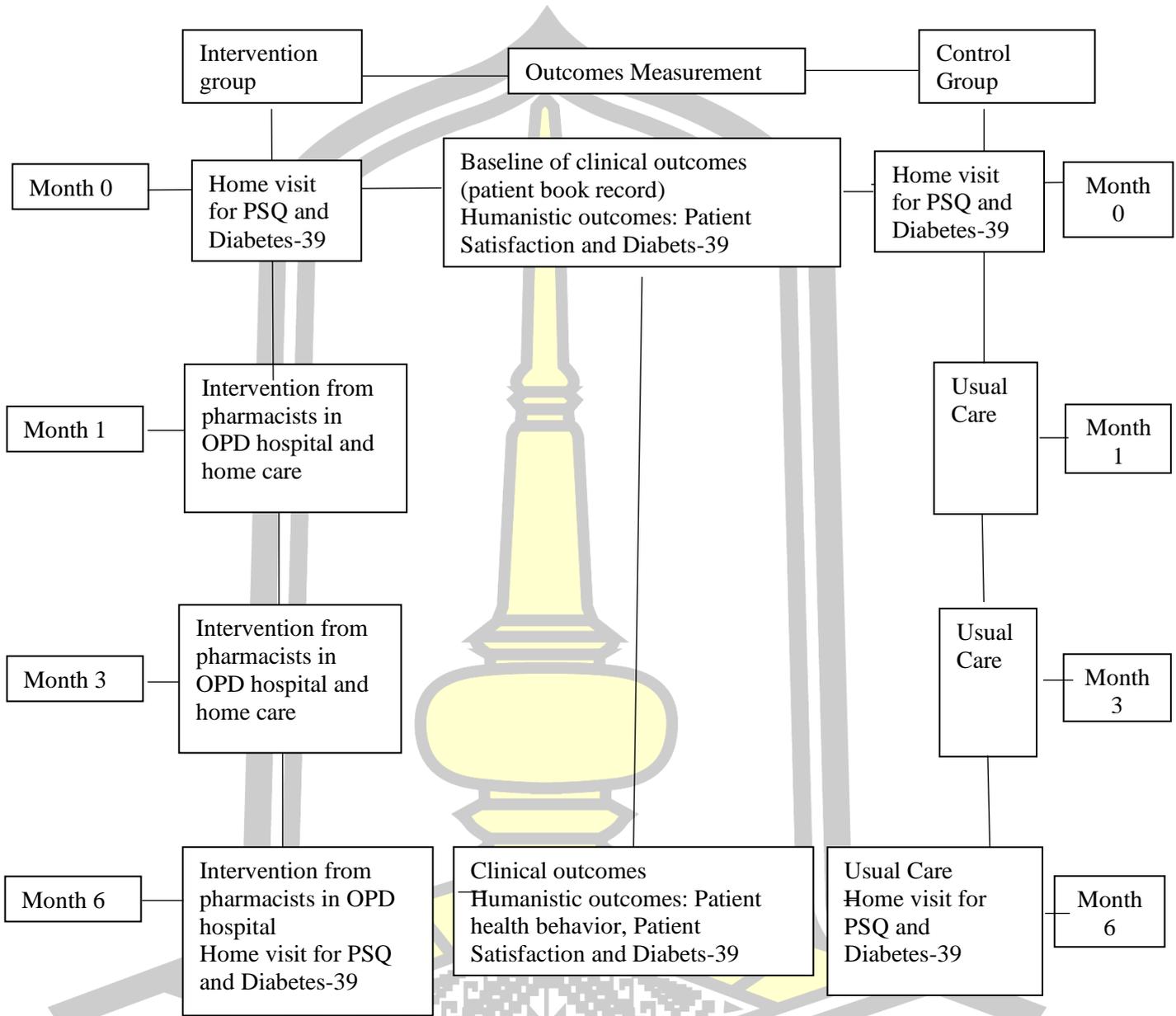
Figure 8: Intervention Flow Diagram
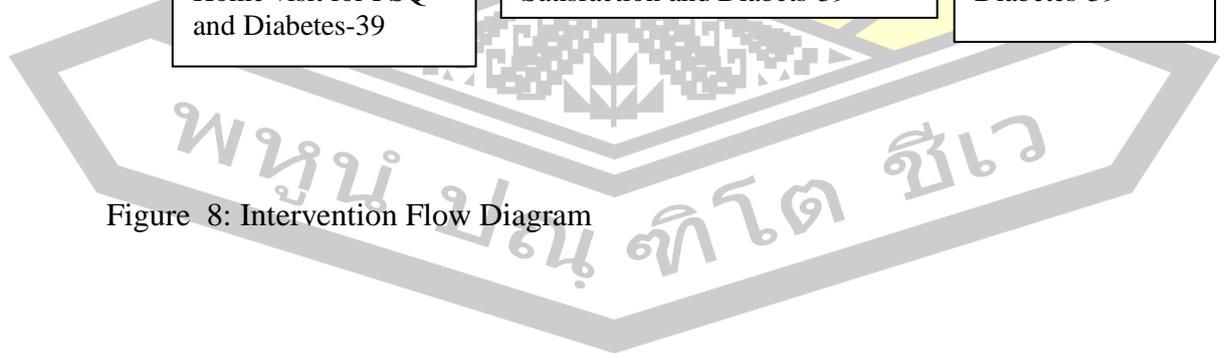
2.2.9. Data analysis

Using SPSS software version 24 to analyze data with confidence interval at 95% (alpha = 0.05)

Descriptive statistic: percentage, frequency, mean, standard deviation, median for patients' characteristics.

Inferential statistic:

1) Comparison of clinical outcomes between groups with continuous variables (BMI, FBS, HbA1C, BP, Creatinine Clearance, GFR, BUN, Lipid profiles, satisfaction mean score and quality of life mean score) by using t-test or Mann Whitney U test.
After randomization, comparison between groups used linear regression with adjusting by age and hypertensive patients.

2) Comparison of proportions of achieving clinical goal by controlling factors related outcomes with Chi-square test. After randomization, comparison between groups used logistic regression with adjusting by age and hypertensive patients.

3) Quality of life and satisfaction analysis: Comparing mean of each dimension between groups by using independent t-test or Mann Whitney U test. Comparing mean within group by using pair t-test or Wilcoxon Signed Rank test.

4) Sub-group analysis was performed later after the randomization in the hypertensive patients.
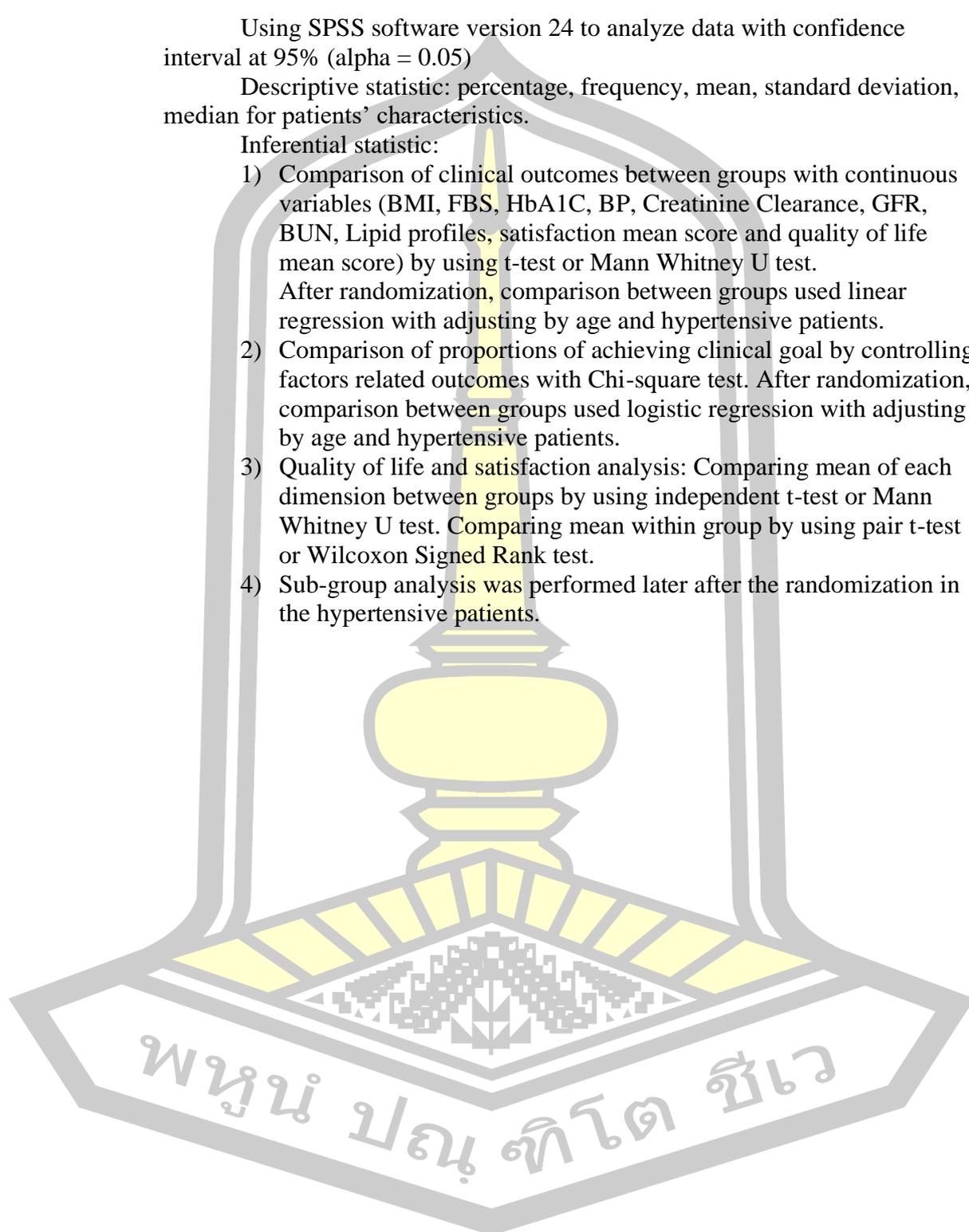
Chapter 4

Results

1. **Phase 1**

   1.1. Systematic review of qualitative studies on patients' and healthcare
   providers' perspectives on diabetes management
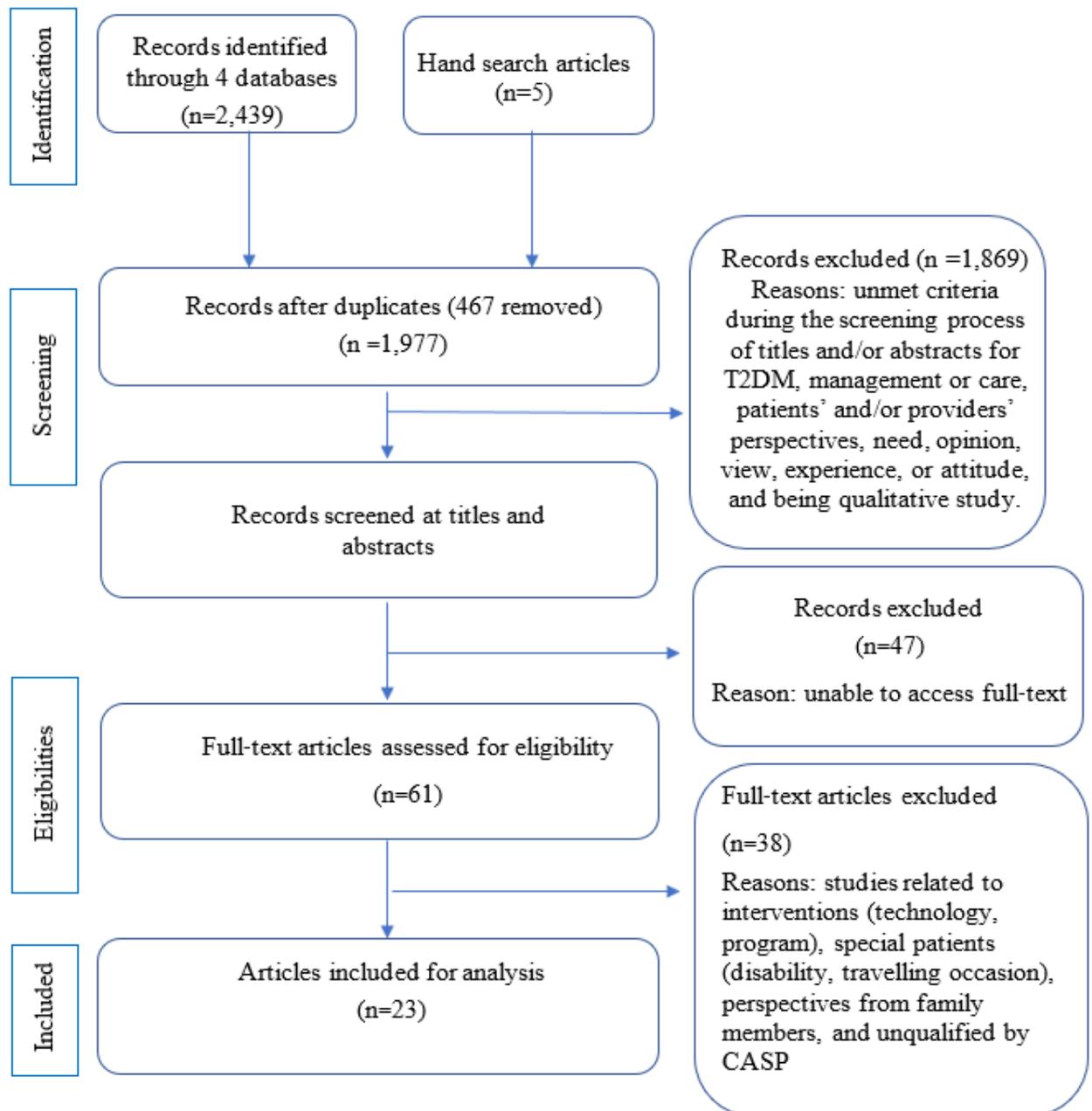
Figure 9 PRISMA flow chart of systematic review

Figure 9 shows the eligible articles included in the study. There were 2,444 included in the identification process. After removal of duplicates (n = 463), an initial yield of 1,981 titles and abstracts were screened. There were 108 eligible titles and abstracts, but only 61 had accessible full-texts. By assessing the quality of the evidence following the criteria in Table 5, there were 23 articles included for content analysis as shown in Table 6. Thirty-eight articles were excluded for the following reasons: 27 articles were intervention studies related to technology and program trials,(36, 87-112) four articles were studies among special groups such as disabled patients or traveling people,(113-116) three articles were based on perspectives from family members,(117-119) and four articles were excluded as they were deemed unqualified by CASP.(120-123) The full explanation for the reasons for excluding the 38 articles is shown in Appendix 2. The different perspectives of the 23 included articles were also noted: three articles studied both the perspectives of health care providers and diabetic patients,(62-64, 124) five articles studied only the perspective of health care providers,(64-68) and 15 articles studied only the perspectives of diabetic patients. (38, 69, 70, 73-82, 125, 126)

Using the CCM framework and original themes identified from the 23 included articles, nine themes concerning the perspectives of healthcare providers and patients were synthesized: 1) community linkage (CL) revealed differences in perspectives on resources and policies, 2) health service systems (HSS) for diabetic patients revealed similarities in perspectives on barriers for medical services, 3) continuity of care (CC) revealed similarities in perspectives on the need for continuity of care, 4) self-management (SM) revealed the similarities in perspectives on barriers in self-care due to the patients' individual situations, 5) providers' support (PS) revealed similar perspectives, 6) referral system (RS) revealed similarities in the perspectives on barriers in transitions from one provider to another, 7) patient-provider interaction (PPI) revealed differences in the perspectives on communication, 8) increased competency of healthcare providers (ICP) revealed no conflict because only the perspective of healthcare providers was considered, and 9) family involvement (FI) revealed similarities in perspectives on facilitating factors and barriers from family members of patients with diabetes. The conclusion of the results is shown in Figure 10.

Community Linkage (CL)

There were two sub-themes related to CL, (1) community and social involvement and (2) resources and policies. From five articles it was determined that community and social involvement contains two sub-themes: community institutions and social support needs. The overall perspectives revealed the desires of healthcare providers to establish sport clubs and/or activities in the community to support healthy lifestyles for T2DM patients. Diabetic patients revealed the need for social support such as meeting with friends to go to a concert or the theater, and talking to others who have the same condition to provide support for their disease.

HP: "I will try to establish a sport group particular for multi-morbid patients not just for diabetes or coronary patients, manage a sports group which I established five years ago. It is a huge success."

P: "Different activities and culture events, such as going to music concerts, open-air theatres and just walking in the forest help me to carry on."

Resources and policies are related to information and available resources. This sub-theme was a theme of four articles. These articles revealed that there were no community-based resources, facilities or health education for people with T2DM. They also revealed that Attention to primary and secondary care, politics, and scientific research on diabetes care has been improved.

P: "I didn't notice that resources were asked about or paid attention to in any way."

HP: "Diabetes is receiving a lot of attention in primary and secondary care and also from politics, which has led to an improvement of the care"

Health service systems for diabetic patient (HSS)

There were three sub-themes related to HSS, (1) medical services, (2) health insurance systems and (3) human workforce. Eleven articles addressed the theme of medical services related to the access and availability of services. Medical services are related to the access and availability of the services. This theme was found in eleven articles. The theme revealed limited accessibility due to no physician availability (such as in Oman), no interest by pharmacists, and great distances from services. However, some countries showed good access to services (e.g. Netherlands). Alternative services were offered including online and/or SMS service for treatment results, separate services for males and females, a special area for talking with each other about their experiences with diabetes, and more health information literature in the waiting areas (e.g. leaflet). However, the information may have been too complicated for the patients to understand. There was also a lack of information on the side effects on diabetes medications.

P: "The only problem is that I can't see my physician right away if I need it, if I badly need it."

HP:" I have four patients who completely refused to go for eye check-up because they find it too far away from their living places. They prefer to be referred to the nearest hospital due to transport costs."

HP: "Dieticians and health educators are not here every time, our nurses are not well trained, not   qualified and do not know the process of care for diabetic patients."

Ten articles examined the health insurance system. They addressed payment systems and the financial burden on patients. One subtheme revealed no coverage in basic care (such as in Netherlands). In Iran, some drugs were not covered by insurance, so patients needed to pay the high cost of care.[74] There was no available insurance for migrants in Australia. Some countries such as Malaysia provided free diabetes medication. The Netherlands, the providers complained about a lack of transparency in health insurance costs. Latino patients in the USA as well as patients in Bangladesh, Canada, Australia, Iran, and Germany faced the barrier of insufficient money to get diabetes care (financial burden). The providers sometimes used their own money to help patients.

HP: "A lot of basic care is not covered by indicators. The most important disadvantage is that they may be misused for financial settlements. That's a bad development as regards transparency."

P: "So because I've not had Medicare so really it is not possible for us to go and check every week, every month because we have not applied for permanent residency."

HP: "...A real problem is the financial factor for the patients and realizing that when we ask them to record the sugar level and every strip costs a dollar...that's one thing the system should change."

Seven articles revealed the theme of the human workforce related to time constraints on providers. Providers had limited time to treat patients. Some patients said that the appointment to see the provider can take a long time. According to physicians, there was also a high workload among providers because of the large number of patients.

HP: "The major factor is the stress I get when the other patients started shouting outside, knocking the door and asking when they will see the doctor which forced me to finish quickly with the consultation."

P: "Sometimes I need to take appointment within a month, but the nearest appointment is available only after 3 months."

Continuity of care (CC)

There were three sub-themes related to CC, (1) team cooperation, (2) case management and (3) tools for medication management. Five articles addressed team cooperation. Providers would like to see more cooperation among them such as clear structure of transition. Patients would like their information to be available for all providers. However, The Netherlands, the collaboration among primary and secondary care was well-organized.

P: "The one in charge of your health care in the system is your GP. So, even though you go to a specialist ... he has to refer to your GP. So, all the information must be fed to the GP."

HP: "[It] would be a wonderful expectation; to be able to say I need the full service or I only need part of the service."

HP: "In this region, the collaboration between primary and secondary care is pretty well-organized. We work in a multidisciplinary team on the same floor, so we can easily ask each other things."

Five articles addressed case management, which was related to the providers' ability to care for a limited number of patients. Providers needed a small number of patients to provide specific and effective care such as managing depressive patients. (66,68,71,76,82) The lower number of patients facilitated the effective care of providers by building a strong connection between them.

HP: "It is very important to see a fewer number of patients, I think ten to fifteen is reasonable. It is also   important to maintain continuity of care as much as possible."

P: "This sort of service (monitoring service) would be of great value especially on the newly diagnosed, it could be for some people, yes. I'm not

saying for me because I manage my own regimen   quite easily, but for some people I still think it could be almost a necessity."

One article addressed a tool for medication management: medication plans for patients. Both patients and providers valued tools for medication management, including: medication plans, visual displays, and comprehensible labeling of medicine packages.

P: "My diabetologist. He actually made me a plan how to fine tune my insulin [...] told me if this leads to low blood sugar I need to…"

Self-management (SM)

There were four sub-themes related to SM, (1) Knowledge and understanding about diabetes and its complications, (2) medication adherence, (3) lifestyle modification, and (4) attitudes and beliefs. There were 10 articles related to the understanding of diabetes, the understanding of diabetes complications due to diabetes, and experiences/awareness of complications due to diabetes. Some patients had knowledge of the pathophysiology of diabetes. Some gained knowledge from the experiences of their friends and/or family. Patients understood diabetes conditions and worried about complications and co-morbidity. Patients were able to identify the symptoms of complications. Patients had their own experiences of diabetic complications (e.g. stroke, problems with eyes or feet). They also acquired knowledge from other patients making them more knowledgeable about their disease. Patients became more aware of complications from diabetes because they found information in literature, or from the experiences of other family members. Such information motivated them to look after their health.

P: "About the cause, well, my father is a diabetic, and my obesity, since I was small I was big and I did not exercise a lot. I know it will affect my eyes, heart and also kidney problem."

P: "I don't see a problem, unless something comes up out of the ordinary. I don't think about it a lot."

HP: "His father died at age 62 of horrible complications of diabetes and this guy was 58. I could not convince him that this was not a death sentence . . . because he just figured that was it."

Five articles addressed medication adherence. This included understanding about taking medicine, good adherence to medicine regimes, and poor adherence to medicine regimes due to either unintentional or intentional factors. Patients showed understanding about the concept of diabetes medication being used for lowering their blood sugar. Some patients expressed concerns about the effect of medications on their kidneys. Patients stated that they often forget to take and/or inject insulin. Some patients did not have time to take medication because they were busy. Some patients refused to take medication in public because they were worried about their image. Some wanted to give a medicine-free day to their bodies by not taking medication. Some adjusted the dose by themselves by skipping or adding more doses of their diabetes medications. Some patients had good adherence by taking their medication as instructed and following their doctor's advice.

> *P: "To control my sugar and because I have diabetes other effects in my eyes, or kidney, so I take it   every day and I control my food also."*
>
> *P: "Most of the time regularly I take, but not at exact time, because in the morning I am very busy."*
>
> *P: "Yes, I take it regularly, but sometimes if I eat a heavy meal or sweets. I take another big tablet   (metformin) to control the sugar level."*
>
> *P: "I don't want anyone to see the medication. I don't like taking it in front of anyone. For me, the biggest problem is when I go to a business dinner. Then, I find it really difficult to find the time to take my medication. In that situation, I don't take it. It's really important to me that no one sees me taking my medication, so skipping it doesn't bother me."*

Eleven articles which addressed lifestyle modification. These included knowledges and understanding of lifestyle modification and living with diabetes. Some patients showed good understanding of the concept of lifestyle modification but did not follow through due to personal context (habit, familiarity, experience). Providers complained about patients not adhering to lifestyle modifications. Patients showed good adherence to lifestyle modifications because of their positive thinking. Patients had their own way of managing their disease (e.g., relaxation). Most of the patients followed lifestyle modifications such as weight and nutrition control because they understood well the consequences of not managing their lifestyle.

> *P: "I'm a relatively smart person, it does not make sense for me to eat incorrectly. It does not make sense for me not to exercise properly. I'm making these bad choices."*
>
> *HP: "To modify patients' diet is a real problem, one patient was angry and said he will eat what he wants and asked me what my grandfathers used to eat long time, they used to depend on dates mainly   and the Omani Halwa and their health was perfect."*
>
> *P: "When I had my foot amputated, I thought there was nothing I could do about it. However, I didn't think my life was over because I was able to live a normal life with the aid of my prosthetic limb. My lifestyle hasn't been limited."*

Fourteen articles addressed attitudes and beliefs. These included the varied attitudes that patients have about diabetes, lifestyle, goal-setting, and medication adherence. Some believed that diabetes is a chronic incurable disease. Some patients had a spiritual, religious, or cultural belief that diabetes is meant to happen in their life. Some patients felt that diabetes is a common disease that they should not be ashamed of it. Some patients compared diabetes with other diseases like cancer or arthritis, but thought it was milder. Some patients expressed curiosity to know more about diabetes by searching for diabetes information in libraries.

> *P: "Diabetes cannot be cured, I know that clearly. The drugs are only for control; you just have to take them."*
>
> *P: "Diabetes compared with other disease for example cancer is good. Because the cancer may make   the breast a lift or chemotherapy. But compared with conditions such as bone fractures heart disease is bad."*

The attitudes towards lifestyle were also varied for diabetes patients. Some patients felt ashamed to be diagnosed with diabetes. Some remained unaware of how to manage their diabetes. Some revealed that their family members did not think their diabetes was important and cooked food that the patients could not eat. Some needed to look after themselves. Some revealed that there is social stigma against diabetic patients.

>P: "At a job interview, interviewers said that their company would find it rather difficult to hire someone with diabetes. They said then and there that diabetes was a disadvantage, and so that was that".

Attitudes towards goal-setting revealed that most patients followed lifestyle recommendations, [81] but blamed themselves for being unable to reach their goals. Providers also felt frustrated when they could not make their patients reach their treatment goal. Providers tried alternative options to help patients reach their goals.

>P: "For instance with the weight, that is something that has always made me lose my hope...Right now, instead of losing weight, and I have been eating less, I am gaining...I don't know if it is the medicine, but that sort of has me a little depressed...I just feel sad. Sometimes I don't even want to take the medicine because I feel like it's not doing anything."

>HP: "Have you gotten to know the patient? Have you really addressed the issues at hand? Have you had enough time, given the patient enough time to work on this? Have you provided the resources? Have you clearly identified what the challenges and issues are so that the patient can work on it? Have you communicated specific enough goals that patients can reach, can work towards?"

Attitudes towards medication adherence revealed that providers thought that patients need motivation, as some patients were not comfortable with using insulin and other medicines.

>HP: "The difference between knowing and doing. It's easier for patients to have something done to them, like take a pill, as opposed to doing something for themselves. It takes a lot of self-motivation and encouragement and education"

>P: "I usually do not take the drug, because I must control myself, not the drug control myself."

Providers' support (PS)

There was one sub-theme related to PS: effective healthcare providers. Thirteen articles addressed this sub-theme. The effective healthcare providers theme is related to administration (effective treatment plans), services (helpful/satisfaction), and the implementation of standard care. Several providers used effective techniques to help patients manage their diabetes such as education, treatment plans, individual care plans, and forming small groups for educating patients. Many articles revealed that providers support patients by using effective approaches to understand their patients well. Patients were very thankful for the providers who gave good recommendations. Good relationships among the providers and patients led to better care. Some providers did not like the new guidelines and thought that the implementation of a standard care framework for diabetes care was needed.

P: "You actually have to discuss it with the doctor, because the impact on each person is often different, and needs to be matched with your blood sugar levels and related to one personally."

P: "Support from the nurse is the thing. I wish the nurses would have the strength to empower us and the hurry would go away; today it's important to find a good nurse."

HP: "The new guidelines make me feel awful. I have enough trouble doing what I'm doing and then trying to do menopausal counseling, osteoporosis counseling, smoking cessation counseling…[for   diabetes] it makes me think I might scream."

The counseling provided by nurses promoted the participation of diabetes patients in planning their treatment and in improving their balance of care. The content of counselling should be appropriate for diabetes care.

P: "I know that I have to take the responsibility [for the care]; it's harmful for me if I don't. This is   what the nurse also said."

Referral system (RS)

There was one sub-theme related to RS: barrier in transition between levels of care. Seven articles addressed this subtheme. Patients complained about being given unclear information during the discharge process. Patients were not able to see the same provider when they came back for follow-up visits.

P: "If I had been told at the beginning, when I checked in, that would have helped, that I would eventually be discharged, and go back to my own doctor."

P: "... At the infirmary ... definitely the continuity of care just was not there ... I didn't see the same doctor in 3 years. I saw a different doctor every time ... I got different types of advice ..."

HP: "We have no way of knowing who comes back and who doesn't come back for care"

Patient-provider interaction (PPI)

There were two sub-themes related to PPI, (1) provider communication skills and language barriers, and (2) preferences in care. 12 articles addressed provider communication skills and language barriers. Several patients complained that providers had poor communication skills (e.g. fussing and lecturing instead of talking). Language differences also caused communication barriers between patients and providers.

P: "He (physician) seems to spend a lot of time lecturing instead of saying 'would it help you if I did this?' or if he would make a suggestion that didn't sound like he was treating me like a child."

P: "I'm very sad that my previous doctor was not, because current doctor talking in Farsi and I did not know the language, I do not understand something."

Five articles addressed preferences in care. This included patients preferring specialists or a familiar provider, and providers' preferences. Several patients

preferred to see the same doctor every time they came back for a visit. Providers mentioned that patients preferred specialists more than primary care physicians.

> *HP: "...Patients are sometimes stubborn, and they don't want to hear it from us, they'd rather hear it from an endocrinologist than hear it from us…"*
>
> *P: "As continuity I like to see the same doctor every time if possible…"*

Increase competency of healthcare providers (ICP)

There was one sub-theme related to ICP: continuing professional education. There were nine articles related to this subtheme. Providers such as nurses needed more continuing professional education in order to update their knowledge on good T2DM care. Inadequate skills is the largest barrier to managing diabetes care.

> *HP: "I need more training for treating these patients."*
>
> *HP: "One of the problems I can see is that I watch residents (medical trainees) in the hospital and they are pretty good with insulin…, but once you get out into a community to get your patients started on insulin, then the GP is losing his knowledge very quickly... you know if you are not doing something every day you become rusty fairly quickly and then you become insecure."*
>
> *HP: "A lot has changed in diabetes care over the past 10-15 years that you can't keep up with. We need to make sure that family physicians don't lose their expertise in diabetes care because of the substitution of care by the practice and diabetes nurses."*

Family involvement (FI)

There were two sub-themes related to FI, (1) family as facilitators and (2) family as barriers. There were seven articles related to family as facilitators. Family members play an important role in supporting, motivating, and encouraging diabetic patients in terms of lifestyle modification, nutrition, and medication. Patients tend to follow recommendations in the presence of family support.

> *P: "My wife gives me comfort. She advised me to eat vegetables scheduled to attend the program in any way I eat vegetables and salads."*
>
> *P: "Without my family and my wife I probably wouldn't be alive"*
>
> *HP: "Often we invite the wives of patients with diabetes because they are responsible for the diet."*

There was one article related to family as barriers.[71] Sometimes, family members were barriers to the healthy lifestyles of patients by making the patients eat unhealthy food.

> *P: "My wife, she gives little importance to my illness. I feel she helps with the needs of my disease very little. She cooks foods that I am not supposed to eat, and if I do not eat them she said that she is not going to prepare food for me again."*
>
> *P: "I don't want to eat fried food, but my children want fried food."*
>
> *HP: ". . .when they think about food and they say '. . .it is my spouse that cooks.' I tell them have your spouse help you. . . go with you to see the nutritionist. . . I tell them to get the whole family involved"*

Proposed conceptual diagram of patients' and healthcare providers' perspectives on diabetes management

There were nine themes identified in this review as shown in Table 4. Six themes (CL, HSS, CC, SM, PS, RS) were linked to CCM while the other three themes (PPI, ICP, FI) were added to the CCM framework. Five themes showed similar perspectives between patients and healthcare providers: HSS, CC, SM, RS and FI. These themes showed agreement from both providers' and patients' perspectives. For example, both showed the same difficulties in using health services such as the limitation of medical services and health insurance. Both of them wanted the same type of continuity of care such as good cooperation among healthcare providers. Both agreed that experiences about diabetes shared by friends and family helped the patients become more aware of diabetic complications. Both agreed that there were difficulties in the referral system with patients not knowing when or where to follow up. Both valued the family members who are supportive of patients with diabetes. However, both also agreed that family members can be a barrier for managing diabetes. Two themes showed differences among the perspectives of patients and healthcare providers: CL and PPI. These themes revealed disagreement in terms of community linkages such as the point of resource and policy. Healthcare providers and patients blame each other for difficulties in communication. The last two themes (PS and ICP) revealed neither similarities nor differences. Both addressed providers' support but in different aspects and only healthcare providers gave their perspectives on competency. The main result of this review is to show that these nine themes are the key factors that can help improve diabetes treatments as well as patients' health outcomes. A diagram (Figure 10) showing the linkage of the nine themes between patients and health care providers.
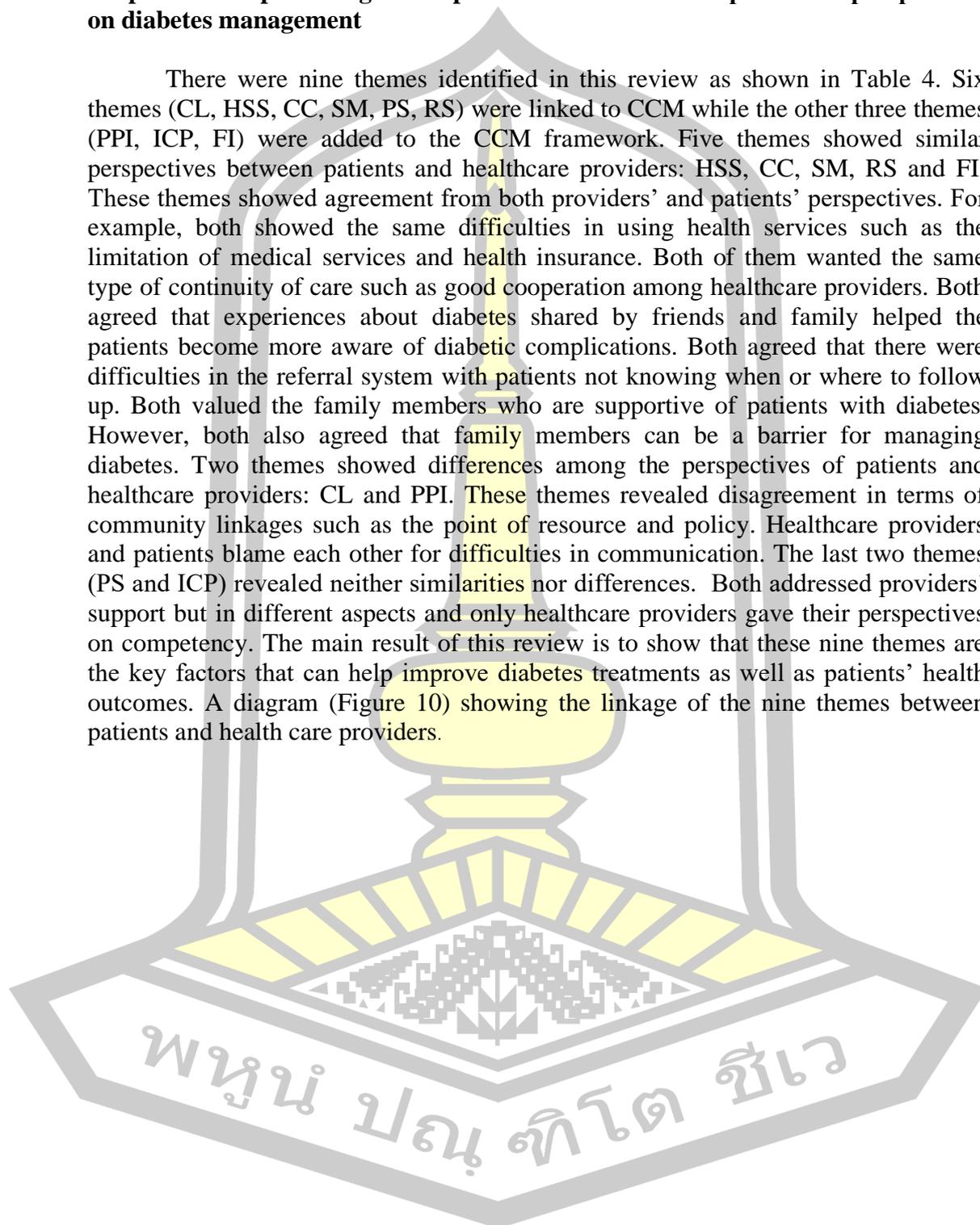
Table 4 Data Extraction by thematic analysis using CCM model framework and original themes from included articles

N.	Chronic Care Model	Original Themes from Included Articles	Studied Themes	
			Major Themes	Sub-Themes
1	Community linkages: Encourage patients to participate community program Form partnership with the community Advocate for policies to improve patient care	Initiation of physical activity Society/community Activities in communities, establishment of sport groups Prevention and lifestyle interventions Lack of Information about community-based resources Information about community-based resources Involvement of other community institutions Self-management and health education (in community) Community resources and policies (need more attention from the community)	1. Community linkages	1.1 Community and social involvement 1.1.1 Community institutions 1.1.2 Social support needs 1.2 Resources and policies
2	Health System: Support improvement organization Promote effective strategies Handling of errors and quality problems Provide incentives Develop agreements to facilitate care	Availability and costs of diagnosis and care Systemic facilitators: home services, diabetes education centers (DECs) as a valuable resource and stress the importance of referring the patient soon after diagnosis System-related barriers Inadequate information Lack/overload of information on potential adverse effects Lack of teamwork approach Knowledge of dietary recommendations Obstacles: A perceived low level of interest in offering diabetes services by pharmacists Quality Assurance Systems	2. Health service system	2.1 Medical services 2.1.1 Access to services 2.1.2 Limited services 2.2 Health insurance system 2.2.1 Payment system 2.2.2 Financial burdens 2.3 Human workforce: time constraints

		Bundled payment system Role of health insurers Cost of medication (Note: free med coverage for patients) "High costs" of diabetes medications and supplies Lack of financial aid for patients-GP (Note: not enough money for fruits) Structural/environmental factors Personal background-diabetes medication is expensive Workload Time Constraints Lack of time-GP-nurse Obstacles: Time constraints in a busy pharmacy Provision of services at the right time and place		
3	Delivery System Design: Roles among team Use plan to support evidence-based care Case management for complex patients Regular follow-up by care team Give appropriate care to patients (cultural)	Multidisciplinary collaboration Image (Note: role of dietitian) Affinity (Note: interest in DM as a family physician) Continuity of care Cross-boundary or team continuity (Note: effective communication between professionals and services, and with patients) Level of patient "trust" in primary care provider, strength of relationship with specialist team Organizational efficiency of diabetes clinics (Note: small group for continuity of care) Difficult to reach some groups Target specific groups of patients in need of additional support Frequency of seeing depressed patients -provider (Note: standard care but ignore) Culture (Note: use appropriate care for individual culture)	3. Continuity of care	3.1 Team cooperation 3.2 Case management 3.3 Tools for medication management

		Tools for medication management Medication reconciliation		

4	Self-Management Support:
	Emphasize patient-centered care
	Use effective self-management support
	Organize internal and community resources to support ongoing self-care
		Causes
		Identity of diabetes and the main features of its illness course:
		IDENTITY Etiological factors: genetic heritage and over-consumption of sugary food
		Perceived severity and its assessment
		Uni-dimensionality and its impact on health behaviors: concurrent progression of these clues
		Complications
		Prioritizing health conditions -patient prioritizing another condition over their diabetes
		Emotional impact of co-morbidity management
		Denial of diagnosis (Note: patients' awareness)
		Lack of awareness of symptoms
		Knowledge of the disease
		Diabetes complications as a motivator
		Other sources of information
		Knowledge about diabetes and medications
		Experiences of adverse effects of medications
		Forgetting to take medication or get a repeat prescription
		Issues related to adherence
		Adjustment of dose by patients
		Awareness of need to take medication
		Lack of motivation by patients-GP-nurse-patient
		The relationship of depressive symptoms and diabetes-patient, provider
		Patient barriers: lack of acceptance of diabetes as a chronic illness,
			4. Self-management	4.1 Knowledge and understanding of diabetes and its complications
				  4.1.1 Knowledge and understanding of diabetes
				  4.1.2 Understanding of diabetic complications
				  4.1.3 Experiences and awareness of diabetes complications
				4.2 Medication adherence
				  4.2.1 Knowledge and understanding of medication talking
				  4.2.2 Unintentionally poor adherence
				  4.2.3 Intentionally poor adherence
				  4.2.4 Good adherence
				4.3 Lifestyle modification
				  4.3.1 Knowledge and understanding

		patient adherence
		Poor patient adherence (to lifestyle modification)
		Self-Care Practice
		Self-management practices
		"Ongoing access to education" and resources- No information- No quotation
		More patient self-motivation -patient- No quotation
		Managing depressive symptoms-patient-provider
		Adherence to self-care
		Awareness and understanding of diabetes and its effective management
		Comparison with other diabetes patients
		Patients' beliefs about illness
		Comparison of diabetes mellitus with other diseases
		Accepting attitude to the disease
		Knowledge of the disease
		Beliefs about illness
		Beliefs and attitudes regarding diabetes self-management
		Denial of ability
		Creating a personal image of the illness
		Experiencing changes in self-worth based on that image of the illness
		Defining a personal relationship with the illness
		Strategically adjusting behaviors in social situations based on that relationship with the illness
		Four types of strategies:
		Adjustment to the Illness
		Social Disconnection
		Social Avoidance
		Role Conflict
		Maintaining Balance Between Patient and Social Roles
				4.3.2 Living with diabetes
				4.4 Belief-attitude
				  4.4.1 Diabetes
				  4.4.2 Lifestyle
				  4.4.3 Goal setting
				  4.4.4 Medication adherence

		Criticism of personal character Stigma and cultural differences-provider-no depression in Samoan people Patients' Self-Blame for Difficulty Achieving Treatment Goals Doctors' and nurses' frustration with non-adherent patients Healthcare Goals External Influences of Healthcare Goals Physicians' Perceived Responsibility for Patients' Difficulty Achieving Treatment Goals Patients' Perceptions of Physicians' Reactions to Unmet Goals Physicians' Perceptions of Patients' Reactions		

5	Decision Support:
	Embed evidence-guideline to clinical practice
	Shared evidence-based guideline with patients to encourage participation
	Use proven provider education methods
	Integrate specialist expertise and primary care
		Tailored, adequate information
		Standardized registration and exchange of information
		Company outreach visit
		Motivation-self management support
		Patient facilitators: responsibility and control over their diabetes, early educational interventions
		Individual care plan -self management support
		Administrative role (e.g. service reminder or arranging for the supply of diabetes medication)
		Support given by the nurse
		Doctors' attitudes support: Friendliness of pharmacists
		Care Standard
		Implementation of CS
		Planned Care Is Infrequent
		Systemic barriers: time and physician remuneration, CPGs as assisting them, they felt "overwhelmed" by the large number of guidelines.
		Bench-marking
			5. Providers' support	5.1 Effective healthcare providers
				  5.1.1 Administrative for effective treatment plan
				  5.1.2 Helpful services/satisfaction
				  5.1.3 Implementation of standard care
				  5.1.4. Counselling content by nurses

		Delivering information on diabetes (Note: inadequate counseling, good counseling) Own role, individualized orientation (goals, forms) of counselling Time Medication orientation Small issues in everyday life (Note: content and form of counseling)		
6	Clinical Information Systems Provide timely reminders Identify relevant subpopulation for proactive care Facilitate individual patient care planning Share information with patients and providers to coordinate care Monitor performance of practice team and care system	Discharge from specialist care PCP care after discharge Continuity of information: excellent information transfer following the patient Expectations at initial referral	6. Referral system	6.1 Barriers in transition between each level of care
7		Trusting patient–provider relationship Communication problems related to language Provider warnings Office visits (Note: poor skills in communication) Communication and continuity of care with healthcare professionals Diagnosis (Note: poor skills) Human interactions in health organizations	7. Patient-provider interaction *(Additional theme)*	7.1 Providers' communication skill and language barrier 7.2 Preferences for care 7.2.1 Preference for specialists 7.2.2 Preference for

		Improvement of health-care professionals' behaviors (Note: good communication concerns) Lack of support for medication self-management - poor communication skills Indifference to seriousness of diabetes -HP poor communication skills Frustration with management Degree of alignment of "patient self-management expectations" and treatment goals with PCP/specialist center Specialist care (Note: specialist preferred) "Self-management" abilities, "compliance", attitude about "seriousness of diabetes" PCP expectations of specialist referral Use of "effective communication, coordination of care", "individualized care plans", "ongoing phone advice", "diabetes passport" PCP expectations and "attitudes" with those of patient/specialist referral center Ease of "access to support" services, timely re-referral for patients and physicians Relational (or longitudinal) continuity: an ongoing therapeutic relationship between a patient and one or more providers		familiarity providers 7.2.3 Preference to general practitioners
8		Physician facilitators: continuing medical education (CME), Information technology Physician barriers: specifically, not having a systematic way to 'recall' or track their patients with diabetes through their computer system Offers of training -nurse Training offered for nurses -nurse More training offered by nurses -patient Education (Note: well trained, insufficient knowledge)	8. Competency of healthcare providers *(Additional theme)*	8.1. Continuing profession education

		Support: convenience of pharmacies Obstacles: lack of a private area PCP "knowledge" and "confidence" related to medication adjustment and behavior change Obstacles: reservations about the pharmacists' skill and knowledge in diabetes management Team approach to medication communication Involvement with nurses-GP More support by GP-nurse (Note: need small group for nutrition counseling)		
9		Involvement with family members Family Supported by primary care team Note: family support required Impact of medical and family relationships on well-being Supportive relationships	9. Family involvement *(Additional theme)*	9.1 Family as facilitators 9.2 Family as barriers
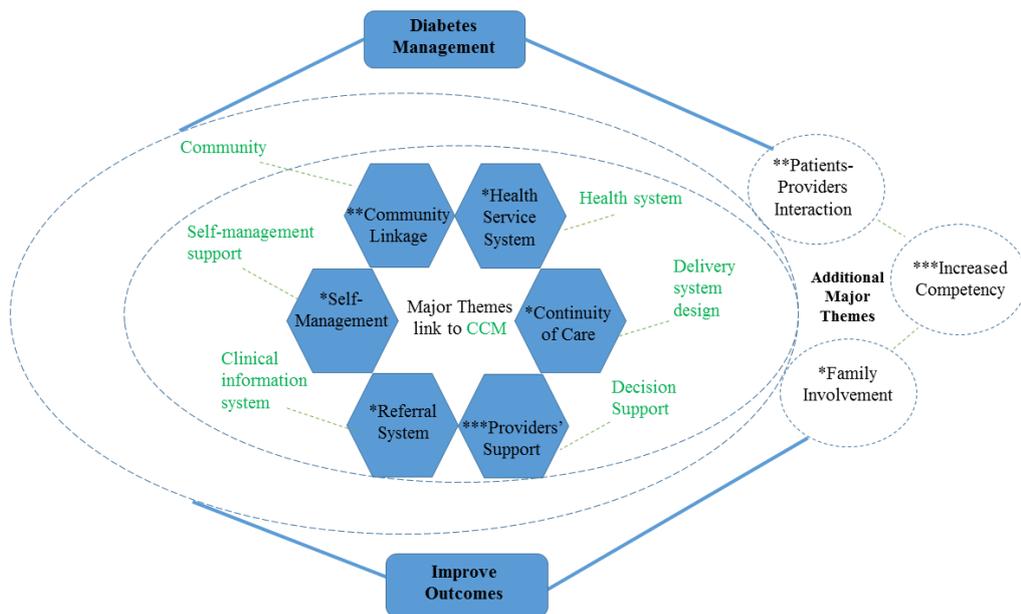
Figure 10 Perspectives of Patients and Healthcare providers on Diabetes Management

* Similarities among perspectives of patients and healthcare providers on diabetes management

** Differences among perspectives of patients and healthcare providers on diabetes management

*** There was no overlap of perspectives between patients and healthcare providers on diabetes management
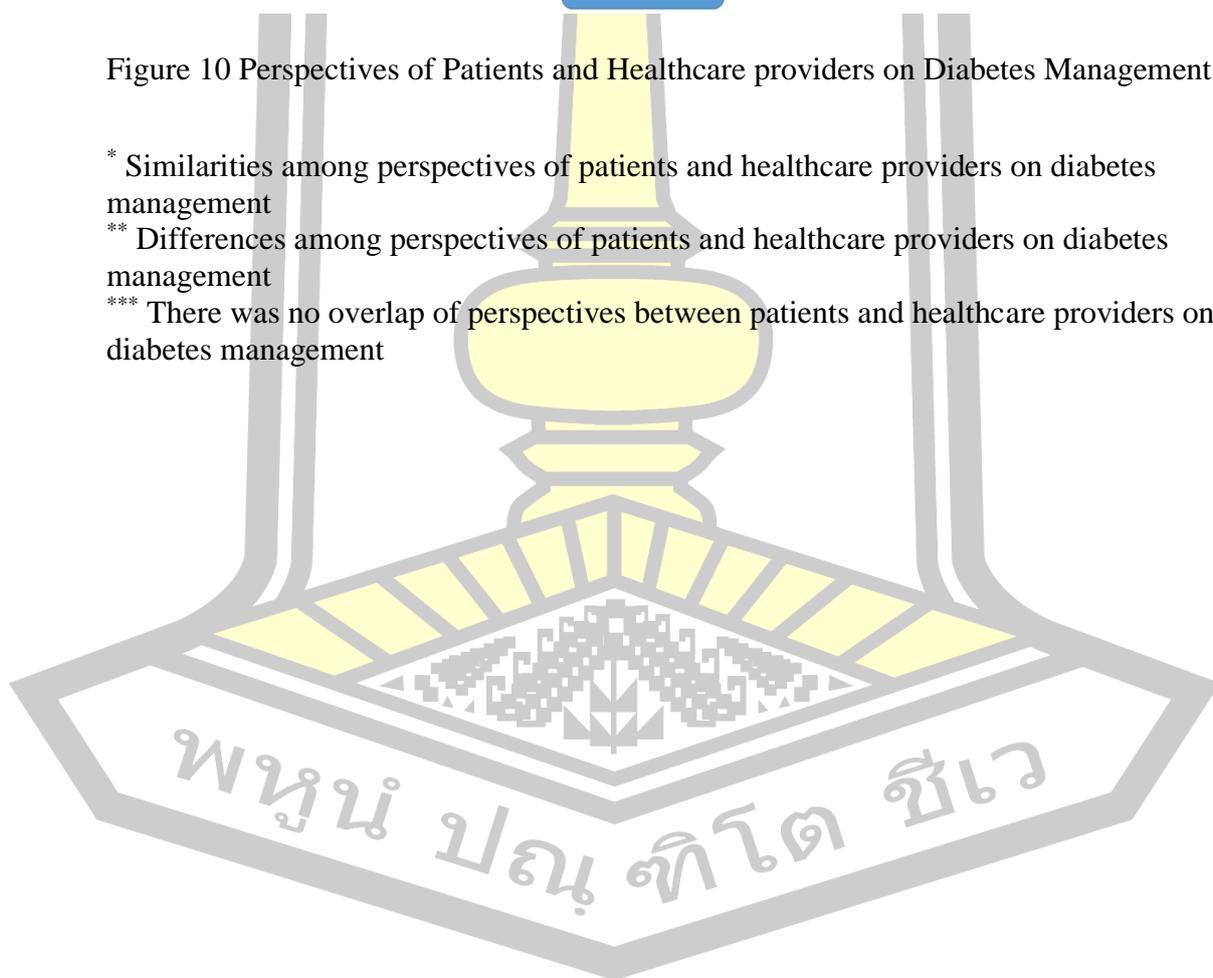
1.2. Formulation of patient satisfaction questionnaire (PSQ)

1.2.1. Patient Satisfaction Questionnaire (PSQ)

The Patient Satisfaction Questionnaire (PSQ) had 45 items. The dimensions and distribution of items are shown in Figure 11.
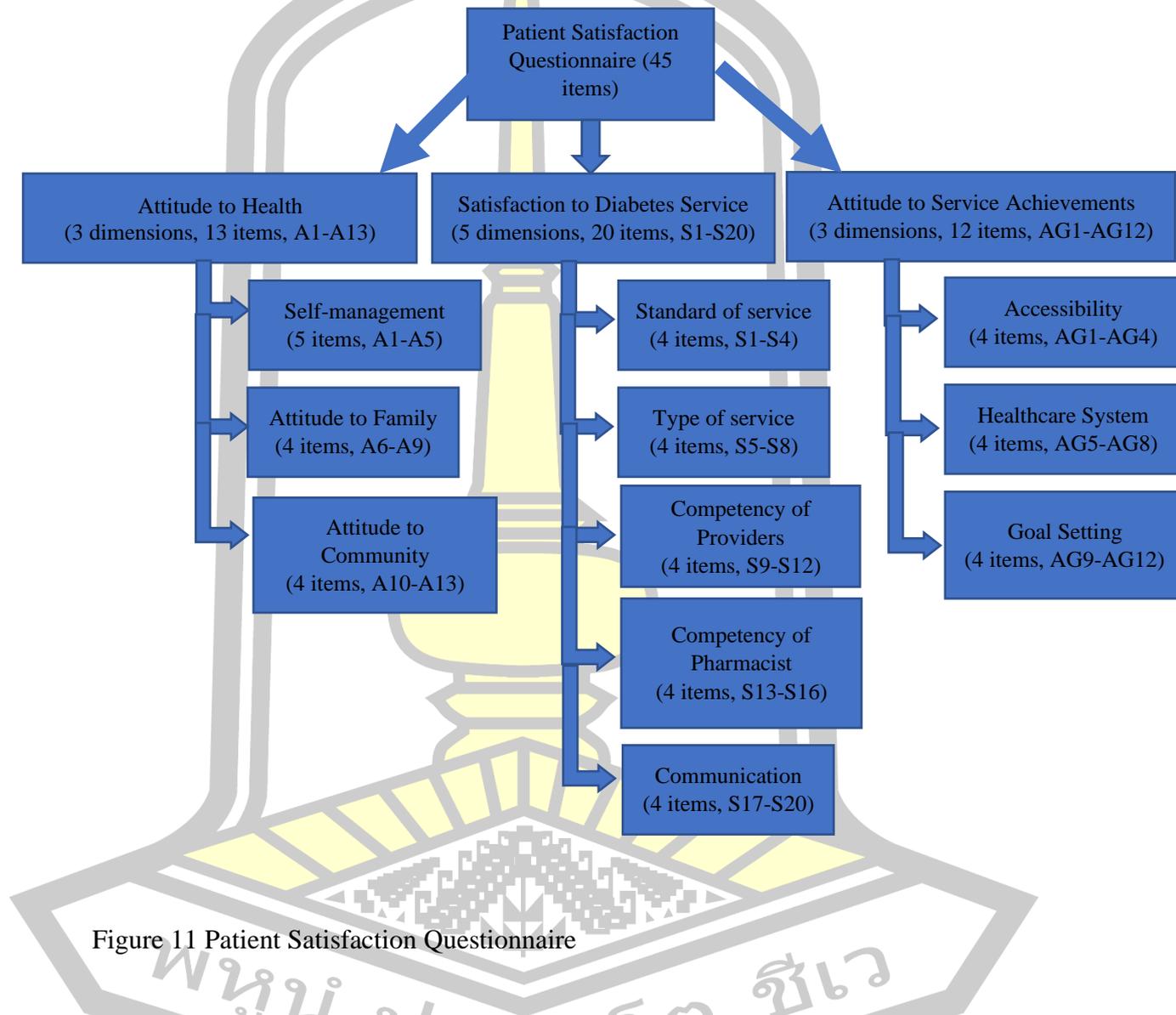
Figure 11 Patient Satisfaction Questionnaire

Demographic data of patients

Demographic data of the 150 subjects recruited for both versions are depicted in Table 5. Some differences of both versions were present for incomes, co-morbidities, insurances, family members, distance from diabetic service (p-value<0.05).

Table 5 Characteristics of patients for questionnaire properties testing

Characteristics (n=150)	Lao PDR	Thailand	p-value
Sex, n (%)			
Male	71 (47.30)	88 (58.70)	0.064 [a]
Female	79 (52.70)	62 (41.30)	
Age (year), Mean $\pm$ SD	56.80 $\pm$ 10.80	60.70 $\pm$ 11.30	0.685 [b]
Occupation, n (%)			
Civil servant	37 (24.70)	38 (25.30)	
Employee	14 (9.30)	13 (8.70)	
Commercial	19 (12.70)	28 (18.70)	0.099 [a]
Farmer	3 (2.00)	18 (12.00)	
Retired	32 (21.30)	30 (20.00)	
Other (No job)	45 (30.00)	23 (15.30)	
Education, n (%)			
No Education	6 (4.00)	9 (6.00)	
Elementary	35 (23.50)	34 (22.70)	
Primary school	31 (20.80)	14 (9.30)	
High school	25 (16.80)	26 (17.30)	0.091 [a]
Diploma	16 (10.70)	9 (6.00)	
Bachelor	24 (16.10)	38 (25.30)	
Higher than bachelor	12 (8.10)	20 (13.30)	
Income, n (%)			
$\geq$ 1,300,000 LAK/ $\geq$ 5,000 THB	60 (40.30)	46 (30.70)	
1,300,001-2,500,000 LAK/ 5,001- 10,000 THB	56 (37.60)	23 (15.30)	
2,500,001-3,900,000 LAK/ 10,001-15,000 THB	23 (15.40)	13 (8.70)	<0.001 [a]
> 3,900,000 LAK/ 15,001-20,000 THB	10 (6.70)	12 (8.00)	
$\geq$ 20,001 THB	n/a	56 (37.3)	
Married status, n (%)			
Single	6 (4.00)	10 (6.70)	
Married	121 (81.20)	103 (68.70)	
Widow	18 (12.10)	26 (17.30)	0.082 [a]
Divorced	3 (2.00)	7 (4.60)	
Separated	1 (0.70)	4 (2.70)	
Family members (person), Mean $\pm$ SD	4.80 $\pm$ 2.40	3.85 $\pm$ 1.80	<0.001 [c]
Distance from service (Km), Mean $\pm$ SD	23.50 $\pm$ 89.80	8.70 $\pm$ 12.70	<0.007 [c]
Duration of diabetes (Year), Mean $\pm$ SD	8.30 $\pm$ 7.20	8.80 $\pm$ 7.60	0.861 [c]
Co-morbidity, n (%)			
No	69 (46.60)	38 (25.30)	<0.001 [a]
Yes	79 (53.40)	112 (74.70)	
Source of Information for diabetes, n (%)			
Healthcare providers	98 (66.70)	93 (62.00)	
Radio/TV	9 (6.10)	7 (4.70)	0.139 [a]
Social media	1 (0.70)	3 (2.00)	

Characteristics (n=150)	Lao PDR	Thailand	p-value
Friends/cousins	10 (6.80)	5 (3.30)	
Various sources	28 (19.70)	42 (28.00)	
Insurance, n (%)			
Universal Coverage	3 (2.00)	48 (32.00)	
Civil servant	78 (52.70)	2 (1.30)	
Security social	27 (18.20)	88 (58.70)	<0.001 [a]
Community insurance	7 (4.70)	10 (6.70)	
Private insurance	1 (0.70)	1 (0.70)	
Other (pay by their own)	32 (21.60)	1 (0.70)	

[a] Chi-square test, [b] Independent t-test, [c] Mann-Whitney U Test

Construct validity

Principle component analysis was used. KMO measure for sampling adequacy for Lao language was 0.753 and Thai language was 0.847. The Bartlett's test of Sphericity showed significant p-value for all the languages indicating that the sample size was adequate for factor analysis as shown in Table 6.

Table 6 Sampling measurement of both versions of PSQ

KMO and Bartlett's Test		Lao PDR	Thailand
Kaiser-Meyer-Olkin Measure of Sampling Adequacy.		0.753	0.847
Bartlett's Test of Sphericity	Approx. Chi-Square	5004.72	4768.226
	Df	990	990
	Sig.	0.000	0.000

Total variance explained of major dimensions for factor component

Table 7 explains each major dimension. The items A1-A13 consisted of three components in both countries and can explain the attitude to health 65.38% in Lao PDR and 62.88% in Thailand. The item S1-S20 consisted of four components in both countries and can explain the satisfaction to diabetes service 74.19 % in Lao PDR and 70.44% in Thailand. The item AG1-AG12 consisted of three components in Lao PDR and in two components in Thailand and can explain the attitude to service achievements 66.47% in Lao PDR and 62.95% in Thailand. The whole questionnaire pack can explain the patient satisfaction to diabetes service 71.23% in Lao version and 71.66% in Thailand.

Table 7 Total variance explained for 3 major dimensions

Component	Lao PDR		Thailand	
	Eigenvalue	Extraction sums of squared loadings (%)	Eigenvalue	Extraction sums of squared loadings (%)
Attitude to Health (A1-A13)				
1	4.37	33.64	4.64	35.70
2	2.53	53.10	2.08	51.72
3	1.595	65.377	1.45	62.875
Satisfaction to Diabetes Service (S1-S20)				
1	10.89	54.39	9.96	49.78
2	1.84	63.60	1.57	57.64
3	1.11	69.16	1.45	64.87
4	1.01	74.18	1.11	70.44
Attitude to Service Achievements (AG1-AG12)				
1	5.42	45.15	6.15	51.29
2	1.45	57.26	1.40	62.96
3	1.10	66.47		
The whole pack of questionnaire (45 items)		71.23*		71.66*

Factor rotation
Attitude to health (A1-A13)
　　　　Table 8 explains that the items A1-A13 consisted of three components in both countries. And the sub-dimension A1-A5, A6-A9 and A10-A13 were grouped in each component in both countries.

Table 8 Factor rotation by Oblimin with Kaiser Normalization with the eigenvalue > 1 for Attitude to Health

Items	Lao PDR			Thailand		
	Component 1	Component 2	Component 3	Component 1	Component 2	Component 3
A1		0.75	-0.18	0.37		
A2		0.75		0.75	0.11	
A3		0.67		0.76		
A4	-0.24	0.67	0.13	0.63		
A5	0.10	0.65	0.16	0.83	-0.12	
A6		0.31	0.51	0.42		-0.50
A7	0.20	-0.13	0.71			-0.85
A8			0.88			-0.91
A9			0.87			-0.90
A10	0.89	-0.11	0.10	0.21	0.76	
A11	0.92			0.11	0.84	
A12	0.92				0.86	

Items	Lao PDR			Thailand		
	Component 1	Component 2	Component 3	Component 1	Component 2	Component 3
A13	0.86	0.10		-0.15	0.77	

Satisfaction to diabetes service (S1-S20)

Table 9 explains that items S1-S20 consisted of four components in both countries. However, there were differences in term of grouping of each item in both countries. Lao PDR revealed that S1-S6 were grouped in component 2, S7-S9 were grouped in component 4, S10-S16 and S19-S20 were grouped in component 1 while S17-S18 have no group. None of items are grouped in component 3 because the value was negative (-). Thailand revealed that S1-S4 were grouped in component 2, S5-S11 were grouped in component 3, S12-S16 were grouped in component 4 and S17-S20 were grouped in component 1.

Table 9 Factor rotation by Oblimin with Kaiser Normalization with the eigenvalue > 1 for Satisfaction to Diabetes Service

Items	Lao PDR				Thailand			
	Component 1	Component 2	Component 3	Component 4	Component 1	Component 2	Component 3	Component 4
S1	-0.13	0.93			0.14	0.73	-0.15	0.16
S2		0.94			0.18	0.86		-0.13
S3		0.52		0.33	-0.26	0.57	0.20	0.32
S4		0.54	-0.35			0.68		0.132
S5		0.74				0.35	0.55	
S6	0.21	0.87	0.12			0.45	0.45	
S7				0.92	-0.12	-0.15	0.82	0.14
S8	0.42	0.11		0.53			0.82	
S9		0.34	-0.36	0.29	0.31		0.56	
S10	0.41	0.34	-0.15	0.10	0.43	0.24	0.49	-0.10
S11	0.34	0.27	-0.34	0.20	0.34	0.13	0.55	
S12	0.44	0.36	-0.18		0.40		0.31	0.32
S13	0.56	0.11		0.32				0.93
S14	0.87		-0.10			0.12		0.84
S15	0.96			-0.11	0.20			0.75
S16	0.77		-0.25		0.16			0.80
S17			-0.85		0.79			0.12
S18			-0.98	-0.12	0.72	0.25		
S19	0.21		-0.60	0.21	0.62	-0.12	0.11	0.33
S20	0.17		-0.74	0.11	0.69	0.11		0.22

Attitude to service achievements (AG1-AG12)

The table 10 explains that items AG1-AG12 consisted of three components in Lao PDR and two components in Thailand. However, the data shows that in Lao PDR AG1-AG2, AG4-AG6 were grouped in component 2, AG3, AG6-AG8, AG10, AG12 were grouped in component 1. There were no items grouped in component 3 because the value was negative (-). Thailand revealed that AG1-AG2 were grouped in component 2, AG3-AG12 were grouped in component 1.

Table 10 Factor rotation by Oblimin with Kaiser Normalization with the eigenvalue >
1 for attitude to service achievements

Items	Lao PDR			Thailand	
	Component 1	Component 2	Component 3	Component 1	Component 2
AG1		0.91			0.96
AG2		0.90		0.13	0.87
AG3	0.79			0.47	0.23
AG4	0.34	0.35	-0.28	0.56	
AG5		0.29	-0.51	0.70	0.14
AG6	0.83	0.22	0.15	0.78	
AG7	0.73	-0.20	-0.26	0.83	
AG8	0.71		-0.12	0.62	0.23
AG9		-0.11	-0.83	0.75	0.12
AG10	0.24		-0.75	0.90	-0.18
AG11			-0.85	0.88	-0.11
AG12	0.42	0.30	-0.25	0.75	-0.17

Factor loading

The factor loadings of PSQ Lao version are shown in Table 11. There are 5 sub-dimensions consisting of factor scores lower than 0.5. Those sub-dimensions were standard of service, type of service, accessibility, healthcare system and goal setting. The lowest score was 0.094 which was item AG5 of healthcare system sub-dimension. The factor scores of PSQ Thai version are shown in Table 12. There was only one sub-dimension consisting of factor score lower than 0.5 which was self-management. The item A1 of self-management sub-dimension had factor score 0.434. After adjusting factor loadings by cutting the items that were lower than 0.5, all of the other factor loadings were higher, these adjusted factor loading are shown in Table 11 and Table 12

Table 11 Factor loading of Lao version

Item	1	2	3	4	5	6	7	8	9	10	11
A1	0.715										
A2	0.761										
A3	0.688										
A4	0.696										
A5	0.671										
A6		0.602									
A7		0.775									
A8		0.876									
A9		0.848									
A10			0.916								
A11			0.949								
A12			0.925								
A13			0.859								
S1				0.881/ 0.911[b]							
S2				0.896/ 0.912[b]							
S3				0.406[a]							

Item	1	2	3	4	5	6	7	8	9	10	11
S4				0.691/0.855[b]							
S5					0.734/0.909[b]						
S6					0.805/0.870[b]						
S7					0.427[a]						
S8					0.527/0.792[b]						
S9						0.861					
S10						0.888					
S11						0.857					
S12						0.898					
S13							0.951				
S14							0.978				
S15							0.969				
S16							0.983				
S17								0.920			
S18								0.915			
S19								0.867			
S20								0.881			
AG1									0.886/0.892[b]		
AG2									0.900/0.909[b]		
AG3									0.440[a]		
AG4									0.426[a]/0.697[b]		
AG5										0.094[a]	
AG6									0.791/0.863[b]		
AG7									0.841/0.879[b]		
AG8									0.902/0.895[b]		
AG9										0.373[a]	
AG10										0.944/0.942[b]	
AG11										0.915/0.915[b]	
AG12										0.750/0.810[b]	

[a] Factor loading lower than 0.5
[b] Factor loading after adjusted (cut the item that lower than 0.5)

Table 12 Factor loading of Thai version

Item	1	2	3	4	5	6	7	8	9	10	11
A1	0.434[a]										
A2	0.744/0.744[b]										
A3	0.761/0.768[b]										
A4	0.669/0.695[b]										
A5	0.816/0.830[b]										
A6		0.701									
A7		0.828									

Item	1	2	3	4	5	6	7	8	9	10	11
A8		0.915									
A9		0.897									
A10			0.841								
A11			0.884								
A12			0.834								
A13			0.747								
S1				0.856							
S2				0.873							
S3				0.664							
S4				0.657							
S5					0.641						
S6					0.516						
S7					0.767						
S8					0.780						
S9						0.820					
S10						0.816					
S11						0.856					
S12						0.764					
S13							0.959				
S14							0.967				
S15							0.962				
S16							0.967				
S17								0.840			
S18								0.876			
S19								0.626			
S20								0.884			
AG1									0.840		
AG2									0.863		
AG3									0.682		
AG4									0.612		
AG5										0.722	
AG6										0.759	
AG7										0.809	
AG8										0.859	
AG9											0.697
AG10											0.867
AG11											0.906
AG12											0.766

[a] Factor loading lower than 0.5
[b] Factor loading after adjusted (cut the item that lower than 0.5)

Pearson correlation analysis
Correlation, convergent and discriminant Validity

The Pearson correlation analysis of the Lao version is shown in Table 13. The lowest correlation was 0.064 in accessibility sub-dimension, the highest correlation was 0.969 in competency of pharmacist sub-dimension. The convergent validity of this PSQ Lao version's correlation was 79.54% and the discriminant validity was 88.68%. The Pearson correlation analysis of Thai version is also shown in Table 13. The lowest correlation was 0.233 in type of service sub-dimension, the highest correlation was 0.941 in the competency of pharmacist sub-dimension, same as the Lao version. The convergent validity and discriminant validity of this PSQ Thai version's correlation were higher than Lao version, 93.63% and 92.68% respectively.

Table 13 Correlation, convergent and discriminant validity of PSQ Lao and Thai version

Dimensions	Lao PDR			Thailand		
	Correlation of items with their own scales (range)	Convergent validity	Discriminant validity	Correlation of items with their own scales (range)	Convergent validity	Discriminant validity
Attitude to knowledge on self-management (AS)	0.48-0.58	5/5 (100.00%)	55/55 (100.00%)	0.27-0.62	4/5 (80.00%)	52/55 (94,54%)
Attitude to family (AF)	0.40-0.73	4/4 (100.00%)	41/44 (93,20%)	0.53-0.79	4/4 (100.00%)	44/44 (100.00%)
Attitude to community (AC)	0.76-0.91	4/4 (100.00%)	44/44 (100.00%)	0.58-0.77	4/4 (100.00%)	44/44 (100.00%)
Satisfaction to the standard of services (SS)	0.26-0.56	3/4 (75.00%)	35/44 (79,54%)	0.45-0.70	4/4 (100.00%)	44/44 (100.00%)
Satisfaction to the type of services (ST)	0.20-0.37	0/4 (0.00)	23/44 (52,27%)	0.23-0.54	2/4 (50.00%)	44/44 (100.00%)
Satisfaction to the competency of providers (SC)	0.75-0.81	4/4 (100.00%)	42/44 (95,45%)	0.59-0.72	4/4 (100.00%)	44/44 (100.00%)
Satisfaction to the competency of pharmacists (SCP)	0.92-0.97	4/4 (100.00%)	44/44 (100.00%)	0.93-0.94	4/4 (100.00%)	44/44 (100.00%)
Satisfaction to the communication with providers (SCM)	0.77-0.85	4/4 (100.00%)	44/44 (100.00%)	0.45-0.72	4/4 (100.00%)	38/44 (86.36%)
Attitude to the accessibility of service (AGS)	0.17-0.46	2/4 (50.00%)	36/44 (81,81%)	0.44-0.62	4/4 (100.00%)	33/44 (75.00%)
Attitude to the health service system (AGSS)	0.06-0.56	3/4 (75.00%)	39/44 (86,63%)	0.53-0.71	4/4 (100.00%)	35/44 (79.54%)
Attitude to goal setting (AGG)	0.20-0.73	3/4 (75.00%)	39/44 (86,63%)	0.51-0.78	4/4 (100.00%)	37/44 (84.09%)
Average		79.54%	88.68%		93.63%	92.68%

Cronbach's alpha coefficient

The reliability test by using Cronbach's alpha of both versions are shown in Table 14. Both versions show the same highest Cronbach's alpha at 0.974 for Lao version and 0.979 for Thai version in the competency of pharmacist sub-dimension. The overall 45 items of Cronbach's alpha was 0.945 and 0.948 for Lao and Thai version respectively.

Table 14 Cronbach's alpha coefficient of Thai and Lao version

Dimensions	Reliability (Cronbach's alpha)	
	Thailand	Lao PDR
Attitude to knowledge on self-management (AS)	0.724	0.749
Attitude to family (AF)	0.856	0.782
Attitude to community (AC)	0.846	0.933
Satisfaction to the standard of services (SS)	0.763	0.708
Satisfaction to the type of services (ST)	0.613	0.514
Satisfaction to the competency of providers (SC)	0.831	0.899
Satisfaction to the competency of pharmacists (SCP)	0.974	0.979
Satisfaction to the communication with providers (SCM)	0.823	0.918
Attitude to the accessibility of service (AGS)	0.745	0.612
Attitude to the health service system (AGSS)	0.796	0.641
Attitude to goal setting (AGG)	0.825	0.750
Overall 45 items	0.945	0.948

1.3. Diabetes-39 questionnaire (D-39)

The Diabetes-39 had 39 items. The dimensions and distribution of items are shown in Figure 12.
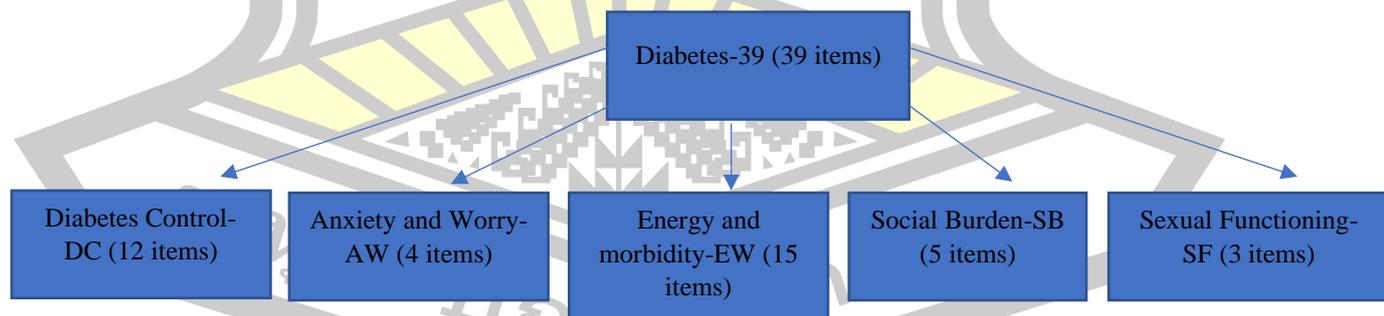
Figure 12 Diabetes-39 questionnaire dimensions

Missing data

The highest percentage of missing data in Lao version of Diabetes-39 was item AW6 (Anxiety and Worry), EM7 and EM29 (energy and morbidity) with the rate 1.3%, is shown in Table 15.

Table 15 Missing data of Diabetes-39 questionnaire

Item	Dimension	Mean	SD	Percentage of choices							Missing data	
				1	2	3	4	5	6	7	Count	Percentage
1	DC	2.63	1.95	47.30	10.70	10.70	12.70	7.30	4.70	6.70	0	0.00
2	AW	2.89	1.84	34.00	16.00	14.00	13.00	12.00	6.70	4.00	0	0.00
3	EM	3.25	1.74	23.30	12.00	22.00	17.30	13.30	8.70	3.30	0	0.00
4	DC	2.35	1.69	46.30	19.30	12.00	7.30	7.30	4.70	2.70	1	0.70
5	DC	2.93	1.81	32.70	13.30	18.70	14.00	10.70	6.70	4.00	0	0.00
6	AW	3.27	2.11	32.40	10.80	16.20	8.10	12.80	9.50	10.10	2	1.30
7	EM	3.06	2.00	34.50	12.20	13.50	17.60	6.10	7.40	8.80	2	1.30
8	AW	2.95	1.96	36.70	12.70	12.00	17.30	7.30	6.70	7.30	0	0.00
9	EM	3.33	1.81	23.50	12.80	16.10	21.50	12.10	9.40	4.70	1	0.70
10	EM	2.66	1.73	39.30	12.00	20.00	10.70	11.30	3.30	3.30	0	0.00
11	EM	2.30	1.70	51.70	14.10	10.10	11.40	4.00	7.40	1.30	1	0.70
12	EM	3.73	1.85	16.00	13.30	14.70	21.30	14.70	12.00	8.00	0	0.00
13	EM	3.55	1.75	16.70	12.70	20.00	22.00	13.30	9.30	6.00	0	0.00
14	DC	3.72	1.95	18.70	13.30	12.70	20.00	14.00	10.70	10.70	0	0.00
15	DC	3.64	1.80	12.70	18.00	18.00	22.70	10.70	8.70	9.30	0	0.00
16	EM	2.91	1.95	36.00	16.70	12.00	11.30	10.00	8.00	6.00	0	0.00
17	DC	2.32	1.78	53.00	12.80	12.10	6.00	7.40	5.40	3.40	1	0.70
18	DC	2.41	1.70	47.30	14.70	12.00	11.30	6.70	6.70	1.30	0	0.00
19	SB	2.67	1.80	40.70	15.30	12.00	12.00	10.70	7.30	2.00	0	0.00
20	SB	1.91	1.62	65.80	12.80	6.70	3.40	5.40	2.70	3.40	1	0.70
21	SF	2.49	1.93	51.30	9.30	13.30	10.00	4.00	5.30	6.70	0	0.00
22	AW	2.40	1.75	49.30	14.70	8.00	12.70	8.00	4.70	2.70	0	0.00
23	SF	2.62	2.02	48.30	12.80	8.70	11.40	5.40	4.70	8.70	1	0.70
24	DC	2.81	1.85	36.00	16.00	17.30	8.70	10.00	8.00	4.00	0	0.00
25	EM	2.62	1.95	48.70	10.00	10.00	10.00	9.30	7.30	4.70	0	0.00
26	SB	2.83	1.88	38.70	12.00	15.30	11.30	12.00	6.00	4.70	0	0.00
27	DC	2.01	1.62	61.10	12.80	8.70	8.70	2.00	3.40	3.40	1	0.70
28	DC	2.73	1.84	41.30	10.00	16.00	14.00	7.30	8.00	3.30	0	0.00
29	EM	2.50	1.77	45.90	14.20	11.50	10.80	10.80	3.40	3.40	2	1.30
30	SF	2.52	1.98	50.70	12.70	8.00	11.30	5.30	4.00	8.00	0	0.00
31	DC	2.70	1.79	38.70	13.30	18.00	13.30	7.30	4.70	4.70	0	0.00
32	EM	2.53	1.75	42.70	16.70	12.70	13.30	6.70	4.00	4.00	0	0.00
33	EM	2.94	1.82	34.00	12.70	14.00	18.00	11.30	6.00	4.00	0	0.00
34	EM	1.89	1.49	66.00	8.00	10.70	8.00	3.30	2.00	2.00	0	0.00
35	EM	2.99	1.89	32.00	15.30	16.00	14.70	9.30	6.00	6.70	0	0.00
36	EM	2.74	1.82	38.00	14.70	15.30	13.30	9.30	4.70	4.70	0	0.00
37	SB	1.83	1.53	69.10	9.40	7.40	6.00	2.70	2.70	2.70	1	0.70
38	SB	2.78	1.98	42.70	10.70	14.00	12.70	4.70	9.30	6.00	0	0.00
39	DC	3.51	1.96	23.30	13.30	11.30	20.70	12.0	11.30	8.00	0	0.00

Construct validity

Principle component analysis was used. The Kaiser-Meyer-Olkin (KMO) Measure was used for sampling measurement. The KMO value was not significant (0.917) which means that the sample size (n=150) for testing this Diabetes-39 Lao version was adequate as shown in Table 16

Table 16 Sampling measurement

KMO and Bartlett's Test		
Kaiser-Meyer-Olkin Measure of sampling adequacy.		0.917
Bartlett's Test of Sphericity	Approx. Chi-Square	4433.4
	df	741
	Sig.	0.000

Total Variance Explained of Major Dimensions for Factor Component

Table 17 shows the five components (dimensions) of Diabetes-39. All the five components had the eigenvalues more than 1 and the whole five dimensions were able to explain the quality of life of diabetes patients at 63.72%

Table 17 Total variance explained

Component	Eigenvalues	Extraction Sums of Squared Loadings (%)
1	17.251	17.634
2	2.350	33.992
3	2.202	48.308
4	1.664	59.718
5	1.384	63.721*

Factor rotation

Table 18 explained that item 1(DC), 4(DC), 5(DC), 17(DC), 18(DC), 24(DC), 27(DC), 28(DC), 39(DC), 2(AW), 6(AW), 11(EM), 19(SB) and 26(SB) were grouped in component 1. Item 25(EM), 29(EM), 32(EM), 33(EM), 34(EM), 35(EM), 36(EM), 37(EM) and 38(EM) were grouped in component 2. Item 14(DC), 15(DC), 8(AW), 22(AW), 3(EM), 7(EM), 9(EM), 10(EM), 12(EM), 13(EM) and 16(EM) were grouped in component 3. Item 31(DC), 20(SB), 21(SF), 23(SF) and 30(SF) were grouped in component 4. None of item were grouped in component 5.

Table 18 Factor Rotation of Diabetes-39 by Varimax with Kaiser Normalization

Items	Components				
	1	2	3	4	5
1(DC)	0.685		0.217	0.120	0.260
4(DC)	0.767	0.250	0.218		
5(DC)	0.717		0.243	0.224	
14(DC)	0.148	0.391	0.649	0.276	-0.203

Items	Components				
	1	2	3	4	5
15(DC)		0.118	0.647	0.296	
17(DC)	0.473	0.308		0.240	0.570
18(DC)	0.638	0.524	0.169	0.120	0.122
24(DC)	0.558	0.322	0.188	0.370	
27(DC)	0.597	0.423	-0.134	0.221	0.217
28(DC)	0.658	0.374	0.104	0.247	-0.134
31(DC)	0.451	0.395	0.148	0.547	
39(DC)	0.319	0.525	0.349	0.230	-0.386
2(AW)	0.462		0.445		0.340
6(AW)	0.554		0.521		
8(AW)	0.471	0.270	0.588		0.222
22(AW)	0.208	0.563	0.371	0.248	0.217
3(EM)	0.470		0.625	0.132	-0.103
7(EM)	0.144	0.155	0.672	0.109	0.389
9(EM)	0.493	0.276	0.563		-0.145
10(EM)	0.287	0.527	0.528		
11(EM)	0.602	0.370	0.228	0.121	0.121
12(EM)		0.236	0.631	0.162	
13(EM)	0.178	0.314	0.593	0.252	
16(EM)		0.410	0.526	0.273	0.277
25(EM)	0.310	0.522	0.280	0.403	0.124
29(EM)	0.385	0.459		0.358	-0.107
32(EM)	0.452	0.459	0.229	0.290	
33(EM)	0.204	0.672	0.363		-0.135
34(EM)	0.373	0.605	0.103	0.233	0.133
35(EM)	0.148	0.524	0.275		0.110
36(EM)		0.789	0.170	0.216	
19(SB)	0.483	0.361	0.395	0.357	-0.200
20(SB)	0.194	0.442	0.172	0.478	0.418
26(SB)	0.514	0.438	0.228	0.391	-0.137
37(SB)	0.274	0.638		0.261	0.223
38(SB)	0.367	0.496	0.276	0.368	
21(SF)	0.121	0.102	0.327	0.808	
23(SF)	0.220	0.213	0.240	0.823	
30(SF)	0.145	0.236		0.860	

Factor Score

Table 19 showed the factor scores of Diabetes-39 Lao version. All items have factor scores above 0.5

Table 19: Factor loading of 39 items of Diabetes-39 Lao version

Items	1	2	3	4	5
1	0.667				
4	0.765				
5	0.697				
14	0.610				
15	0.505				
17	0.69				
18	0.836				
24	0.789				
27	0.674				
28	0.801				
31	0.770				
39	0.630				
2		0.720			
6		0.780			
8		0.889			
22		0.732			
3			0.644		
7			0.635		
9			0.741		
10			0.767		
11			0.681		
12			0.578		
13			0.689		
16			0.678		
25			0.770		
29			0.640		
32			0.717		
33			0.714		
34			0.698		
35			0.601		
36			0.656		
19				0.801	
20				0.752	
26				0.836	
37				0.776	
38				0.825	
21					0.919
23					0.957
30					0.919

Convergent and discriminant validity

Table 20 shows the correlation between items and their own scales (dimensions). Diabetes-39 Lao version had the lowest correlation value of 0.467 at the dimension of Diabetes Control, the highest correlation value of 0.897 at the dimension of Sexual Functioning. Diabetes-39 Lao version had convergent validity of 100% and discriminant validity of 88.87%.

Table 20 Correlation, convergent and discriminant validity of Diabetes-39 Lao version

Dimension	Number of items	Correlation of items with their own scales (range)	Convergent validity	Discriminant validity
Diabetes Control	12	0.467-0.790	12/12 (100.00%)	53/60 (88.33%)
Anxiety and Worry	4	0.509-0.752	4/4 (100.00%)	16/20 (80.00%)
Energy and Morbidity	15	0.531-0.722	15/15 (100.00%)	66/75 (88.00%)
Social Burden	5	0.614-0.725	5/5 (100.00%)	22/25 (88.00%)
Sexual Functioning	3	0.822-0.897	3/3 (100.00%)	15/15 (100.00%)
Average			100.00%	88.87%

Reliability Test with Cronbach's Alpha coefficient

Table 21 shows the Cronbach's alpha values from Diabetes-39 Lao version. The Cronbach's alpha values of all dimensions were higher than 0.7. None of Pearson correlation value between dimensions was higher than Cronbach's alpha value.

Table 21 Cronbach alpha and Pearson Correlation of Diabetes-39 Lao version

Dimensions	Diabetes Control	Anxiety and Worry	Energy and Morbidity	Social Burden	Sexual Functioning
Diabetes Control	0.906*				
Anxiety and Worry	0.748	0.787*			
Energy and Morbidity	0.835	0.758	0.917*		
Social Burden	0.833	0.688	0.826	0.856*	
Sexual Functioning	0.583	0.412	0.575	0.659	0.924*
All 39 items	0.966*				

* Cronbach's alpha coefficient

Compare Diabetes-39 Lao version and Diabates-39 Thai version

Diabetes-39 Thai version had higher value of missing data than Lao version (1.8% and 1.3%) as shown in Table 22.

Table 22 Comparing Missing Data of Diabetes-39 Lao and Thai version

Dimensions	Items	Diabetes-39 Lao version (n=150)		Diabetes-39 Thai version (n=397)	
		Mean $\pm$ SD	Missing data (%)	Mean $\pm$ SD	Missing data (%)
Diabetes Control	1	2.63 $\pm$ 1.95	0 (0.00)	2.26 $\pm$ 1.73	3 (0.80)
	4	2.35 $\pm$ 1.69	1 (0.70)	2.58 $\pm$ 1.72	0 (0.00)
	5	2.93 $\pm$ 1.81	0 (0.00)	3.01 $\pm$ 1.81	1 (0.30)
	14	3.72 $\pm$ 1.95	0 (0.00)	3.35 $\pm$ 1.98	1 (0.30)
	15	3.64 $\pm$ 1.80	0 (0.00)	3.16 $\pm$ 1.76	1 (0.30)
	17	2.32 $\pm$ 1.78	1 (0.70)	2.43 $\pm$ 1.66	1 (0.30)
	18	2.41 $\pm$ 1.70	0 (0.00)	2.47 $\pm$ 1.60	1 (0.30)
	24	2.81 $\pm$ 1.85	0 (0.00)	2.61 $\pm$ 1.66	4 (1.00)
	27	2.01 $\pm$ 1.62	1 (0.70)	1.99 $\pm$ 1.50	2 (0.50)
	28	2.73 $\pm$ 1.84	0 (0.00)	2.27 $\pm$ 1.51	0 (0.00)
	31	2.70 $\pm$ 1.79	0 (0.00)	2.29 $\pm$ 1.52	0 (0.00)
	39	3.51 $\pm$ 1.96	0 (0.00)	3.06 $\pm$ 1.75	0 (0.00)
Anxiety and Worry	2	2.89 $\pm$ 1.84	0 (0.00)	2.73 $\pm$ 1.94	0 (0.00)
	6	3.27 $\pm$ 2.11	2 (1.30)	3.19 $\pm$ 2.15	0 (0.00)
	8	2.95 $\pm$ 1.96	0 (0.00)	2.98 $\pm$ 1.80	2 (0.50)
	22	2.40 $\pm$ 1.75	0 (0.00)	2.23 $\pm$ 1.49	1 (0.30)
Energy and Morbidity	3	3.25 $\pm$ 1.74	0 (0.00)	3.35 $\pm$ 1.74	1 (0.30)
	7	3.06 $\pm$ 2.00	2 (1.30)	3.01 $\pm$ 1.99	2 (0.50)
	9	3.33 $\pm$ 1.81	1 (0.70)	3.15 $\pm$ 1.73	1 (0.30)
	10	2.66 $\pm$ 1.73	0 (0.00)	2.50 $\pm$ 1.71	1 (0.30)
	11	2.30 $\pm$ 1.70	1 (0.70)	2.30 $\pm$ 1.58	0 (0.00)
	12	3.73 $\pm$ 1.85	0 (0.00)	2.87 $\pm$ 1.79	2 (0.50)
	13	3.55 $\pm$ 1.75	0 (0.00)	2.73 $\pm$ 1.74	2 (0.50)
	16	2.91 $\pm$ 1.95	0 (0.00)	2.88 $\pm$ 1.79	1 (0.30)
	25	2.62 $\pm$ 1.95	0 (0.00)	2.89 $\pm$ 1.78	1 (0.30)
	29	2.50 $\pm$ 1.77	2 (1.30)	1.93 $\pm$ 1.48	0 (0.00)
	32	2.53 $\pm$ 1.75	0 (0.00)	2.62 $\pm$ 1.60	2 (0.50)
	33	2.94 $\pm$ 1.82	0 (0.00)	2.50 $\pm$ 1.78	1 (0.30)
	34	1.89 $\pm$ 1.49	0 (0.00)	1.38 $\pm$ 1.03	0 (0.00)
	35	2.99 $\pm$ 1.89	0 (0.00)	2.81 $\pm$ 1.84	0 (0.00)
	36	2.74 $\pm$ 1.82	0 (0.00)	2.50 $\pm$ 1.73	0 (0.00)
Social Burden	19	2.67 $\pm$ 1.79	0 (0.00)	2.26 $\pm$ 1.68	0 (0.00)
	20	1.91 $\pm$ 1.62	1 (0.70)	1.36 $\pm$ 1.00	0 (0.00)
	26	2.83 $\pm$ 1.88	0 (0.00)	2.30 $\pm$ 1.61	3 (0.80)
	37	1.83 $\pm$ 1.53	1 (0.70)	1.53 $\pm$ 1.12	1 (0.30)
	38	2.78 $\pm$ 1.98	0 (0.00)	2.14 $\pm$ 1.59	0 (0.00)
Social Functioning	21	2.49 $\pm$ 1.93	0 (0.00)	1.98 $\pm$ 1.60	6 (1.50)
	23	2.62 $\pm$ 2.02	1 (0.70)	2.07 $\pm$ 1.62	7 (1.80)
	30	2.52 $\pm$ 1.98	0 (0.00)	2.08 $\pm$ 1.55	5 (1.30)

Comparing reliability (Cronbach's alpha)

Table 23 shows that Lao version of Diabetes-39 had the Cronbach's alpha value higher than 0.7 obtained in other countries. It also shows a higher value than original version in three dimensions such as diabetes control, social burden and sexual functioning and also higher value than the Thai version in three dimensions i.e. energy and morbidity, social burden and sexual functioning.

Table 23 Comparing Cronbach's alpha value of Diabetes-39 Lao version with other languages

Dimensions/ languages	Original (n=262)	Denmark (n=86)	Norway (n=132)	Sweden (n=137)	Finland (n=192)	Taiwan (n=280)	Thai (n=397)	Laos (n=150)
Diabetes Control	0.900	0.890	0.900	0.920	0.880	> 0.700	0.920	0.910
Anxiety and worry	0.810	0.820	0.820	0.850	0.830	> 0.700	0.820	0.790
Energy and morbidity	0.930	0.910	0.910	0.930	0.890	> 0.700	0.910	0.920
Social burden	0.840	0.880	0.830	0.820	0.840	> 0.700	0.780	0.860
Sexual function	0.880	0.920	0.880	0.910	0.920	> 0.700	0.880	0.920

2. Phase 2. Randomized Controlled Trial (RCT)

2.1. Mutual protocol for clinical trial

There were a total of 7 healthcare providers (1 diabetes doctor, 2 nutritionists, 2 pharmacists and 2 OPD nurses) in the focus group on March 14, 2019 who approved the thesis protocol (diabetes care intervention led by a pharmacist in Lao PDR).

Summary of perspectives of the providers' in the Focus Group

1. They agreed and welcomed to have the researcher for conducting the thesis in Mahosot hospital.
2. All of them, especially doctors, nurses and nutritionists, clearly understood the benefit of an inter-disciplinary team for taking care of diabetes patients as well as pharmacist's role. They would like to see hospital pharmacists continue this diabetes care after completion of the research project.
3. Pharmacists stated that the main difficulty to provide diabetes care was lack of human resources and capacity.
4. Nutritionists suggested that both university and hospital should be more collaborative especially in updating the knowledge for pharmacists in the hospital.
5. The guidelines protocol is shown in Table 24 and 25 below

Table 24 Guidelines protocol used in clinical trial (RCT)

N	Patients clinical laboratory	Glucose lowering agents
1	HbA1c = 6.5%, FPG> 126 mg/dL or new case	- Life style modification: exercise, food restriction → refer to nutritionist
2	HbA1c = 7-7.5%, FPG = 126-165 mg/dL	- Start Metformin* (Base line), dose 500-2000 mg/day + lifestyle modification - ASCVD 10 years risk score should be calculated in case that has family history of CVD, smoking or patient who is > 40 years with HTN and DLD - Link for calculation → http://tools.acc.org/ASCVD-Risk-Estimator-Plus/#!/calculate/estimate/ (or use QR code below to link to the calculation website)

3	HbA1c > 7.5-9%, FPG > 165-212 mg/dL	- Start 2 combination from Metformin + Sulfonylurea (Glibenclamide-Daonil®)* + lifestyle modification
		- Alternative drug can be used with Metformin is:
		    Thiazolidinediones (pioglitazone-Utmos®)*
		    DPP-4 inhibitors (gliptin)
		    SGLT-2 inhibitors (gliflozin)
		    Alpha-glucosidase inhibitors
		    Repaglinide
		    Basal insulin*
		    GLP1-analog (exenatide, loraglutide)

4	If still not reach the goal	Triple medications: metformin* + sulfonylurea* + pioglitazone* or metformin + sulfonylurea + DPP-4 with lifestyle modification
5	If still not reach the goal or FPG>300 mg/dL, HbA1c >11%	- Glucose lowering agent (tablet) + Insulin* at night Insulin consideration* - When the patient has severe hyperglycemia and used triple medications without reaching goal, patient has malnutrition, operation, pregnant, chronic pancreatitis Basal insulin* start with 10 ui or 0.2 ui/kg, patient needs to meet with pharmacist for Insulin* education - - New Case need to learn how to use Insulin
Medications used for prevention of complications		
6	Hypertension + CKD: BP>140/90 mmHg with CKD	- ACEI (Anapril)* or ARB (Losartan)* for Renal Failure prevention. Avoid to use in combination. - Avoid using NSAIDs, Aminoglycoside (gentamicin, amikacin, streptomycin) - Lifestyle modification, salt limitation including other sodium (MSG) and avoid green vegetables. → meet nutritionist - If BP goal not reached, add more HTN medication (according to the Hypertension Guideline)
7	Lipid profiles: <40 year with LDL > 100 mg/dL (2.5 mmol/L), smoker, CVD family history	Lifestyle modification 3-6 months if LDL still high start statin moderate-intensity**
8	>40-75 year with LDL > 70 mg/dL (1.8 mmol/L)	- Start moderate-intensity statin** (Atorvastatin-Atorin®* 10 mg, Simvastatin-Bestatin®* 20 mg) + lifestyle modification (exercise, food restriction, meet nutritionist) - If goal not reached, start high-intensity statin** (Atorvastatin 40 mg) + lifestyle modification

N	Patients clinical laboratory	Glucose lowering agents
9	Patient with triglyceride 500-1000 mg/dL (5.7-11.4 mmol/L)	lifestyle modification, Fibrate, Gemfibrozin can be considered to prevent pancreatitis, if patient on Statin, avoid use in combination because it will harm the liver and induce rhabdomyolysis.
10	Patient with high risk (>14.7%) from ASCVD 10 years' risk score calculation	Should give ASA* 81 mg/day (recommendation dose is 75-162 mg/day) + Statin for ASCVD prevention. If ASA contra-indication, consider Clopidogrel* 75 mg/day
	- Smoking cessation for the smokers→ meet pharmacist - Suggest patient to avoid second hand smoke - Medication counselling → meet pharmacist	

* medication that exist in Mahosot hospital
** Statin intensity class Table 27

Table 25 High, moderate, and low-intensity statin therapy (used in the RCTs reviewed by the expert panel)

High intensity	Moderate intensity	Low intensity
• Daily dosage lowers LDL-C by approximately ≥ 50% on average • Atorvastatin (Lipitor), 40 to 80 mg • Rosuvastatin (Crestor), 20 (40) mg	• Daily dosage lowers LDL-C by approximately 30% to 50% on average • Atorvastatin, 10 (20) mg • Rosuvastatin, (5) 10 mg • Simvastatin (Zocor), 20 to 40 mg • Pravastatin (Pravachol), 40 (80) mg • Lovastatin (Mevacor), 40 mg • Fluvastatin XL (Lescol XL), 80 mg • Fluvastatin, 40 mg twice daily • Pitavastatin (Livalo), 2 to 4 mg	• Daily dosage lowers • LDL-C by < 30% average • Simvastatin, 10 mg • Pravastatin, 10 to 20 mg • Lovastatin, 20 mg • Fluvastatin, 20 to 40 mg • Pitavastatin, 1 mg

2.2.Clinical Trial
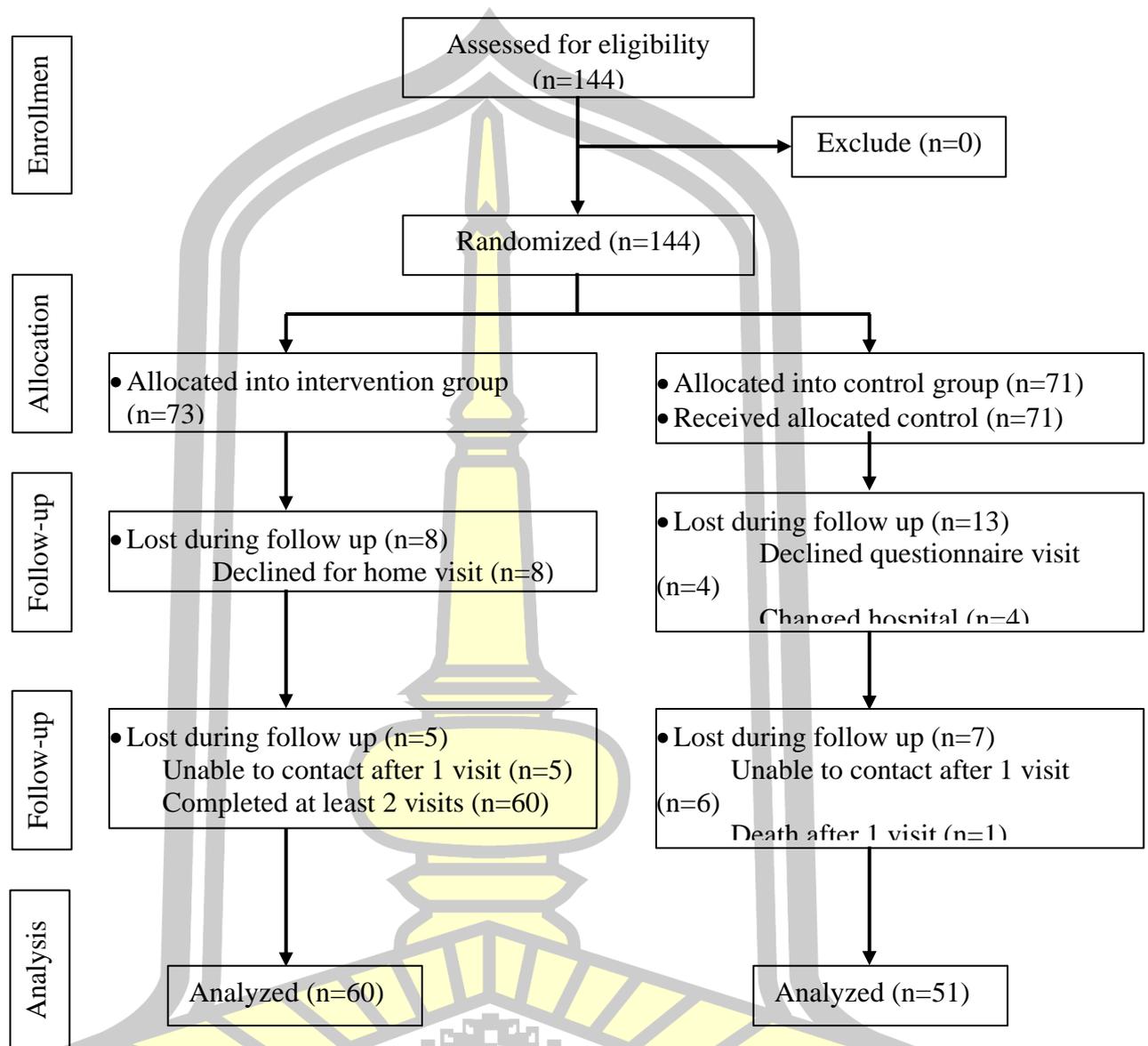
Figure 13: Consort Diagram 2010 for clinical trial

The consort diagram 2020 (Figure 13) shows how the 144 patients were randomized into 2 groups. Seventy-three patients were allocated to intervention group. Seventy-one patients were allocated to control group. After follow-up through the process of clinical trial, there were 60 and 51 of patients in the intervention and control groups respectively were analyzed.

2.3.Patients characteristics

Characteristics were not significantly different between the groups except age, distance from diabetes service, number of co-morbidities and patients with hypertensive co-morbidity as shown in Table 26

Table 26 Characteristics of patients in clinical trial (RCT)

Characteristics	Intervention Group (n=60) n (%)	Control Group (n=51) n (%)	p-value
Sex			
Male	24 (40.00)	25 (49.10)	0.340[a]
Female	36 (60.00)	26 (50.90)	
Age (mean ± SD)	60.10 ± 8.70	56.47 ± 10.20	*0.044[c]*
Occupation			
Civil servant	9 (15.00)	12 (23.50)	
Commercial	10 (16.70)	11 (21.60)	0.127[a]
Retired	27 (45.00)	12 (23.50)	
No job	14 (23.30)	16 (31.40)	
Education			
Elementary School	17 (28.40)	23 (45.10)	
Secondary School	14 (23.30)	13 (25.50)	
Diploma	15 (25.00)	4 (7.80)	0.072[a]
Bachelor and higher	14 (23.30)	11 (21.60)	
Income per month			
< 2,500,000 LAK	51 (85.00)	42 (82.40)	0.706[a]
> 2,500,000 LAK	9 (15.00)	9 (17.60)	
Social Status			
Alone	18 (30.00)	8 (15.70)	0.115[a]
With partner	42 (70.00)	43 (84.30)	
Number of family members (mean ± SD)	5.40 ± 2.60	5.20 ± 2.10	0.850[d]
Distance from the service, Km (Mean ± SD)	8.00 ± 7.10	11.43 ± 8.90	*0.015[d]*
Number of co-morbidities (mean ± SD)	1.40 ± 0.90	0.88 ± 0.70	*0.001[d]*
Having co-morbidity	49 (81.70)	36 (70.60)	0.170[a]
Hypertension	51 (85.00)	32 (62.70)	*0.009[a]*
Chronic Kidney Disease	7 (11.70)	3 (5.90)	0.338[b]
Dyslipidemia	16 (26.70)	8 (15.70)	0.175[b]
Cardiovascular Disease	6 (10.00)	4 (7.80)	0.751[b]
Thyroid Disorder	2 (3.30)	0 (0.00)	0.499[b]
Source of Diabetes Knowledge			
Healthcare providers	37 (61.60)	28 (54.90)	
From others	13 (21.70)	16 (31.40)	0.535[a]
Not received	10 (16.70)	7 (13.70)	
Insurance			
Civil servant insurance	30 (50.00)	24 (47.10)	
Social security	13 (21.70)	11 (21.60)	0.230[b]
Community insurance	9 (15.00)	3 (5.90)	
No insurance	8 (13.30)	13 (25.40)	

[a] Chi-square test   [b] Fisher Exact Test
[c] Independent t-test   [d] Mann-Whitney U test for non-parametric

2.4. Pharmacist's interventions

Patients in the intervention group received pharmaceutical care in the hospital and home education on nutrition and medication counselling. Pharmaceutical care for individual patient in the hospital was based on the problems they had while they were visiting 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) in each visit at the diabetes care service. There were 9 DRPs events that occurred in the intervention groups at month 0, 3 and 6 of the follow-up processes such as (1) untreated medications; at three times follow-up, most of the patients did not receive statin and/or aspirin for ASCVD prevention according to their high ASCVD 10 years' risk score. (2) too high dose; at month 0, there were 2 patients who received higher than the maximum dose of pioglitazone and metformin. (3) too low dose; at month 0, one patient received too low dose of metformin, at month 3, one patient received too low dose of losartan according to the high of BP, at month 6, there were 2 patients received too low dose of statin according to their high level of LDL. (4) drug-drug interaction; at month 0 there was one patient who received simvastatin and nifedipine which could cause severe interaction. (5) adverse drug reactions (ADR); at month 0, 3 patients had ADR from medication, all 3 patients had GI disorder due to metformin, at month 3, there was one patient who had swelling due to pioglitazone, at month 6 there was one patient had to be off furosemide due to gout. (6) prescription error; at month 3, researcher found prescription error, where patient was on insulin mixtard, but doctor had prescribed insulin NPH. (7) misunderstanding of posology; at month 0 patient misunderstanding about the posology by taking double of medication posology. (8) use other supplements; at month 3 there were 2 patients used other supplements for treating their DM without asking the permission from the doctor, which could cause affect to the clinical laboratory results, one patient had elevated of creatinine level (acute kidney injury) and one patient had elevated fasting plasma glucose. (9) unable to access to the medication; during month 3 and month 6 of the follow-up process, there were the pandemic of covid-19 around the world, hospital couldn't provide some of medications including glimepiride (sulfonylurea), this medication was not available at community pharmacy as well, there were one patient at month 3 and one at month 6 who were on this medication and unable to access, the researcher consulted the doctor to change to another list of sulfonylurea.

The total of DRPs events in month 0 was 53 (88.3%). The highest DRPs event was untreated medication (84.9%). In month 6, the number of DRPs events decreased compared with month 0 (26.7% at month 6). The details of DRPs events are shown in Table 27.

At month 3, there was one interesting case that had ADR from pioglitazone. On March, 2020, the patient made a phone call to a researcher due to some abnormalities that occurred. He said he had swelling in his legs, feet, hands. The current medications that he had were insulin mixtard 70/30 (20-0-18), pioglitazone 30 mg (1-0-1/2), amlodipine 10mg (0-0-1) and losartan 50mg (1-0-0). A researcher suggested him to come back to the diabetes care service in the hospital before his next appointment in the next two months. He came back to the hospital as suggested. His laboratory results were weight=83 kg, BP=134/64 mmHg, FPG=111.4 mg/dL, Creatinine=134.18 micromole/L and BUN=43.4 mg/dL. He started on pioglitazone 30mg (1-0-1/2) since August, 2019 which was 6 months ago. His

weight on August, 2019 was 81 Kg. A researcher suggested to the doctor to stop pioglitazone because his appearance looked like he had ADR from pioglitazone. The doctor agreed and also stopped amlodipine, because amlodipine could cause the swelling as well. Patient said he was on amlodipine for about 10 years without any swelling symptoms until now. At that moment, the doctor prescribed him insulin mixtard (18-0-16), losartan 50 mg (1-0-0) and furosemide 40 mg (1-1-0). A researcher asked the doctor to follow-up for 2 weeks, doctor agreed. After 2 weeks, he came back for the appointment with BP 140/71 mmHg, FPG=127.4 mg/dL, creatinine=138.94 micromole/L, BUN=44.3 mg/dL, K=3.68 mm/L (a little bit low). He didn't have any swelling symptoms after stopping pioglitazone. A researcher asked the doctor to stop furosemide because his potassium was quite low. The doctor agreed and prescribed him insulin mixtard (18-0-16), losar-plus 50 mg (losartan 50mg + hydrochlorothiazide 12.5mg) (1-0-0), and made an appointment for 3 months' follow-up.

The interventions were also done with diabetes doctors. Most frequent intervention was adding statin/ASA (69.6%) according to the ASCVD 10 years' risk score of the patients. Most of the interventions were agreed by the doctor. The details of the types of intervention are shown in Table 28.

Table 27 Drug-related problems (DRPs)

Drug-related problems (DRPs)	Intervention group (n=60) No (%) [b]		
	Month 0	Month 3	Month 6
Untreated medications	45 (84.90)	7 (53.80)	12 (66.70)
Too high dose	2 (3.80)	0 (0.00)	0 (0.00)
Too low dose	1 (1.90)	1 (7.70)	2 (11.10)
Drug-Drug Interaction (DDI)	1 (1.90)	0 (0.00)	0 (0.00)
Adverse drug reaction (ADR)	3 (5.70)	1 (7.70)	1 (5.60)
Prescription error	0 (0.00)	1 (7.70)	0 (0.00)
Misunderstanding of posology	1 (1.90)	0 (0.00)	0 (0.00)
Use of other supplements	0 (0.00)	2 (15.40)	0 (0.00)
Unable to access to the medication	0 (0.00)	1 (7.70)	1 (5.60)
Total of DRPs Events [a]	53 (88.30)	13 (21.60)	16 (26.70)

[a] Percentage within the number intervention group (n=60)
[b] Percentage within the total of DRPs events in each month
n/a Not applicable

\

Table 28 Intervention types for the intervention group

Pharmacist's interventions	Intervention Group (n=60)			Total No (%)	Doctor acceptance No (%) [c]
	Month 0	Month 3	Month 6		
	No (%) [b]				
Add statin/ASA	39 (69.60)	4 (30.80)	1 (5.60)	44 (50.60)	36 (81.80)
Add blood pressure medication	3 (5.40)	3 (23.10)	0 (0.00)	6 (6.90)	3 (50.00)
Increase dose	2 (3.60)	1 (7.70)	2 (11.10)	5 (5.70)	5 (100.00)
Change medications due to ADR/DDI and unable to access to medications	4 (7.10)	1 (7.70)	4 (22.20)	9 (10.30)	9 (100.00)
Stop medications due to ADR	0 (0.00)	0 (0.00)	2 (11.10)	2 (2.30)	2 (100.00)
Consult doctor on prescription error	0 (0.00)	0 (0.00)	1 (5.60)	1 (1.10)	1 (100.00)
Total of DRPs events	56 (64.40)	13 (14.90)	18 (20.70)	87 (100.00)	56 (64.40)

[b] Percentage within the total of DRPs events in each month

[c] Percentage within the total number of interventions

2.5. Comparison of clinical outcomes between groups

After the study, there was no significant difference between groups in HbA1c and FPG. However, the mean of HbA1c of the intervention group was lower than the control group in month 6. When adjusted for age and hypertension, there was no significant difference, except diastolic blood pressure (DBP) as shown in Table 29.
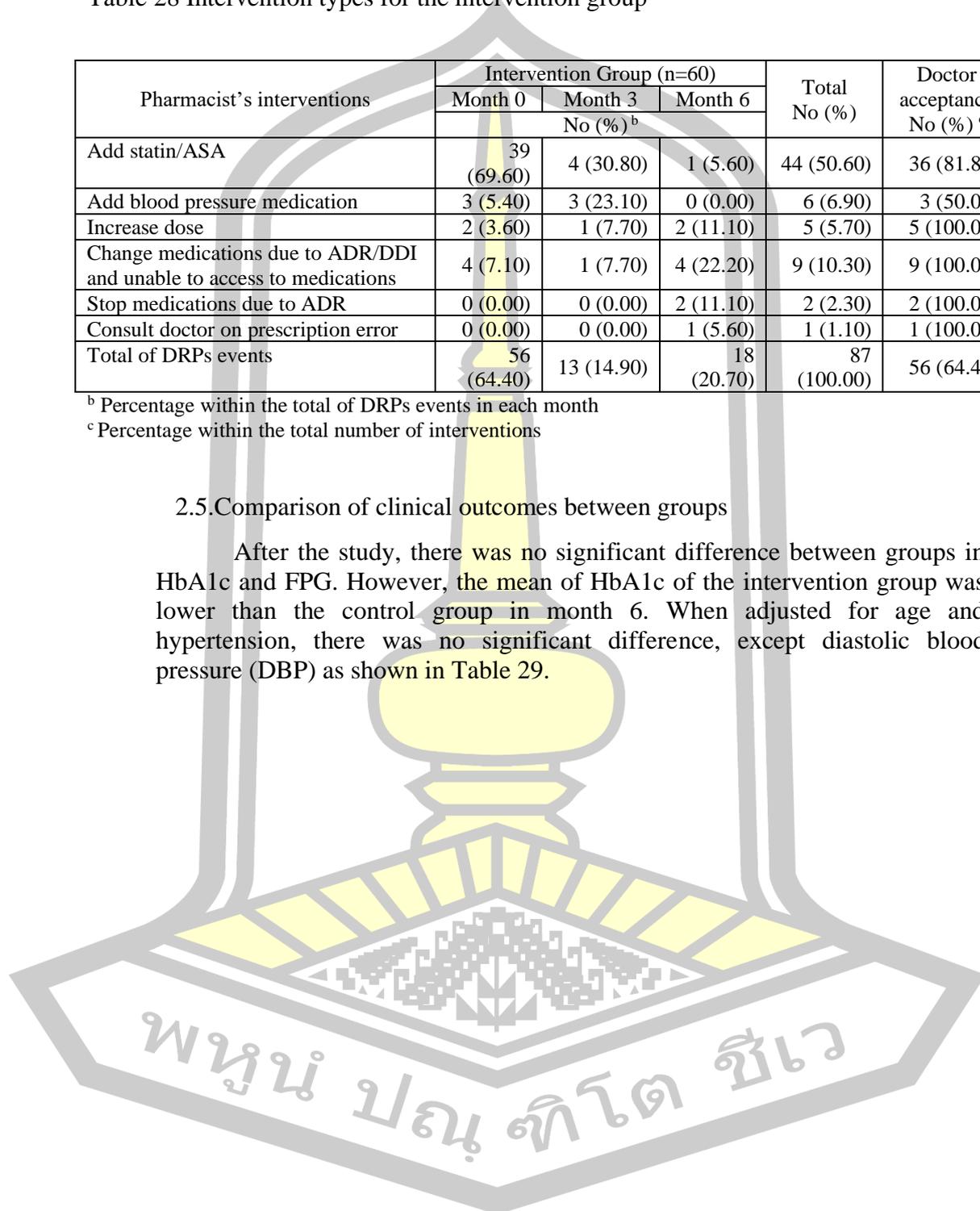
Table 29 Clinical outcomes between groups

Clinical Outcomes (Unit)	Intervention Group (n=60)		Control Group (n=51)		p-value Month 0[a]	p-value Month 6[a]
	Month 0*	Month 6**	Month 0*	Month 6**		
	Mean ± SD					
Primary Outcomes						
HbA1c (%)	9.51 ± 2.18	8.45 ± 1.86	9.26 ± 1.74	8.58 ± 1.78	0.456	0.678
FPS (mg/dL)	175.56 ± 80.22	167.65 ± 63.04	168.95 ± 50.97	160.15 ± 48.79	0.491	0.329
Secondary Outcomes						
SBP (mmHg)	143.13 ± 21.63	145.92 ± 22.49	136.88 ± 21.05	134.47 ± 21.60	0.849	0.070
DBP (mmHg)	78.77 ± 12.49	78.07 ± 11.75	80.84 ± 10.50	78.88 ± 12.70	*<0.001*	*<0.001*
Cholesterol (mg/dL)	212.29 ± 42.51	184.01 ± 41.61	197.42 ± 46.47	194.49 ± 38.73	0.082	0.455[a]
LDL (mg/dL)	130.66 ± 42.54	110.85 ± 31.32	115.50 ± 38.67	118.08 ± 29.94	0.052	0.494
HDL (mg/dL)	50.50 ± 17.39	48.55 ± 16.68	44.23 ± 8.84	45.42 ± 10.57	*0.027*	0.103
Triglyceride (mg/dL)	183.99 ± 98.72	188.25 ± 146.07	214.12 ± 122.98	226.91 ± 143.22	0.153	0.200
BMI (kg/m^2)	26.14 ± 3.21	26.11 ± 3.17	25.34 ± 3.12	25.00 ± 2.93	0.334	0.091
Creatinine (μmole/L)	116.58 ± 65.07	123.17 ± 98.37	102.78 ± 27.86	103.45 ± 33.14	0.380	0.258
GFR (mL/min)	59.12 ± 22.06	57.14 ± 21.36	62.90 ± 22.87	62.11 ± 21.19	0.740	0.890
BUN (mg/dL)	40.02 ± 27.36	41.72 ± 32.60	33.76 ± 12.51	34.19 ± 12.38	0.277	0.260
Number of medications	4.40 ± 1.59	3.95 ± 1.50	2.92 ± 1.40	3.16 ± 1.47	*<0.001*	0.129
Percentage of ASCVD 10 years' risk score (%)[§]	20.77 ± 15.99	18.13 ± 14.67	14.04 ± 10.46	14.19 ± 13.43	0.216	0.920

* The number of samples calculated for BUN: intervention = 50, control = 47

** The number of samples calculated for BUN: intervention = 52, control = 47

[§] Calculated by using http://tools.acc.org/ASCVD-Risk-Estimator-Plus/ - !/calculate/estimate/

[a] Linear regression by adjusted variables: group, age, patients with HTN co-morbidity

n/a stands for not applicable

2.6.Comparison of clinical outcomes within each group

Within group comparison between month 0 and month 3, showed that only lipid profiles of intervention group were significantly decreased, p-value < 0.05. There was no significant difference within the control group as shown in Table 30.

Within group comparison between month 0 and month 6, HbA1c was significantly decreased, p-value < 0.05. HbA1c was slightly lower in the intervention group than the control group, 8.45 and 8.58 respectively. Cholesterol and LDL were significantly decreased in intervention group, p-value < 0.001. BMI was significantly decreased only in control, p-value < 0.05 with mean difference of 0.33 $\pm$ 0.79 as shown in Table 31.

Within group comparison between month 3 and month 6, there was no significant differences in the intervention group. In the control group, BMI showed significant difference, p-value<0.05 with mean difference 0.56 $\pm$ 0.88 as shown in Table 32.

Table 30 Clinical outcomes comparing within the intervention and control groups between Month 0 and Month 3

Clinical Outcomes (Unit)	Intervention Group			p-value	Control Group			p-value
	Month 0	Month 3	Mean difference		Month 0	Month 3	Mean difference	
	(Mean ± SD)				(Mean ± SD)			
Primary Outcomes								
FBS (mg/dL)	177.53 ± 80.16	160.24 ± 45.36	17.29 ± 77.25	0.120[a]	173.41 ± 70.81	159.68 ± 54.63	13.73 ± 40.84	0.214[b]
Secondary Outcomes								
SBP (mmHg)	141.30 ± 22.48	139.86 ± 20.85	1.44 ± 19.36	0.601[a]	132.20 ± 19.24	131.00 ± 20.18	1.20 ± 10.90	0.676[a]
DBP (mmHg)	77.88 ± 12.59	76.58 ± 12.96	1.30 ± 11.61	0.505[b]	80.40 ± 10.02	80.20 ± 9.76	0.20 ± 3.67	1.000[b]
Cholesterol (mg/dL)	211.04 ± 39.16	190.80 ± 43.04	20.24 ± 43.02	*0.006[a]*	207.40 ± 51.56	211.28 ± 56.36	-3.88 ± 25.37	0.591[a]
LDL (mg/dL)	129.97 ± 41.26	115.42 ± 30.91	14.54 ± 43.49	*0.046[a]*	120.53 ± 55.48	126.18 ± 58.06	-5.65 ± 14.66	0.190[a]
HDL (mg/dL)	50.50 ± 17.39	47.03 ± 12.39	4.98 ± 8.98	*0.002[a]*	50.33 ± 7.63	52.17 ± 11.82	-1.84 ± 6.44	0.343[a]
Triglyceride (mg/dL)	190.91 ± 108.34	187.04 ± 110.71	3.87 ± 98.36	0.239[a]	258.88 ± 191.48	267.71 ± 185.33	-8.82 ± 42.64	0.488[a]
BMI (kg/m^2)	25.98 ± 3.19	26.05 ± 3.41	-0.07 ± 1.85	0.784[a]	24.97 ± 3.78	24.99 ± 3.70	-0.03 ± 0.31	0.743[a]
Creatinine (μmole/L)	112.65 ± 46.17	116.05 ± 49.44	-3.39 ± 19.46	0.495[b]	89.94 ± 27.28	88.26 ± 27.75	1.68 ± 12.65	0.674[b]
GFR (mL/min)	58.91 ± 20.57	57.11 ± 20.71	1.80 ± 11.97	0.302[a]	70.62 ± 28.58	69.73 ± 25.53	0.88 ± 15.34	0.826[a]
BUN (mg/dL)	39.34 ± 20.13	38.52 ± 19.30	0.82 ± 16.12	0.635[b]	31.21 ± 11.53	30.38 ± 11.71	0.82 ± 1.42	0.080[b]
Number of treated medications	4.39 ± 1.35	4.22 ± 1.81	0.17 ± 1.41	0.444[a]	2.92 ± 1.61	2.92 ± 1.61	n/a	0.445[a]

[a] Pair t-test for Parametric
[b] Wilcoxon Signed Ranks Test for Non-parametric
n/a the program was not calculated due to the same mean.

Table 31 Clinical outcomes comparing within the intervention and control groups between Month 0 and Month 6

Clinical Outcomes (Unit)	Intervention Group				Control Group			
	Month 0	Month 6	Mean difference	p-value	Month 0	Month 6	Mean difference	p-value
	(Mean ± SD)				(Mean ± SD)			
Primary Outcomes								
HbA1c (%)	9.51 ± 2.18	8.45 ± 1.86	1.06 ± 2.29	*0.001[a]*	9.26 ± 1.74	8.58 ± 1.78	0.68 ± 1.45	*<0.001[b]*
FPG (mg/dL)	175.56 ± 80.22	167.65 ± 63.04	7.91 ± 99.42	0.927[b]	168.95 ± 50.97	160.15 ± 48.79	8.80 ± 50.98	0.213[b]
Secondary Outcomes								
SBP (mmHg)	143.13 ± 21.63	145.92 ± 22.49	-2.60 ± 21.17	0.328[a]	136.88 ± 21.05	134.47 ± 21.60	2.41 ± 20.41	0.403[a]
DBP (mmHg)	78.77 ± 12.49	78.07 ± 11.75	0.70 ± 10.67	0.573[a]	80.84 ± 10.50	78.88 ± 12.70	1.96 ± 9.88	0.162[a]
Cholesterol (mg/dL)	212.29 ± 42.51	184.01 ± 41.61	28.28 ± 51.55	*<0.001[a]*	197.42 ± 46.47	194.49 ± 38.73	2.93 ± 48.06	0.665[a]
LDL (mg/dL)	130.66 ± 42.54	110.85 ± 31.32	19.80 ± 45.04	*0.001[a]*	115.50 ± 38.67	118.08 ± 29.94	-2.58 ± 36.30	0.191[b]
HDL (mg/dL)	50.50 ± 17.39	48.55 ± 16.68	1.94 ± 18.60	0.338[b]	44.23 ± 8.84	45.42 ± 10.57	-1.19 ± 8.77	0.339[a]
Triglyceride (mg/dL)	183.99 ± 98.72	188.19 ± 147.32	-4.20 ± 133.82	0.668[a]	214.12 ± 122.98	226.91 ± 143.22	-12. 79 ± 128.84	0.619[b]
BMI (kg/m²)	26.14 ± 3.21	26.11 ± 3.17	0.03 ± 1.21	0.819[a]	25.34 ± 3.12	25.00 ± 2.93	0.33 ± 0.79	*0.004[a]*
Creatinine (μmole/L)	116.58 ± 65.07	123.17 ± 98.37	-6.59 ± 46.74	0.377[b]	101.46 ± 26.47	103.45 ± 33.14	-1.99 ± 28.56	0.625[a]
GFR (mL/min)	59.12 ± 22.06	57.14 ± 21.36	1.97 ± 10.92	0.166[a]	63.67 ± 22.42	62.10 ± 21.18	1.57 ± 16.36	0.502[a]
BUN (mg/dL)	41.95 ± 28.87	39.50 ± 33.03	2.46 ± 16.10	0.312[b]	33.94 ± 12.79	34.55 ± 12.88	-0.06 ± 11.91	0.570[b]
Number of treated medications	4.26 ± 1.38	3.95 ± 1.50	0.31 ± 1.45	0.110[b]	2.94 ± 1.41	3.16 ± 1.48	-0.22 ± 0.89	0.074[b]
Percentage of ASCVD 10 years' risk score (%)	20.77 ± 15.99	18.13 ± 14.67	1.89 ± 12.20	0.142[b]	14.04 ± 10.46	14.19 ± 13.43	-1.57 ± 1.45	0.284[b]

[a] Pair t-test for Parametric   [b] Wilcoxon Signed Ranks Test for Non-parametric

Table 32 Clinical outcomes comparing within the intervention and control groups between Month 3 and Month 6

Clinical Outcomes (Unit)	Intervention Group			p-value	Control Group			p-value
	Month 3	Month 6	Mean difference		Month 3	Month 6	Mean difference	
	(Mean ± SD)				(Mean ± SD)			
Primary Outcomes								
FPG (mg/dL)	160.24 ± 45.36	171.45 ± 65.53	-11.21 ± 71.50	0.273[a]	159.68 ± 54.63	157.85 ± 37.59	1.83 ± 55.50	0.900[a]
Secondary Outcomes								
SBP (mmHg)	139.86 ± 20.69	144.02 ± 22.45	-4.16 ± 20.98	0.167[a]	131.00 ± 20.02	135.93 ± 26.42	-4.93 ± 21.20	0.383[a]
DBP (mmHg)	76.58 ± 12.96	77.20 ± 12.06	-0.62 ± 11.51	0.705[a]	80.20 ± 9.75	82.33 ± 13.69	-2.13 ± 9.98	0.422[a]
Cholesterol (mg/dL)	190.79 ± 43.04	185.14 ± 45.99	5.65 ± 50.24	0.492[a]	211.28 ± 56.36	179.15 ± 39.97	32.13 ± 55.04	0.057[a]
LDL (mg/dL)	115.42 ± 30.92	114.10 ± 31.02	1.33 ± 39.40	0.837[a]	126.18 ± 58.06	109.97 ± 29.13	16.21 ± 47.97	0.246[a]
HDL (mg/dL)	47.36 ± 12.39	47.56 ± 15.89	-0.21 ± 12.78	0.992[a]	52.17 ± 11.82	47.95 ± 11.67	4.22 ± 7.11	0.064[a]
Triglyceride (mg/dL)	185.73 ± 109.51	201.77 ± 176.75	-16.04 ± 143.64	0.496[a]	267.71 ± 185.33	246.83 ± 177.73	20.88 ± 86.09	0.419[a]
BMI (kg/m^2)	26.05 ± 3.41	26.00 ± 3.11	0.05 ± 1.80	0.838[a]	24.99 ± 3.69	24.44 ± 3.37	0.56 ± 0.88	*0.027[a]*
Creatinine (μmole/L)	116.05 ± 49.44	115.55 ± 52.92	0.51 ± 33.08	0.918[b]	88.26 ± 27.75	97.55 ± 44.84	-9.29 ± 39.42	0.532[b]
GFR (mL/min)	57.11 ± 20.72	56.84 ± 19.94	0.27 ± 12.71	0.883[a]	69.73 ± 25.53	65.33 ± 26.23	4.40 ± 16.79	0.327[a]
BUN (mg/dL)	40.66 ± 21.57	36.50 ± 13.89	4.16 ± 14.09	0.104[b]	30.67 ± 12.19	32.15 ± 9.38	-1.48 ± 9.18	0.638[b]
Number of treated medications	4.22 ± 1.81	3.95 ± 1.50	0.24 ± 1.37	0.263[a]	2.92 ± 1.61	3.23 ± 1.36	-0.31 ± 0.95	0.264[a]

[a] Pair t-test for Parametric

[b] Wilcoxon Signed Ranks Test for Non-parametric

2.7.Comparison clinical outcomes between groups defined by the

achievement of clinical goals

The outcomes were grouped as achieving goals of treatment as follows: HbA1c less than 7%, FPG of 80-130 mg/dL, blood pressure (BP) lower than 140/90 mmHg, LDL-cholesterol less than 100mg/dL and triglyceride less than 150 mg/dL.(9) There was no significant difference between groups for all outcomes at the post-test as shown in Table 33.
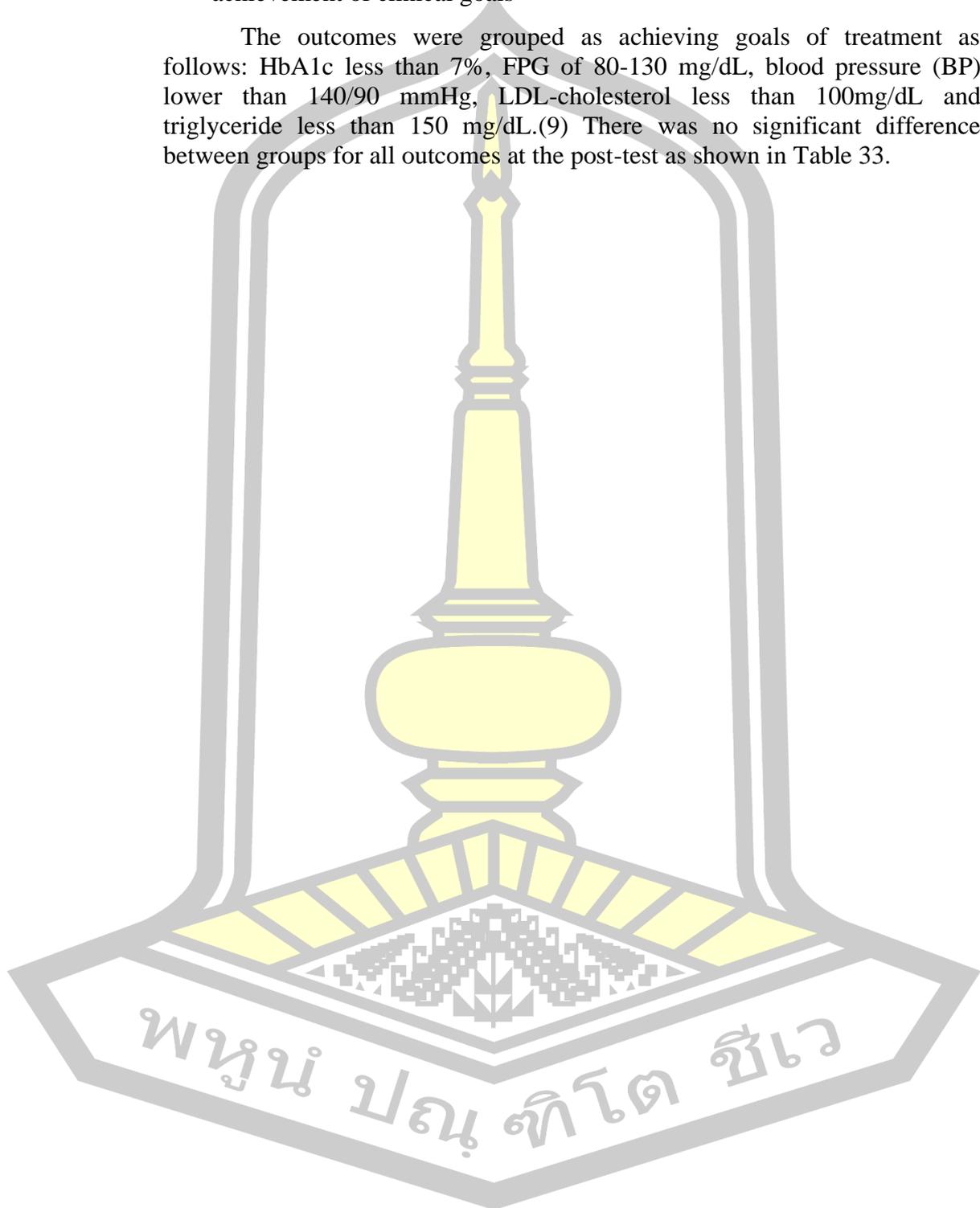
Table 33 Comparison of the proportion of clinical outcomes achieving goals between the control and intervention groups

Clinical outcomes defined by achieving goal (unit)	Intervention Group n=60		Control Group n=51		Month 0			Month 6		
	Month 0	Month 6	Month 0	Month 6	OR	95%CI	p-value[##]	OR	95%CI	p-value[##]
	Number (%)		Number (%)							
Primary Outcomes										
HbA1c (achieved goal <7%)[*]	2 (3.30)	15 (25.00)	1 (2.00)	11 (21.60)	1.72	0.15-19.59	0.660	1.21	0.49-2.94	0.674
FPG (achieved goal 80-130 mg/dL)[**]	22 (36.70)	16 (26.70)	13 (25.50)	17 (33.30)	1.69	0.75-3.84	0.209	0.73	0.32-1.65	0.195
Secondary outcomes										
BP controlled (achieved goal ≤140/90 mmHg)[***]	26 (43.30)	26 (43.30)	31 (60.80)	35 (68.60)	0.49	0.23-1.05	0.068	0.35	0.16-0.76	0.065
LDL (achieved goal <100mg/dL)[#]	12 (20.00)	22 (36.70)	17 (33.30)	15 (29.40)	0.50	0.21-1.81	0.114	1.40	0.63-3.10	0.887
Triglyceride (achieved goal <150mg/dL)[#]	25 (41.70)	31 (51.70)	17 (33.30)	18 (35.30)	1.43	0.66-3.10	0.368	1.96	0.91-4.21	0.054

[*] HbA1c achieved goal according to ADA, 2019: <7% for non-pregnant adult. <8% for patients with a history of hypoglycemia, limited life expectancy, advanced microvascular or macrovascular.
[**] FPG target goal according to ADA, 2019 for adult DM = 80-130 mg/dL
[***] BP target goal according to ACC/AHA, 2014. BP target should be lower than 140/90 mmHg
[#] LDL and Triglyceride target goal according to ADA, 2019. LDL target goal for adult DM <100 mg/dL, Triglyceride target goal for adult DM <150 mg/dL
[##] Comparing clinical outcomes goal achievement by using the logistic regression which controlled variables, age, group, patients with HTN co-morbidity

2.8.Sub-group analysis

According to unequal randomization, sub-group analysis was undertaken in the patients who were diagnosed with hypertension. Table 34 shows that revealed age (cut point at 60 year-old), BP control (BP<140/90 mmHg) and BP medication adjustment at month 3 (cut BP at month 3) were significantly different between groups.

There were various reasons that the patients of the intervention group cut BP medications at month 3. The total 10 patients of intervention group cut BP medications, 2 patients were due to ADR (leg and feet swelling, doctor suspected amlodipine), 1 patient was due to DDI (atenolol plus nifedipine and atenolol plus hydralazine) a researcher suggested to cut atenolol and the doctor agreed, 1 patient had acceptable BP at 125/60 mmHg and already on enalapril for BP control so doctor cut furosemide, 1 patient went to another clinic service to get BP medication, 1 patient's BP dose was increased (losartan) by the doctor, so doctor cut furosemide and a researcher was not able to meet 4 patients at month 3, and collect the medications information from their health follow-up book, so the reasons for cutting BP medications for those 4 patients are not known.

2.9.Intention to treat analysis for clinical outcomes

The intention to treat used the data from patients who had at least one clinical outcome recorded. The test results on Table 35 showed all of clinical outcomes between groups were not statistically significant differences.

The outcomes within group compared month 0 (pre-test) and month 6 (post-test) of intention to treat data revealed that the intervention group had well-controlled of HbA1c, Cholesterol, and LDL with statistically significant differences (p-value 0.001, <0.001 and 0.003 respectively). The control group also had well-controlled of HbA1c and BMI with statistically significant differences (p-value 0.002 and 0.006 respectively). However, the HbA1c mean level of intervention group was lower than control group and the mean difference of HbA1c month 0 vs month 6 of the intervention group was higher (0.99 ± 2.24 and 0.61 ± 1.38) as shown in Table 36.

Table 34 Sub-group analysis of patients with hypertension compared between the intervention and control groups

Patients who diagnosed as Hypertension with BP ≥ 140/90 mmHg (patients with HTN co-morbidity)	Intervention Group (n=51)			Control Group (n=32)			p-value Month 0	p-value Month 3	p-value Month 6
	Month 0	Month 3	Month 6	Month 0	Month 3	Month 6			
	No (%)								
SBP (mmHg) (mean± SD)	146.25 ± 21.79	143.33 ± 19.76	147.94 ± 23.21	146.78 ± 19.61	142.22 ± 16.43	140.53 ± 19.99	0.912[c]	0.876[c]	0.140[c]
DBP (mmHg) (mean± SD)	80.27 ± 12.19	78.60 ± 12.11	79.69 ± 11.26	83.69 ± 10.54	82.67 ± 8.85	80.13 ± 12.91	0.195[c]	0.346[c]	0.871[c]
Age (average) (mean± SD)	61.08 ± 8.17			59.06 ± 9.52					0.308[c]
BP Controlled (<140/90 mmHg)	17 (33.30)	n/a	19 (37.30)	13 (40.60)	n/a	20 (62.50)	0.639[a]	n/a	*0.041[a]*
BP>140/90 without antihypertensive drugs	1 (2.00)	2 (4.00)	n/a	1 (3.10)	n/a	n/a	1.000[b]	0.520[a]	n/a
Treated by									
Calcium Chanel Blocker	23 (45.10)	21 (41.20)	24 (47.10)	12 (37.50)	10 (31.30)	14 (43.80)	0.648[a]	0.485[a]	0.823[a]
Diuretic	9 (17.60)	8 (15.70)	7 (13.70)	6 (18.80)	6 (18.80)	7 (21.90)	1.000[a]	0.768[a]	0.376[a]
Beta Blocker	1 (2.00)	2 (3.90)	2 (3.90)	4 (12.50)	5 (15.60)	3 (9.40)	0.070[b]	0.102[b]	0.369[b]
ACEI/ARB	32 (62.70)	27 (52.90)	29 (58.00)	18 (56.30)	18 (56.30)	15 (46.90)	0.647[a]	0.823[a]	0.369[a]
Others (hydralazine)	1 (2.00)	0 (0.00)	1 (2.00)	0 (0.00)	0 (0.00)	0 (0.00)	1.000[b]	n/a	1.000[b]
Combination of BP medications									
Combination	14 (29.40)	11 (21.50)	14 (27.50)	8 (25.10)	8 (25.10)	8 (25.10)	0.972[b]	1.000[b]	0.249[b]
Single medication	36 (70.60)	40 (88.50)	37 (72.50)	24 (74.90)	24 (74.90)	24 (74.90)			
BP medication dose adjustment during Month 3 and Month 6									
Increase Dose	n/a	4 (7.80)	3 (5.90)	n/a	1 (3.10)	2 (6.30)	n/a	0.644[b]	1.000[b]
Decrease Dose	n/a	1 (2.00)	3 (6.00)	n/a	n/a	n/a	n/a	1.000[b]	0.277[a]
Add more BP medication	n/a	3 (5.90)	5 (9.80)	n/a	n/a	2 (6.30)	n/a	0.281[b]	0.701[b]
Cut BP medication	n/a	10 (19.60)	10 (19.60)	n/a	n/a	4 (12.50)	n/a	*0.011[b]*	0.550[b]
Change BP medication	n/a	n/a	4 (7.80)	n/a	n/a	4 (12.50)	n/a	n/a	0.705[b]

[a] Chi-square test [b] Fisher-Exact test [c] Independent t-test n/a Not applicable

Table 35 Comparison clinical outcomes between groups (Intention to treat)

Clinical Outcomes (Unit)	Intervention Group n=64		Control Group n=57		p-value Month 0[*]	p-value Month 6[*]
	Month 0	Month 6	Month 0	Month 6		
	Mean ± SD		Mean ± SD			
Primary Outcomes						
HbA1c (%)	9.64 ± 2.21	8.64 ± 2.00	9.44 ± 1.86	8.83 ± 1.97	0.379	0.874
FPG (mg/dL)	179.63 ± 83.00	169.38 ± 64.48	178.09 ± 59.42	169.03 ± 58.09	0.606	0.470
Secondary Outcomes						
SBP (mmHg)	142.66 ± 22.09	144.66 ± 22.67	136.95 ± 20.70	134.40 ± 21.68	0.888	0.093
DBP (mmHg)	78.94 ± 12.27	78.25 ± 11.54	80.63 ± 10.04	78.67 ± 12.35	0.229	0.761
Cholesterol (mg/dL)	213.67 ± 41.84	186.98 ± 42.36	197.87 ± 47.67	196. 35 ± 41.31	0.053	0.596
LDL (mg/dL)	130.77 ± 41.52	113.19 ± 31.71	116.89 ± 39.71	120.21 ± 32.24	0.056	0.562
HDL (mg/dL)	50.47 ± 18.08	48.69 ± 17.41	45.60 ± 11.02	46.75 ± 12.21	0.086	0.248
Triglyceride (mg/dL)	177.85 ± 99.68	184.26 ± 142.59	212. 06 ± 119.69	220.69 ± 139.14	0.104	0.195
BMI (kg/m^2)	26.02 ± 3.18	25.99 ± 3.14	25.21 ± 3.05	24.92 ± 2.87	0.226	0.055
Creatinine (µmole/L)	114.57 ± 63.49	120.71 ± 95.70	105.95 ± 36.72	107.94 ± 40.84	0.469	0.347
GFR (mL/min)	59.53 ± 21.77	57.21 ± 21.39	61.89 ± 22.73	59.85 ± 21.76	0.483	0.774
BUN (mg/dL)	39.04 ± 26.90	41.31 ± 32.12	35.45 ± 18.66	36.83 ± 18.79	0.360	0.331
Number of treated medications	4.31 ± 1.58	3.89 ± 1.48	3.00 ± 1.38	3.21 ± 1.44	<0.001	0.209
ASCVD 10 years' risk score (%)	20.93 ± 16.12	18.80 ± 14.58	13.56 ± 10.26	13.70 ± 12.96	0.145	0.864

[*] p-value using linear regression by adjusted variables: group, age, patients with HTN co-morbidity

Table 36 Comparison clinical outcomes within each group Month 0 vs Month 6 (Intention to treat)

Clinical Outcomes (Unit)	Intervention Group			p-value	Control Group			p-value
	Month 0 (Mean $\pm$ SD)	Month 6 (Mean $\pm$ SD)	Mean difference		Month 0 (Mean $\pm$ SD)	Month 6 (Mean $\pm$ SD)	Mean difference	
Primary Outcomes								
HbA1c (%)	9.64 $\pm$ 2.21	8.64 $\pm$ 2.00	0.99 $\pm$ 2.24	0.001	9.44 $\pm$ 1.86	8.83 $\pm$ 1.97	0.61 $\pm$ 1.38	0.002
FPG (mg/dL)	179.64 $\pm$ 83.00	169.38 $\pm$ 64.48	10.24 $\pm$ 98.63	0.409	178.09 $\pm$ 59.42	169.03 $\pm$ 58.09	9.06 $\pm$ 48.88	0.167
Secondary Outcomes								
SBP (mmHg)	142.66 $\pm$ 22.09	144.66 $\pm$ 22.67	-2.00 $\pm$ 20.84	0.446	136.95 $\pm$ 20.70	134.40 $\pm$ 21.68	2.54 $\pm$ 19.48	0.328
DBP (mmHg)	78.94 $\pm$ 12.27	78.25 $\pm$ 11.54	0.69 $\pm$ 10.33	0.596	80.63 $\pm$ 10.04	78.67 $\pm$ 12.35	1.97 $\pm$ 9.45	0.122
Cholesterol (mg/dL)	213.67 $\pm$ 41.84	186.98 $\pm$ 42.36	26.68 $\pm$ 50.29	<0.001	197.87 $\pm$ 47.67	196.35 $\pm$ 41.31	1.52 $\pm$ 46.24	0.805
LDL (mg/dL)	130.77 $\pm$ 41.52	113.19 $\pm$ 31.71	17.58 $\pm$ 44.97	0.003	116.90 $\pm$ 39.71	120.21 $\pm$ 32.24	-3.31 $\pm$ 35.07	0.478
HDL (mg/dL)	50.47 $\pm$ 18.08	48.69 $\pm$ 17.41	1.78 $\pm$ 18.01	0.432	45.60 $\pm$ 11.02	46.75 $\pm$ 12.21	-1.15 $\pm$ 8.31	0.301
Triglyceride (mg/dL)	177.85 $\pm$ 99.68	184.13 $\pm$ 143.73	-6.28 $\pm$ 130.69	0.704	212.06 $\pm$ 119.69	220.69 $\pm$ 139.14	-8.63 $\pm$ 123.91	0.601
BMI (kg/m^2)	26.02 $\pm$ 3.18	25.99 $\pm$ 3.14	0.03 $\pm$ 1.18	0.819	25.21 $\pm$ 3.08	24.92 $\pm$ 2.87	0.29 $\pm$ 0.75	0.006
Creatinine (µmole/L)	114.57 $\pm$ 63.48	120.71 $\pm$ 95.70	-6.14 $\pm$ 45.27	0.282	105.95 $\pm$ 36.72	107.94 $\pm$ 40.84	-1.99 $\pm$ 26.77	0.577
GFR (mL/min)	59.53 $\pm$ 21.77	57.21 $\pm$ 21.39	2.32 $\pm$ 11.13	0.101	61.89 $\pm$ 22.73	59.85 $\pm$ 21.76	2.04 $\pm$ 16.06	0.342
BUN (mg/dL)	40.69 $\pm$ 28.34	39.15 $\pm$ 32.40	1.54 $\pm$ 16.50	0.530	35.94 $\pm$ 19.08	37.36 $\pm$ 19.45	-1.41 $\pm$ 12.69	0.439
Number of treated medications	4.18 $\pm$ 1.39	3.89 $\pm$ 1.48	0.29 $\pm$ 1.41	0.109	3.02 $\pm$ 1.38	3.21 $\pm$ 1.44	-0.20 $\pm$ 0.84	0.086
Percentage of ASCVD 10 years' risk score (%)	20.93 $\pm$ 16.12	18.80 $\pm$ 14.58	2.14 $\pm$ 12.13	0.164	13.56 $\pm$ 10.26	13.70 $\pm$ 12.96	-0.14 $\pm$ 7.74	0.892

All p-value measured by pair t-test

2.10. Humanistic outcomes

2.10.1. Patient Satisfaction to diabetes care service measurement

Patient satisfaction questionnaire (PSQ) was used to measure the satisfaction of patients to diabetes care services. All mean scores of 45 items for patients in both groups at month 0 and month 6 are shown in Table 37. This PSQ used a 5 point-Likert scale to measure satisfaction levels, starting from 1-unsatisfied to 5-very satisfied. The highest score (ceiling) was 5 and the lowest score (floor) was 1.
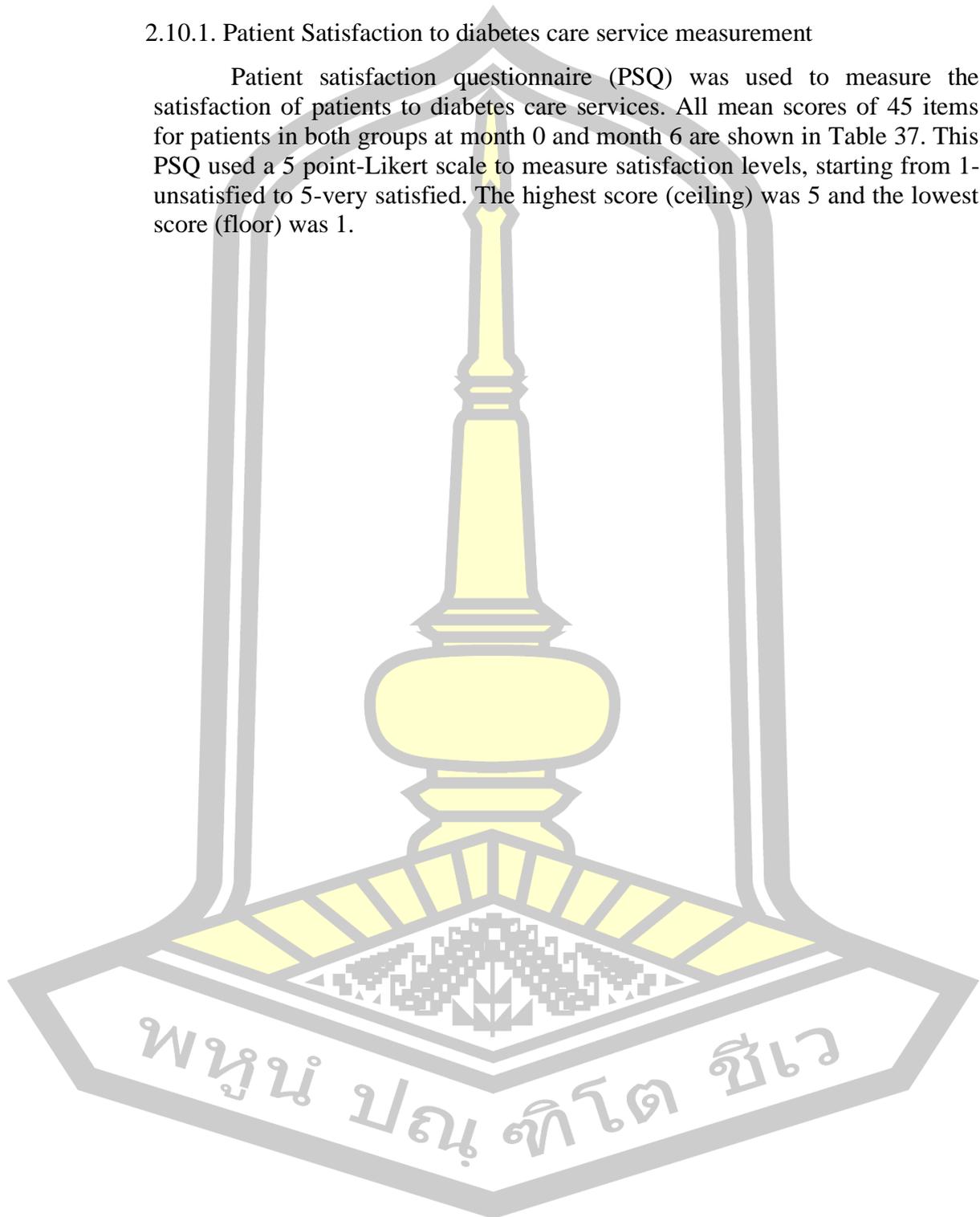
Table 37 Mean score of 45 items PSQ in the intervention and control group at month 0 and month 6

N.	Items*	Intervention group n=60						Control group n=51					
		Month 0			Month 6			Month 0			Month 6		
		Mean ± SD	Floor	Ceiling	Mean ± SD	Floor	Ceiling	Mean ± SD	Floor	Celling	Mean ± SD	Floor	Celling
1	A1	2.97 ± 0.90	1	5	3.33 ± 0.90	1	5	2.96 ± 0.82	1	5	3.41 ± 0.78	1	5
2	A2	3.33 ± 0.80	1	5	3.62 ± 0.64	3	5	3.12 ± 0.68	1	5	3.49 ± 0.70	2	5
3	A3	4.07 ± 0.71	2	5	4.07 ± 0.58	3	5	4.00 ± 0.87	1	5	4.02 ± 0.84	1	5
4	A4	4.47 ± 0.91	1	5	4.73 ± 0.63	2	5	4.06 ± 1.24	1	5	4.25 ± 1.04	1	5
5	A5	4.32 ± 0.73	3	5	4.10 ± 0.78	1	5	4.18 ± 0.71	3	5	4.06 ± 0.76	1	5
6	A6	4.28 ± 0.74	1	5	4.33 ± 0.51	3	5	4.39 ± 0.75	1	5	4.06 ± 0.84	1	5
7	A7	1.83 ± 1.38	1	5	1.77 ± 1.33	1	5	2.06 ± 1.56	1	5	1.82 ± 1.44	1	5
8	A8	3.12 ± 1.52	1	5	2.87 ± 1.55	1	5	3.37 ± 1.51	1	5	3.14 ± 1.41	1	5
9	A9	2.65 ± 1.71	1	5	2.03 ± 1.56	1	5	2.71 ± 1.64	1	5	2.43 ± 1.63	1	5
10	A10	1.12 ± 0.52	1	4	1.07 ± 0.36	1	3	1.16 ± 0.70	1	5	1.24 ± 0.71	1	4
11	A11	1.03 ± 0.26	1	3	1.07 ± 0.41	1	4	1.02 ± 0.14	1	3	1.06 ± 0.24	1	4
12	A12	1.13 ± 0.26	1	4	1.03 ± 0.26	1	3	1.04 ± 0.28	1	4	1.14 ± 0.57	1	4
13	A13	1.07 ± 0.36	1	3	1.02 ± 0.13	1	2	1.00 ± 0.00	1	3	1.02 ± 0.14	1	2
14	S1	3.95 ± 0.59	1	5	3.92 ± 0.46	2	5	4.04 ± 0.49	1	5	4.08 ± 0.44	2	5
15	S2	4.13 ± 0.47	3	5	3.98 ± 0.47	1	5	4.14 ± 0.40	3	5	4.02 ± 0.65	1	5
16	S3	2.17 ± 1.59	1	5	1.80 ± 1.35	1	5	2.37 ± 1.62	1	5	2.41 ± 1.62	1	5
17	S4	3.68 ± 1.23	1	5	3.60 ± 1.03	1	5	3.20 ± 1.43	1	5	3.27 ± 1.39	1	5
18	S5	3.73 ± 1.13	1	5	3.77 ± 0.91	1	5	4.00 ± 0.60	1	5	3.98 ± 0.71	1	5
19	S6	4.20 ± 0.44	3	5	4.00 ± 0.49	1	5	4.10 ± 0.46	3	5	4.16 ± 0.37	1	5
20	S7	1.05 ± 0.39	1	1	3.70 ± 1.44	1	5	1.25 ± 0.80	1	4	3.02 ± 1.72	1	5
21	S8	1.67 ± 1.30	1	5	1.53 ± 1.21	1	5	1.59 ± 1.22	1	5	1.73 ± 1.34	1	5
22	S9	3.68 ± 0.93	1	5	3.83 ± 0.72	1	5	3.68 ± 0.62	1	5	3.82 ± 0.77	1	5
23	S10	4.05 ± 0.72	2	5	4.00 ± 0.37	3	5	3.96 ± 0.53	1	5	3.94 ± 0.68	1	5
24	S11	4.02 ± 0.57	2	5	4.00 ± 0.37	2	5	4.04 ± 0.40	2	5	3.98 ± 0.51	2	5
25	S12	4.00 ± 0.52	3	5	3.93 ± 0.41	2	5	3.96 ± 0.63	3	5	3.90 ± 0.73	1	5

N.	Items*	Intervention group n=60						Control group n=51					
		Month 0			Month 6			Month 0			Month 6		
		Mean ± SD	Floor	Ceiling	Mean ± SD	Floor	Ceiling	Mean ± SD	Floor	Celling	Mean ± SD	Floor	Celling
26	S13	1.13 ± 0.60	1	4	3.68 ± 1.00	1	5	1.35 ± 0.99	1	5	3.04 ± 1.40	1	5
27	S14	1.28 ± 0.87	1	4	3.67 ± 0.99	1	5	1.35 ± 0.99	1	5	3.16 ± 1.35	1	5
28	S15	1.13 ± 0.60	1	4	3.67 ± 0.99	1	5	1.35 ± 0.99	1	5	3.08 ± 1.43	1	5
29	S16	1.15 ± 0.69	1	4	3.67 ± 1.00	1	5	1.35 ± 1.02	1	5	3.16 ± 1.32	1	5
30	S17	3.80 ± 0.99	1	5	3.97 ± 0.49	1	5	3.98 ± 0.62	1	5	3.96 ± 0.63	1	5
31	S18	4.08 ± 0.46	3	5	3.95 ± 0.43	2	5	4.06 ± 0.37	3	5	4.12 ± 0.38	2	5
32	S19	3.67 ± 1.07	1	5	3.85 ± 0.61	1	5	3.73 ± 0.98	1	5	3.88 ± 0.82	1	5
33	S20	4.13 ± 0.60	1	5	4.03 ± 0.32	3	5	4.06 ± 0.58	1	5	4.00 ± 0.57	1	5
34	AG1	4.02 ± 0.89	1	5	3.98 ± 0.60	1	5	3.94 ± 0.71	1	5	3.98 ± 0.65	1	5
35	AG2	4.07 ± 0.84	1	5	3.97 ± 0.61	1	5	3.98 ± 0.65	1	5	4.02 ± 0.58	1	5
36	AG3	2.95 ± 0.91	1	5	3.22 ± 0.87	1	4	3.12 ± 1.05	1	5	3.51 ± 0.99	1	5
37	AG4	4.02 ± 0.73	1	5	3.97 ± 0.41	2	5	4.02 ± 0.51	1	5	3.88 ± 0.62	1	5
38	AG5	3.70 ± 1.29	1	5	3.62 ± 1.09	1	5	3.31 ± 1.41	1	5	3.35 ± 1.45	1	5
39	AG6	3.37 ± 1.40	1	5	3.32 ± 1.26	1	5	3.57 ± 1.25	1	5	3.02 ± 1.44	1	5
40	AG7	3.35 ± 1.25	1	5	3.10 ± 1.23	1	5	3.39 ± 1.10	1	5	3.41 ± 1.06	1	5
41	AG8	2.82 ± 1.36	1	5	3.42 ± 1.05	1	4	3.29 ± 1.71	1	5	3.59 ± 1.02	1	5
42	AG9	4.05 ± 0.70	1	5	3.98 ± 0.47	1	5	3.98 ± 0.71	1	5	4.04 ± 0.56	1	5
43	AG10	3.87 ± 0.72	1	5	4.00 ± 0.26	3	5	4.10 ± 0.30	1	5	3.96 ± 0.45	2	5
44	AG11	3.87 ± 0.70	1	5	3.92 ± 0.33	3	5	4.12 ± 0.33	1	5	4.08 ± 0.34	3	5
45	AG12	3.93 ± 0.66	1	5	3.93 ± 0.36	2	5	4.10 ± 0.30	1	5	4.04 ± 0.40	2	5

* Item A1-A13 measured by 5-likert scales from (1) very little to (5) very much
* Item S1-S20 measured by 5-likert scales from (1) unsatisfied to (5) very satisfied
* Item AG1-AG12 measured by 5-likert scales from (1) not agree to (5) very agree
Note: There's no missing data in this questionnaire

Table 38 shows the mean comparison between groups at month 0 and month 6. There was no significant difference between groups at month 0. But Month 6 satisfaction to the competency of pharmacists (SCP) showed significant difference between groups, p-value<0.05. The lowest mean score was dimension attitude to community (AC) at month 0 for both groups. The highest mean score at month 0 for intervention group was satisfaction to the competency of providers (SC) and for control group was attitude to goal setting (AGG). At month 6, the lowest mean score for both groups were attitude to community (AC) same as month 0. The highest mean score was attitude to knowledge on self-management (AS) for intervention group and attitude to goal setting (AGG) for control group.

Within group comparison between month 0 and month 6, the intervention group showed 3 dimensions (AS, ST and SCP) with significant differences within months, p-value<0.05. Control group had 4 dimensions (AS, AF, ST and SCP) with significant differences, p-value<0.05. AS, ST, and SCP were significantly increased in the means at month 6, but AF decreased significantly as shown in Table 39.
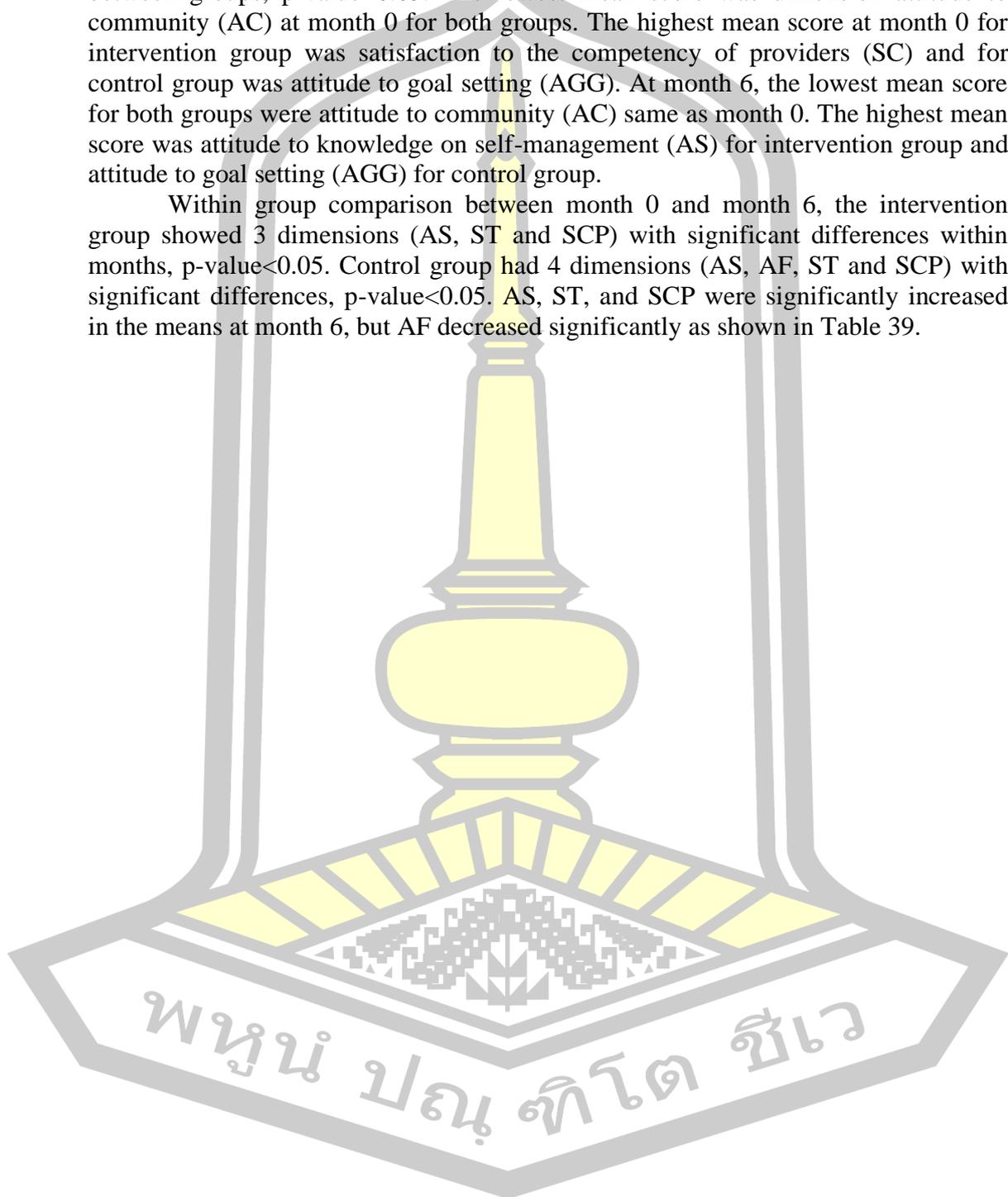
Table 38 Comparison PSQ dimension between the intervention and control groups at month 0 and month 6

Dimensions*	Intervention Group Mean $\pm$ SD (n=60)		Control Group Mean $\pm$ SD (n=51)		p-value month 0**	p-value month 6**
	Month 0	Month 6	Month 0	Month 6		
Attitude to Knowledge on Self-management (AS, A1-A5)	3.83 $\pm$ 0.47	3.97 $\pm$ 0.35	3.66 $\pm$ 0.56	3.85 $\pm$ 0.52	0.105	0.184
Attitude to Family (AF, A6-A9)	2.97 $\pm$ 0.95	2.75 $\pm$ 0.91	3.13 $\pm$ 0.90	2.86 $\pm$ 0.88	0.310	0.392
Attitude to Community (AC, A10-A13)	1.09 $\pm$ 0.34	1.05 $\pm$ 0.27	1.05 $\pm$ 0.22	1.11 $\pm$ 0.33	0.453	0.094
Satisfaction with the Standard of Services (SS, S1-S4)	3.48 $\pm$ 0.62	3.11 $\pm$ 0.55	3.43 $\pm$ 0.61	3.19 $\pm$ 0.99	0.732	0.214
Satisfaction with the Type of services (ST, S5-S8)	2.66 $\pm$ 0.54	3.25 $\pm$ 0.51	2.74 $\pm$ 0.58	3.22 $\pm$ 0.72	0.604	0.561
Satisfaction with the Competency of Providers (SC, S9-S12)	3.94 $\pm$ 0.52	3.94 $\pm$ 0.32	3.96 $\pm$ 0.40	3.91 $\pm$ 0.54	0.283	0.932
Satisfaction with the Competency of Pharmacists (SCP, S13-S16)	1.18 $\pm$ 0.60	3.67 $\pm$ 0.99	1.35 $\pm$ 0.91	3.10 $\pm$ 1.31	0.234	*0.010*
Satisfaction with the Communication with Providers (SCM, S17-S20)	3.92 $\pm$ 0.56	3.95 $\pm$ 0.32	3.96 $\pm$ 0.45	3.99 $\pm$ 0.53	0.610	0.249
Attitude to the Accessibility of Service (AGS, AG1-AG4)	3.76 $\pm$ 0.72	3.78 $\pm$ 0.45	3.76 $\pm$ 0.50	3.84 $\pm$ 0.55	0.509	0.431
Attitude to the Health Service System (AGSS, AG5-AG8)	3.31 $\pm$ 0.87	3.36 $\pm$ 0.72	3.39 $\pm$ 0.75	3.34 $\pm$ 0.72	0.740	0.568
Attitude to Goal Setting (AGG, AG9- AG12)	3.93 $\pm$ 0.65	3.96 $\pm$ 0.25	4.07 $\pm$ 0.34	4.03 $\pm$ 0.32	0.149	0.143

* Dimension AS, AF and AC measured by 5-likert scales from (1) very little to (5) very much

* Dimension SS, ST, SC, SCP and SCM measured by 5-likert scales from (1) unsatisfied to (5) very satisfied

* Dimension AGS, AGSS and AGG measured by 5-likert scales from (1) not agree to (5) very agree

** All p-value is Mann-Whitney U test for Non-parameter

Table 39 Within group comparison of PSQ between the intervention and control groups at month 6

Dimensions*	Intervention Group Mean ± SD (n=60)			p-value**	Control Group Mean ± SD (n=51)			p-value**
	Month 0	Month 6	Mean difference		Month 0	Month 6	Mean difference	
Attitude to Knowledge on Self-management (AS)	3.83 ± 0.47	3.97 ± 0.35	-0.14 ± 0.53	*0.040*	3.66 ± 0.56	3.85 ± 0.52	-0.18 ± 0.45	*0.010*
Attitude to Family (AF)	2.97 ± 0.95	2.75 ± 0.91	0.22 ± 0.97	0.168	3.13 ± 0.90	2.86 ± 0.88	0.27 ± 0.72	*0.010*
Attitude to Community (AC)	1.09 ± 0.34	1.05 ± 0.27	0.04 ± 0.43	0.398	1.05 ± 0.22	1.11 ± 0.33	-0.06 ± 0.33	0.172
Satisfaction with the Standard of Services (SS)	3.48 ± 0.62	3.11 ± 0.55	0.18 ± 0.74	0.072	3.43 ± 0.61	3.19 ± 0.99	0.04 ± 0.77	0.850
Satisfaction with the Type of services (ST)	2.66 ± 0.54	3.25 ± 0.51	-0.78 ± 0.74	*<0.001*	2.74 ± 0.58	3.22 ± 0.72	-0.57 ± 0.89	*<0.001*
Satisfaction with the Competency of Providers (SC)	3.94 ± 0.52	3.94 ± 0.32	-0.01 ± 0.43	0.990	3.96 ± 0.40	3.91 ± 0.54	0.12 ± 0.77	0.587
Satisfaction with the Competency of Pharmacists (SCP)	1.18 ± 0.60	3.67 ± 0.99	-3.30 ± 1.45	*<0.001*	1.35 ± 0.91	3.10 ± 1.31	-2.32 ± 1.99	*<0.001*
Satisfaction with the Communication with Providers (SCM)	3.92 ± 0.56	3.95 ± 0.32	-0.07 ± 0.66	0.731	3.96 ± 0.45	3.99 ± 0.53	0.02 ± 0.84	0.640
Attitude to the Accessibility of Service (AGS)	3.76 ± 0.72	3.78 ± 0.45	-0.05 ± 0.92	0.876	3.76 ± 0.50	3.84 ± 0.55	-0.04 ± 0.43	0.070
Attitude to the Health Service System (AGSS)	3.31 ± 0.87	3.36 ± 0.72	-0.96 ± 1.16	0.815	3.39 ± 0.75	3.34 ± 0.72	0.15 ± 0.90	0.645
Attitude to Goal Setting (AGG)	3.93 ± 0.65	3.96 ± 0.25	-0.06 ± 0.81	0.908	4.07 ± 0.34	4.03 ± 0.32	0.05 ± 0.35	0.406

* Dimension AS, AF and AC measured by 5-likert scales from (1) very little to (5) very much
* Dimension SS, ST, SC, SCP and SCM measured by 5-likert scales from (1) unsatisfied to (5) very satisfied
* Dimension AGS, AGSS and AGG measured by 5-likert scales from (1) not agree to (5) very agree
** All p-value is Wilcoxon Signed Ranks test for Non-parametric

2.10.2.   Diabetes-39 questionnaire for measuring the quality of life

There are 39 items, 5 dimensions of Diabetes-39 were: 1) Diabetes Control (DC), 2) Anxiety and Worry (AW), 3) Energy and Morbidity (EM), 4) Social Burden (SB) and 5) Sexual Functioning (SF). Table 40 showed all mean score of 39 items D-39 for patients in both groups at month 0 and month 6. When compared between groups at month 0 and month 6, there was no significant difference as shown in Table 41. When compared within each at month 6 there was no significant difference in the intervention group, however, the control group showed significantly higher mean in the social burden (SB), p-value=0.044 as shown in Table 42.
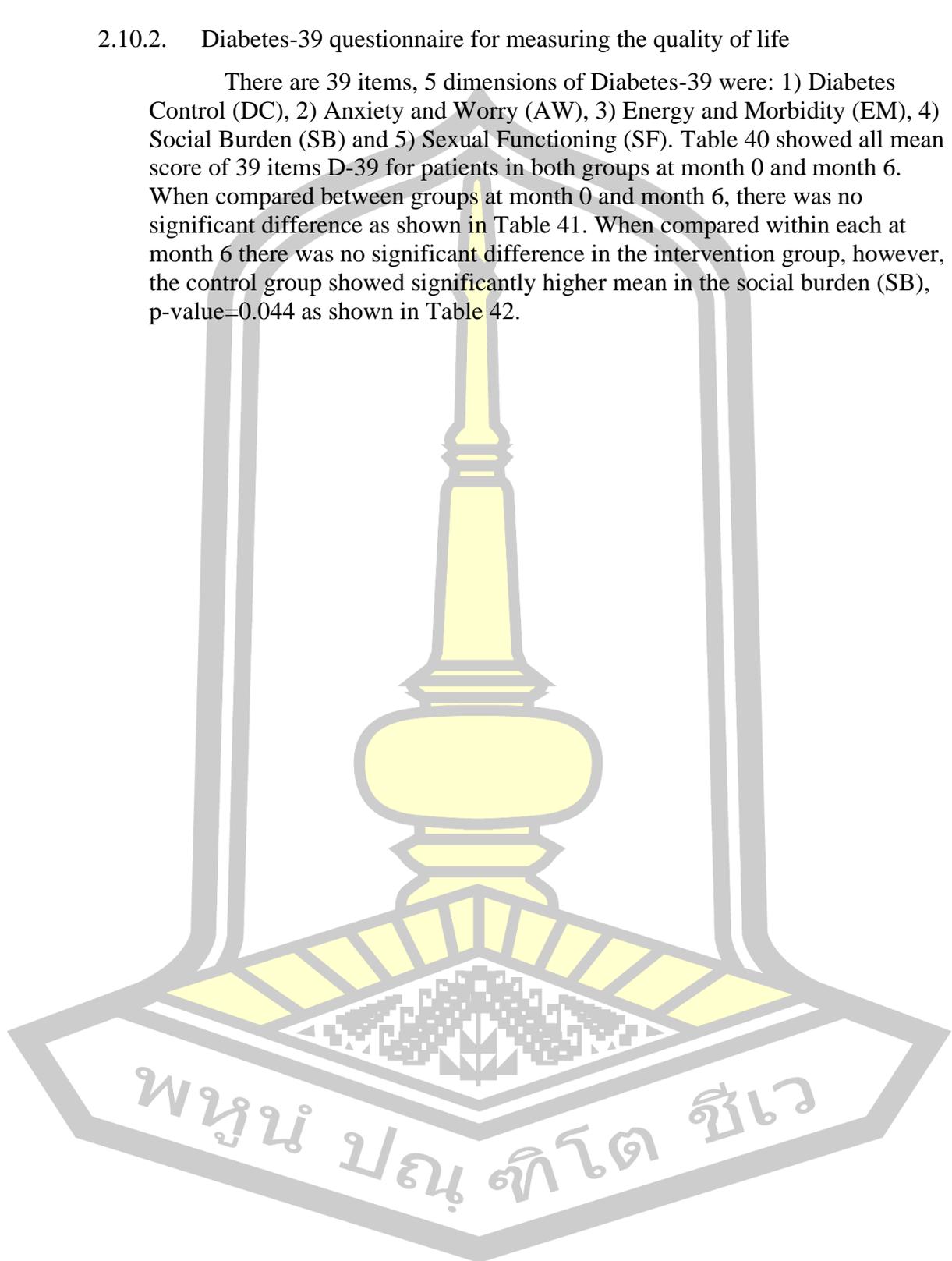
Table 40 Mean, floor, ceiling of D-39 items between the intervention and control group at month 0 and month 6

No.	Items*	Intervention Group n=60						Control Group n=51					
		Month 0			Month 6			Month 0			Month 6		
		Mean ± SD	Floor	Ceiling	Mean ± SD	Floor	Ceiling	Mean ± SD	Floor	Celling	Mean ± SD	Floor	Celling
1	1DC	2.43 ± 2.05	1	7	2.12 ± 1.73	1	7	2.29 ± 2.07	1	7	2.78 ± 2.18	1	7
2	2AW	2.42 ± 1.90	1	7	2.30 ± 1.74	1	7	2.33 ± 1.89	1	7	2.63 ± 1.94	1	7
3	3EM	3.37 ± 1.83	1	7	3.28 ± 1.86	1	7	3.53 ± 1.98	1	7	3.43 ± 1.74	1	7
4	4DC	1.97 ± 1.59	1	7	2.23 ± 1.61	1	7	2.73 ± 1.91	1	7	3.00 ± 2.11	1	7
5	5DC	2.73 ± 1.58	1	7	2.98 ± 1.68	1	7	3.57 ± 2.10	1	7	3.76 ± 2.17	1	7
6	6AW	3.05 ± 2.13	1	7	3.23 ± 2.02	1	7	3.20 ± 2.06	1	7	3.69 ± 2.30	1	7
7	7EM	2.77 ± 1.87	1	7	2.77 ± 1.86	1	7	2.82 ± 2.10	1	7	2.98 ± 2.17	1	7
8	8AW	2.75 ± 1.99	1	7	2.85 ± 1.86	1	7	3.00 ± 2.14	1	7	3.08 ± 2.07	1	7
9	9EM	3.10 ± 1.84	1	7	3.07 ± 1.68	1	7	3.16 ± 1.86	1	7	3.69 ± 1.89	1	7
10	10EM	2.32 ± 1.75	1	7	2.44 ± 1.59	1	7	2.43 ± 1.68	1	7	2.80 ± 2.05	1	7
11	11EM	1.93 ± 1.48	1	6	2.33 ± 1.71	1	7	2.51 ± 1.92	1	7	2.57 ± 2.01	1	7
12	12EM	3.63 ± 1.98	1	7	3.76 ± 1.95	1	7	3.49 ± 2.24	1	7	3.51 ± 2.17	1	7
13	13EM	3.43 ± 1.87	1	7	3.70 ± 1.76	1	7	3.49 ± 1.76	1	7	3.82 ± 1.80	1	7
14	14DC	4.02 ± 2.04	1	7	4.02 ± 1.97	1	7	4.22 ± 2.10	1	7	4.49 ± 2.02	1	7
15	15DC	3.82 ± 1.94	1	7	3.83 ± 1.97	1	7	3.88 ± 1.80	1	7	4.02 ± 1.94	1	7
16	16EM	2.60 ± 1.78	1	7	2.60 ± 1.98	1	7	2.59 ± 1.86	1	7	2.96 ± 1.98	1	7
17	17DC	1.78 ± 1.45	1	7	1.90 ± 1.43	1	7	2.06 ± 1.73	1	7	2.29 ± 1.79	1	7
18	18DC	1.98 ± 1.56	1	7	2.33 ± 1.57	1	7	2.27 ± 2.05	1	7	2.84 ± 1.96	1	7
19	19SB	2.73 ± 1.99	1	7	2.63 ± 1.75	1	7	2.86 ± 2.00	1	7	3.24 ± 1.97	1	7
20	20SB	1.63 ± 1.56	1	7	1.50 ± 1.14	1	7	1.67 ± 1.52	1	7	1.88 ± 1.71	1	7
21	21SF	2.38 ± 2.08	1	7	2.30 ± 1.99	1	7	2.08 ± 1.72	1	7	2.45 ± 2.10	1	7
22	22AW	2.33 ± 1.74	1	7	2.43 ± 1.71	1	7	2.00 ± 1.74	1	7	2.16 ± 1.67	1	7
23	23SF	2.13 ± 1.82	1	7	2.13 ± 1.90	1	7	2.18 ± 1.79	1	7	2.33 ± 1.99	1	7
24	24DC	2.53 ± 1.82	1	7	2.40 ± 1.52	1	7	2.71 ± 1.91	1	7	2.67 ± 1.86	1	7
25	25EM	2.72 ± 1.86	1	7	2.52 ± 1.99	1	7	2.88 ± 2.18	1	7	2.49 ± 2.00	1	7
26	26SB	2.83 ± 1.82	1	7	2.58 ± 1.88	1	7	2.84 ± 2.06	1	7	2.65 ± 1.93	1	7

No.	Items*	Intervention Group n=60						Control Group n=51					
		Month 0			Month 6			Month 0			Month 6		
		Mean ± SD	Floor	Ceiling	Mean ± SD	Floor	Ceiling	Mean ± SD	Floor	Celling	Mean ± SD	Floor	Celling
27	27DC	1.48 ± 1.28	1	7	1.67 ± 1.43	1	7	1.57 ± 1.29	1	6	1.78 ± 1.63	1	7
28	28DC	2.03 ± 1.49	1	7	2.23 ± 1.54	1	7	2.63 ± 2.05	1	7	2.57 ± 2.11	1	7
29	29EM	1.77 ± 1.43	1	7	2.15 ± 1.75	1	7	1.75 ± 1.67	1	7	2.16 ± 1.87	1	7
30	30SF	2.07 ± 1.77	1	7	1.83 ± 1.67	1	7	2.04 ± 1.65	1	7	2.53 ± 1.89	1	7
31	31DC	2.35 ± 1.70	1	6	2.72 ± 1.89	1	7	2.12 ± 1.81	1	7	2.82 ± 1.87	1	7
32	32EM	2.37 ± 1.61	1	7	2.71 ± 2.03	1	7	2.65 ± 2.14	1	7	2.82 ± 1.87	1	7
33	33EM	2.63 ± 1.80	1	7	2.50 ± 1.93	1	7	2.29 ± 1.84	1	7	2.43 ± 1.90	1	7
34	34EM	1.48 ± 1.05	1	5	1.70 ± 1.38	1	7	1.75 ± 1.51	1	7	1.86 ± 1.64	1	7
35	35EM	3.03 ± 1.93	1	7	2.98 ± 2.03	1	7	2.35 ± 1.64	1	7	2.86 ± 1.94	1	7
36	36EM	2.63 ± 1.94	1	7	2.28 ± 1.81	1	7	1.98 ± 1.63	1	7	2.47 ± 1.84	1	7
37	37SB	1.62 ± 1.35	1	7	1.63 ± 1.40	1	7	1.61 ± 1.51	1	7	1.90 ± 1.65	1	7
38	38SB	2.48 ± 2.12	1	7	2.63 ± 1.75	1	7	2.22 ± 1.86	1	7	2.75 ± 1.93	1	7
39	39DC	3.98 ± 1.92	1	7	3.81 ± 1.97	1	7	4.06 ± 2.17	1	7	3.88 ± 2.22	1	7

* All items measured by 7 scales of the affect to quality of life from (1) no affected to my quality of life (7) the most affected to my quality of life

Note: There's no missing data in this questionnaire

Table 41 Comparison D-39 dimension between the intervention and control group at month 0 and month 6

No.	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	Month 0	Month 6		
1	Diabetes Control (DC)	2.54 ± 1.19	2.68 ± 1.19	2.79 ± 1.41	3.12 ± 1.53	0.378	0.175
2	Anxiety and Worry (AW)	2.61 ± 1.64	2.70 ± 1.35	2.48 ± 1.61	2.89 ± 1.66	0.625	0.851
3	Energy and Morbidity (EM)	2.62 ± 1.24	2.71 ± 1.22	2.20 ± 1.43	2.86 ± 1.38	0.767	0.651
4	Social Burden (SB)	2.20 ± 1.38	2.20 ± 1.20	2.18 ± 1.43	2.48 ± 1.54	0.879	0.495
5	Sexual Functioning (SF)	2.09 ± 1.71	2.09 ± 1.69	2.05 ± 1.60	2.44 ± 1.85	0.958	0.225

* All dimensions measured by 7 scales of the affect to quality of life from (1) no affected to my quality of life (7) the most affected to my quality of life
** All p-value is Mann-Whitney U test for Non-parametric

Table 42 Within group comparison D-39 dimensions between the intervention and control groups at month 6

Dimensions*	Intervention Group Mean ± SD (n=60)			p-value**	Control Group Mean ± SD (n=51)			p-value**
	Month 0	Month 6	Mean difference		Month 0	Month 6	Mean difference	
Diabetes Control (DC)	2.54 ± 1.19	2.68 ± 1.19	-0.13 ± 0.89	0.274	2.79 ± 1.41	3.12 ± 1.53	-0.32 ± 1.14	0.057
Anxiety and Worry (AW)	2.61 ± 1.64	2.70 ± 1.35	-0.07 ± 1.21	0.515	2.48 ± 1.61	2.89 ± 1.66	-0.39 ± 1.37	0.062
Energy and Morbidity (EM)	2.62 ± 1.24	2.71 ± 1.22	-0.08 ± 1.01	0.505	2.20 ± 1.43	2.86 ± 1.38	-0.29 ± 1.02	0.074
Social Burden (SB)	2.20 ± 1.38	2.20 ± 1.20	0.02 ± 0.94	0.933	2.18 ± 1.43	2.48 ± 1.54	-0.28 ± 0.96	*0.044*
Sexual Functioning (SF)	2.09 ± 1.71	2.09 ± 1.69	0.02 ± 1.11	0.931	2.05 ± 1.60	2.44 ± 1.85	-0.37 ± 1.43	0.073

* All dimensions measured by 7 scales of the affect to quality of life from (1) no affected to my quality of life (7) the most affected to my quality of life
** All p-value is Wilcoxon Signed Ranks test for Non-parametric

2.10.3. Correlation of humanistic outcomes with HbA1c at month 6

There was no of significant correlation between the humanistic outcomes (PSQ and D-39) in both months 0 and 6 and with HbA1c at month 6 in both groups as shown in Table 43.

Table 43 Correlation of humanistic outcomes with HbA1c at month 6 of intervention and control group

Humanistic outcomes	Intervention (n=60)		Control (n=51)	
	Pearson correlation	p-value	Pearson correlation	p-value
Patient Satisfaction (PSQ) at month 0				
Attitude to Knowledge on Self-management (AS)	0.006	0.961	0.123	0.391
Attitude to Family (AF)	0.002	0.998	0.134	0.347
Attitude to Community (AC)	-0.064	0.627	-0.067	0.638
Satisfaction with the Standard of Services (SS)	0.152	0.246	0.005	0.971
Satisfaction with the Type of services (ST)	-0.014	0.917	0.225	0.112
Satisfaction with the Competency of Providers (SC)	-0.022	0.868	-0.039	0.785
Satisfaction with the Competency of Pharmacists (SCP)	-0.075	0.571	0.123	0.388
Satisfaction with the Communication with Providers (SCM)	-0.038	0.774	0.086	0.547
Attitude to the Accessibility of Service (AGS)	-0.015	0.909	-0.027	0.146
Attitude to the Health Service System (AGSS)	0.135	0.302	-0.060	0.674
Attitude to Goal Setting (AGG)	-0.048	0.718	-0.035	0.805
Patient Satisfaction (PSQ) at month 6				
Attitude to Knowledge on Self-management (AS)	0.022	0.865	0.036	0.801
Attitude to Family (AF)	0.175	0.180	0.099	0.489
Attitude to Community (AC)	-0.087	0.509	-0.077	0.591
Satisfaction with the Standard of Services (SS)	0.157	0.232	0.026	0.854
Satisfaction with the Type of services (ST)	-0.059	0.653	0.205	0.149
Satisfaction with the Competency of Providers (SC)	0.036	0.783	0.044	0.760
Satisfaction with the Competency of Pharmacists (SCP)	-0.029	0.826	0.093	0.518
Satisfaction with the Communication with Providers (SCM)	0.032	0.807	0.007	0.960
Attitude to the Accessibility of Service (AGS)	-0.015	0.908	-0.236	0.095
Attitude to the Health Service System	0.074	0.574	-0.120	0.401

Humanistic outcomes	Intervention (n=60)		Control (n=51)	
	Pearson correlation	p-value	Pearson correlation	p-value
(AGSS)				
Attitude to Goal Setting (AGG)	-0.048	0.717	-0.087	0.544
Diabetes 39 at month 0				
Diabetes Control (DC)	-0.079	0.546	0.195	0.171
Anxiety and Worry (AW)	-0.110	0.401	0.084	0.559
Energy and Morbidity (EM)	-0.048	0.718	0.216	0.127
Social Burden (SB)	-0.087	0.507	0.238	0.093
Sexual Functioning (SF)	-0.052	0.694	0.144	0.314
Diabetes 39 at month 6				
Diabetes Control (DC)	0.054	0.680	0.179	0.210
Anxiety and Worry (AW)	-0.002	0.990	0.212	0.136
Energy and Morbidity (EM)	0.108	0.411	0.214	0.132
Social Burden (SB)	0.040	0.759	0.116	0.416
Sexual Functioning (SF)	-0.083	0.526	0.206	0.148

Chapter 5

Discussion

This study was designed to be carried out in 2 phases. The first, questionnaire development consisted of systematic review of qualitative studies in order to formulate the patient satisfaction questionnaire (PSQ), and to translate the Diabetes-39 questionnaire from Thai version to Lao version. Second, a randomized controlled trial (RCT)

1. Systematic review of qualitative studies

This systematic review identified nine major themes from patients' and healthcare providers' perspectives on diabetes management. Using the CCM framework, three new emerging themes were identified (PPI, ICP, and FS) in addition to the six CCM major themes (CL, HSS, CC, SM, PS, RS). These key findings covered broad dimensions of diabetes management in terms of individual care, community involvement, and healthcare systems. The review also showed differences and similarities in perspectives among health care providers and patients, which can help to improve diabetes care systems as well as patients' outcomes.

This systematic review used CASP as quality assessment criteria, in which definitions of each criterion had been more robustly determined for qualitative studies to be finally included in the reviews. In addition, this review showed the variety of health care providers' and patients' perspectives from several continents (Europe, Asia, North America) reflecting various contexts of diabetes care systems. A few studies have previously undertaken a systematic review of qualitative studies (36-38). Those studies focused on a particular group (South Asians) and used meta-ethnography, (36) interpretivist concepts (37) and the theoretical domain framework(38) for extracting themes. The results of those studies focused on facilitators and barriers of diabetes management, (36) patients' self-management (37) and providers' perspectives on effective diabetes management.(38) Those studies did not cover the healthcare system but only self-care practices. Furthermore, none of the studies used the CCM framework for extracting the themes of qualitative studies. This study was the first systematic review using CCM of both healthcare providers' and patients' perspectives on the services of diabetes management. It was the first to use the original themes from included articles as an analytical framework to gain insights for improving services and systems of diabetes care as well as outcomes for patients.

A previous study by Baptista et al (2016) revealed that CCM does not improve clinical outcomes of diabetes patients in isolate elements. However, it seems to be more useful if the six elements of CCM are combined with other interventions.(127) Strickland et al (2010) revealed that diabetes patients who were seen in practices that have implemented more CCM features were significantly more likely to receive appropriate diabetes care such as behavior counselling.(127) This review found three new emerging themes from CCM and these might reveal more in terms of improving diabetes care—especially in psychological contexts.

This systematic review found both facilitators and barriers of diabetes management in each theme from the perspectives of diabetes patients and healthcare

providers. Examples of facilitators mostly came from developed countries, such as good organization in the theme CL (Germany, The Netherland). (63, 67) Good collaboration in each care level was found in HSS (The Netherland, Finland) (67, 82, 124) and good support provided by nurses was found in PS (Finland).(82) However, more continuing education for healthcare providers is needed in The Netherlands, Germany, and Canada (63, 64, 67) as well as a more transparent insurance system in The Netherlands(67) In the theme of family support it was shown that family members are facilitators in both developing and developed countries including Iran(73), Finland(82), and Germany.(63) Most of the barriers came from developing countries such as Oman and Bangladesh. In Asia there remains a lack of healthcare providers of HSS(65, 78) along with poor accessibility to diabetes services of HSS.(126) There were still barriers for individual care, such as self-management and lifestyle behavior in both developing countries (Oman) and developed countries (USA and Japan). (62, 65, 77) Developing countries (Iran) and developed countries (USA, Canada, and UK) have difficulty in communication between patients and healthcare providers in the PPI theme. (64, 69, 73, 76) Continuity of care and referral systems may also be barriers in both developed and developing countries, such as lack of team cooperation in Canada,(64) and difficulty in managing continuity of care in Oman (65) and Australia. (80) Thus, the aforementioned message of each theme from this review could be the basis for the initial setting of diabetes care in countries without effective systems for diabetes care, especially developing countries.

The results from previous qualitative reviews showed several barriers for diabetes management. Rushforth et al. (2016) showed the barriers only from the providers' perspective to achieve effective diabetes management in primary care, including limited time and resources for clinicians, lack of confidence in knowledge of guidelines and skills, initiating and facilitating patient behavior change, frustrations over patient compliance, and anxieties about treatment intensification.(38) In this review, barriers were found in the HSS theme such as providers' lack of time.(63-65, 80) Providers also required more Continuing Professional Education (CPE) in the ICP theme.(63-65, 67, 68, 71, 76, 80, 124) Handelsman et al (2011) discussed clinical inertia as a barrier to diabetes care due to multiple treatment guidelines, algorithms and goals recommended by different organizations and societies.(7) This review has confirmed clinical inertia due to new guidelines that frustrated healthcare providers(67, 68) in the theme of PS. Sohal et al (2015) reported barriers to diabetes management including lack of understanding about diabetes management and facilitating factors including trusting care providers, appropriate exercise and dietary advice, and family involvement.(36)

This systematic review mentions understanding about self-management in the SM theme. Some patients had good understanding, but didn't follow good management guidelines due to their personal context.(62, 65, 68, 70, 81) This review also supports family involvement for better diabetes care.(63, 70, 72-74, 80, 82) However, in the FI theme, this review also shows that family can be a barrier.(70) It is important that both patients and their family members know how to manage diabetes. Franklin et al (2017) studied patients' and healthcare professionals' perceptions of interaction to better understand the context in which interactions shape self-management and opportunities for collaborative goal-setting.(37) In the SM theme,

this review also shows that collaborative goal setting is a key to better diabetes care.(62, 65, 67, 70, 74, 77, 79, 81)

This systematic review mentioned the difficulty of access to care in the HSS theme.(65, 71, 78) Jones and Crowe (2017) studied factors impacting diabetes management among minorities including treatment accessibility and acceptability, and cultural roles within families.(41) Park et al. (2015) revealed that East Asian immigrants showed struggles with multi-contextual barriers, a lack of consensus on cultural strategies, and language barriers.(40) These reviews were excluded from our research because they focused on minorities whereas our research focused on general perspectives which can be implemented in wide areas. However, there are similarities among the perspectives of Asian immigrants and the patients in our study such as cultural beliefs and attitudes which can be barriers to diabetes care (65, 68) in the SM theme and language barriers(65, 67, 73, 78) in the PPI theme.

McSharry et al (2016) stated that medication-taking for Type 2 diabetes is a unique adherence context, which requires the development of condition-specific interventions. The present findings indicate that patients understand the need for medications but adjust dosage and timing in their daily lives.(39) This review showed the theme of medication adherence which corresponded with McSharry's (2016) study in terms of unique adherence contexts. Some studies in this review showed medication adherence is dependent on patients' personal context (72, 73) in the SM theme.

According to this systematic review, there were several barriers in diabetes management which require further improvement such as referral systems, continuity of care, and improved self-management by patients. Those aspects were consistent with previous qualitative reviews as mentioned above in terms of barriers. This review also found interesting points in healthcare providers' competency which requires more attention from healthcare systems to improve diabetes care. In addition to the barriers, there were some supportive factors such as community linkage, family involvement, and providers' support. This review found several studies (63, 72-74, 80, 82) which revealed that family members of diabetes patients were the most supportive persons for their care. This suggests that the new diabetes management strategies should also focus on family members and community support. Our suggestion for approaching families is to implement home care in order to create mutual understanding of proper diabetes management.

Limitation of this systematic review is that it may not have used all related articles due to limited ability to retrieve all resources, limiting accessibility to about 45.5%. This study also excluded intervention studies such as program and technology interventions. Publication bias is a factor in this study as only published articles were selected. In an effort to eliminate selection bias, two researchers worked independently to retrieve and choose articles in accordance with the CASP criteria. This study might not be applicable to specific groups of diabetes patients (e.g. travelling patients, patients with disabilities, and events such as Ramadan).

In conclusion, this review found nine themes from both diabetic patients and healthcare providers to improve health outcomes, In-depth information showed facilitating factors in some themes such as community involvement, team cooperation, providers' support and family involvement. There were also numerous barriers in the themes that involved perspectives of diabetes management. Hence,

addressing these barriers may be deemed useful in improving diabetes care. This is basic information for diabetes care development in order to achieve better patient outcomes and better healthcare systems for continuous quality improvement (CQI).

2. Questionnaire development

2.1. Patient Satisfaction Questionnaire (PSQ)

This study resulted in a the new tool for measuring patient satisfaction towards diabetes management in Lao PDR and Thailand which developed in Lao and Thai languages. This tool was developed based on the systematic review of qualitative studies of patients' and healthcare providers' perspectives on diabetes management. (128)

The main themes from the systematic review of qualitative studies (128) was used as the main ideas to formulate dimensions of this PSQ. The main themes including community linkage (CL) were the main ideas to formulate PSQ dimension of attitude to community (AC). Health service system (HSS) was the main idea to formulate dimensions of satisfaction with the standard of services (SS), satisfaction with the type of services (ST), attitude to the accessibility of services (AGS), attitude to health service system (AGSS) and attitude to goal setting (AGG). Provider support (PS) was the main idea to formulate dimensions of satisfaction with the competency of providers (SC), satisfaction with the competency of pharmacists (SCP) and attitude to goal setting (AGG). Self-management (SM) was the main idea to formulate dimension of attitude to knowledge and self-management (AS). Family involvement (FI) was the main idea to formulate dimension of attitude to family (AF).

Effective diabetes management is a key to success in achieving treatment goals for diabetic patients. Perspectives from both patients and healthcare providers can be one indicator that reflects the quality of diabetes management or services.(128) This tool used the key themes of those perspectives to construct the dimensions and items of the questionnaire which consists 3 main dimensions, 11 sub-dimensions and 45 items covering self-attitude (self-care, family, community), satisfaction with the diabetes management services of diabetic patients.

There are several tools or questionnaires that have been developed for measuring patient satisfaction towards various services, but only a few were developed specifically for diabetic patients. Anderson et al (2004) developed the tool for measuring satisfaction with insulin treatment through literature review, however this tool only focused on the satisfaction with insulin treatment.(129) Brose et al (2010) developed a questionnaire for the retinopathy treatment satisfaction, which covered only on retinopathy of diabetic patients.(130) Paddock et al (2000) developed a questionnaire to evaluate patient satisfaction with diabetes disease management, however, this tool was developed through the perspectives of healthcare providers only, and focused mainly on diabetes self-management. (49) This study developed the PSQ which covered the perspectives of both patients and healthcare providers and focused widely on diabetes such as diabetes services, and self-management which involved with family and community.

Wilbur et al (2016) had validated the previous Arabic version of diabetes treatment satisfaction questionnaires (DTSQs) in Qatar, the DTSQs adapted for Qatar is a valid and reliable instrument to assess treatment satisfaction of diabetes patients

in the country. However, the tool had some limitations such as the country context, where the education of the population in the country was one of the obstacles for completing the questionnaire. The PSQ of Thai and Lao versions also faced the same context limitation because the diabetes services of both countries were different.(131)

There were some items' factor loadings of PSQ in both versions which were lower than 0.5. Those items were less relevant to its' dimension or component.(132) Six factor loading of PSQ in the Lao version which were lower than 0.5 were found in S3 (satisfaction to annual health check-up), S7 (satisfaction to diabetes home care service), AG3 (attitude to the waiting time to get diabetes services), AG4 (attitude to extra-expense of diabetes service), AG5 (attitude to health insurance), and AG9 (attitude to equality of health service base on insurance type). The PSQ Thai version consisted of only one item which was lower than 0.5 which was A1 (attitude to diabetes self-management knowledge). These results from data analysis revealed obvious differences in diabetes treatment services between Lao PDR and Thailand. Thus, in the future, the questionnaire should be adapted more specifically for each country.

The questionnaire PSQ in both Thai and Lao version and D-39 Lao version are valid and reliable for use in related research in the future. However, this study has some limitations, i.e., the questionnaire was developed through systematic review of perspectives on diabetes management from various countries, thus the structure of questionnaire may vary and not specific to the context of Lao PDR and Thailand.

2.2. Diabetes-39 questionnaire (D-39)

The translation of Diabetes-39 Thai version (Songraksa et al, 2009)(52) to the Lao version indicated good construct and reliability. Psychometric properties were performed in order to test construct validity and reliability. Reliability test was analyzed by Cronbach's alpha. The result of factor loading of Lao version showed that all 39 items had factor loading of more than 0.5.

Diabetes-39 Lao version had strong convergent validity as shown by the good correlation among their own scales (dimensions) and strong discriminant validity as shown by lower correlation with other scales (dimensions). The Lao version had the average Convergent Validity at 100% and Discriminant Validity at 88.87%. All five dimensions of Lao version had Cronbach's alpha > 0.7 (range from 0.787-0.924). While the Thai version also had strong Cronbach's alpha values ranging from 0.78-0.92 as well. (52)

Queiroz et al (2009) validated Diabetes-39 questionnaire in the first stage of cultural adaptation to Portuguese, presented high internal consistency levels. The total score of Cronbach's alpha coefficient of 0.917, showed good internal consistency.(133) The original version had Cronbach's alpha values ranging from 0.81-0.93. (51) Denmark had values ranging from 0.82-0.92, Norway values ranged from 0.82-0.91, Sweden values ranged from 0.82-0.93, Finland values ranged from 0.83-0.92, Taiwan had values was more than 0.7 for all dimensions. (52) Thus, D-39 Lao version and versions in other languages had good values of Cronbach's alpha.

Diabetes-39 Lao version remains the weakness in factor rotation for constructing the fit component and requires further development. However, the factor loading and reliability showed a good value and was acceptable for use in Lao diabetes patients.

Conclusion of this study, D-39 Lao version was valid and reliable to use in future research.

Limitation of this study was that the Lao version was translated from Thai and not from the original version (English). However, the retranslation was performed by using a forward-backward method to ensure similarity of both versions.

3. Randomized controlled trial

At the end of the study, there was no significant differences between groups in both primary and secondary outcomes. However, the intervention group showed significant improvement in HbA1c, total cholesterol and LDL-cholesterol at month 6 (post-test), p<0.05, while there was no significant improvement in the control group. The humanistic outcomes showed one significant difference when compared between groups after the study, which was the Competency of Pharmacist (SCP), p<0.05. Only the control group showed significant lower scores in the attitude to family when compared within group after 6 months, p<0.05. Quality of life was not different between the intervention and control groups, however, the control group showed significant higher scores in social burden (SB) after the study when compared to the pretest, p<0.05.

Even though there were no significant differences of HbA1c between groups, the intervention group tended to have lower mean HbA1c. Our results are not consistent to other studies. Several studies found that patients who received pharmacist interventions in diabetes care has statistically significant differences in mean HbA1c .(22, 134, 135).

Stading et al (2019) found a statistically significant result which indicated an overall difference in HbA1c over a 2-year period between clinical pharmacist with a team (dietitian, and primary care provider) and control patients initiating insulin therapy (p-value = 0.025), clinical pharmacist reviewed FPG reading, HbA1c value, optimize medication dosing, provide diabetes education and follow-up laboratory testing, with pharmacist team patients, on average, displaying lower HbA1c values compared to patients managed without the pharmacist. (134) Meade et al (2018) found that the education and interventions provided by the pharmacist resulted in a decreased mean HbA1c, p-value <0.001. (135) A systematic review and meta-analysis study found the overall result of a total of 37 articles included in the review showed a favorable outcome with pharmacist care interventions on HbA1c. Pharmacist intervention included assess, monitor, initiate, and modify medication use and providing education services to healthcare professionals as well as to patients (22) The analysis for the intervention period showed that interventions of less than 6 months did not affect the clinical parameters of the patient (p-value=0.333). (22) In the second group, 6–12 months of pharmacist intervention showed an improved effect, and the patients exhibited 36.4% more mean HbA1c level changes than the usual care group (p-value<0.001). The longest intervention period was more than 12 months and it exhibited better effect on HbA1c reduction, with 38.8% more change in levels of HbA1c than the usual care group. (22) This study was after 6 months of intervention; thus, it might not have changed then level of HbA1c that much. This study was the first pharmaceutical care intervention for diabetic patients in Lao PDR, thus, the intervention process did not go smoothly because only a few diabetic doctors had participated in the focus group meeting before starting the intervention, so the rest

of the doctors in the clinical setting had a lack of understanding on the role of pharmacist in terms of pharmaceutical care. This study did not provide diabetes education to the other healthcare professionals as mentioned in other study. (22)

Lipid outcomes, the intervention of our study showed significant improvement in total cholesterol and LDL after 6 months. Our result is consistent with a study in Jordan which showed that 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 6 months (p-value<0.001) compared to 24.7 and 28.8% respectively at baseline. (136) Our study, showed that the intervention group reached LDL goal 36.7% higher than control group which reached 29.4%.

A systematic review of randomized controlled trials revealed that pharmacist-led interventions with medication counseling, patient education, distribution of interventions materials, individualized care plans, and check-in meetings, in the vast majority of trials (n = 29) showed statistically significant improvement in BP in the intervention groups at follow-up.(137) In this study, SBP and DBP means at month 6 of the intervention group were higher than control group with statistically significant difference. Blood pressure goals that were achieved was higher in the control group than the treatment group at the post test. The reason that the intervention has higher mean of SBP and DBP were due to the age of patients who were allocated to both groups. The mean age of patients in the intervention group was higher than control with significant difference, p-value<0.05 and with sub-group analysis, the age was also statistically significantly related to the BP control at month 6, p<0.05. Increasing age related with increasing chance of raising BP as the strongest link between inflammation/ oxidative stress and hypertension appears to be vascular dysfunction. In fact, the relationships among these three biological mechanisms have been termed the "Vascular Health Triad" which has been implicated separately in both aging and hypertension. (138) The effect on BP tended to be more important if the intervention was conducted monthly or more frequently compared with less frequently than once a month.(139) In this study, the patients of the intervention group met the pharmacist at the diabetes care service not more than 2 times, so BP was not dramatically changed. A more substantial difference in effect on BP was observed according to the type of pharmacist care, and pharmacist-led care being associated with a larger effect on systolic and diastolic BP compared with collaborative care.(139) This study was not focused on aggressive BP control and that could be the reason why the SBP and DBP were not well-controlled.

The humanistic outcomes showed only significant difference between groups on dimension of Satisfaction to the Competency of Pharmacists (SCP). The intervention group had higher mean score of satisfaction (SCP) when compared with control group, p-value=0.010. Several studies have also revealed that pharmacist services in diabetes care improved patient satisfaction.(140, 141) Satisfaction and impact domains 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. (140) Patient satisfaction with overall diabetes care improved after 6 months, and 95.7% of patients reported being very satisfied or satisfied with the diabetes care provided by their pharmacists.(141)

People with diabetes have a worse quality of life than people with no chronic illness.(142) This study used D-39 which was firstly developed by Boyer et al (1997) (51) and which has been translated into several languages including Thai language by Songraksa K, 2009. (52) The result of this study showed no significant difference between groups. However, the control group showed significant difference within group comparison in the dimension of Social Burden (SB), p-value<0.05. The study of Sroisong, 2019 stated that 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. (143) This study found the highest mean score was equal to 3.12 in the dimension of Diabetes Control (DC) of control group. Other dimensions in both groups in this study found the mean score did not exceed 3.00, which means most of the problems from diabetes had little effect on the quality of life of the patients. However, there was quite a variance in individual patient because the floor and ceiling D-39 scores ranged from 1 to 7 in each item of D-39 questionnaire. Thus, in order to improve patient quality of life, the healthcare provider should focus on each individual problem. Another study also found the highest mean quality of life score was in Social Burden (SB) dimension. (144) Anxiety and Worry (AW) had the greatest impact (median score = 41) and Sexual Functioning (SF), the lowest impact (median Score = 0) on quality of life. Older age, later age of onset, longer diabetes duration, better glucose control and not using insulin were associated with a higher Anxiety and Worry (AW) score.(145) In this study it was found that Energy and morbidity (EM) had the highest mean score in the intervention group and Diabetes Control had the highest mean score of the control group. There was no significant correlation between PSQ and D-39 and HbA1c at month 6.

The randomized controlled trial had several limitations. First, the participants' characteristics were not equal. There were differences between groups in age and underlying hypertension which might have affected the outcomes of the study. The JAMA guide to statistics and methods stated that using the permuted block method, as the sample size increases, the 2 groups will become more perfectly balanced.(146) This study samples were not large (there were 144 patients in total), so the sampling method might have affected the equality between groups. However, the analysis was performed by adjusting these differences. Second, there was a higher number of patients in control group who were lost to follow-up (>20%). However, sample size calculation was prior estimated the dropout rate at 20%. Third, the process of following-up patients at the diabetes care service in the hospital was done by one researcher. Because of limited time in the process of service and data collection, some patients in the invention group did not meet face-to-face in every visit with the researcher, this might not affect the outcomes to change dramatically from baselines. Furthermore, the research was performed by the same healthcare providers without blinding, the quality of care might be contaminated between groups. According to the protocol to administering questionnaires at home in both groups, that might affect the outcomes (HbA1C) even though the visits in the intervention group were more often. Surprisingly, blood pressure outcome was better in the control group when compared with the treatment group. The explanation to this might related to the protocol of the study developed with the hospital which focus on diabetes including changing

medications only in diabetes medication. Moreover, the intervention group had higher hypertensive patients than the control significantly. Lastly, the medication adherence rate was not calculated but rather used an interview in every visit, future research should find a better way to record and calculate medication adherence rate as it might affect the clinical outcomes.

Diabetes care intervention led by pharmacist showed improvement in HbA1c control and significantly reduced total cholesterol and LDL. Diabetes patients were satisfied with competency of the pharmacist. Nevertheless, further trial needs to be conducted with more time and inter-professional collaboration.

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 Education and Counseling. 2018;101(1):92-8.
2.   IDF. IDF Diabetes Atlas 2017 [cited 2019 January 6]. 8:[Available from: http://diabetesatlas.org/resources/2017-atlas.html.
3.   Zhuo X, Zhang P, Hoerger TJ. Lifetime Direct Medical Costs of Treating Type 2 Diabetes and Diabetic Complications. American journal of preventive medicine. 2013;45(3):253-61.
4.   WHO. WHO Country Cooperation Strategy for the Lao People's Democratic Republic 2012- 2015 World Health Organization; 2015 [Available from: http://www.wpro.who.int/countries/lao/ccs_lao_en.pdf.
5.   WHO. Diabetes Country-profiles Lao PDR World Health Organization; [Available from: www.who.int/diabetes/country-profiles/lao_en.pdf.
6.   Low W-Y, Lee Y-K, Samy AL. Non-communicable diseases in the Asia-Pacific region: Prevalence, risk factors and community-based prevention. International Journal of Occupational Medicine and Environmental Health. 2015;28(1):20-6.
7.   Handelsman Y, Jellinger PS. Overcoming Obstacles in Risk Factor Management in Type 2 Diabetes Mellitus. The Journal of Clinical Hypertension. 2011;13(8):613-20.
8.   Khan H, Lasker SS, Chowdhury TA. Exploring reasons for very poor glycaemic control in patients with Type 2 diabetes. Primary Care Diabetes. 2011;5(4):251-5.
9.   ADA. Standards of Medical Care in Diabetes—2019 2019 [Available from: http://care.diabetesjournals.org/content/42/Supplement_1/S1.
10.   Association TD. Thailand 2017 Anti-hyperglycemic therapy in type 2 diabetes-general recommendations 2017.
11.   Hughes JD, Wibowo Y, Sunderland B, Hoti K. The role of the pharmacist in the management of type 2 diabetes: current insights and future directions. Integrated pharmacy research & practice. 2017;6:15-27.
12.   Stellefson M, Dipnarine K, Stopka C. The chronic care model and diabetes management in US primary care settings: a systematic review. Preventing chronic disease. 2013;10:E26-E.
13.   Pimouguet C, Le Goff M, Thiébaut R, Dartigues JF, Helmer C. Effectiveness of disease-management programs for improving diabetes care: a meta-analysis. CMAJ : Canadian Medical Association journal = journal de l'Association medicale canadienne. 2011;183(2):E115-E27.
14.   Chen J-H, Ou H-T, Lin T-C, Lai EC-C, Yang Kao Y-H. Pharmaceutical care of elderly patients with poorly controlled type 2 diabetes mellitus: a randomized controlled trial. International Journal of Clinical Pharmacy. 2016;38(1):88-95.
15.   Alfayez OM, Al Yami MS, Fazel MT. The impact of pharmacists providing direct patient care as members of interprofessional teams on diabetes management. Saudi pharmaceutical journal : SPJ : the official publication of the Saudi Pharmaceutical Society. 2017;25(7):1019-21.
16.   Rodriguez de Bittner M, Chirikov VV, Breunig IM, Zaghab RW, Shaya FT. Clinical effectiveness and cost savings in diabetes care, supported by pharmacist counselling. Journal of the American Pharmacists Association. 2017;57(1):102-8.e4.
17.   Triller D, Hamilton R, Briceland L, Waite N, Audette C, Furman C. Home care

pharmacy: extending clinical pharmacy services beyond infusion therapy. American Journal of Health-System Pharmacy. 2000;57(14):1326-31.

18. 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. Research in Social and Administrative Pharmacy. 2018.

19. Funk JL. Disorders of the Endocrine Pancreas. In: Hammer GD, McPhee SJ, editors. Pathophysiology of Disease: An Introduction to Clinical Medicine, 8e. New York, NY: McGraw-Hill Education; 2019.

20. ADA. Standards of medical care in diabetes: American Diabetes Association

2017 [Available from: https://professional.diabetes.org/sites/professional.diabetes.org/files/media/standardofcare2017fulldeckfinal_0.pdf.

21. Hepler CD, Strand LM. Opportunities and responsibilities in pharmaceutical care. American journal of hospital pharmacy. 1990;47(3):533-43.

22. Jeong S LM, Ji E. Effect of pharmaceutical care interventions on glycemic control in patients with diabetes: a systematic review and meta-analysis. Therapeutics and Clinical Risk Management. 2018;14:1813-29.

23. Roughead L, Semple S, Vitry A. The Value of Pharmacist Professional Services in the Community Setting2003.

24. Van Den Bemt PM, Egberts TC, de Jong-van den Berg LT, Brouwers JR. Drug-related problems in hospitalised patients. Drug safety. 2000;22(4):321-33.

25. Wilmer CM, Huiskes VJB, Natsch S, Rennings AJM, van den Bemt BJF, Bos JM. Drug-related problems in a clinical setting: a literature review and cross-sectional study evaluating factors to identify patients at risk. European Journal of Hospital Pharmacy. 2015;22(4):229-35.

26. Gallimore CE, Sokhal D, Zeidler Schreiter E, Margolis AR. Pharmacist medication reviews to improve safety monitoring in primary care patients. Families, systems & health : the journal of collaborative family healthcare. 2016;34(2):104-13.

27. Brandt M, Hallas J, Graabaek T, Pottegard A. Description of a practice model for pharmacist medication review in a general practice setting. Pharmacy practice. 2014;12(3):420.

28. Disease NIoDaDaK. Chronic Care Model 2019 [cited 2019 January 8]. Available from: https://www.niddk.nih.gov/health-information/communication-programs/ndep/health-professionals/practice-transformation-physicians-health-care-teams/team-based-care/chronic-care-model.

29. Smith M. Pharmacists' role in improving diabetes medication management. Journal of diabetes science and technology. 2009;3(1):175-9.

30. Lao People's Democratic Republic Health System Review. 2014.

31. Nocon A, Rhodes PJ, Wright JP, Eastham J, Williams DR, Harrison SR, et al. Specialist general practitioners and diabetes clinics in primary care: a qualitative and descriptive evaluation. Diabetic Medicine. 2004;21(1):32-8.

32. Wagner EH, Austin BT, Davis C, Hindmarsh M, Schaefer J, Bonomi A. Improving chronic illness care: translating evidence into action. Health affairs (Project Hope). 2001;20(6):64-78.

33. Peytremann-Bridevaux I, Lauvergeon S, Mettler D, Burnand B. Diabetes care: Opinions, needs and proposed solutions of Swiss patients and healthcare professionals: a

qualitative study. Diabetes research and clinical practice. 2012;97(2):242-50.

34. Lewis CP, Newell JN. Patients' perspectives of care for type 2 diabetes in Bangladesh -a qualitative study. BMC Public Health. 2014;14:737.

35. Strickland PA, Hudson SV, Piasecki A, Hahn K, Cohen D, Orzano AJ, et al. Features of the Chronic Care Model (CCM) associated with behavioral counseling and diabetes care in community primary care. Journal of the American Board of Family Medicine : JABFM. 2010;23(3):295-305.

36. Sohal T, Sohal P, King-Shier KM, Khan NA. Barriers and Facilitators for Type-2 Diabetes Management in South Asians: A Systematic Review. PLoS One. 2015;10(9):e0136202.

37. Franklin M, Lewis S, Willis K, Bourke-Taylor H, Smith L. Patients' and healthcare professionals' perceptions of self-management support interactions: Systematic review and qualitative synthesis. Chronic illness. 2018;14(2):79-103.

38. Rushforth B, McCrorie C, Glidewell L, Midgley E, Foy R. Barriers to effective management of type 2 diabetes in primary care: qualitative systematic review. British Journal of General Practice. 2016;66(643):e114.

39. McSharry J, McGowan L, Farmer AJ, French DP. Perceptions and experiences of taking oral medications for the treatment of Type 2 diabetes mellitus: a systematic review and meta-synthesis of qualitative studies. Diabetic Medicine. 2016;33(10):1330-8.

40. Park C, Nam S, Whittemore R. Incorporating Cultural Perspectives into Diabetes Self-Management Programs for East Asian Immigrants: A Mixed-Study Review. Journal of immigrant and minority health. 2016;18(2):454-67.

41. Jones V, Crowe M. How people from ethnic minorities describe their experiences of managing type-2 diabetes mellitus: A qualitative meta-synthesis. International Journal of Nursing Studies. 2017;76:78-91.

42. Donabedian A. Evaluating the quality of medical care. 1966. The Milbank quarterly. 2005;83(4):691-729.

43. Fung D, Cohen MM. Measuring patient satisfaction with anesthesia care: a review of current methodology. Anesthesia and analgesia. 1998;87(5):1089-98.

44. Aharony L, Strasser S. Patient satisfaction: what we know about and what we still need to explore. Medical care review. 1993;50(1):49-79.

45. Hendriks AA, Vrielink MR, Smets EM, van Es SQ, De Haes JC. Improving the assessment of (in)patients' satisfaction with hospital care. Medical care. 2001;39(3):270-83.

46. Salomon L, Gasquet I, Mesbah M, Ravaud P. Construction of a scale measuring inpatients' opinion on quality of care. International journal for quality in health care : journal of the International Society for Quality in Health Care. 1999;11(6):507-16.

47. Gonzalez N, Quintana JM, Bilbao A, Escobar A, Aizpuru F, Thompson A, et al. Development and validation of an in-patient satisfaction questionnaire. International journal for quality in health care : journal of the International Society for Quality in Health Care. 2005;17(6):465-72.

48. Carey RG, Seibert JH. A patient survey system to measure quality improvement: questionnaire reliability and validity. Medical care. 1993;31(9):834-45.

49. Paddock LE, Veloski J, Chatterton ML, Gevirtz FO, Nash DB. Development and validation of a questionnaire to evaluate patient satisfaction with diabetes disease management. Diabetes Care. 2000;23(7):951-6.

50.   Wei J, Shen L, Yang HB, Qin JB, Huang W, Zhang JJ, et al. Development and validation of a Chinese outpatient satisfaction questionnaire: evidence from 46 public general hospitals and 5151 outpatients. Public Health. 2015;129(11):1523-9.

51.   Boyer JG, Earp JA. The development of an instrument for assessing the quality of life of people with diabetes. Diabetes-39. Medical care. 1997;35(5):440-53.

52.   Songraksa K LS. Development of a disease specific quality of life instrument: Thai version of the Diabetic-39. Songkla Medical Journal. 2009;27(1):35-49.

53.   Chen G, Iezzi A, McKie J, Khan MA, Richardson J. Diabetes and quality of life: Comparing results from utility instruments and Diabetes-39. Diabetes Research & Clinical Practice. 2015;109(2):326-33.

54.   Doherty Y, Hall D, James PT, Roberts SH, Simpson J. Change counselling in diabetes: the development of a training programme for the diabetes team. Patient Education and Counseling. 2000;40(3):263-78.

55.   McGill M, Blonde L, Chan JCN, Khunti K, Lavalle FJ, Bailey CJ. The interdisciplinary team in type 2 diabetes management: Challenges and best practice solutions from real-world scenarios. Journal of Clinical and Translational Endocrinology. 2017;7:21-7.

56.   Choi TS, Davidson ZE, Walker KZ, Lee JH, Palermo C. Diabetes education for Chinese adults with type 2 diabetes: A systematic review and meta-analysis of the effect on glycemic control. Diabetes Research & Clinical Practice. 2016;116:218-29.

57.   Huang XL, Pan JH, Chen D, Chen J, Chen F, Hu TT. Efficacy of lifestyle interventions in patients with type 2 diabetes: A systematic review and meta-analysis. European journal of internal medicine. 2016;27:37-47.

58.   Chen L, Pei JH, Kuang J, Chen HM, Chen Z, Li ZW, et al. Effect of lifestyle intervention in patients with type 2 diabetes: a meta-analysis. Metabolism. 2015;64(2):338-47.

59.   Rice K, Te Hiwi B, Zwarenstein M, Lavallee B, Barre DE, Harris SB. Best Practices for the Prevention and Management of Diabetes and Obesity-Related Chronic Disease among Indigenous Peoples in Canada: A Review. Canadian Journal of Diabetes. 2016;40(3):216-25.

60.   Batik O, Phelan EA, Walwick JA, Wang G, LoGerfo JP. Translating a community-based motivational support program to increase physical activity among older adults with diabetes at community clinics: a pilot study of Physical Activity for a Lifetime of Success (PALS). Preventing chronic disease. 2007;5(1):A18-A.

61.   Wichit N, Mnatzaganian G, Courtney M, Schulz P, Johnson M. Randomized controlled trial of a family-oriented self-management program to improve self-efficacy, glycemic control and quality of life among Thai individuals with Type 2 diabetes. Diabetes Research & Clinical Practice. 2017;123:37-48.

62.   Beverly EA, Ritholz MD, Brooks KM, Hultgren BA, Lee Y, Abrahamson MJ, et al. A qualitative study of perceived responsibility and self-blame in type 2 diabetes: reflections of physicians and patients. J Gen Intern Med. 2012;27(9):1180-7.

63.   Goetz K SJ, Campbell S, Rosemann T, Rueter G, Raum E, et al. . The importance of social support for people with type 2 diabetes – a qualitative study with general practitioners, practice nurses and patients. GMS Psycho-Social-Medicine. 2012.

64.   Brez S, Rowan M, Malcolm J, Izzi S, Maranger J, Liddy C, et al. Transition from specialist to primary diabetes care: A qualitative study of perspectives of primary care physicians. BMC Family Practice. 2009;10(1):39.

65.   Noor Abdulhadi NM, Al-Shafaee MA, Wahlström R, Hjelm K. Doctors' and nurses' views on patient care for type 2 diabetes : an interview study in primary health care in Oman. Primary Health Care Research and Development. 2013;14(3):258-69.

66.   Kern D, Mainous A. Disease management for diabetes among family physicians and general internists: Opportunism or planned care? Family medicine. 2001;33:621-5.

67.   Raaijmakers LG, Hamers FJ, Martens MK, Bagchus C, de Vries NK, Kremers SP. Perceived facilitators and barriers in diabetes care: a qualitative study among health care professionals in the Netherlands. BMC family practice. 2013;14:114-.

68.   Brown JB, Harris SB, Webster-Bogaert S, Wetmore S, Faulds C, Stewart M. The role of patient, physician and systemic factors in the management of type 2 diabetes mellitus. Family Practice. 2002;19(4):344-9.

69.   Matthews SM, Peden AR, Rowles GD. Patient-provider communication: understanding diabetes management among adult females. Patient Education and Counseling. 2009;76(1):31-7.

70.   Carbone ET, Rosal MC, Torres MI, Goins KV, Bermudez OI. Diabetes self-management: Perspectives of Latino patients and their health care providers. Patient Education and Counseling. 2007;66(2):202-10.

71.   Dutton H RM, Liddy C, Maranger J, Ooi TC, Malcolm J, et al. Patient Perspectives on Discharge from Specialist Type 2 Diabetes Care Back to Primary Care: A Qualitative Study. Canadian Journal of Diabetes. 2014;38(3):191-7.

72.   Al-Qazaz HK, Hassali MA, Shafie AA, Syed Sulaiman SA, Sundram S. Perception and knowledge of patients with type 2 diabetes in Malaysia about their disease and medication: a qualitative study. Research in Social and Administrative Pharmacy. 2011;7(2):180-91.

73.   Karimi Moonaghi H, Namdar Areshtanab H, Jouybari L, Arshadi Bostanabad M, McDonald H. Facilitators and barriers of adaptation to diabetes: experiences of Iranian patients. J Diabetes Metab Disord. 2014;13(1):17-.

74.   Held RF, DePue J, Rosen R, Bereolos N, Nu'usolia O, Tuitele J, et al. Patient and health care provider views of depressive symptoms and diabetes in American Samoa. Cultur Divers Ethnic Minor Psychol. 2010;16(4):461-7.

75.   Lai WA, Chie W-C, Lew-Ting C-Y. How diabetic patients' ideas of illness course affect non-adherent behaviour: a qualitative study. The British journal of general practice. 2007;57(537):296-302.

76.   Alazri MH, Neal RD, Heywood P, Leese B. Patients' experiences of continuity in the care of type 2 diabetes: a focus group study in primary care. The British journal of general practice. 2006;56(528):488-95.

77.   Kato A, Fujimaki Y, Fujimori S, Izumida Y, Suzuki R, Ueki K, et al. A qualitative study on the impact of internalized stigma on type 2 diabetes self-management. Patient Education and Counseling. 2016;99(7):1233-9.

78.   Al-Azri M, Al-Azri H, Al-Hashmi F, Al-Rasbi S, El-Shafie K, Al-Maniri A. Factors Affecting the Quality of Diabetic Care in Primary Care Settings in Oman: A qualitative study on patients' perspectives. Sultan Qaboos Univ Med J. 2011;11(2):207-13.

79.   Beverly EA, Wray LA, Chiu CJ, Weinger K. Perceived challenges and priorities in co-morbidity management of older patients with Type 2 diabetes. Diabetic medicine. 2011;28(7):781-4.

80.   Dhippayom T, Krass I. Supporting self-management of type 2 diabetes: is there a

role for the community pharmacist? Patient Prefer Adherence [Internet]. 2015 2015; 9:[1085-92 pp.]. Available from: http://europepmc.org/abstract/MED/26257514.

81.   Huang ES, Gorawara-Bhat R, Chin MH. Self-reported goals of older patients with type 2 diabetes mellitus. J Am Geriatr Soc. 2005;53(2):306-11.

82.   Halkoaho A, Kangasniemi M, Niinimäki S, Pietilä A-M. Type 2 diabetes patients' perceptions about counselling elicited by interview: is it time for a more health-oriented approach? European Diabetes Nursing. 2014;11(1):13-8.

83.   Oxford. (CASP) CASP. 10 Questions to help you make sense of qualitative research. 2006.

84.   Zaza S, Wright-De Aguero LK, Briss PA, Truman BI, Hopkins DP, Hennessy MH, et al. Data collection instrument and procedure for systematic reviews in the Guide to Community Preventive Services. Task Force on Community Preventive Services. American journal of preventive medicine. 2000;18(1 Suppl):44-74.

85.   Sewell MMM. Using Focus Group for Evaluation 2019 [cited 2019 January 8]. Available from: https://cals.arizona.edu/sfcs/cyfernet/cyfar/focus.htm.

86.   Lahavisavapanich R WS, Wongthawarawat W. Impact of education and counseling provided by clinical pharmacist on diabetic outpatents. Thai Journal of Health Research. 2006;20(1):19-40.

87.   Cassimatis M, Kavanagh DJ, Smith AC. Perceived Needs for Supported Self-management of Type 2 Diabetes: A Qualitative Investigation of the Potential for a Web-based Intervention. Australian Psychologist. 2014;49(2):75-85.

88.   Andrews SM, Sperber NR, Gierisch JM, Danus S, Macy SL, Bosworth HB, et al. Patient perceptions of a comprehensive telemedicine intervention to address persistent poorly controlled diabetes. Patient Prefer Adherence. 2017;11:469-78.

89.   Mathiesen AS, Thomsen T, Jensen T, Schiøtz C, Langberg H, Egerod I. The influence of diabetes distress on digital interventions for diabetes management in vulnerable people with type 2 diabetes: A qualitative study of patient perspectives. Journal of Clinical & Translational Endocrinology. 2017;9:41-7.

90.   Furler J, Walker C, Blackberry I, Dunning T, Sulaiman N, Dunbar J, et al. The emotional context of self-management in chronic illness: A qualitative study of the role of health professional support in the self-management of type 2 diabetes. BMC Health Serv Res. 2008;8:214-.

91.   Mathew R, Gucciardi E, De Melo M, Barata P. Self-management experiences among men and women with type 2 diabetes mellitus: a qualitative analysis. BMC Family Practice. 2012;13(1):122.

92.   Moser A, van der Bruggen H, Widdershoven G, Spreeuwenberg C. Self-management of type 2 diabetes mellitus: a qualitative investigation from the perspective of participants in a nurse-led, shared-care programme in the Netherlands. BMC Public Health. 2008;8(1):91.

93.   Odgers-Jewell K, Isenring E, Thomas R, Reidlinger DP. Process evaluation of a patient-centred, patient-directed, group-based education program for the management of type 2 diabetes mellitus. Nutrition & Dietetics. 2017;74(3):243-52.

94.   Smith C, McNaughton DA, Meyer S. Client perceptions of group education in the management of type 2 diabetes mellitus in South Australia. Australian Journal of Primary Health. 2016;22(4):360-7.

95.   Hearnshaw H, Barlow J, Hainsworth J. Supporting a curriculum for delivering Type 2 diabetes patient self-management education: A patient-needs assessment.

Primary Health Care Research and Development. 2005;6:291-9.

96.   Wermeling M, Thiele-Manjali U, Koschack J, Lucius-Hoene G, Himmel W. Type 2 diabetes patients' perspectives on lifestyle counselling and weight management in general practice: a qualitative study. BMC Family Practice. 2014;15(1):97.

97.   Berenguera A, Molló-Inesta À, Mata-Cases M, Franch-Nadal J, Bolíbar B, Rubinat E, et al. Understanding the physical, social, and emotional experiences of people with uncontrolled Type 2 diabetes: a qualitative study. Patient Prefer Adherence. 2016;10:2323-32.

98.   Beverly EA, Wray LA. The role of collective efficacy in exercise adherence: a qualitative study of spousal support and type 2 diabetes management. Health Educ Res. 2010;25(2):211-23.

99.   Burridge LH, Foster MM, Donald M, Zhang J, Russell AW, Jackson CL. Making sense of change: patients' views of diabetes and GP-led integrated diabetes care. Health Expectations. 2016;19(1):74-86.

100.   Chapman A, Yang H, Thomas SA, Searle K, Browning C. Barriers and enablers to the delivery of psychological care in the management of patients with type 2 diabetes mellitus in China: a qualitative study using the theoretical domains framework. BMC Health Serv Res. 2016;16:106-.

101.   Concha JB, Mayer SD, Mezuk BR, Avula D. Diabetes Causation Beliefs Among Spanish-Speaking Patients. The Diabetes Educator. 2015;42(1):116-25.

102.   Gucciardi E, Fortugno M, Senchuk A, Beanlands H, McCay E, Peel EE. Self-monitoring of blood glucose in Black Caribbean and South Asian Canadians with non-insulin treated Type 2 diabetes mellitus: a qualitative study of patients' perspectives. BMC Endocr Disord. 2013;13:46-.

103.   Halperin IJ, Mukerji G, Maione M, Segal P, Wolfs M, Goguen J, et al. Adult Patient Perspectives on Care for Type 1 and Type 2 Diabetes Across the Institute of Medicine's 6 Domains of Quality. Canadian Journal of Diabetes. 2018;42(1):36-43.

104.   Lawton J, Rankin D, Peel E, Douglas M. Patients' perceptions and experiences of transitions in diabetes care: a longitudinal qualitative study. Health Expect. 2009;12(2):138-48.

105.   Malpass A, Andrews R, Turner KM. Patients with Type 2 Diabetes experiences of making multiple lifestyle changes: a qualitative study. Patient Education and Counseling. 2009;74(2):258-63.

106.   Ogunrinu T, Gamboa-Maldonado T, Ngewa RN, Saunders J, Crounse J, Misiri J. A qualitative study of health education experiences and self-management practices among patients with type 2 diabetes at Malamulo Adventist Hospital in Thyolo District, Malawi. Malawi Medical Journal. 2017;29(2):118-23.

107.   Peel E, Parry O, Douglas M, Lawton J. Blood glucose self-monitoring in non-insulin-treated type 2 diabetes: a qualitative study of patients' perspectives. The British journal of general practice 2004;54(500):183-8.

108.   Ralston JD, Revere D, Robins LS, Goldberg HI. Patients' experience with a diabetes support programme based on an interactive electronic medical record: qualitative study. BMJ. 2004;328(7449):1159-.

109.   Richardson BS, Willig AL, Agne AA, Cherrington AL. Diabetes Connect: African American Women's Perceptions of the Community Health Worker Model for Diabetes Care. Journal of Community Health. 2015;40(5):905-11.

110.   Sunaert P, Vandekerckhove M, Bastiaens H, Feyen L, Bussche PV, De

Maeseneer J, et al. Why do GPs hesitate to refer diabetes patients to a self-management education program: a qualitative study. BMC family practice. 2011;12:94-.

111.   Yamakawa M, Makimoto K. Positive experiences of type 2 diabetes in Japanese patients: An exploratory qualitative study. International Journal of Nursing Studies. 2008;45(7):1032-41.

112.   Fort MP, Alvarado-Molina N, Peña L, Mendoza Montano C, Murrillo S, Martínez H. Barriers and facilitating factors for disease self-management: a qualitative analysis of perceptions of patients receiving care for type 2 diabetes and/or hypertension in San José, Costa Rica and Tuxtla Gutiérrez, Mexico. BMC Family Practice. 2013;14(1):131.

113.   Patel NR, Kennedy A, Blickem C, Reeves D, Chew-Graham C. "I'm Managing My Diabetes between Two Worlds": Beliefs and Experiences of Diabetes Management in British South Asians on Holiday in the East—A Qualitative Study. Journal of Diabetes Research. 2016;2016:5436174.

114.   Gillani SW, Sulaiman SAS, Abdul MIM, Saad SY. A qualitative study to explore the perception and behavior of patients towards diabetes management with physical disability. Diabetology & Metabolic Syndrome. 2017;9(1):58.

115.   Barbara S, Krass I. Self management of type 2 diabetes by Maltese immigrants in Australia: can community pharmacies play a supporting role? Internal Journal of Pharmacy Practice. 2013;21(5):305-13.

116.   Almansour HA, Chaar B, Saini B. Pharmacists' perspectives about their role in care of patients with diabetes observing Ramadan. Research in Social and Administrative Pharmacy. 2017;13(1):109-22.

117.   Ali HI, Baynouna LM, Bernsen RM. Barriers and facilitators of weight management: perspectives of Arab women at risk for type 2 diabetes. Health & Social Care in the Community. 2010;18(2):219-28.

118.   Samuel-Hodge CD, Cene CW, Corsino L, Thomas C, Svetkey LP. Family diabetes matters: a view from the other side. J Gen Intern Med. 2013;28(3):428-35.

119.   Hu J, Amirehsani K, Wallace DC, Letvak S. Perceptions of barriers in managing diabetes: perspectives of Hispanic immigrant patients and family members. Diabetes Educ. 2013;39(4):494-503.

120.   Cotugno JD, Ferguson M, Harden H, Colquist S, Stack AA, Zimmerman JI, et al. "I wish they could be in my shoes": patients' insights into tertiary health care for type 2 diabetes mellitus. Patient Prefer Adherence. 2015;9:1647-55.

121.   Pooley CG, Gerrard C, Hollis S, Morton S, Astbury J. 'Oh it's a wonderful practice … you can talk to them': a qualitative study of patients' and health professionals' views on the management of type 2 diabetes. Health & Social Care in the Community. 2001;9(5):318-26.

122.   Ritholz MD, Beverly EA, Brooks KM, Abrahamson MJ, Weinger K. Barriers and facilitators to self-care communication during medical appointments in the United States for adults with type 2 diabetes. Chronic Illn. 2014;10(4):303-13.

123.   Pilkington FB, Daiski I, Lines E, Bryant T, Raphael D, Dinca-Panaitescu M, et al. Type 2 Diabetes in Vulnerable Populations: Community Healthcare Providers' Perspectives on Health Service Needs and Policy Implications. Canadian Journal of Diabetes. 2011;35(5):503-11.

124.   Längst G, Seidling HM, Stützle M, Ose D, Baudendistel I, Szecsenyi J, et al. Factors associated with medication information in diabetes care: differences in

perceptions between patients and health care professionals. Patient Prefer Adherence. 2015;9:1431-41.

125.   Al-Qazaz HK, Hassali MA, Shafie AA, Syed Sulaiman SA, Sundram S. Perception and knowledge of patients with type 2 diabetes in Malaysia about their disease and medication: a qualitative study. Res Social Adm Pharm. 2011;7(2):180-91.

126.   Lewis CP, Newell JN. Patients' perspectives of care for type 2 diabetes in Bangladesh -a qualitative study. BMC public health. 2014;14:737-.

127.   Baptista DR, Wiens A, Pontarolo R, Regis L, Reis WCT, Correr CJ. The chronic care model for type 2 diabetes: a systematic review. Diabetology & Metabolic Syndrome. 2016;8(1):7.

128.   Sibounheuang P, Olson PS, Kittiboonyakun P. Patients' and healthcare providers' perspectives on diabetes management: A systematic review of qualitative studies. Research in Social and Administrative Pharmacy. 2020;16(7):854-74.

129.   Anderson RT, Skovlund SE, Marrero D, Levine DW, Meadows K, Brod M, et al. Development and validation of the insulin treatment satisfaction questionnaire. Clinical Therapeutics. 2004;26(4):565-78.

130.   Brose LS, Bradley C. Psychometric Development of the Individualized Retinopathy-Dependent Quality of Life Questionnaire (RetDQoL). Value in Health. 2010;13(1):119-27.

131.   Wilbur K, Al Hammaq AO. Validation of an Arabic version of the Diabetes Treatment Satisfaction Questionnaire in Qatar. Diabetes research and clinical practice. 2016;113:53-9.

132.   Ximénez C. Recovery of Weak Factor Loadings When Adding the Mean Structure in Confirmatory Factor Analysis: A Simulation Study. Front Psychol. 2016;6:1943-.

133.   Queiroz FAd, Pace AE, Santos CBd. Cross-cultural adaptation and validation of the instrument Diabetes - 39 (D-39): brazilian version for type 2 diabetes mellitus patients - stage 1. Revista Latino-Americana de Enfermagem. 2009;17:708-15.

134.   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.

135.   Meade LT, Tart RC, Buzby HL. Evaluation of Diabetes Education and Pharmacist Interventions in a Rural, Primary Care Setting. Diabetes Spectrum. 2018;31(1):90.

136.   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. International Journal of Clinical Pharmacy. 2011;33(2):229-36.

137.   Reeves L, Robinson K, McClelland T, Adedoyin CA, Broeseker A, Adunlin G. Pharmacist Interventions in the Management of Blood Pressure Control and Adherence to Antihypertensive Medications: A Systematic Review of Randomized Controlled Trials. Journal of Pharmacy Practice. 2020:0897190020903573.

138.   Buford TW. Hypertension and aging. Ageing Research Reviews. 2016;26:96-111.

139.   Valérie Santschi P, PhD , Arnaud Chiolero , MD, PhD , April L. Colosimo , MSc, MLIS , Robert W. Platt , PhD , Patrick Taffé , PhD , Michel Burnier , MD , Bernard Burnand , MD, MPH , and Gilles Paradis , MD, MSc. Improving Blood Pressure Control Through Pharmacist Interventions: A Meta-Analysis of Randomized

Controlled Trials. 2014.

140. 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;45:809-17.

141. Daniel G. Garrett M, FASHP, Benjamin M. Bluml, BPharm. Patient Self-Management Program for Diabetes: First-Year Clinical, Humanistic, and Economic Outcomes. 2005.

142. Rubin RR, Peyrot M. Quality of life and diabetes. Diabetes/Metabolism Research and Reviews. 1999;15(3):205-18.

143. Sroisong S. Quality of Life of Patients with Type II diabetes. Journal of Disease and Health Risk DPC3. 2019;13.

144. Thapa S, Pyakurel P, Baral DD, Jha N. Health-related quality of life among people living with type 2 diabetes: a community based cross-sectional study in rural Nepal. BMC Public Health. 2019;19(1):1171.

145. Walker MT-R. Quality of Life in Caribbean Youth with Diabetes. West Indian Medical Journal. 2009(

Vol 58, Issue 3 (2009)):

250–6.

146. Broglio K. Randomization in Clinical Trials: Permuted Blocks and Stratification [cited 2020 November 24]. Available from: https://jamaevidence.mhmedical.com/content.aspx?bookid=2742&sectionid=233567426 .
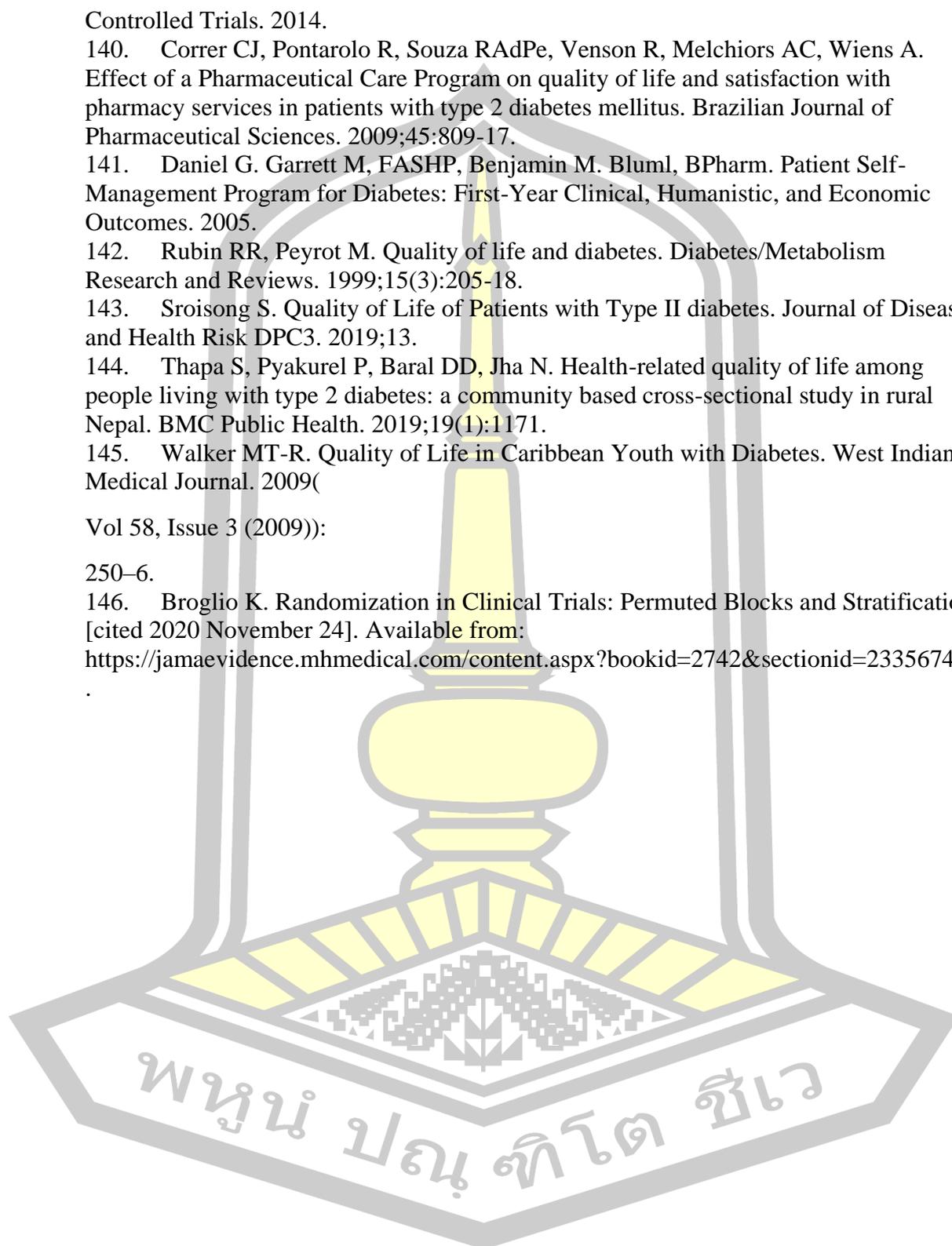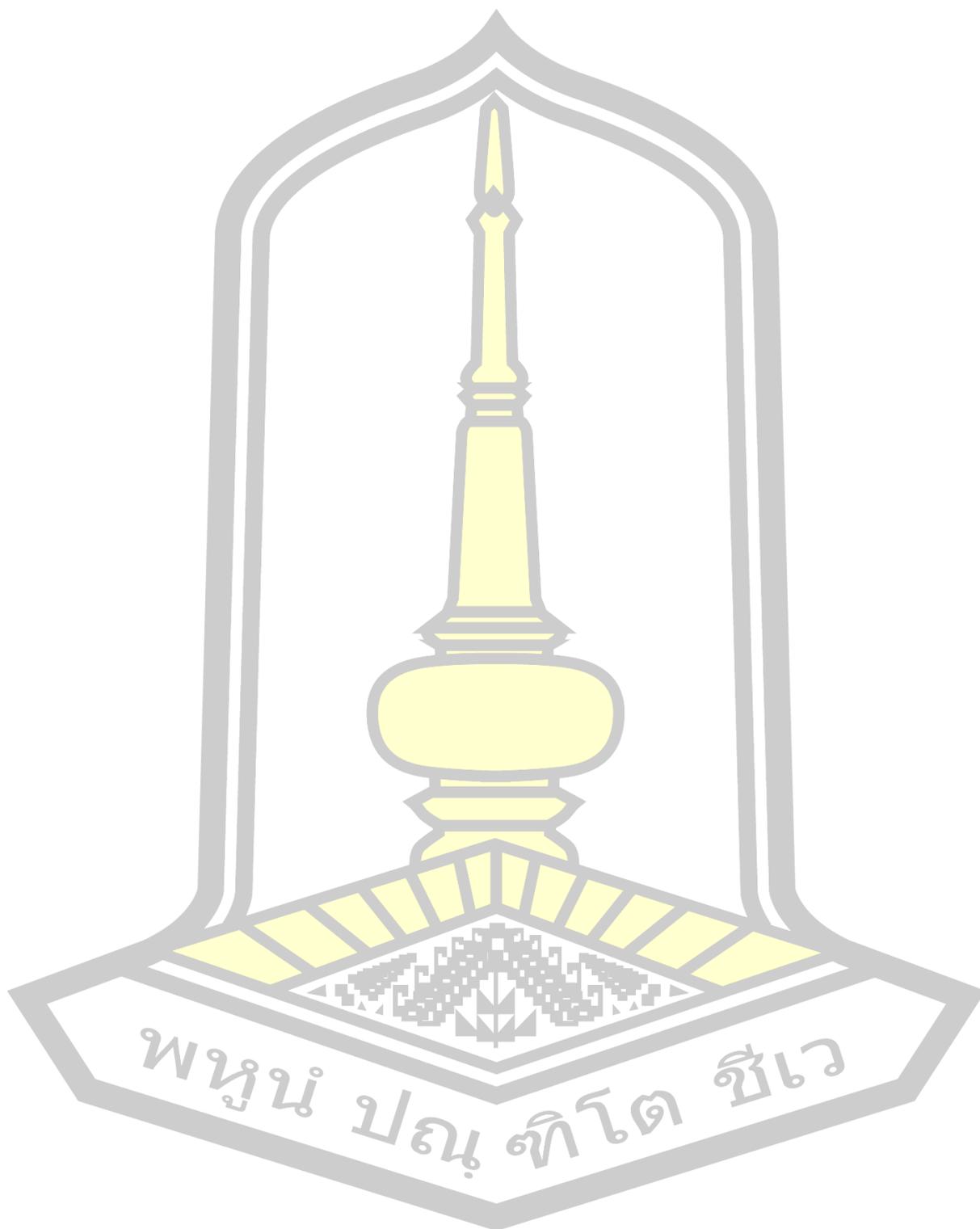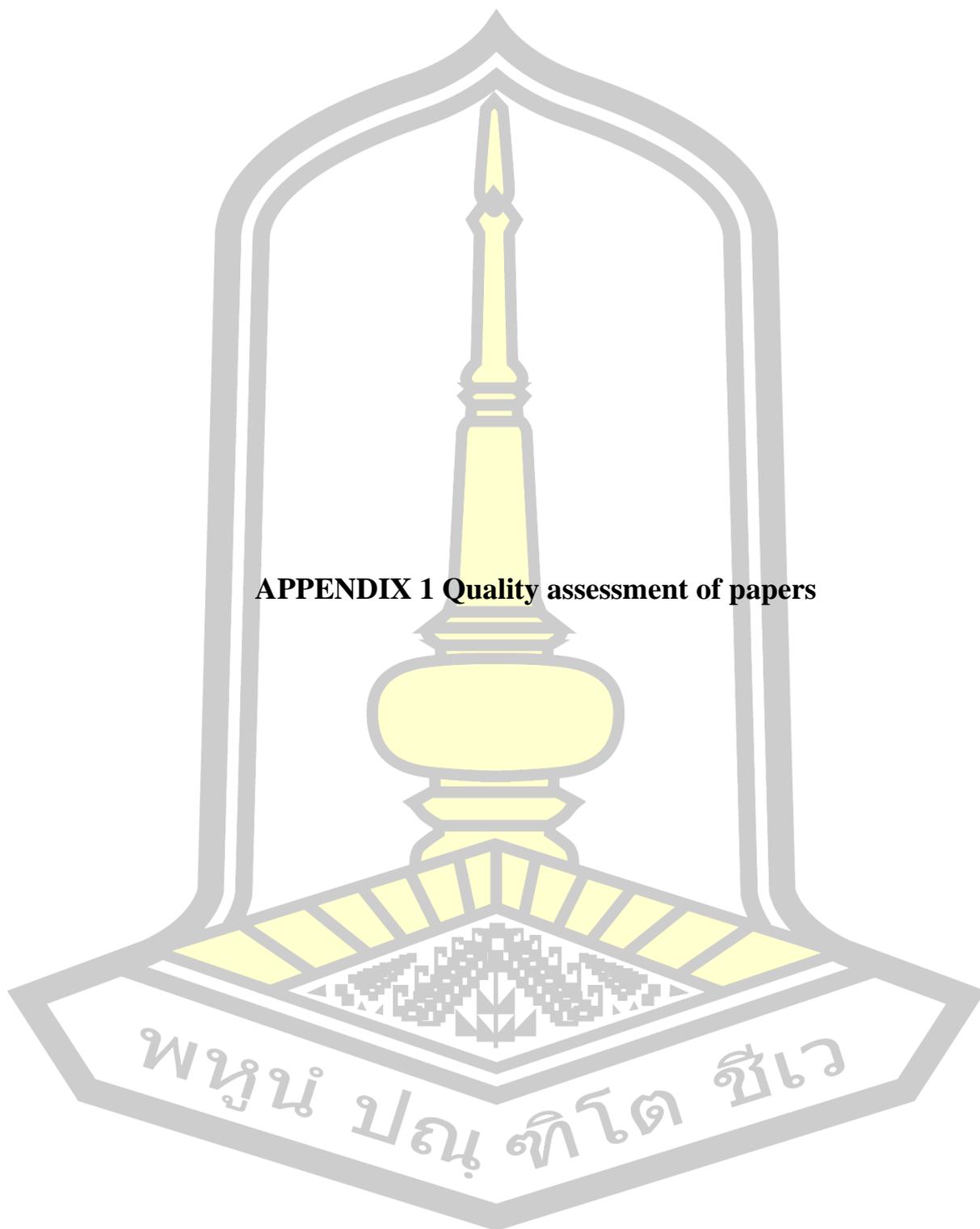
APPENDIX 1 Quality assessment of papers

Table 44 Appendix 1-CASP checklist for assessing the quality of the qualitative studies

Screening Questions	Criteria	Score
1. Clear research aims	Clear aims and relevant introduction	1
2. An appropriate methodology	Appropriate participants with outcomes of perspectives to diabetes management	1
Detailed Questions		
3. The appropriate research design	The researcher has discussed about methods used	1
4. The appropriate recruitment	Clear explanation of participant's recruitment process, which can be considered best to address the research question	1
5. The proper data collection	Clear explanation on how data was collected (e.g. focused-group discussion, semi-structured interview)	1
	Clear form of data (e.g. audio-tape recordings, video material, notes)	
	The researcher justified the methods chosen	
6. The relationship between researchers and participants	Researchers critically examined their own role and potential bias and influence during the formulation of research questions and collection of data	1
7. Ethical issues	Has details of ethical approval	1
8. Rigorous data analysis	Clear explanation of the analysis process (e.g. content analysis and/or thematic analysis with clear themes)	1
9. A clear finding statement	Findings are explicitly stated, with adequate discussion relating to the research questions	1
10. Research value	Findings contribute and relate to current practice	1
	Has a suggestion for further research and policy	
	Total	10
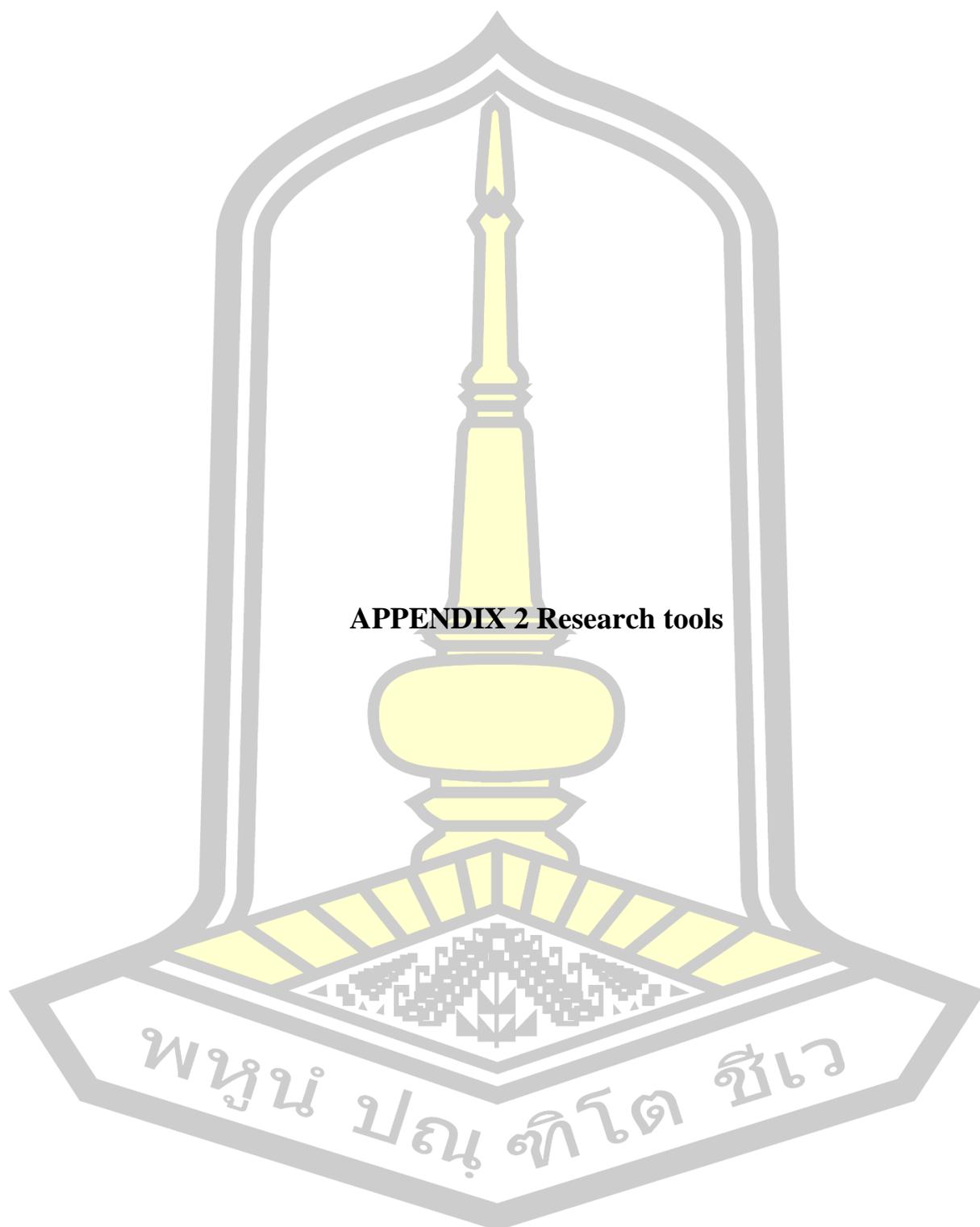
APPENDIX 2 Research tools

Table 45 Appendix 2-Participant Record Form

Record date…………………….

Meet inclusion criteria

☐ Patient diagnosed with type 2 diabetes
☐ More than 18 Years old
☐ No participation in any other study in the past 3 months
☐ HbA1c > 8%
☐ Willingness to participate

Signature………………………………. Researcher;
Date…………………………………..

Demographic information		Research ID	
HN	Sex	Age	
Date of Birth	Education		
Duration of T2DM diagnosed		Insurance	
Past medical history	Current medications		
1.	1.	6.	
2.	2.	7.	
3.	3.	8.	
4.	4.	9.	
	5.	10.	
Complications state………………………..		☐ No	☐ Yes,
Disability state………………………..		☐ No	☐ Yes,
Annual health check-up State…………………..	☐ Yes Result ☐ Normal ☐ Abnormal ☐ No		
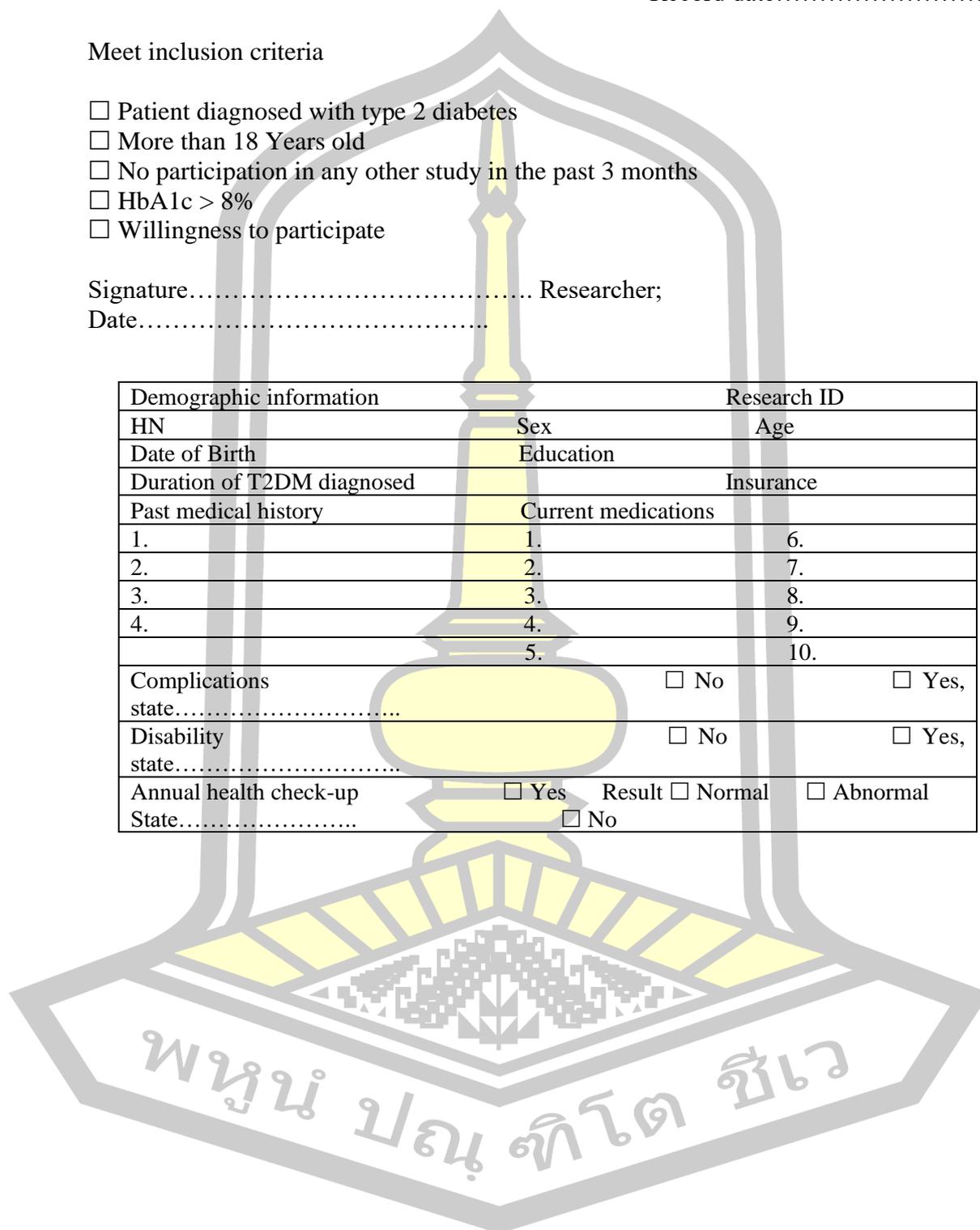
Table 46 Appendix2-Laboratory Record Form

Research ID…………………………

Visit Date	Month 0 ………….	Month 3 ……………	Month 6 …………	Note
HbA1C				
FBS				
Height				
Weight				
BMI				
BP				
Pulse				
Respiratory function				
Temperature				
Cholesterol				
TG				
HDL				
LDL				
SCr				
Microalbumin				
Microfilament				
Recorder				
Note				
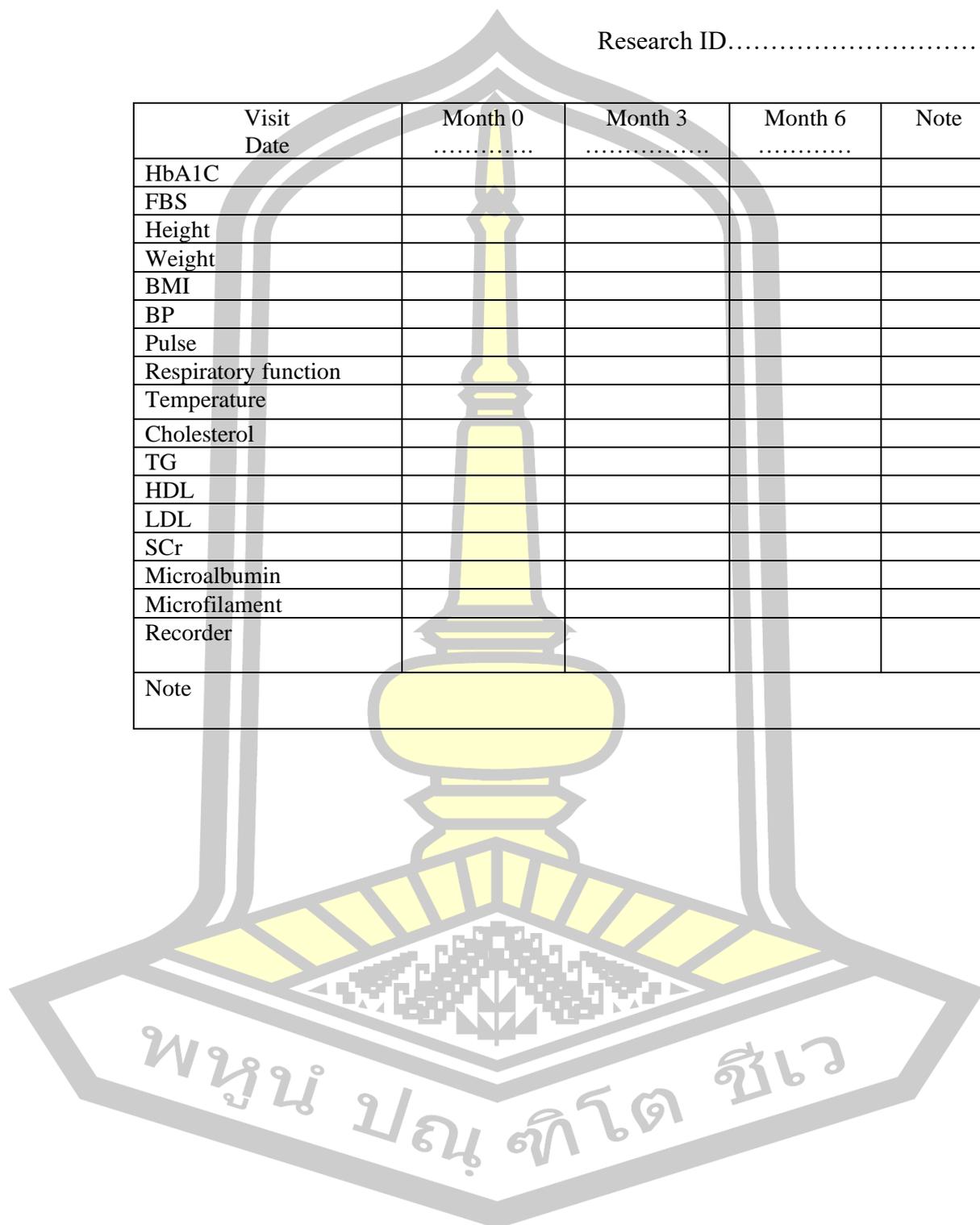
Table 47 Appendix 2-Participant Evaluation Form (Follow-up sheet)

Age… Insurance………………….

Participant in charge of

☐ None   ☐ Husband   ☐ Wife   ☐ Children   ☐ Cousin   ☐ Other

Evaluation Type	Month ….. Date………….	Month ….. Date………….	Month ….. Date………….
General	☐ Came with the appointment ☐ Did not follow the appointment	☐ Came with the appointment ☐ Did not follow the appointment	☐ Came with the appointment ☐ Did not follow the appointment
Wound	☐ None ☐ Yes, please state the position………………	☐ None ☐ Yes, please state the position………………	☐ None ☐ Yes, please state the position………………
Numb sensation in hand and feet	☐ None ☐ Yes, please characterize………………	☐ None ☐ Yes, please characterize………………	☐ None ☐ Yes, please characterize………………
Skin	☐ Normal ☐ Itching ☐ Swelling ☐ Dry ☐ Other	☐ Normal ☐ Itching ☐ Swelling ☐ Dry ☐ Other	☐ Normal ☐ Itching ☐ Swelling ☐ Dry ☐ Other
Ears and hearing	☐ Normal in both ears ☐ Normal hearing ☐ Abnormal, please state…………	☐ Normal in both ears ☐ Normal hearing ☐ Abnormal, please state…………	☐ Normal in both ears ☐ Normal hearing ☐ Abnormal, please state…………
Cardiovascular System	☐ Normal ☐ Abnormal heart rate ☐ Chess pain ☐ Short breath ☐ Unable to lay down	☐ Normal ☐ Abnormal heart rate ☐ Chess pain ☐ Short breath ☐ Unable to lay down	☐ Normal ☐ Abnormal heart rate ☐ Chess pain ☐ Short breath ☐ Unable to lay down
Reproductive System	☐ Normal ☐ Frequently urinate ☐ Sexual desire decreased ☐ Hematuria ☐ Abnormal leucorrhoea	☐ Normal ☐ Frequently urinate ☐ Sexual desire decreased ☐ Hematuria ☐ Abnormal leucorrhoea	☐ Normal ☐ Frequently urinate ☐ Sexual desire decreased ☐ Hematuria ☐ Abnormal leucorrhoea
Endocrine System	☐ Normal ☐ Hair fall/loss ☐ Unable to be in hot and cold condition	☐ Normal ☐ Hair fall/loss ☐ Unable to be in hot and cold condition	☐ Normal ☐ Hair fall/loss ☐ Unable to be in hot and cold condition
Eyes and vision	☐ Normal ☐ Able to read newspaper ☐ Abnormal for color vision ☐ Glaucoma	☐ Normal ☐ Able to read newspaper ☐ Abnormal for color vision ☐ Glaucoma	☐ Normal ☐ Able to read newspaper ☐ Abnormal for color vision ☐ Glaucoma
Respiratory System	☐ Normal ☐ Dry cough ☐ Dry cough and bleeding	☐ Normal ☐ Dry cough ☐ Dry cough and bleeding	☐ Normal ☐ Dry cough ☐ Dry cough and bleeding
Gastro-intestinal System	☐ Normal ☐ Heart burn ☐ Nausea, vomiting	☐ Normal ☐ Heart burn ☐ Nausea, vomiting	☐ Normal ☐ Heart burn ☐ Nausea, vomiting

Evaluation Type	Month ….. Date………….	Month ….. Date………….	Month ….. Date………….
	☐ Constipation ☐ Abdominal pain	☐ Constipation ☐ Abdominal pain	☐ Constipation ☐ Abdominal pain
Neurologic System	☐ Normal ☐ Memory decrease ☐ Frequently loss of memory	☐ Normal ☐ Memory decrease ☐ Frequently loss of memory	☐ Normal ☐ Memory decrease ☐ Frequently loss of memory
Muscle and bone	☐ Normal ☐ Joint pain ☐ Joint swelling ☐ Muscle pain ☐ Back pain	☐ Normal ☐ Joint pain ☐ Joint swelling ☐ Muscle pain ☐ Back pain	☐ Normal ☐ Joint pain ☐ Joint swelling ☐ Muscle pain ☐ Back pain
Glycaemia	☐ Normal ☐ Hypoglycemia, Frequency……../month ☐ Hyperglycemia, Frequency……../month	☐ Normal ☐ Hypoglycemia, Frequency……../month ☐ Hyperglycemia, Frequency……../month	☐ Normal ☐ Hypoglycemia, Frequency……../month ☐ Hyperglycemia, Frequency……../month
Food behavior	☐ Suitable/well-controlled Please state……………… ☐ Not suitable/uncontrolled please state………	☐ Suitable/well-controlled Please state……………… ☐ Not suitable/uncontrolled please state………	☐ Suitable/well-controlled Please state……………… ☐ Not suitable/uncontrolled please state………
Physical activity behavior	☐ Physical activity >= 150 min/week ☐ Physical activity less than 150 min/week ☐ No physical activity, reason………………… Please state the type of activity………………..	☐ Physical activity >= 150 min/week ☐ Physical activity less than 150 min/week ☐ No physical activity, reason………………… Please state the type of activity………………..	☐ Physical activity >= 150 min/week ☐ Physical activity less than 150 min/week ☐ No physical activity, reason………………… Please state the type of activity………………..
Risk factors and behavior	☐ Obesity ☐ Not physically active ☐ Smoking ☐ Drinking alcohol ☐ Stress ☐ Dyslipidemia	☐ Obesity ☐ Not physically active ☐ Smoking ☐ Drinking alcohol ☐ Stress ☐ Dyslipidemia	☐ Obesity ☐ Not physically active ☐ Smoking ☐ Drinking alcohol ☐ Stress ☐ Dyslipidemia
Medications, please state which medication and dosing	1………………………… 2………………………… 3………………………… 4………………………… 5………………………… 6…………………………	1………………………….. 2………………………….. 3………………………….. 4………………………….. 5………………………….. 6…………………………..	1………………………….. 2………………………….. 3………………………….. 4………………………….. 5………………………….. 6…………………………..
Following medication plan	☐ Follow ☐ Not follow, please state…………………	☐ Follow ☐ Not follow, please state…………………	☐ Follow ☐ Not follow, please state…………………
Complications	☐ None ☐ Heart…… ☐ Eye…….. ☐ Kidney…… ☐ Feet………	☐ None ☐ Heart…… ☐ Eye…….. ☐ Kidney…… ☐ Feet………	☐ None ☐ Heart…… ☐ Eye…….. ☐ Kidney…… ☐ Feet………

Evaluation Type	Month ….. Date………….	Month ….. Date………….	Month ….. Date………….
Next appointment			
Recorder			
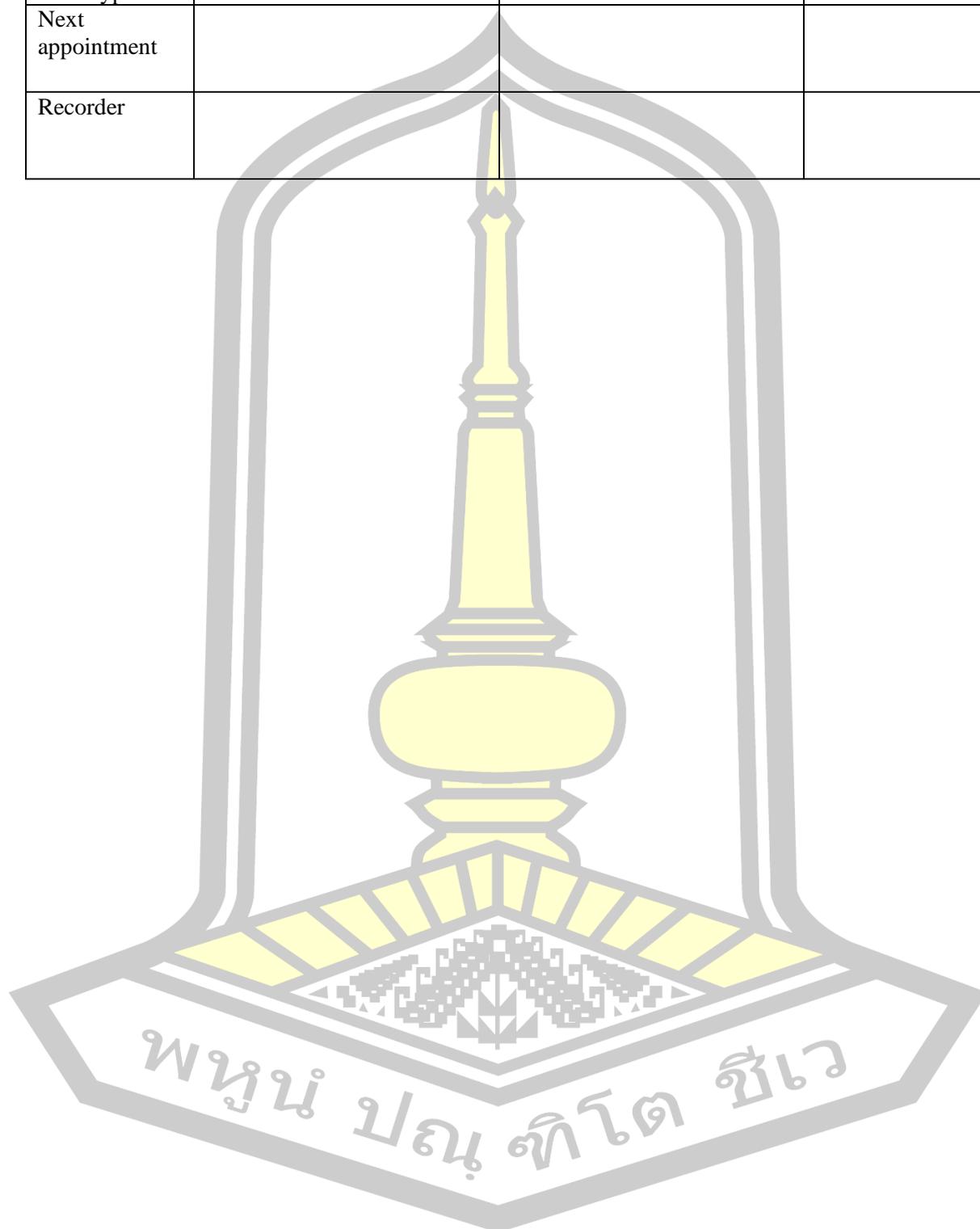
Table 48 Appendix 2-Drug-related Problems Evaluation Form

Evaluation Type	Month 0 Date………….	Month 3 Date………….	Month 6 Date………….
Drug-related problems (DRP)	☐ Not received the appropriate drug ☐ Too low dose ☐ Too high dose ☐ Adverse drug reaction ☐ Drug-drug interaction, food drug interaction ☐ Patient error, please state………….	☐ Not received the appropriate drug ☐ Too low dose ☐ Too high dose ☐ Adverse drug reaction ☐ Drug-drug interaction, food drug interaction ☐ Patient error, please state………….	☐ Not received the appropriate drug ☐ Too low dose ☐ Too high dose ☐ Adverse drug reaction ☐ Drug-drug interaction, food drug interaction ☐ Patient error, please state………….
Effect of DRP	☐ Hyperglycemia ☐ Hypoglycemia ☐ Hospitalization ☐ Poor control of glycemia ☐ No effect ☐ Other	☐ Hyperglycemia ☐ Hypoglycemia ☐ Hospitalization ☐ Poor control of glycemia ☐ No effect ☐ Other	☐ Hyperglycemia ☐ Hypoglycemia ☐ Hospitalization ☐ Poor control of glycemia ☐ No effect ☐ Other
Solutions	☐ Consult the doctors ☐ Adaptation of posology ☐ Stop medication ☐ Change medication ☐ Continue medication ☐ Other……………….	☐ Consult the doctors ☐ Adaptation of posology ☐ Stop medication ☐ Change medication ☐ Continue medication ☐ Other……………….	☐ Consult the doctors ☐ Adaptation of posology ☐ Stop medication ☐ Change medication ☐ Continue medication ☐ Other……………….
Effect from the solution	☐ Get better ☐ The same ☐ Other……………….	☐ Get better ☐ The same ☐ Other……………….	☐ Get better ☐ The same ☐ Other……………….
Recorder			
Note			

Table 49 Appendix 2-Medication Counseling Form

Number of counseling	Number of DRP	Type of DRP	Detail	Prevention and solution
1 Date………..				
2 Date………..				
3 Date………..				
4 Date………..				
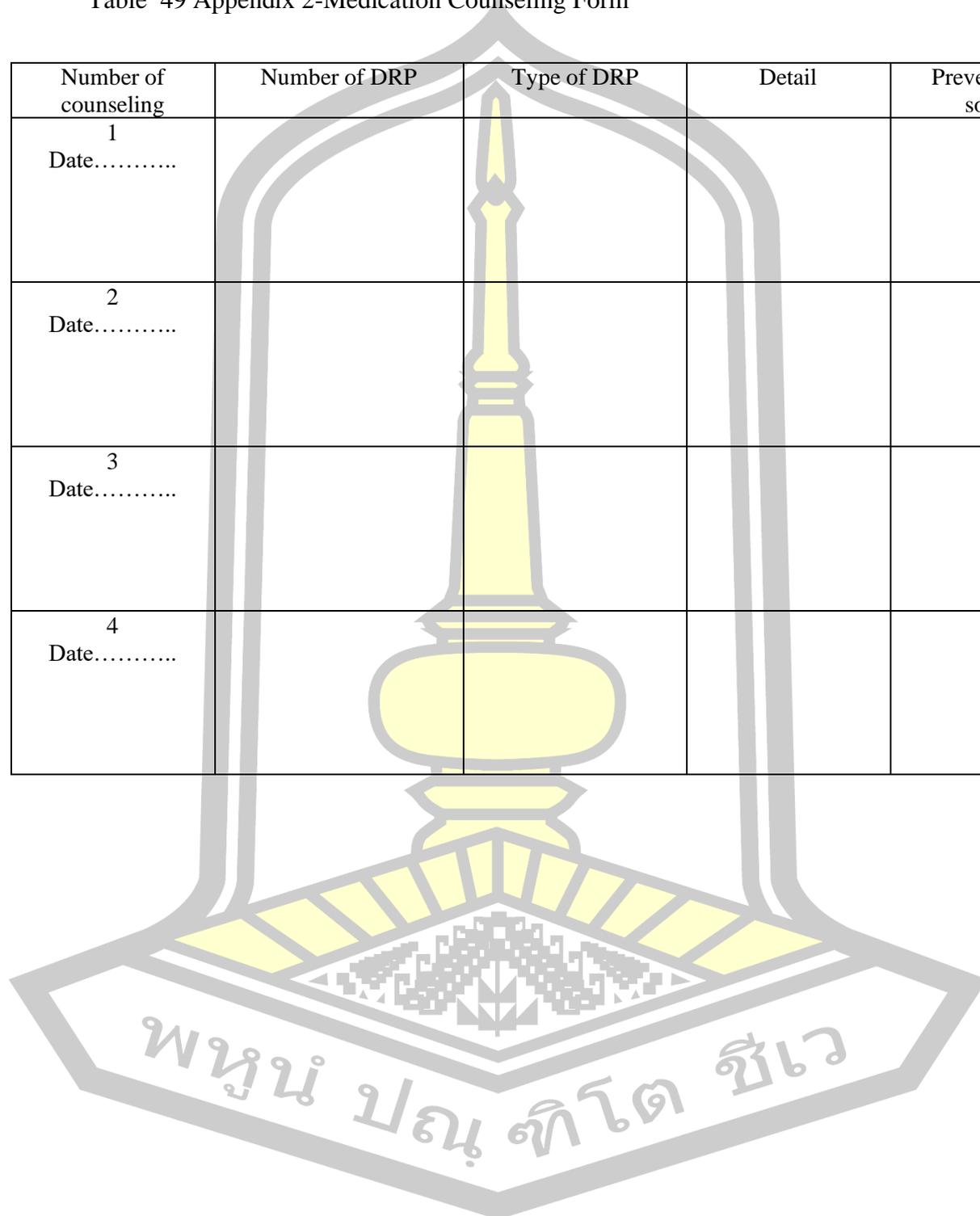
Table 50 Appendix 2-Home Visit Record Forms

Research ID……………………..
Date of visit…………………………...

Current symptom: ☐ Normal   ☐ Hyperglycemia   ☐ Hypoglycemia
Diabetes complications: ☐ No   ☐ Yes,
pleasestate……………………………...
Current medications: 1.
                      2.
                      3.
                      4.
                      4.
Psychosocial status: ☐ Normal
                      ☐ Depressed, please state the
problem…………………………….
Physical exam: BMI………………. Kg/m^2
                BP………………… mmHg
                Eye………………...
                Skin condition…………………….
                Sensation………………………...
                Albumin urea………………………
Laboratory record:

HbA1c…………………………
FBS……………………………
LDL……………………………
HDL……………………………
Cholesterol…………………….
Triglyceride……………………
GFR……………………………
Creatinine Clearance………......

Drug-related Problems: ☐ No   ☐ Yes, please
state…………………………...

Table 51 Appendix 2-Diabetes 39 Questionnaires Original Version

	Not affected at all						Extremely effect
1. Your diabetes medication schedule	1	2	3	4	5	6	7
2. Worries about money matters	1	2	3	4	5	6	7
3. Limited energy levels	1	2	3	4	5	6	7
4. Following your doctor's prescribed treatment plan for diabetes	1	2	3	4	5	6	7
5. Food restrictions required to control your diabetes	1	2	3	4	5	6	7
6. Concerns about your future	1	2	3	4	5	6	7
7. Other health problems besides diabetes	1	2	3	4	5	6	7
8. Stress or pressure in your life	1	2	3	4	5	6	7
9. Feelings of weakness	1	2	3	4	5	6	7
10. Restrictions on how far you can walk	1	2	3	4	5	6	7
11. Any daily exercises for your diabetes	1	2	3	4	5	6	7
12. Loss or blurring of vision	1	2	3	4	5	6	7
13. Not being able to do what you want	1	2	3	4	5	6	7
14. Having diabetes	1	2	3	4	5	6	7
15. Losing control of your blood sugar levels	1	2	3	4	5	6	7
16. Other illnesses besides diabetes	1	2	3	4	5	6	7
17. Testing your blood sugar levels	1	2	3	4	5	6	7
18. The time required to control your diabetes	1	2	3	4	5	6	7
19. The restrictions your diabetes places on your family and friends	1	2	3	4	5	6	7
20. Being embarrassed because you have diabetes	1	2	3	4	5	6	7
21. Diabetes interfering with your sex life	1	2	3	4	5	6	7
22. Feeling depressed or low	1	2	3	4	5	6	7
23. Problems with sexual functioning	1	2	3	4	5	6	7
24. Getting your diabetes well controlled	1	2	3	4	5	6	7
25. Complications from your diabetes	1	2	3	4	5	6	7
26. Doing things that your family and friends don't do	1	2	3	4	5	6	7
27. Keeping a record of your blood sugar levels	1	2	3	4	5	6	7
28. The need to eat at regular intervals	1	2	3	4	5	6	7
29. Not being able to do housework or other jobs around the house	1	2	3	4	5	6	7
30. A decreased interest in sex	1	2	3	4	5	6	7
31. Having to organize your daily life around diabetes	1	2	3	4	5	6	7
32. Needing to rest often	1	2	3	4	5	6	7
33. Problems in climbing stairs or walking up steps	1	2	3	4	5	6	7
34. Having trouble caring for yourself (dressing, bathing, or using the toilet)	1	2	3	4	5	6	7
35. Restless sleep	1	2	3	4	5	6	7
36. Walking more slowly than others	1	2	3	4	5	6	7
37. Being identified as a diabetic	1	2	3	4	5	6	7
38. Having diabetes interfere with your family life	1	2	3	4	5	6	7
39. Diabetes in general	1	2	3	4	5	6	7

Table 52 Appendix 2-Patient satisfaction questionnaire Thai version

แบบสอบถามความคิดเห็นกับความพึงพอใจของผู้ป่วยเบาหวานต่อการจัดการโรคเบาหวาน

แบบสอบถามนี้มีวัตถุประสงค์เพื่อพัฒนาเครื่องมือในการวัดความพึงพอใจ และ ความคิดเห็นต่อการจัดการ โรคเบาหวาน โดยแบบสอบถามแบ่งเป็น 4 ส่วน คือ ส่วนที่ 1 เป็นข้อมูลทั่วไปมีจำนวน 13 ข้อ ส่วนที่ 2 ความคิดเห็นต่อสุขภาพของผู้ป่วย จำนวน 13 ข้อ ส่วนที่ 3 มิติความพึงพอใจ จำนวน 20 ข้อ และส่วนที่ 4 ความคิดเห็นต่อเป้าหมายการรักษา จำนวน 13 ข้อ

คำแนะนำในการตอบ ขอให้ท่านทาเครื่องหมายกากบาท (X) ลงในช่องว่างข้างหน้าของตัวเลือกที่ ท่าน เลือกซึ่งท่านคิดว่างตรงกับตัวท่านมากที่สุด

ส่วนที่ 1 ข้อมูลทั่วไปของผู้ป่วย (Patient Characteristics)

1. เพศ ( ) 1.ชาย   ( ) 2.หญิง

2. วัน เดือน ปี เกิด................................

3. อาชีพ

  ( ) 1. ข้าราชการ   ( ) 2. รับจ้าง   ( ) 3. ค้าขาย

  ( ) 4. เกษตรกร   ( ) 5. เกษียณ   ( ) 6. อื่นๆ โปรดระบุ...........................

4.ระดับการศึกษาในปัจจุบัน

  ( ) 1. ไม่ได้รับการศึกษา   ( ) 2. ประถม   ( ) 3. มัธยมศึกษาตอนต้น

  ( ) 4. มัธยมศึกษาตอนปลาย   ( ) 5. อนุปริญญา   ( ) 6. ปริญญาตรี

  ( ) 7. สูงกว่าปริญญาตรี   ( ) 8. อื่นๆ โปรดระบุ............................

5. รายได้เฉลี่ยต่อเดือนของท่าน (รวมรายได้พิเศษอื่นๆแล้ว)

  ( ) 1. น้อยกว่าหรือเท่ากับ 5,000 บาท   ( ) 2. 5,001-10,000 บาท   ( ) 3. 10,001-15,000 บาท

  ( ) 4. 15,001-20,000 บาท   ( ) 5. มากกว่าหรือเท่ากับ 20,001 บาท

6. สถานะภาพสมรส

  ( ) 1.โสด   ( ) 2. แต่งงาน ( ) 3. หม้าย ( ) 4. หย่า   ( ) 5. แยกกันอยู่

7. จำนวนสมาชิกในบ้านที่อยู่อาศัยร่วมกับท่านประจำ................................คน

  โปรดระบุ ความสัมพันธ์ ( ) พ่อ/แม่ ( ) ปู่ /ย่า ( ) พี่/น้อง   ( ) ลูก ( ) หลาน   ( ) อื่นๆ

8. ระยะทางจากบ้านถึงหน่วยบริการประจำที่ท่านรับการรักษาโรคเบาหวาน..............................กิโลเมตร

  8.1. ชื่อของหน่วยบริการประจำที่ท่านรับการรักษาโรคเบาหวานเป็นประจำ......................................

10. ระยะเวลาของการเป็นโรคเบาหวาน ....(กี่) เดือน...................................(กี่) ปี

11. นอกจากโรคเบาหวาน ท่านมีโรคร่วมอื่นหรือไม่

( ) 1. ไม่มี   ( ) 2. มี (สามารถระบุได้มากว่า 1 โรค)...

12. แหล่งข้อมูลข่าวสารการรับรู้เกี่ยวกับโรคเบาหวานที่ท่านเคยได้รับพายใน 3 เดือนที่ผ่านมา (สามารถเลือก ได้ มากกว่า 1 ข้อ)

( ) 1. ผู้ให้บริการ (หมอ/พยาบาล/เภสัชกร/นักโภชนาการ)   ( ) 2. สื่อวิทยุ โทรทัศน์

( ) 3. สื่อสังคมออนไลน์ (Facebook, Line, Twitter...)   ( ) 4. เพื่อน/ญาติพี่น้อง

( ) 5. อื่นๆ โปรดระบุ............................

13. **รูปแบบประกันสุขภาพที่ท่านใช้อยู่ณปัจจุบัน** (สามารถเลือกได้มากกว่า 1 ข้อ)

( ) 1. **ประกันสุขภาพถ้วนหน้า**   ( ) 2. **สิทธิ์ประกันข้าราชการ**

( ) 3. **ประกันสังคม**   ( ) 4. **ประกันสุขภาพเอกชน**

( ) 5. อื่นๆ โปรดระบุ............................

<u>ส่วนที่ 2 ความคิดเห็นต่อสุขภาพผู้ป่วย</u>

1. ท่านมีองค์ความรู้ในระดับใดเพื่อใช้ในการดูแลโรคเบาหวานของท่านตัวอย่างเช่นการควบคุมระดับน้ำตาล ไม่ได้จะทำให้เกิดภาวะแทรกซ้อนที่รุนแรง และ การรับประทานยาอย่างต่อเนื่องจะช่วยชะลอไม่ให้เกิดภาวะ แทรกซ้อนที่รุนแรง เป็นต้น

( ) 1. น้อยที่สุด   ( ) 2. น้อย   ( ) 3. ปานกลาง   ( ) 4. มาก   ( ) 5. มากที่สุด

2. ท่านมีความสามารถรับมือกับโรคเบาหวานของท่านได้ในระดับใด ตัวอย่างเช่น ปรับเปลี่ยนพฤติกรรมเพื่อ รักษาโรคเบาหวานอย่างเช่นไม่กินหวาน, ออกกำลังกายเป็นประจำ เป็นต้น

( ) 1. น้อยที่สุด   ( ) 2. น้อย   ( ) 3. ปานกลาง   ( ) 4. มาก   ( ) 5. มากที่สุด

3. ท่านมีกำลังใจเพื่อที่จะดูแลโรคเบาหวานของท่านในระดับใด ตัวอย่างเช่น กำลังใจจากครอบครัว, กำลังใจจากตัวท่านเอง เป็นต้น

( ) 1. น้อยที่สุด ( ) 2. น้อย   ( ) 3. ปานกลาง   ( ) 4. มาก   ( ) 5. มากที่สุด

4. ท่านมีความสามารถในระดับใดเพื่อที่จะควบคุมการรับประทานยารักษาโรคเบาหวานตัวอย่างเช่นการรับประทานยาอย่างสม่ำเสมอเป็นต้น

( ) 1. น้อยที่สุด ( ) 2. น้อย ( ) 3. ปานกลาง ( ) 4. มาก ( ) 5. มากที่สุด

5. ท่านมีความภูมิใจต่อความสามารถในการดูแล**สุขภาพ**ของท่านในระดับใด

( ) 1. น้อยที่สุด ( ) 2. น้อย ( ) 3. ปานกลาง ( ) 4. มาก ( ) 5. มากที่สุด

6. ครอบครัวเป็นแรงผลักดันให้ท่านดูแลตัวเองได้ดีขึ้นในระดับใด

( ) 1. น้อยที่สุด ( ) 2. น้อย ( ) 3. ปานกลาง ( ) 4. มาก ( ) 5. มากที่สุด

7. ครอบครัวมีส่วนร่วมพูดคุยกับผู้ให้บริการเพื่อให้เข้าใจการดูแลท่านดียิ่งขึ้นในระดับใด

( ) 1. น้อยที่สุด ( ) 2. น้อย ( ) 3. ปานกลาง ( ) 4. มาก ( ) 5. มากที่สุด

8. ครอบครัวของท่านใส่ใจเรื่องการเตรียมอาหารสำหรับท่านในระดับใด

( ) 1. น้อยที่สุด ( ) 2. น้อย ( ) 3. ปานกลาง ( ) 4. มาก ( ) 5. มากที่สุด

9. ครอบครัวของท่านใส่ใจเรื่องการรับประทานยารักษาโรคเบาหวานของท่านในระดับใด

( ) 1. น้อยที่สุด ( ) 2. น้อย ( ) 3. ปานกลาง ( ) 4. มาก ( ) 5. มากที่สุด

 10. ในชุมชนของท่านมีการรวมกลุ่มหรือชมรมโรคเบาหวานเพื่อช่วยเหลือกันในระดับใด

( ) 1. น้อยที่สุด ( ) 2. น้อย ( ) 3. ปานกลาง ( ) 4. มาก ( ) 5. มากที่สุด

11. ในชุมชนของท่านมีการจัดกิจกรรมให้ความรู้เพื่อการดูแลโรคเบาหวานในระดับใด

( ) 1. น้อยที่สุด ( ) 2. น้อย ( ) 3. ปานกลาง ( ) 4. มาก ( ) 5. มากที่สุด

12. ในชุมชนของท่านมีการจัดกิจกรรมสนับสนุนการดูแลโรคเบาหวาน เช่น เต้นแอโรบิก วิ่ง ในระดับใด

( ) 1. น้อยที่สุด ( ) 2. น้อย ( ) 3. ปานกลาง ( ) 4. มาก ( ) 5. มากที่สุด

13. ในชุมชนของท่านมีงบประมาณในการจัดกิจกรรมเพื่อสนับสนุนการดูแลสุขภาพของผู้ป่วยโรคเบาหวาน ในระดับใด

( ) 1. น้อยที่สุด ( ) 2. น้อย ( ) 3. ปานกลาง ( ) 4. มาก ( ) 5. มากที่สุด

ส่วนที่ 3 มิติของความพึงพอใจ (Domains of Satisfaction)

ในแต่ละคำถามต่อไปนี้ ต้องการทราบว่าความพึงพอใจของท่าน ต่อปัจจัยเหล่านี้มีมากน้อยเพียงใด โดยให้ท่านทำ เครื่องหมาย กากบาท (X) ลงในช่องว่างข้างคำถาม โดยมีระดับความพึงพอใจดังต่อไปนี้

5 = พอใจมากที่สุด 4 = พอใจมาก 3 = ไม่แน่ใจ 2= ไม่ค่อยพอใจ 1 = ไม่พอใจมากที่สุด

n/a = ไม่เคยรับบริการ หรือ ไม่สามารถตอบได้

ลำ ดับ	คำถาม	ระดับความพึงพอใจ					
		5	4	3	2	1	n/a
มาตรฐานการบริการ							
1	ท่านพอใจที่มีระบบการบริการรักษาโรคเบาหวานที่แยกเป็นสัดส่วน อย่างชัดเจน						
2	ท่านพอใจต่อมาตรฐานการตรวจสุขภาพอย่างต่อเนื่องทุกครั้งที่เข้ารับการรักษา (ได้แก่ ตรวจความดันโลหิต น้ำหนักและระดับน้ำตาล)						
3	ท่านพอใจต่อมาตรฐานการตรวจสุขภาพประจำปีที่ท่านได้รับ (เช่น ตรวจตา ตรวจไต ตรวจเท้า ตรวจหัวใจ)						
4	ท่านพอใจที่ได้รับการบริการที่ครอบคลุมภายใต้ระบบประกันสุขภาพที่ท่านมี (บัตรทอง 30 บาท ประกันสังคม ข้าราชการ เป็นต้น)						
รูปแบบของการบริการ							
5	ท่านพอใจที่มีระบบให้ข้อมูลความรู้เกี่ยวกับโรคเบาหวานแก่ท่าน						
6	ท่านพอใจที่มีระบบติดตามผลการรักษาโรคเบาหวานอย่างต่อเนื่อง						
7	ท่านพอใจต่อระบบการออกไปเยี่ยมบ้านของหน่วยบริการ						
8	ท่านพอใจต่อระบบเก็บข้อมูลของหน่วยบริการ เช่น การตอบแบบสอบ ถามความพึงพอใจที่หน่วยบริการจัดทำไว้ให้						
ความสามารถทางวิชาชีพของทีมผู้ให้บริการประกอบด้วย หมอ พยาบาล นักโภชนาการ							
9	ท่านพอใจที่ผู้ให้บริการหลายคนที่รักษาท่านนั้นได้เข้าใจประวัติการรักษา ของท่านมาก่อน						
10	ท่านพอใจในความสามารถของทีมผู้ให้บริการที่ได้ให้ข้อมูลที่เป็นประโยชน์ในการดูแลสุขภาพเพื่อการรักษาโรคเบาหวานของท่าน						
11	ท่านพอใจที่ทีมผู้ให้บริการวางแผนการรักษาอย่างเฉพาะเจาะจงที่เหมาะ สมกับวิถีชีวิตของท่าน						
12	ท่านพอใจที่ทีมผู้ให้บริการให้เวลาในการดูแลเอาใจใส่ในการรักษาโรคเบาหวานของท่านอย่างต่อเนื่องและเพียงพอ						

ลำ ดับ	คำถาม	ระดับความพึงพอใจ					
		5	4	3	2	1	n/a
ความสามารถทางวิชาชีพของเภสัชกร							
13	ท่านพอใจที่เภสัชกรได้เข้าใจประวัติการรักษาและการใช้ยาของท่านมาก่อน						
14	ท่านพอใจในความสามารถของเภสัชกรที่ได้ให้ข้อมูลที่เป็นประโยชน์โดยเฉพาะเรื่องการใช้ยาเพื่อการรักษาโรคเบาหวานของท่าน						
15	ท่านพอใจที่เภสัชกรวางแผนการใช้ยาอย่างเฉพาะเจาะจงที่เหมาะสมกับ วิถีชีวิตของท่าน						
16	ท่านพอใจที่เภสัชกรให้เวลาในการดูแลเอาใจใส่ในการรักษาโรคเบาหวาน ของท่านอย่างต่อเนื่องและเพียงพอ						
ทักษะการสื่อสารของผู้ให้บริการประกอบด้วย หมอ/พยาบาล/เภสัชกร/นักโภชนาการ							
17	ท่านพอใจที่ในระหว่างการพูดคุย ท่านได้มีการ ซักถาม ตอบคำถามร่วมกับ ผู้ให้บริการ						
18	ท่านพอใจต่อการแสดงออกด้วยความเป็นมิตรของผู้ให้บริการในระหว่างการพูดคุย						
19	ท่านพอใจที่ผู้ให้บริการได้ถามความคิดเห็นของท่านเพื่อการวางแผนการรักษาร่วมกัน						
20	ท่านพอใจที่ผู้ให้บริการพูดคุยเรื่องแผนการรักษากับท่านด้วยภาษาที่เข้าใจง่าย						

ส่วนที่ 4 มิติของความคิดเห็นต่อการบริการ และเป้าหมายการรักษา (Domains of Attitude to Service and Treatment Goal)

ในแต่ละคำถามต่อไปนี้ ต้องการทราบว่าความคิดเห็นของท่าน ต่อปัจจัยเหล่านี้มีความเห็นด้วยมากน้อยเพียง ใดโดยให้ท่านทำ เครื่องหมาย กากบาท (X) ลงในช่องว่างข้างคำถาม โดยมีระดับความคิดเห็นดังต่อไปนี้

5 = เห็นด้วยอย่างยิ่ง   4 = เห็นด้วย   3 = ไม่แน่ใจ   2= ไม่เห็นด้วย   1 = ไม่เห็นด้วยอย่างยิ่ง

n/a = ไม่เคยรับบริการ หรือ ไม่สามารถตอบได้

ลำ ดับ	คำถาม	ระดับความคิดเห็น					
		5	4	3	2	1	n/a
การเข้าถึงการให้บริการ (Accessibility to service)							
1	ท่านคิดว่าระยะทางจากบ้านถึงหน่วยบริการภาครัฐสะดวกสบายสำหรับท่าน						
2	การเดินทางของท่านเพื่อเข้ารับการรักษาโรคเบาหวานที่หน่วยบริการภาครัฐสะดวกสบายสำหรับท่าน						
3	ท่านใช้ระยะเวลาในการรอคอยไม่นานเพื่อเข้ารับการตรวจรักษาโรคเบาหวานที่หน่วยบริการภาครัฐ						
4	ค่าใช้จ่ายในการรักษาโรคเบาหวาน (เช่น ค่าเดินทาง ค่ายาที่ต้องจ่าย เพิ่มเติม) ไม่สูง						

ลำ ดับ	คำถาม	ระดับความคิดเห็น					
		5	4	3	2	1	n/a
	เกินกว่าที่ท่านจะจ่ายได้						
ระบบบริการสุขภาพ (Healthcare system)							
5	ระบบประกันสุขภาพที่ท่านใช้อยู่ครอบคลุมค่าใช้จ่ายด้านยาและ การรักษาอย่างครบถ้วน						
6	หน่วยบริการที่ท่านรับการรักษาต้องมีระบบส่งต่อผู้ป่วยฉุกเฉิน (เช่นรถพยาบาล) ไปรับการรักษาที่โรงพยาบาลได้ทันท่วงที						
7	ระบบฐานข้อมูล เช่นกานบันทึกประวัติผู้ป่วยของหน่วยบริการมีความ ทันสมัยเป็นต้น						
8	พื้นที่การให้บริการมีความทันสมัยและมีสื่อการเรียนรู้เรื่องสุขภาพเช่น โปสเตอร์ แผ่น พับ หนังสือ เป็นต้น						
เป้าหมายการรักษา (Target goal)							
9	ท่านได้รับสิทธิ์การรักษาที่เท่าเทียมพายใต้ระบบประกันสุขภาพที่ท่านใช้						
10	การเข้าถึงการให้บริการได้อย่างสะดวกทำให้สามารถบรรลุเป้าหมายการ รักษา						
11	การตรวจสุขภาพที่เหมาะสมและมีมาตรฐานทำให้สามารถบรรลุเป้าหมาย การรักษา						
12	ความสามารถรับมือกับโรคเบาหวานของท่านรวมถึงการมีส่วนร่วมของ ครอบครัวและชุมชนทำให้ท่านสามารถควบคุมระดับน้ำตาลได้ตามเป้า หมาย						

ขอขอบคุณทุกท่านที่ให้ความร่วมมือในกรตอบแบบสอบถาม
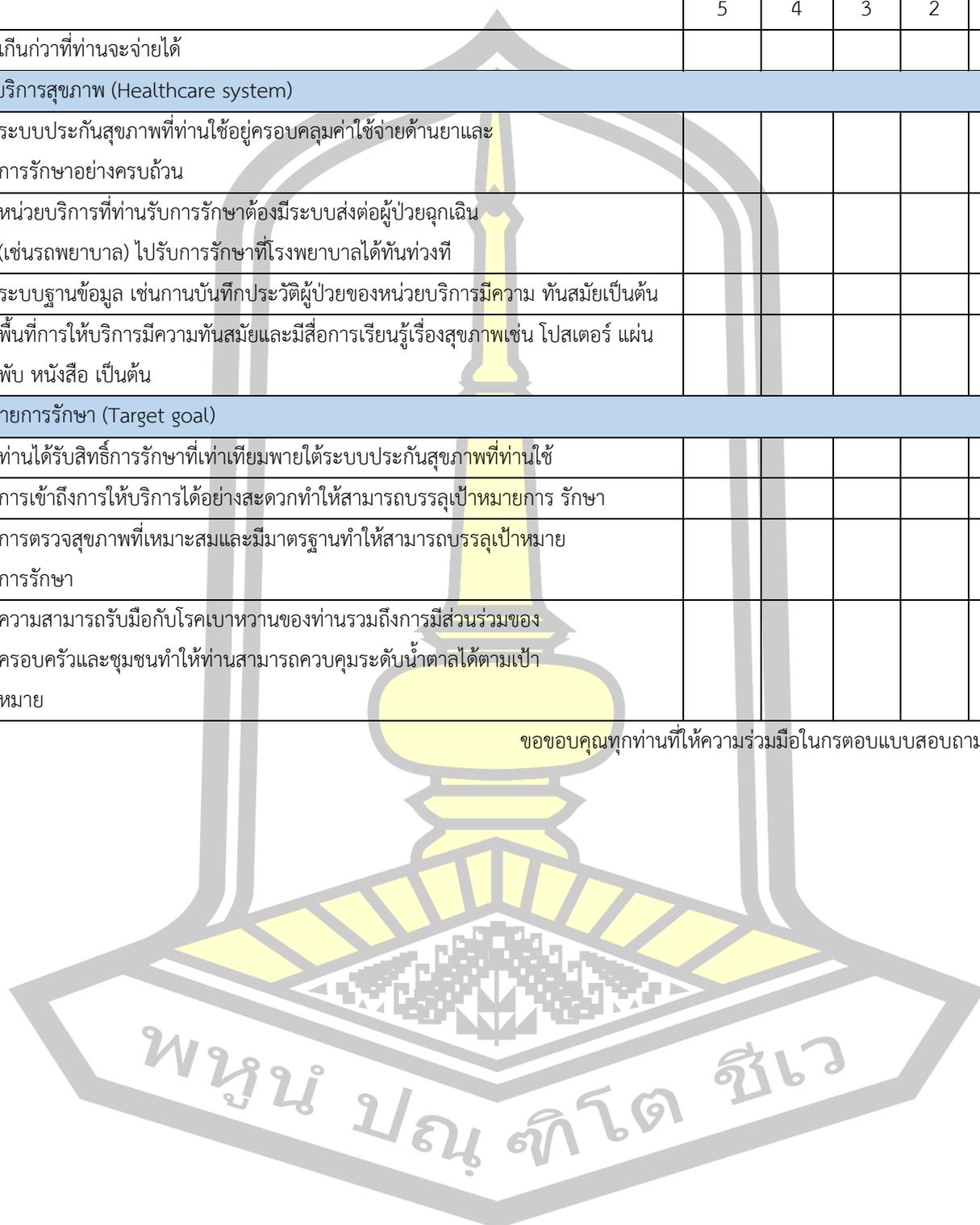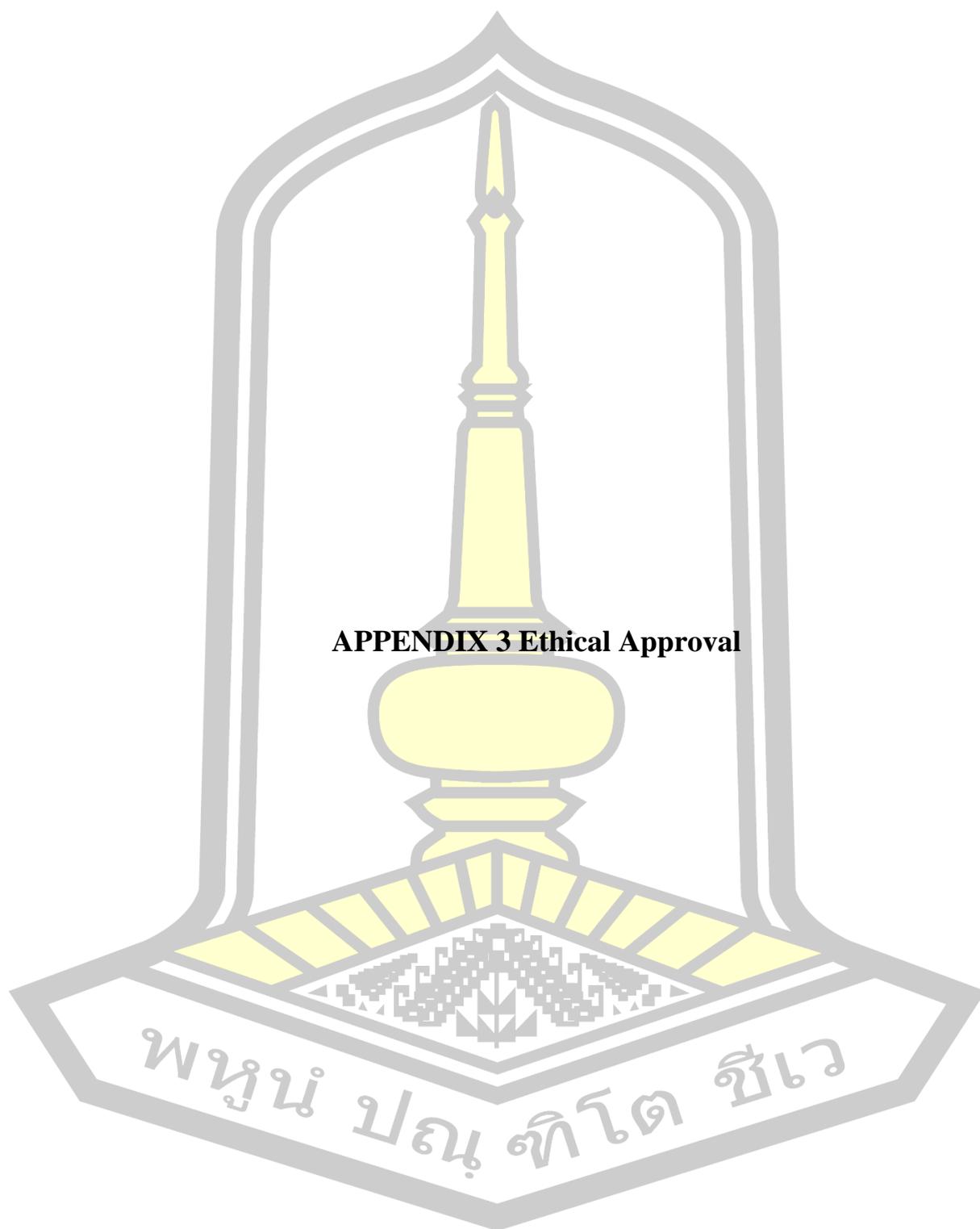
APPENDIX 3 Ethical Approval

Appendix 3.1 Ethical approval for questionnaire development from MSU Ethics Committee
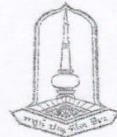
คณะกรรมการจริยธรรมการวิจัยในมนุษย์ มหาวิทยาลัยมหาสารคาม

เอกสารรับรองโครงการวิจัย

เลขที่การรับรอง : 063 / 2561

ชื่อโครงการวิจัย (ภาษาไทย) การพัฒนาแบบสอบถามความพึงพอใจและคุณภาพชีวิตต่อการจัดการโรคเบาหวาน

ชื่อโครงการวิจัย (ภาษาอังกฤษ) : Development of patient satisfaction and quality of life to diabetes management.

ผู้วิจัย : ผู้ช่วยศาสตราจารย์ ดร.พยอม สุขเอนกนันท์
หน่วยงานที่รับผิดชอบ : คณะเภสัชศาสตร์
สถานที่ทำการวิจัย : จังหวัดมหาสารคาม

ประเภทการพิจารณาแบบ : คณะกรรมการเต็มชุด

วันที่รับรอง : 30 เมษายน 2561   วันหมดอายุ : 29 เมษายน 2562

       ข้อเสนอการวิจัยนี้ ได้รับการพิจารณาและให้ความเห็นชอบจากคณะกรรมการจริยธรรมการวิจัยในมนุษย์ มหาวิทยาลัยมหาสารคามแล้ว และอนุมัติในด้านจริยธรรมให้ดำเนินการศึกษาวิจัยเรื่องข้างต้นได้ บนพื้นฐานของโครงร่างงานวิจัยที่คณะกรรมการฯ ได้รับและพิจารณา เมื่อเสร็จสิ้นโครงการแล้วให้ผู้วิจัยส่งแบบฟอร์มการปิดโครงการและรายงานผลการดำเนินงานมายังคณะกรรมการจริยธรรมการวิจัยในมนุษย์ มหาวิทยาลัยมหาสารคาม หรือหากมีการเปลี่ยนแปลงใดๆ ในโครงการวิจัย ผู้วิจัยจักต้องยื่นขอรับการพิจารณาใหม่

(ศาสตราจารย์ สัมพันธ์ ฤทธิเดช)
ประธานคณะกรรมการจริยธรรมการวิจัยในมนุษย์

ทั้งนี้ การรับรองนี้มีเงื่อนไขดังที่ระบุไว้ด้านหลังทุกข้อ (ดูด้านหลังของเอกสารรับรองโครงการวิจัย)

Appendix 3.2 Ethical approval for clinical trial from MSU Ethics Committee

MAHASARAKHAM UNIVERSITY ETHICS COMMITTEE FOR

RESEARCH INVOLVING HUMAN SUBJECTS

Certificate of Approval

Approval number: 023 / 2019

Title : Outcomes of Diabetes Care Intervention led by Pharmacists in Lao PDR.

Principal Investigator : Ms. Phoutsathaphone Sibounheuang
Responsible Department : Faculty of Pharmacy
Research site : Lao PDR

Review Method : Expedited review

Date of Manufacture : 20 February 2019   expire : 19 February 2020

This research application has been reviewed and approved by the Ethics Committee for Research Involving Human Subjects, Mahasarakham University, Thailand. Approval is dependent on local ethical approval having been received. Any subsequent changes to the consent form must be re-submitted to the Committee.

(Prof. Dr.Sampan Rittidech)
Chairman

Approval is granted subject to the following conditions: (see back of this Certificate)

Appendix 3.3 Ethical approval for clinical trial from MSU Ethics Committee (Extended review)

MAHASARAKHAM UNIVERSITY ETHICS COMMITTEE FOR

RESEARCH INVOLVING HUMAN SUBJECTS

Certificate of Approval

Approval number: 023 / 2019

Title : Outcomes of Diabetes Care Intervention led by Pharmacists in Lao PDR.

Principal Investigator : Ms. Phoutsathaphone Sibounheuang
Responsible Department : Faculty of Pharmacy
Research site : Lao PDR

Review Method : Expedited review

Date of Manufacture : 26 June 2020   expire : 25 June 2021
Time of Renewal 1   Expiry Date : 25 June 2021

   This research application has been reviewed and approved by the Ethics Committee for Research Involving Human Subjects, Mahasarakham University, Thailand. Approval is dependent on local ethical approval having been received. Any subsequent changes to the consent form must be re-submitted to the Committee.

Ratru S.

(Asst. Prof. Ratree Sawangjit)
Chairman

Approval is granted subject to the following conditions: (see back of this Certificate)

Appendix 3.4 Ethical approval for questionnaire development from National Ethics Committee Lao PDR

Lao People's Democratic Republic
Peace Independence Democracy Unity Prosperity

Ministry of Health
National Ethics Committee
for Health Research (NECHR)

No _081_ /NECHR
Vientiane Capital 22 / 8 / 18

Approval Notice

Ms Phoutsathaphone Sibounheuang
Email: noysbh@gmail.com
Tel: +85620550083420

RE: Ethical Approval for Health Research

Title: "**Development tool of patient satisfaction and quality of life to diabetes management**"

(submission ID:2018.82.Vie).

Dear Ms Phoutsathaphone Sibounheuang,

The National Ethics Committee for Health Research of the Lao People's Democratic Republic have reviewed and approved your research.

Please note the following information about your approved research protocol:

Approval period: August 2018 – August 2019
Approved Subject Enrollment: 150
Study site: Vientiane Capital
Sponsor: Mahasarakham University. **Budget**: 10,360,000 LAK
Implementing Panel/Project Investigator: Ms. Phoutsathaphone Sibounheuang

Please note that the Ethics Committee reserves the right to ask for further questions, seek additional or monitor the conduct of your research and consent process.

Principle Investigator is required to notify the Secretary of the National Ethic Committee for Health Research:
- Any significant change to the project and the reason for that change, including an indication of ethical implications (if any);
- Serious adverse effects on participants and the action taken to address those effects;
- Any other unforeseen events or unexpected developments that merit notification;
- The inability of the Principal Investigator to continue in that role, or any other change in research personnel involved in the project;
- Any expiry of the insurance coverage provided with respect to sponsored clinical trials and proof of re-insurance;
- A delay of more than 12 months in the commencement of the project; and,
- Termination or closure of the project.

Additionally, the Principal Investigator is required to submit a progress report on the anniversary of approval and on completion of the project.

President of National Ethics Committee for Health Research

Prof.Dr. Douangdao SOUKALOUN

Appendix 3.5 Ethical approval for clinical trial from National Ethics Committee Lao PDR

Lao People's Democratic Republic
Peace Independence Democracy Unity Prosperity
===== 000 =====

Ministry of Health
National Ethics Committee
for Health Research (NECHR)

No 13 /NECHR
Vientiane Capital 14./0.2/2019

Approval Notice

Ms. Phoutsathaphone Sibounheuang
Email: noysbh@gmail.com
Tel: +85620 55008342

RE: Ethical Approval for Health Research

Title: "Outcomes of Diabetes Care Intervention led by Pharmacists in Lao PDR" (Submission ID: 2019.4.Vie)

Dear Ms. Phoutsathaphone Sibounheuang.

The National Ethics Committee for Health Research of the Lao People's Democratic Republic have reviewed and approved your research.

Please note the following information about your approved research protocol:

Approval period: February 2019 – February 2020
Approved Subject Enrollment: 158 (79 for each group)
Study Site: Vientiane Capital
Sponsor: Mahasarakham University **Budget**: 24 152 400 Kip (LAK)
Implementing Panel/Project Investigator: Ms. Phoutsathaphone Sibounheuang

Please note that the Ethics Committee reserves the right to ask for further questions, seek additional or monitor the conduct of your research and consent process.

Principle Investigator is required to notify the Secretary of the National Ethic Committee for Health Research:
- **Any significant change to the project and the reason for that change, including an indication of ethical implications (if any);**
- **Serious adverse effects on participants and the action taken to address those effects;**
- **Any other unforeseen events or unexpected developments that merit notification;**
- **The inability of the Principal Investigator to continue in that role, or any other change in research personnel involved in the project;**
- **Any expiry of the insurance coverage provided with respect to sponsored clinical trials and proof of re-insurance;**
- **A delay of more than 12 months in the commencement of the project; and,**
- **Termination or closure of the project.**

Additionally, the Principal Investigator is required to submit a progress report on the anniversary of approval and on completion of the project.

President of National Ethics Committee for Health Research

Prof.Dr. Douangdao SOUKALOUN

Appendix 3.6 Ethical approval for clinical trial from National Ethics Committee Lao PDR (Extended review)

Lao People's Democratic Republic
Peace Independence Democracy Unity Prosperity
===== 000 =====

Ministry of Health
National Ethics Committee
for Health Research (NECHR)

No 07 /NECHR
Vientiane Capital 06 / 02 / 2020

Approval Notice

Ms. Phoutsathaphone Sibounheuang
Email: noysbh@gmail.com
Tel: +85620 55008342

RE: Ethical Approval for Health Research

Title: "Outcomes of Diabetes Care Intervention led by Pharmacists in Lao PDR" (Request for Extension Submission ID: 2019.4.Vie)

Dear Ms. Phoutsathaphone Sibounheuang,

The National Ethics Committee for Health Research of the Lao People's Democratic Republic have reviewed and approved your research.

Please note the following information about your approved research protocol:

Approval period: January 2020 – January 2021
Approved Subject Enrollment: 158 (79 for each group)
Study Site: Vientiane Capital
Sponsor: Mahasarakham University **Budget:** 24 152 400 Kip (LAK)
**Implementing Panel/Project Investigator:** Ms. Phoutsathaphone Sibounheuang

Please note that the Ethics Committee reserves the right to ask for further questions, seek additional or monitor the conduct of your research and consent process.

Principle Investigator is required to notify the Secretary of the National Ethic Committee for Health Research:

- Any significant change to the project and the reason for that change, including an indication of ethical implications (if any);
- Serious adverse effects on participants and the action taken to address those effects;
- Any other unforeseen events or unexpected developments that merit notification;
- The inability of the Principal Investigator to continue in that role, or any other change in research personnel involved in the project;
- Any expiry of the insurance coverage provided with respect to sponsored clinical trials and proof of re-insurance;
- A delay of more than 12 months in the commencement of the project; and,
- Termination or closure of the project.

Additionally, the Principal Investigator is required to submit a progress report on the anniversary of approval and on completion of the project.

President of National Ethics Committee for Health Research

Prof.Dr. Douangdao SOUKALOUN

**APPENDIX 4 Accepted manuscript for publication on Title:
Patients' and healthcare providers' perspectives on diabetes
management: A systematic review of qualitative studies**

Patients' and healthcare providers' perspectives on diabetes management: A systematic review of qualitative studies

Phoutsathaphone Sibounheuang (Ph.D Student)[a,*], Phayom Sookaneknun Olson (Pharm.D., Ph.D.)[b], Pattarin Kittiboonyakun (Ph.D.)[c]

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ARTICLE INFO

ABSTRACT

Background: Despite the availability of evidence-based guidance to deliver effective diabetes care, many patients do not achieve goals as recommendations. This systematic review was to synthesize useful insight perspectives by patients and providers to identify factors related to diabetes management using Chronic Care Model.
Objective: This systematic review aimed to synthesize perspectives by patients and providers in order to identify factors related to diabetes management.
Methods: Databases were searched including CINAHL, PubMed, Science Direct, and Web of Science from January 2001 to September 2017. Combination of search terms were used like 'qualitative,' 'diabetes management,' 'patients' perspective,' and 'provider's perspective.' All qualitative studies used were in English with available full text. Chronic Care Model framework was used to analyze the content and to organize the findings.
Results: Of 108 articles used, only 23 of this met the inclusion criteria. Nine factors were identified including community linkage, health service system for diabetic patients, continuity of care, self-management, providers' support, referral system, patient-provider interaction, increasing competency of healthcare providers and family support. Community linkage was revealed to be an important factor to encourage diabetic patients to look after their disease while health service system showed the limit of accessibility due to location, medical service availability, finance, information, and time. Continuity of care has shown lack of coordination in referral system within a health care team and self-management was dependent on the knowledge, beliefs, attitude, and behavior of the patient. More so, providers' support through an effective plan and/or strategy has also indicated to help patients get their target goal. Poor interaction between patients and health providers was found to be largely attributed to language barrier and lack of communication skill. Improving competency for the health providers can be achieved through continuing professional education. Both perspectives supported a family involvement and community resources for diabetes patients.
Conclusion: Factors related to diabetes management from nine themes showed various gaps in both perspectives. Further research on new models for diabetes management is required.

Introduction

Diabetes is an important public health problem—one of four priority non-communicable diseases (NCDs) targeted for action by world leaders. Globally, 451 million adults aged 18–99 were living with diabetes in 2017 and this is expected to be 693 million in 2045. Prevalence was estimated to be 8.4% in 2017 and is predicted to rise to 9.9% in 2045.[1] Despite the well-known long-term benefits of adequate glycemic control on reducing complications and death, many diabetic

patients still fail to achieve treatment targets, poorly adhere to the treatment, and thus remain at risk for complications. Due to greater diabetes prevalence and the focus of improving health services for diabetes shifted from secondary to primary care, the improvements of such quality of cares were found in previous studies in the UK,[2] Norway,[3] and Australia.[4]

A systematic review of 19 qualitative studies revealed some barriers in diabetes management covering four themes: healthcare worker interactions, engaging in physical activity, adjusting for proper diets, and

adhering to the regimen of diabetic medications. These barriers were; for instance: poor interactions between healthcare providers and patients, poor adherence to physical activity, misconceptions of healthy diets, and inadequate knowledge and understanding of the roles of medications.[5] Furthermore, Khan et al. (2011) had conducted a prevalence study of poor glycemic control in 1261 diabetes patients and found that 143 had poor control (HbA1c ≥ 10%). The reasons for poor glycemic control included poor adherence to lifestyle changes (26.5%), side effects of medications (16.4%), infrequent attendance at the clinic (16.4%), poor adherence to taking medications (14.0%), lack of knowledge of diabetes (14.0%), insulin refusal (11.7%), lack of titration of tablets (7.8%) or insulin (12.5%), and social issues (10.9%).[6] Despite the existence of many well-defined targets and practice guidelines for the management of hyperglycemia, hypertension, and dyslipidemia in patients with T2DM, clinical inertia exists due to periodic revisions of guidelines causing confusion among healthcare providers.[7]

The Chronic Care Model (CCM) was developed in response to health system failures to meet the needs of people with chronic illnesses. It aims to provide a comprehensive framework for the organization of health services in order to improve outcomes for people with chronic conditions.[8] The strategies are centered on patients' needs,[9] focusing on individual patients to address specific societal, cultural, and religious factors.[10] Strickland et al. (2010) revealed that CCM implementation for all six dimensions in primary care practice was associated with better diabetes assessment and treatment, and a higher rate of behavior counseling with increased rates of positive conduct resulting from the counseling.[11] One systematic review[12] and other studies showed CCM-based intervention improved clinical outcomes of diabetes care[8][13–15] such as improved HbA1c,[8][12] and cardiovascular risk profiles,[13] and increased knowledge and empowerment scores.[8] However, another systematic review[16] and meta-analysis study[17] did not show improved clinical outcomes, and there was little effect on diabetic patient outcomes and process of care. These circumstances could be explained by not all key elements of the CCM applying to the interventions.[16,17] These studies[16,17] suggested that six important elements of the CCM were essential to be incorporated into the developed interventions in order to ultimately improve quality of diabetes care and patients' health outcomes.

In order to gain in-depth understanding about patients and health care providers' contexts of diabetes management, previous systematic reviews of qualitative studies showed some important results; for example, patients' and health care providers' perceptions of self-management support interaction,[18] barriers to effective management[19] and understanding unique adherence context of diabetic patients' medication-taking behaviors.[20] The qualitative reviews of special situations of ethnic minorities such as South Asian,[5] East Asian Immigrants,[21] Ethnic Minorities were also studied.[22] However, the reviews that gave insights into both healthcare providers' and patients' perspectives on diabetes management and outcomes by using the framework of the CCM were scarce. Therefore, this study aimed to explore the perspectives of both health care providers and diabetic patients utilizing the CCM as an analytical framework in order to gain more in-depth information regarding their contexts as well as to identify factors that can help to improve the provision of diabetes care services.

Methods

Search strategies

Four electronic databases were searched: PubMed (Medline), Science Direct, Web of Science, and CINAHL. The search was restricted to peer-reviewed studies published in English between January 2001 and September 2017. A manual search was also performed in which all the references cited in previous reviews were screened for studies that met the inclusion criteria. All identified titles and abstracts were independently screened and selected by two authors. Any discrepancies

were discussed and resolved by consensus. A combination of search terms was used for this review to identify articles and original qualitative studies related to patients' and providers' perspectives and diabetes management. Keywords and strategies were 'Type 2 Diabetes Management' used with a Boolean 'AND' to conjugate with the following words 'Patient needs,' 'Patient perceptions,' 'Patient opinions,' 'Patient perspectives,' 'Provider needs,' 'Provider perceptions,' 'Provider opinions,' and 'Provider perspectives'. Full search strategies have been shown in Appendix 1-search terms strategy for perspectives from providers and patients about diabetes management.

Eligibility

The authors began by examining studies that were (1) qualitative studies involving T2DM patients and, (2) studies which aimed to evaluate patients' and providers' perspectives on diabetes management. All studies were available in full-text format with the quotations shown in the result part of included articles. The Critical Appraisal Skills Program (CASP) for qualitative research (Oxford, 2006)[23] was used and assigned a value point (as shown in Table 1) to each article. The first two screening questions of CASP were considered by two independent researchers with two points to be gained. Other criteria were assigned a value of one point each. Articles included for the study were required to have at least five points, as assessed by two independent researchers.

The authors excluded studies which were characterized one or more of the following: (1) trialed an intervention in the study (e.g. technology, program, training, education), (2) studied special groups of patients such as immigrants or disabled patients, or examined special events such as Ramadan or travels, or (3) described other perspectives such as that of family members, or people who were only at risk for T2DM.

Critical appraisal of studies

The checklist for assessing methodological quality of a qualitative research study followed CASP 2006 (Table 1).[23] For an article to meet the inclusion it must earn all five points from the first five questions of CASP as described above (see Table 1). An abbreviated version of the first five questions are (1) clear objectives, (2) appropriate methodology, (3) an explanation of how the qualitative research methods were used, (4) a clear explanation of the participant's recruitment process, and (5) a clear explanation of the data collection process. Values for the critical assessments of included articles are shown in Table 2.

Data extraction

A data extraction form was developed as a modification of the form used by Zaza et al. (2000).[24] Microsoft Excel was used to sort retrieved articles by author, publication year, aim, study design, sampling and participants, method of analysis, and findings.

Data analysis

According to the various styles of qualitative reports, we examined every article at least 5 times. Thematic analysis was used in this study. Major themes and sub-themes from articles were extracted and quotations supporting each major theme and sub-theme were identified and then put in a matrix using Microsoft Excel version 2013. This was done to synthesize and reorganize the major themes and sub-themes in compliance with the CCM framework model. When identified themes were not consistent with the CCM, they were re-categorized as additional major themes and sub-themes as necessary. After that, we arranged the identified quotations corresponding to the related themes. These additional major themes and sub-themes were analyzed and categorized in the table. This process was reviewed and checked by three

Table 1
CASP checklist for assessing the quality of the qualitative studies.

Screening Questions	Criteria	Score
1. Was there a clear statement of the aims of the research? *Consider:* • What was the goal of the research? • Why it was thought important? • Its relevance	1. The study must have clear research aims/objectives with a good relevant introduction focusing on the following points: Perspectives of either health care professionals or patients or both on diabetes management	1
2. Is a qualitative methodology appropriate? *Consider:* • If the research seeks to interpret or illuminate the actions and/or subjective experiences of research participants • Is qualitative research the right methodology for addressing the research goal?	2.1 The study must show appropriate qualitative methods chosen (interviews, observation, or document reviews) to address research objectives. 2.2 The study must have proper inclusion and exclusion criteria for selecting participants (including health care professionals or diabetic patients or both) to address research objectives. *2.1 and 2.2 are to be met to gain a full score of 1 point.*	1

The study must achieve a score of 2 on the first two screening questions before moving onto detailed questions.

Detailed Questions	Criteria	Score
3. Was the research design appropriate to address the aims of the research? *Consider:* • if the researcher has justified the research design (e.g. have they discussed how they decided which methods to use?)	3. The study must have an explanation of how the qualitative research methods were used.	1
4. Was the recruitment strategy appropriate to the aims of the research? *Consider:* • If the researcher has explained how the participants were selected • If they explained why the participants they selected were the most appropriate to provide access to the type of knowledge sought by the study • *If* there are any discussions around recruitment (e.g. why some people chose not to take part)	4. The study must show a clear explanation of the participant recruitment process–how they were selected, how they provided information addressing research questions and/or objectives.	1
5. Was the data collected in a way that addressed the research issue? *Consider:* • If the setting for data collection was justified • If it is clear how data were collected (e.g. focus group, semi-structured interview etc.) • If the researcher has justified the methods chosen • If the researcher has made the methods explicit (e.g. • for interview method, is there an indication of how interviews were conducted, or did they use a topic guide?) • If methods were modified during the study. If so, has the researcher explained how and why? • If the form of data is clear (e.g. tape recordings, video material, notes etc) • If the researcher has discussed saturation of data	5. The study must show a clear explanation of the data collection process including: 5.1 research setting 5.2 how data were collected 5.3 clear justification for the qualitative research methods chosen 5.4 form of data used *5.1 and 5.4 are to be met to gain a full score of 1 point.*	1
6. Has the relationship between researcher and participants been adequately considered? Consider whether it is clear: • If the researcher critically examined their own role, potential bias and influence during (a) Formulation of the research questions (b) Data collection, including sample recruitment and choice of location • How the researcher responded to events during the study and whether they considered the implications of any changes in the research design	6. The study explained relationships between researchers and participants: • Researchers critically examined their own role and looked for potential bias and influence during the formulation of research questions and collection of data.	1
7. Has ethical issues been taken into consideration? *Consider:* • If there are sufficient details of how the research was explained to participants for the reader to assess whether ethical standards were maintained • If the researcher has discussed issues raised by the study (e.g.issues around informed consent or confidentiality or how they have handled the effects of the study on the participants during and after the study) • If approval has been sought from the ethics committee	7. The study must show ethical approval from the ethics committee and details of informed consent, confidentiality of data and how they handled any other ethical issues during and after study.	1
8. Was the data analysis sufficiently rigorous? *Consider:* • If there is an in-depth description of the analysis process. • If thematic analysis is used. If so, is it clear how the categories/themes were derived from the data? • Whether the researcher explains how the data presented or were selected from the original sample to demonstrate the analysis process. • If sufficient data are presented to support the findings. • To what extent contradictory data are taken into account • Whether the researcher critically examined their own role, potential bias and influence during analysis and selection of data for presentation	8. The study must have clear explanations about: 8.1 in-depth process of qualitative analysis-what type of qualitative analysis methods used (e.g. content analysis, thematic analysis, or framework analysis) how themes were identified, validated and categorized. 8.2 Whether the researcher critically examined their own role, and looked for potential bias and influence during analysis and selection of data for presentation. *8.1 and 8.2 are to be met to gain a full score of 1 point.*	1
9. Is there a clear statement of findings? *Consider:* • If the findings are explicit. • If there is adequate discussion of the evidence both for and against the researchers arguments • If the researcher has discussed the credibility of their findings (e.g. triangulation, respondent validation, more than one analyst) • If the findings are discussed in relation to the original research question?	9. The study must have the following attributes: clearly explain the findings on the following points: 9.1 A clear explanation consistent with or against research objectives 9.2 Validation of thematic framework and other information validity (e.g. triangulation) *9.1 and 9.2 are to be met to gain a full score of 1 point.*	1

Table 1 (*continued*)

10. How valuable is the research? Consider: ● If the researcher discusses the contribution the study makes to existing knowledge or understanding e.g. do they consider the findings in relation to current practice or policy? or relevant research-based literature? ● If they identify new areas where research is necessary ● If the researchers have discussed whether or how the findings can be transferred to other populations or considered other ways the research may be used	10. The study must show value on any of the following points: ● Contributions to existing knowledge related to practice, policy, or research-based literature ● New findings in the area related to the study ● Findings to be transferred to other populations ● Suggestions given for further research	1
	Total	10

researchers and when disagreements arose, the themes were discussed and the final thematic framework in Table 3 was agreed upon by consensus. These processes were conducted by three researchers from September 2017 to April 2018.

Results

Fig. 1 shows the eligible articles included in the study. There were 2444 included in the identification process. After removal of duplicates (n = 463), an initial yield of 1981 titles and abstracts were screened. There were 108 eligible titles and abstracts, but only 61 had accessible full-texts. By assessing the quality of the evidence following the criteria in Table 1, there were 23 articles included for content analysis as shown in Table 2. Thirty-eight articles were excluded for the following reasons: 27 articles were intervention studies related to technology and program trials,[5][25–50] four articles were studies among special groups such as disabled patients or travelling people,[51–54] three articles were based on perspectives from family members,[55–57] and four articles were excluded as they were deemed unqualified by CASP.[58–61] The full explanation for the reasons for excluding the 38 articles is shown in Appendix 2. The different perspectives of the 23 included articles were also noted: three articles studied both the perspectives of health care providers and diabetic patients,[62–64] five articles studied only the perspective of health care providers,[65–69] and 15 articles studied only the perspectives of diabetic patients.[70–84] The studies were performed in 14 countries: USA,[46,52,61,71,81,83] America Samoa,[76] Canada,[65,69,72] Taiwan,[74] Japan,[79] Malaysia,[73] Oman,[66,80] Iran,[74] Australia,[82] Germany,[63] Netherland,[64,68] Finland,[84] UK[78] and Bangladesh,[75] as shown in Table 2.

Using the CCM framework and original themes identified from the 23 included articles, nine themes concerning the perspectives of healthcare providers and patients were synthesized: (1) community linkage (CL) revealed differences in perspectives on resources and policies, (2) health service systems (HSS) for diabetic patients revealed similarities in perspectives on barriers for medical services, (3) continuity of care (CC) revealed similarities in perspectives on the need for continuity of care, (4) self-management (SM) revealed the similarities in perspectives on barriers in self-care due to the patients' individual situations, (5) providers' support (PS) revealed similar perspectives, (6) referral system (RS) revealed similarities in the perspectives on barriers in transitions from one provider to another, (7) patient-provider interaction (PPI) revealed differences in the perspectives on communication, (8) increased competency of healthcare providers (ICP) revealed no conflict because only the perspective of healthcare providers was considered, and (9) family involvement (FI) revealed similarities in perspectives on facilitating factors and barriers from family members of patients with diabetes. The conclusion of the results is shown in Table 3 and Fig. 2.

Community linkage (CL)

There were two sub-themes related to CL, (1) community and social involvement and (2) resources and policies. From five articles it was determined that community and social involvement contains two sub-

themes: community institutions and social support needs.[63,68,74,79,84] The overall perspectives revealed the desires of healthcare providers to establish sport clubs and/or activities in the community to support healthy lifestyles for T2DM patients.[63,68] Diabetic patients revealed the need for social support such as meeting with friends to go to a concert or the theater,[68,84] and talking to others who have the same condition to provide support for their disease.[79]

> HP: "I will try to establish a sport group particular for multi-morbid patients not just for diabetes or coronary patients, manage a sports group which I established five years ago. It is a huge success."[63] P: "Different activities and culture events, such as going to music concerts, open-air theatres and just walking in the forest help me to carry on."[84]

Resources and policies are related to information and available resources. This sub-theme was a theme of four articles.[63,68,74,84] These articles revealed that there were no community based resources[63,84], facilities or health education for people with T2DM.[66,68] They also revealed that Attention to primary and secondary care, politics, and scientific research on diabetes care has been improved.[68]

> P: "I didn't notice that resources were asked about or paid attention to in any way."[84]

> HP: "Diabetes is receiving a lot of attention in primary and secondary care and also from politics, which has led to an improvement of the care"[68]

Health service systems for diabetic patient (HSS)

There were three sub-themes related to HSS, (1) medical services, (2) health insurance systems and (3) human workforce. Eleven articles addressed the theme of medical services related to the access and availability of services.[64,66–70,72,73,75,80,82] Medical services are related to the access and availability of the services. This theme was found in eleven articles. The theme revealed limited accessibility due to no physician availability (such as in Oman),[66,72,80] no interest by pharmacists,[82] and great distances from services.[75] However, some countries showed good access to services (e.g. Netherlands).[68,69] Alternative services were offered including online and/or SMS service for treatment results,[80] separate services for males and females,[80] a special area for talking with each other about their experiences with diabetes, and more health information literature in the waiting areas (e.g. leaflet).[80] However, the information may have been too complicated for the patients to understand.[64,67,70] There was also a lack of information on the side effects on diabetes medications.[73]

> P: "The only problem is that I can't see my physician right away if I need it, if I badly need it."[72]

> HP:" I have four patients who completely refused to go for eye check-up because they find it too far away from their living places. They prefer to be referred to the nearest hospital due to transport costs."[75]

> HP: "Dieticians and health educators are not here every time, our nurses are not well trained, not qualified and do not know the process of care

Table 2
Overview of included studies and CASP scores.

Coding article	Authors/year/ Country/setting	Aims	Study design	Sampling/participants	Analysis method	Finding	CASP score
1	Beverly et al. 2012[62] USA Primary Care	To explore physicians' and T2DM patients' perceptions, attitudes, and behaviors that support or imped the physician-patient relationship T2DM treatment.	In-depth face-to-face interviews	Purposive sampling of 19 endocrinologists and primary care physicians and 34 patients diagnosed with T2DM at least two years prior	Content analysis by independently marking and categorizing key words, phrases, and texts to identify themes	Two themes of physician perspectives are 1) responsibility for patients' difficulty achieving treatment goals and 2) patients' reactions. Two themes of patient perspectives are 1) patients' self-blame for difficultly achieving treatment goals and 2) physicians reactions to unmet goals.	8
2	Goetz et al. 2012[63] Germany Primary Care	To explore general practitioners', nurses' and T2DM patients' views, experiences, and perspectives on the importance of social support in caring for people with T2DM and their roles in providing social support.	Focus groups	General practitioners (n = 10), practice nurses (N = 10), and people with diabetes (n = 9)	Thematic analysis using qualitative content analysis	Three main themes of social support are 1) current situation, 2) barriers and problems, and 3) future perspectives.	10
3	Gerda Jängst et al. 2015[64] Netherlands Primary Care	To investigate which factors participants perceived to enhance or impede medication information provision in primary care.	Semi-structured focus groups	T2DM patients (n = 25),general practitioners (n = 13), and health care assistants (n = 10) (four patients had both a general practitioner and a health care assistant)	Transcribed verbatim, content analysis	Two main themes are 1) factors perceived to enhance medication information provision (including tailored, adequate information, trusting patient–provider relationship, medication reconciliation, tools for medication management, team approach to medication communication), 2) factors perceived to impede medication information provision (including inadequate information, lack/overload of information on potential adverse effects, medication reconciliation impeded, lack of support for medication self-management, and system-related barriers).	8
4	Brez et al. 2009[65] Canada Hospital	To explore PCPs' perspectives and concerns related to reassuming responsibility for diabetes care after referral to a specialized diabetes center.	Focus groups	Participants included 22 primary care physicians representing a variety of referral frequencies, practice types, and settings.	Themes identified using a constant comparison method	Three main themes are 1) primary care physician readiness for transition of care from specialist, 2) patient readiness for discharge, and 3) systems factors and transition of care from specialist.	9
5	Abdulhadi et al. 2012[66] Oman Primary Care	To explore the experiences of primary health-care providers' encounters with patients with T2DM, and their preferences and suggestions for future improvement of diabetes care.	Semi-structured interviews	Nineteen doctors and seven nurses who worked in primary health care in Oman.	Content analysis	Four main themes are 1) organizational factors, 2) patient factors, 3) factors related to health-care providers, and 4) suggestions to improve diabetes care.	8
6	Kern DH et al. 2001[67] USA Primary Care	The study captured the PCPs' perceived barriers on the delivery of diabetes care, how diabetes care was delivered, how PCPs preferred to deliver diabetes care, and how they reconciled any inconsistencies.	In-depth interviews, using a semi-structured interview tool	Twelve PCPs: both family physicians and internists	Interpretive form of qualitative data analysis known as the editing style.	Three main themes are 1) planned care, 2) time constraint, and 3) quality assurance system.	9
7	Raaijmakers LGM et al. 2013[68] Netherlands Primary Care	To investigate the facilitating and impeding factors among HCPs (Health Care Professionals) using a qualitative research design.	Semi-structured interviews	Eight teen health care professionals in Netherlands	Data were analyzed using the NVivo qualitative research software package. The Chronic Care Model (CCM) was used to classify the facilitating factors and barriers	Seven main themes are 1) community resources and policies, 2) organization of health care, 3) self-management support, 4) delivery system design, 5) decision support, 6) clinical information systems, and 7) HCP-related factors.	8
8	Brown JB et al. 2002[69] Canada Primary Care	To explore family physicians' issues and perceptions regarding the barriers and facilitating factors of the management of patients with T2DM.	Focus groups	Physician participants included 16 males and 14 females who attended one of four focus groups with an average of seven physicians per group	The researchers compared field notes and discussed the group process. The strategy of constant comparison analysis	Three main themes are 1) patient facilitating factors and barriers, 2) physician facilitating factors and barriers,	8.5

Table 2 (continued)

Coding article	Authors/year/ Country/setting	Aims	Study design	Sampling/participants	Analysis method	Finding	CASP score
					was used. Central themes were identified across all focus groups.	and 3) system facilitating factors and barriers.	
9	Matthews et al. 2008[70] USA Primary Care	To explore the experiences, attitudes, and beliefs of adult women living with diabetes and how they managed their diabetes.	Focus groups	Five females who have T2DM	Thematic analysis	Three major themes affecting adherence to treatment regimens are 1) communication with the healthcare providers, 2) knowledge of diabetes, and 3) the consequences of poor glycemic control.	8
10	Carbone et al. 2006[71] USA Health Center	To inform the refinement of self-management interventions tailored to Latino patients with T2DM.	Focus groups	Twenty patients were invited to participate in each group	A structured framework to systematically review the findings	Five main themes are 1) diabetes-related knowledge, 2) beliefs and attitudes regarding diabetes self-management, 3) self-management practices, 4) perceived barriers, and 5) perceived facilitating factors.	7
11	Dutton et al. 2014[72] Canada Specialist Clinic	To explore patients' expectations and experiences concerning discharge from a specialized diabetes centre back to primary care.	One-on-one semi-structured interviews	Twelve of T2DM patients who have been discharged from the Tertiary Care Diabetes Referral Centre in Ottawa, Canada.	Grounded theory techniques where NVivo 9 was used to organize the coding process	Four main themes are 1) expectations at initial referral, 2) specialist care, 3) discharge from specialist care, and 4) primary care physicians' (PCP) care after discharge.	8
12	Al-Qazaz et al. 2011[73] Malaysia University Health Clinic	(1) To explore T2DM patients' experience and knowledge about diabetes. (2) To explore the experiences of diabetic patients in terms of their medications, and (3) To understand the factors contributing to medication adherence in Malaysia.	Semi-structured interview guide	Twelve patients diagnosed with T2DM who attended the USM clinic and received their medications and health care from the same clinic.	Thematic content analysis. The transcripts were analyzed line by line for relevant content and to identify categories of emerging themes for coding.	Four themes are 1) knowledge about diabetes and its medication, 2) experiences of adverse effects of medication, 3) issues related to adherence, and 4) the impact of medical and family relationships on well-being.	9
13	Moonaghi et al. 2014[74] Iran Primary Care	To explore the facilitating factors and barriers in adaptation among T2DM Iranian patients using qualitative research methods.	In-depth, semi-structured and face-to-face interviews	Purposive samples of 15 T2DM patients	Content analysis focusing on contextual meaning to "provide knowledge and understanding of the phenomenon under study"	Three themes are 1) individual content with subthemes of beliefs, personal background, and previous experience, 2) supportive system with subthemes of family, society and health organizations, and 3) self-comparison with other disease and other diabetes patients	8
14	Lewis et al. 2014[75] Bangladesh Primary Care	To understand patients' experiences in the treatment of their T2DM.	In-depth interviews	Twenty-three participants with T2DM in five sites across two administrative districts of Bangladesh	Interview transcripts were coded and emergent themes identified	Two main themes are 1) awareness and understanding of diabetes and its effective management, and 2) availability and costs of diagnosis and care.	6
15	Held et al. 2010[76] America Samoa Health Center	To identify agenda items related to depressive symptoms and its relationship to diabetes.	Focus groups	Thirty-nine American Samoan adults with diabetes	Thematic analysis with NVivo 8	Four main themes are 1) the relationship of depressive symptoms and diabetes, 2) managing depressive symptoms, 3) frequency of seeing depressed patients and 4) stigma and cultural differences.	8
16	Wen An Lai et al. 2006[77] Taiwan Rural Area	To gain insight into the perceptions of patients with diabetes, especially ideas of the illness course and perceived severity, and their impacts on self-care behavior.	In-depth patient interviews and focus groups	A purposive sampling strategy for 22 patients (in-depth interview) and 53 patients in seven focus groups	The transcripts of the interviews were analyzed with editing and immersion/ crystallization styles	Three main themes are 1) diagnosis of diabetes and the main features of its course, 2) perceived severity and its assessment, and 3) unidimensionality and its impact on health behaviors.	7
17	Alazri MH et al. 2010[78] UK Rural vs Urban	To explore perceptions and experiences of continuity of care in general practice from the perspectives of patients with T2DM, focusing on the advantages and disadvantages of different types of continuity.	Focus groups	Seventy-nine patients with T2DM from seven practices in Leeds, UK	Framework approach	Three main themes are 1) relational or longitudinal continuity, 2) cross-boundary or team continuity, and 3) continuity of information.	7
18							8.5

Table 2 (*continued*)

Coding article	Authors/year/Country/setting	Aims	Study design	Sampling/participants	Analysis method	Finding	CASP score
	Kato et al., 2016 Japan[79] Tertiary Hospital	To explore how patients with T2DM psychologically and behaviorally respond to social stigma.	Semi-structured interviews	Participants were adults aged 30-64 diagnosed with T2DM. A total of 26 patients participated.	Transcribed verbatim and analyzed using a grounded theory approach	Four main themes are 1) encountering negative experiences, 2) re-evaluating self with T2DM, 3) reconstructing a sense of identity, and 4) maintaining a balance between managing T2DM and social roles.	
19	Al-Azri et al. 2011[80] Oman Primary Care Health Center	To explore diabetic patients views of factors affecting the quality of services delivered in primary care in Oman– a developing country with a high incidence of diabetes.	Semi-structured face to face interviews	Nineteen type 2 diabetic patients recruited from four primary healthcare centers (PCHs) in Muscat region, the capital city of Oman.	Framework approach	Two main themes are 1) communication and continuity of care with healthcare professionals, and 2) provision of services at the right time and place.	7
20	Beverly et al. 2011[81] USA Primary Care	To explore older patients' perceived impact of chronic co-morbid conditions on T2DM self-management.	Focus groups	Purposive sampling to select 32 T2DM patients aged 60 and older with at least one other chronic health condition.	Identified codes to describe the overarching themes	Three themes are 1) diabetes complications as a motivator, 2) prioritizing health conditions, and 3) emotional impact of co-morbidity management.	6.5
21	Dhippayom et al. 2015[82] Australia Pharmacy	To identify potential unmet needs and explore preferences for pharmacist-delivered support for T2DM.	Focus groups	Thirty-two consumers with T2DM	Thematic analysis	The key three themes are 1) the experiences of diabetes services received, 2) the potential to deliver self-management services, and 3) the suggested role of the pharmacist in supporting diabetes management.	7
22	Huang ES et al. 2005[83] USA Primary Care	To specifically examine how older patients defined their healthcare goals, what factors shaped their goals, and the extent to which their goals related to self-care behavior.	In-depth one-on-one semi-structured interviews	Patients aged 65 and older with T2DM (n = 28).	Developed a scheme for systematically coding by a two-step process: first is face-sheet summary of themes for each transcript, and second is comparing interview notes and reconciling any differences between them	Three main themes are 1) healthcare goals, 2) external influences of healthcare goals, and 3) self-care practices.	9
23	Halkoaho A et al. 2013[84] Finland Public Health Organization	To understand how health-promoting aspects are realized in counseling according to T2DM	Semi-structured interview	Participants (9 males and 6 females) with T2DM, who were Finnish, living in Eastern Finland, aged 58–81.	Inductive content analysis described by Graneheim and Lundman, guided by interview themes	Three main themes are 1) coping resources of patients with diabetes, 2) the content of the counseling, and 3) the form of the counseling.	9

Table 3
Data Extraction by Thematic Analysis using the CCM framework and original themes from Included articles.

N.	Chronic Care Model	Original Themes from Included Articles	Studied Themes	
			Major Themes	Sub-Themes
1	**Community linkages:** • Encourage patients to participate community program • Form partnership with the community • Advocate for policies to improve patient care	• Initiation of physical activity[63] • Society/community[74] • Activities in communities[84], establishment of sport groups[63] • Prevention and lifestyle interventions[68] • Lack of information about community based resources[68] • Information about community based resources[63] • Involvement of other community institutions[63] • Self-management and health education (in community)[66] • Community resources and policies (need more attention from the community)[68]	1. Community linkages	1.1 Community and social involvement 1.1.1 Community institutions 1.1.2 Social support needs 1.2 Resources and policies
2	**Health System:** • Support improvement organization • Promote effective strategies • Handling of errors and quality problems • Provide incentives • Develop agreements to facilitate care	• Availability and costs of diagnosis and care[75] • Systemic facilitators[69], home services, diabetes education centers (DECs) as a valuable resource and stress the importance of referring the patient soon after diagnosis • System-related barriers[64] • Inadequate information[64] • Lack/overload of information on potential adverse effects[64] • Lack of teamwork approach[66] • Knowledge of dietary recommendations[70] • Obstacles: A perceived low level of interest in offering diabetes services by pharmacists[82] • Quality Assurance Systems[67] • Bundled payment system[68] • Role of health insurers[68] • Cost of medication[77] (Note: free med coverage for patients) • "High costs" of diabetes medications and supplies[65] • Lack of financial aid for patients[65]-GP (Note: not enough money for fruits) • Structural/environmental factors[55] • Personal background[74]-diabetes medication is expensive • Workload[69] • Time Constraints[67] • Lack of time[65]-GP-nurse • Obstacles: Time constraints in a busy pharmacy[82] • Provision of services at the right time and place[80]	2. Health service system	2.1 Medical services 2.1.1 Access to services 2.1.2 Limited services 2.2 Health insurance system 2.2.1 Payment system 2.2.2 Financial burdens 2.3 Human workforce: time constraints
3	**Delivery System Design:** • Roles among team • Use plan to support evidence based care • Case management for complex patients • Regular follow-up by care team • Give appropriate care to patients (cultural)	• Multidisciplinary collaboration[68] • Image[68] (Note: role of dietitian) • Affinity[86] (Note: interest in DM as a family physician) • Continuity of care[68] • Cross-boundary or team continuity[78] (Note: effective communication between professionals and services, and with patients) • Level of patient "trust" in primary care provider, strength of relationship with specialist team[66] • Organizational efficiency of diabetes clinics[66] (Note: small group for continuity of care) • Difficult to reach some groups[68] • Target specific groups of patients in need of additional support[82] • Frequency of seeing depressed patients[76]-provider (Note: standard care but ignore) • Culture[71] (Note: use appropriate care for individual culture) • Tools for medication management[64]	3. Continuity of care	3.1 Team cooperation 3.2 Case management 3.3 Tools for medication management

Table 3 (*continued*)

N.	Chronic Care Model	Original Themes from Included Articles	Studied Themes	
			Major Themes	Sub-Themes
4	Self-Management Support: • Emphasize patient-centered care • Use effective self-management support • Organize internal and community resources to support ongoing self-care	• Medication reconciliation[64] • Causes[71] • Identity of diabetes and the main features of its illness course: IDENTITY Etiological factors: genetic heritage and over-consumption of sugary food[77] • Perceived severity and its assessment[77] • Uni-dimensionality and its impact on health behaviors: concurrent progression of these clues[77] • Complications[71] • Prioritizing health conditions[81] - patient prioritizing another condition over their diabetes • Emotional impact of co-morbidity management[81] • Denial of diagnosis[70] (Note: patients' awareness) • Lack of awareness of symptoms[84] • Knowledge of the disease[84] • Diabetes complications as a motivator[81] • Other sources of information[70] • Knowledge about diabetes and medications[73] • Experiences of adverse effects of medications[73] • Forgetting to take medication or get a repeat prescription[73] • Issues related to adherence[73] • Adjustment of dose by patients[73] • Awareness of need to take medication[73] • Lack of motivation by patients[83] -GP-nurse-patient • The relationship of depressive symptoms and diabetes[78]-patient, provider • Patient barriers[69]: lack of acceptance of diabetes as a chronic illness, patient adherence • Poor patient adherence[66] (to lifestyle modification) • Self Care Practice[83] • Self-management practices[71] • "Ongoing access to education" and resources[65] - No information-No quotation • More patient self-motivation[65]-patient- No quotation • Managing depressive symptoms[76]-patient-provider • Adherence to self-care[36] • Awareness and understanding of diabetes and its effective management[75] • Comparison with other diabetes patients[74] • Patients' beliefs about illness[46] • Comparison of diabetes mellitus with other diseases[74] • Accepting attitude to the disease[84] • Knowledge of the disease[84] • Beliefs about illness[74] • Beliefs and attitudes regarding diabetes self-management[71] • Denial of ability[79] • Creating a personal image of the illness[79] • Experiencing changes in self-worth based on that image of the illness[79] • Defining a personal relationship with the illness[79] • Strategically adjusting behaviors in social situations based on that relationship with the illness[79] • Four types of strategies:	4. Self-management	4.1 Knowledge and understanding of diabetes and its complications 4.1.1 Knowledge and understanding of diabetes 4.1.2 Understanding of diabetic complications 4.1.3 Experiences and awareness of diabetes complications 4.2 Medication adherence 4.2.1 Knowledge and understanding of medication talking 4.2.2 Unintentionally poor adherence 4.2.3 Intentionally poor adherence 4.2.4 Good adherence 4.3 Lifestyle modification 4.3.1 Knowledge and understanding 4.3.2 Living with diabetes 4.4 Belief-attitude 4.4.1 Diabetes 4.4.2 Lifestyle 4.4.3 Goal setting 4.4.4 Medication adherence

Table 3 (continued)

N.	Chronic Care Model	Original Themes from Included Articles	Major Themes	Sub-Themes
		- Adjustment to the Illness - Social Disconnection - Social Avoidance - Role Conflict[79] ● Maintaining Balance Between Patient and Social Roles[79] ● Criticism of personal character[79] ● Stigma and cultural differences[76]—provider-no depression in Samoan people ● Patients' Self-Blame for Difficulty Achieving Treatment Goals[62] ● Doctors' and nurses' frustration with non-adherent patients[46] ● Healthcare Goals[83] ● External Influences of Healthcare Goals[83] ● Physicians' Perceived Responsibility for Patients' Difficulty Achieving Treatment Goals[62] ● Patients' Perceptions of Physicians' Reactions to Unmet Goals[62] ● Physicians' Perceptions of Patients' Reactions[62]		
5	**Decision Support:** ● Embed evidence-guideline to clinical practice ● Shared evidence based guideline with patients to encourage participation ● Use proven provider education methods ● Integrate specialist expertise and primary care	● Tailored, adequate information[44] ● Standardized registration and exchange of information[48] ● Company outreach visit[63] ● Motivation[59],self management support ● Patient facilitators[59]: responsibility and control over their diabetes, early educational interventions ● Individual care plan[58]—self management support ● Administrative role (e.g. service reminder or arranging for the supply of diabetes medication)[62] ● Support given by the nurse[44] ● Doctors' attitudes[46,71] support: Friendliness of pharmacists[82] ● Care Standard[48] ● Implementation of CS[68] ● Planned Care Is Infrequent[67] ● Systemic barriers[69], time and physician remuneration, CPGs as assisting them, they felt "overwhelmed" by the large number of guidelines. ● Bench-marking[68] ● Delivering information on diabetes[80] (Note: inadequate counseling, good counseling) ● Own role, individualized orientation (goals, forms) of counseling[66] ● Time[64] ● Medication orientation[64] ● Small issues in everyday life[64] (Note: content and form of counseling)	5. Providers' support	5.1 Effective healthcare providers 5.1.1 Administrative for effective treatment plan 5.1.2 Helpful services/satisfaction 5.1.3 Implementation of standard care 5.1.4. Counseling content by nurses
6	**Clinical Information Systems** ● Provide timely reminders ● Identify relevant subpopulation for proactive care ● Facilitate individual patient care planning ● Share information with patients and providers to coordinate care ● Monitor performance of practice team and care system	● Discharge from specialist care[72] ● PCP care after discharge[72] ● Continuity of information[76], excellent information transfer following the patient ● Expectations at initial referral[72]	6. Referral system	6.1 Barriers in transition between each level of care
7		● Trusting patient-provider relationship[64]		

Table 3 (*continued*)

| N.	Chronic Care Model	Original Themes from Included Articles	Studied Themes	
			Major Themes	Sub-Themes
		• Communication problems related to language[66] • Provider warnings[70] • Office visits[70] (Note: poor skill in communication) • Communication and continuity of care with healthcare professionals (14) • Diagnosis[70] (Note: poor skill) • Human interactions in health organizations[74] • Improvement of health-care professionals' behaviors[66] (Note: good communication concerns) • Lack of support for medication self-management[64] - poor communication skill • Indifference to seriousness of diabetes[70] -HP poor communication skill • Frustration with management[70] • Degree of alignment of "patient self-management expectations" and treatment goals with PCP/specialist center[65] • Specialist care[72] (Note: specialist preferred) • "Self-management" abilities, "compliance", attitude about "seriousness of diabetes"[65] • PCP expectations of specialist referral[65] • Use of "effective communication, coordination of care", "individualized care plans", "ongoing phone advice", "diabetes passport"[65] • PCP expectations and "attitudes" with those of patient/specialist referral center[65] • Ease of "access to support" services, timely re-referral for patients and physicians[65] • Relational (or longitudinal) continuity[76], an ongoing therapeutic relationship between a patient and one or more providers	7. Patient-provider interaction (*Additional theme*)	7.1 Providers' communication skill and language barrier 7.2 Preferences for care 7.2.1 Preference for specialists 7.2.2 Preference for familiarity providers 7.2.3 Preference to general practitioners
8		• Physician facilitators[69], continuing medical education (CME), Information technology • Physician barriers[69]: specifically, not having a systematic way to "recall" or track their patients with diabetes through their computer system • Offers of training[63] -nurse • Training offered for nurses[63] -nurse • More training offered by nurses[63] -patient • Education[68] (Note: well trained, insufficient knowledge) • Support: convenience of pharmacies[62] • Obstacles: lack of a private area[62] • PCP "knowledge" and "confidence" related to medication adjustment and behavior change[65] • Obstacles: reservations about the pharmacists' skill and knowledge in diabetes management[62] • Team approach to medication communication[64] • Involvement with nurses[63]-GP • More support by GP[63]-nurse (Note: need small group for nutrition counseling)	8. Competency of healthcare providers (*Additional theme*)	8.1. Continuing profession education
9		• Involvement with family members[63] • Family[74] • Supported by primary care team[65] Note: family support required • Impact of medical and family relationships on well-being[73] • Supportive relationships[64]	9. Family involvement (*Additional theme*)	9.1 Family as facilitators 9.2 Family as barriers

Fig. 1. PRISMA Flow chart for the eligible articles.

for diabetic patients."[66]

Ten articles examined health insurance system.[63],[65],[67–69],[71],[73–75],[82] They addressed payment systems and the financial burden on patients. One subtheme revealed no coverage in basic care (such as in Netherlands).[68] In Iran, some drugs were not covered by insurance, so patients needed to pay the high cost of care.[74] There was no available insurance for migrants in Australia.[82] Some countries such as Malaysia provided free diabetes medication.[73] The Netherlands, the providers complained about a lack of transparency in health insurance costs.[68] Latino patients in the USA as well as patients in Bangladesh, Canada, Australia, Iran, and Germany faced the barrier of insufficient money to get diabetes care (financial burden).[63],[65],[69],[71],[75],[82] The providers sometimes used their own money to help patients.[75]

HP: "A lot of basic care is not covered by indicators. The most important disadvantage is that they may be misused for financial settlements. That's a bad development as regards transparency."[68]

P: "So because I've not had Medicare so really it is not possible for us to go and check every week, every month because we have not applied for permanent residency."[82]

HP: " … A real problem is the financial factor for the patients and

realizing that when we ask them to record the sugar level and every strip costs a dollar … that's one thing the system should change."[65]

Seven articles revealed the theme of the human workforce related to time constraints on providers.[63–67],[80],[82] Providers had limited time to treat patients.[63–67],[82] Some patients said that the appointment to see the provider can take a long time.[80] According to physicians, there was also a high workload among providers because of the large number of patients.[66]

HP: "The major factor is the stress I get when the other patients started shouting outside, knocking the door and asking when they will see the doctor which forced me to finish quickly with the consultation."[66]

P: "Sometimes I need to take appointment within a month, but the nearest appointment is available only after 3 months."[80]

Continuity of care (CC)

There were three sub-themes related to CC, (1) team cooperation, (2) case management and (3) tools for medication management. Five articles addressed team cooperation.[65],[68],[69],[78],[82] Providers would like to see more cooperation among them such as clear structure of transition.[65],[69],[78] Patients would like their information available for all
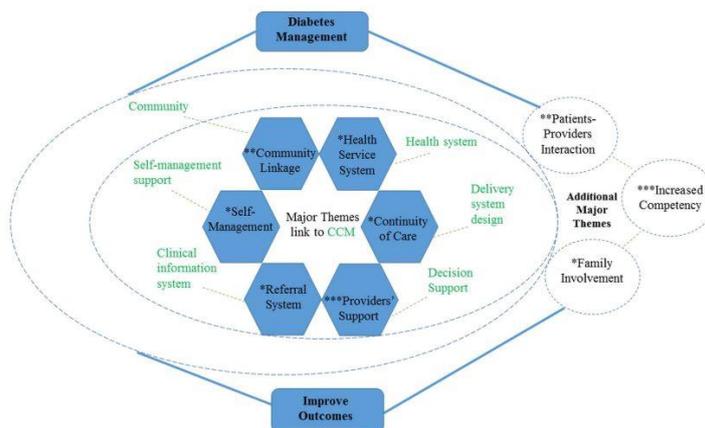
Fig. 2. Perspectives of patients and healthcare providers on diabetes management.
* Similarities among perspectives of patients and healthcare providers on diabetes management.
** Differences among perspectives of patients and healthcare providers on diabetes management.
*** There was no overlap of perspectives between patients and healthcare providers on diabetes management.

providers.[82] However, The Netherlands, the collaboration among primary and secondary care was well-organized.[68]

> P: "The one in charge of your health care in the system is your GP. So, even though you go to a specialist … he has to refer to your GP. So all the information must be fed to the GP."[78]

> HP: "[It] would be a wonderful expectation; to be able to say I need the full service or I only need part of the service."[65]

> HP: "In this region, the collaboration between primary and secondary care is pretty well-organized. We work in a multidisciplinary team on the same floor, so we can easily ask each other things."[68]

Five articles addressed case management,[66,68,71,76,82] which was related to the providers' ability to care for a limited number of patients. Providers needed a small number of patients to provide specific and effective care such as managing depressive patients.[66,68,71,76,82] The lower number of patients facilitated the effective care of providers by building a strong connection between them.[66]

> HP: "It is very important to see a fewer number of patients, I think ten to fifteen is reasonable. It is also important to maintain continuity of care as much as possible."[66]

> P: "This sort of service (monitoring service) would be of great value especially on the newly diagnosed, it could be for some people, yes. I'm not saying for me because I manage my own regimen quite easily, but for some people I still think it could be almost a necessity."[82]

One article addressed a tool for medication management: medication plans for patients.[64] Both patients and providers valued tools for medication management, including: medication plans, visual displays, and comprehensible labeling of medicine packages.[64]

> P: "My diabetologist. He actually made me a plan how to fine tune my insulin […] told me if this leads to low blood sugar I need to …"[64]

Self-management (SM)

There were four sub-themes related to SM, (1) Knowledge and understanding about diabetes and its complications, (2) medication adherence, (3) lifestyle modification, and (4) attitudes and beliefs. There were 10 articles related to the understanding of diabetes, the understanding of diabetes complications due to diabetes, and experiences/awareness of complications due to diabetes.[68–71,73–75,77,81,83] Some patients had knowledge of the pathophysiology of diabetes.[73,74,77] Some gained knowledge from the experiences of their friends and/or family.[68,74,75,77] Patients understood diabetes conditions and worried about complications and co-morbidity.[73,77] Patients were able to identify the symptoms of complications. Patients had their own experiences of diabetic complications (e.g. stroke, problems with eyes or feet).[70,71,81,83] They also acquired knowledge from other patients making them more knowledgeable about their disease.[69] Patients became more aware of complications from diabetes because they found information in literature,[70] or from the experiences of other family members.[69,77,83] Such information motivated them to look after their health.[73,77,81,83]

> P: "About the cause, well, my father is a diabetic, and my obesity, since I was small I was big and I did not exercise a lot. I know it will affect my eyes, heart and also kidney problem."[73]

> P: "I don't see a problem, unless something comes up out of the ordinary. I don't think about it a lot."[71]

> HP: "His father died at age 62 of horrible complications of diabetes and this guy was 58. I could not convince him that this was not a death sentence … because he just figured that was it."[69]

Five articles addressed medication adherence.[73,74,77,79,83] This included understanding about taking medicine, good adherence to medicine regimes, and poor adherence to medicine regimes due to either unintentional or intentional factors. Patients showed understanding about the concept of diabetes medication being used for lowering their blood sugar.[73] Some patients expressed concerns about the effect of medications on their kidneys.[77,83] Patients stated that they often forget to take and/or inject insulin. Some patients did not have time to take medication because they were busy.[73,74] Some patients refused to take medication in public because they were worried about their image.[79]

Some wanted to give a medicine-free day to their bodies by not taking medication.[73] Some adjusted the dose by themselves by skipping or adding more doses of their diabetes medications.[73] Some patients had good adherence by taking their medication as instructed and following their doctor's advice.[73]

P: "To control my sugar and because I have diabetes other effects in my eyes, or kidney, so I take it every day and I control my food also."[73]

P: "Most of the time regularly I take, but not at exact time, because in the morning I am very busy."[73] P: "Yes, I take it regularly, but sometimes if I eat a heavy meal or sweets. I take another big tablet (metformin) to control the sugar level."[73]

P: "I don't want anyone to see the medication. I don't like taking it in front of anyone. For me, the biggest problem is when I go to a business dinner. Then, I find it really difficult to find the time to take my medication. In that situation, I don't take it. It's really important to me that no one sees me taking my medication, so skipping it doesn't bother me."[79]

Eleven articles which addressed lifestyle modification.[62,63,66,68,69,71,75,76,79,81,84] These included knowledge and understanding of lifestyle modification and living with diabetes. Some patients showed good understanding of the concept of lifestyle modification, but did not follow through due to personal context (habit, familiarity, experience).[62,66,69,71,83] Providers complained about patients not adhering to lifestyle modifications.[63,66,68,76] Patients showed good adherence to lifestyle modifications because of their positive thinking.[79] Patients had their own way of managing their disease (e.g. relaxation).[76] Most of the patients followed lifestyle modifications such as weight and nutrition control because they understood well the consequences of not managing their lifestyle.[75,84]

P: "I'm a relatively smart person, it does not make sense for me to eat incorrectly. It does not make sense for me to exercise properly. I'm making these bad choices."[62]

HP: "To modify patients' diet is a real problem, one patient was angry and said he will eat what he wants and asked me what my grandfathers used to eat long time, they used to depend on dates mainly and the Omani Halwa and their health was perfect."[66]

P: "When I had my foot amputated, I thought there was nothing I could do about it. However, I didn't think my life was over because I was able to live a normal life with the aid of my prosthetic limb. My lifestyle hasn't been limited."[79]

Fourteen articles addressed attitudes and beliefs.[62,66–69,71,73,74,76,77,79,81,83,84] These included the varied attitudes that patients have about diabetes, lifestyle, goal-setting, and medication adherence. Some believed that diabetes is a chronic incurable disease.[69,74,77,79] Some patients had a spiritual, religious, or cultural belief that diabetes is meant to happen in their life.[66,69] Some patients felt that diabetes is a common disease that they should not be ashamed of.[79] Some patients compared diabetes with other diseases like cancer or arthritis, but thought it was milder.[74,81] Some patients expressed curiosity to know more about diabetes by searching for diabetes information in libraries.[84]

P: "Diabetes cannot be cured, I know that clearly. The drugs are only for control; you just have to take them."[77]

P: "Diabetes compared with other disease for example cancer is good. Because the cancer may make the breast a lift or chemotherapy. But compared with conditions such as bone fractures heart disease is bad."[74]

The attitudes towards lifestyle were also varied for diabetes patients.[66,68,69,79,83,84] Some patients felt ashamed to be diagnosed with diabetes.[79] Some remained unaware of how to manage their diabetes.[68] Some revealed that their family members did not think their diabetes was important and cooked food that the patients could not eat.[66,69]

Some needed to look after themselves.[83,84] Some revealed that there is social stigma against diabetic patients.[79]

P: "At a job interview, interviewers said that their company would find it rather difficult to hire someone with diabetes. They said then and there that diabetes was a disadvantage, and so that was that".[79]

Attitudes towards goal-setting[62,66,68,71,76,79,81,83] revealed that most patients followed lifestyle recommendations,[81] but blamed themselves for being unable to reach their goals.[62,71,76,79] Providers also felt frustrated when they could not make their patients reach their treatment goal.[62,66,69] Providers tried alternative options to help patients reach their goals.[68]

P: "For instance with the weight, that is something that has always made me lose my hope … Right now, instead of losing weight, and I have been eating less, I am gaining … I don't know if it is the medicine, but that sort of has me a little depressed … I just feel sad. Sometimes I don't even want to take the medicine because I feel like it's not doing anything."[62]

HP: "Have you gotten to know the patient? Have you really addressed the issues at hand? Have you had enough time, given the patient enough time to work on this? Have you provided the resources? Have you clearly identified what the challenges and issues are so that the patient can work on it? Have you communicated specific enough goals that patients can reach, can work towards?"[62]

Attitudes towards medication adherence[69,73] revealed that providers think that patients need motivation, as some patients were not comfortable with using insulin and other medicines.[69,73]

HP: "The difference between knowing and doing. It's easier for patients to have something done to them, like take a pill, as opposed to doing something for themselves. It takes a lot of self-motivation and encouragement and education"[69]

P: "I usually do not take the drug, because I must control myself, not the drug control myself."[73]

Providers' support (PS)

There was one sub-theme related to PS: effective healthcare providers. 13 articles addressed this sub-theme.[63,64,66–69,71–74,76,82,84] The effective healthcare providers theme is related to administration (effective treatment plans), services (helpful/satisfaction), and the implementation of standard care. Several providers used effective techniques to help patients manage their diabetes such as education, treatment plans, individual care plans, and forming small groups for educating patients.[63,64,67–69,71,74,82] Many articles revealed that providers support patients by using effective approaches to understand their patients well.[69,71,82,84] Patients were very thankful for the providers who gave good recommendations.[64,73] Good relationships among the providers and patients led to better care.[66,72,74,84] Some providers did not like the new guidelines, and thought that the implementation of a standard care framework for diabetes care is needed.[68,69]

P: "You actually have to discuss it with the doctor, because the impact on each person is often different, and needs to be matched with your blood sugar levels and related to one personally."[64]

P: "Support from the nurse is the thing. I wish the nurses would have the strength to empower us and the hurry would go away; today it's important to find a good nurse."[84]

HP: "The new guidelines make me feel awful. I have enough trouble doing what I'm doing and then trying to do menopausal counseling, osteoporosis counseling, smoking cessation counseling … [for diabetes] it makes me think I might scream."[69]

The counseling provided by nurses promoted the participation of diabetes patients in planning their treatment and in improving their

balance of care.[76] The content of counseling should be appropriate for diabetes care.[84]

> P: *"I know that I have to take the responsibility [for the care]; it's harmful for me if I don't. This is what the nurse also said."*[84]

Referral system (RS)

There was one sub-theme related to RS: barrier in transition between levels of care. Seven articles addressed this sub-theme.[67–69,72,78,80,82] Patients complained about being given unclear information while in the discharge process.[72,78] Patients were not able to see the same provider when they came back for follow-up visits.[67–69,78,80,82]

> P: *"If I had been told at the beginning, when I checked in, that would have helped, that I would eventually be discharged, and go back to my own doctor."*[72]

> P: *" … At the infirmary … definitely the continuity of care just was not there … I didn't see the same doctor in 3 years. I saw a different doctor every time … I got different types of advice … "*[78]

> HP: *"We have no way of knowing who comes back and who doesn't come back for care"*[67]

Patient-provider interaction (PPI)

There were two sub-themes related to PPI, (1) provider communication skill and language barriers, and (2) preferences in care. 12 articles addressed provider communication skill and language barriers.[62,64,66–68,70,71,74,75,80,82,84] Several patients complained that providers had poor communication skills (e.g. fussing and lecturing instead of talking).[62,64,70,71,75,80,82,84] Language differences also caused communication barriers between patients and providers.[66,68,74,80]

> P: *"He (physician) seems to spend a lot of time lecturing instead of saying 'would it help you if I did this?' or if he would make a suggestion that didn't sound like he was treating me like a child."*[70]

> P: *"I'm very sad that my previous doctor was not, because current doctor talking in Farsi and I did not know the language, I do not understand something."*[74]

Five articles addressed preferences in care.[65,68,78,80,82] This included patients preferring specialists or a familiar provider, and providers' preferences. Several patients preferred to see the same doctor every time they came back for a visit.[78,80] Providers mentioned that patients preferred specialists more than primary care physicians.[65,68,82]

> HP: *" … Patients are sometimes stubborn, and they don't want to hear it from us, they'd rather hear it from an endocrinologist than hear it from us … "*[65]

> P: *"As continuity I like to see the same doctor every time if possible … "*[78]

Increase competency of healthcare providers (ICP)

There was one sub-theme related to ICP: continuing professional education. There were nine articles related to this sub-theme.[63–66,68,69,72,78,82] Providers such as nurses needed more continuing professional education in order to update their knowledge on good T2DM care. Inadequate skill is the largest barrier to managing diabetes care.[63–66,68,69,72,78,82]

> HP: *"I need more training for treating these patients."*[63]

> HP: *"One of the problems I can see is that I watch residents (medical trainees) in the hospital and they are pretty good with insulin …, but once you get out into a community to get your patients started on insulin,*

then the GP is losing his knowledge very quickly … you know if you are not doing something every day you become rusty fairly quickly and then you become insecure."[65]

> HP: *"A lot has changed in diabetes care over the past 10–15 years that you can't keep up with. We need to make sure that family physicians don't lose their expertise in diabetes care because of the substitution of care by the practice and diabetes nurses."*[68]

Family involvement (FI)

There were two sub-themes related to FI, (1) family as facilitators and (2) family as barriers. There were seven articles related to family as facilitators.[63,71,73,74,76,82,84] Family members play an important role in supporting, motivating, and encouraging diabetic patients in terms of lifestyle modification, nutrition, and medication.[71,73,74,82,84] Patients tend to follow recommendations in the presence of family support.[63,76]

> P: *"My wife gives me comfort. She advised me to eat vegetables scheduled to attend the program in any way I eat vegetables and salads."*[74]

> P: *"Without my family and my wife I probably wouldn't be alive"*[84]

> HP: *"Often we invite the wives of patients with diabetes because they are responsible for the diet."*[63]

There was one article related to family as barriers.[71] Sometimes, family members were barriers to the healthy lifestyles of patients by making the patients eat unhealthy food.[71]

> P: *"My wife, she gives little importance to my illness. I feel she helps with the needs of my disease very little. She cooks foods that I am not supposed to eat, and if I do not eat them she said that she is not going to prepare food for me again."*[71]

> P: *"I don't want to eat fried food, but my children want fried food."*[71]

> HP: *" … when they think about food and they say ' … it is my spouse that cooks.' I tell them have your spouse help you … go with you to see the nutritionist … I tell them to get the whole family involved"*[71]

Proposed conceptual figure of patients' and healthcare providers' perspectives on diabetes management

There were nine themes identified in this review. Six themes (CL, HSS, CC, SM, PS, RS) were linked to CCM while the other three themes (PPI, ICP, FI) were added to the CCM framework. Five themes showed similar perspectives between patients and healthcare providers: HSS, CC, SM, RS and FI. These themes showed agreement from both providers' and patients' perspectives. For example, both showed the same difficulties in using health services such as the limitation of medical services and health insurance. Both of them wanted the same type of continuity of care such as good cooperation among healthcare providers. Both agreed that experiences about diabetes shared by friends and family helped the patients become more aware of diabetic complications. Both agreed that there were difficulties in the referral system with patients not knowing when or where to follow up. Both valued the family members who are supportive of patients with diabetes. However, both also agreed that family members can be a barrier for managing diabetes. Two themes showed differences among the perspectives of patients and healthcare providers: CL and PPI. These themes revealed disagreement in terms of community linkages such as the point of resource and policy. Healthcare providers and patients blame each other for difficulties in communication. The last two themes (PS and ICP) revealed neither similarities nor differences. Both addressed providers' support but in different aspects and only healthcare providers gave their perspectives on competency. The main result of this review is to show that these nine themes are the key factors that can help improve diabetes treatments as well as patients' health outcomes. A figure

showing the linkage of the nine themes between patients and health care providers is shown Fig. 2.

Discussion

This review identified nine major themes from patients' and healthcare providers' perspectives on diabetes management. Using the CCM framework, three new emerging themes were identified (PPI, ICP, and FS) in addition to the six CCM major themes (CL, HSS, CC, SM, PS, RS). These key findings covered broad dimensions of diabetes management in terms of individual care, community involvement, and healthcare systems. The review also showed differences and similarities in perspectives among health care providers and patients, which can help to improve diabetes care systems as well as patients' outcomes.

This review used CASP as quality assessment criteria, in which definitions of each criterion had been more robustly determined for qualitative studies to be finally included in the reviews. In addition, this review showed the variety of health care providers' and patients' perspectives from several continents (Europe, Asia, North America) reflecting various contexts of diabetes care systems. A few studies have previously undertaken a systematic review of qualitative studies.[5,18,19] Those studies focused on a particular group (South Asians) and used meta-ethnography,[5] interpretivist concepts[18] and the theoretical domain framework[19] for extracting themes. The results of those studies focused on facilitators and barriers of diabetes management,[5] patients' self-management[18] and providers' perspectives on effective diabetes management.[19] Those studies did not cover the healthcare system but only self-care practices. Furthermore, none of the studies used the CCM framework for extracting the themes of qualitative studies. This study is the first systematic review using CCM of both healthcare providers' and patients' perspectives on the services of diabetes management. It is the first to use the original themes from included articles as an analytical framework to gain insights for improving services and systems of diabetes care as well as outcomes for patients.

A previous study from Baptista et al. (2016) revealed that CCM does not improve clinical outcomes of diabetes patients in isolate elements. However, it seems to be more useful if the six elements of CCM are combined with other interventions.[16] Strickland et al. (2010) revealed that diabetes patients who were seen in practices that have implemented more CCM features were significantly more likely to receive appropriate diabetes care such as behavior counseling.[11] This review found three new emerging themes from CCM and these might reveal more in terms of improving diabetes care—especially in psychological contexts.

This review found both facilitators and barriers of diabetes management in each theme from the perspectives of diabetes patients and healthcare providers. Examples of facilitators mostly came from developed countries, such as good organization in the theme CL (Germany, The Netherland).[63,68] Good collaboration in each care level was found in HSS (The Netherland, Finland)[64,68,84], and good support provided by nurses was found in PS (Finland).[84] However, more continuing education for healthcare providers is needed in The Netherlands, Germany, and Canada[63,65,68] as well as a more transparent insurance system in The Netherlands.[68] In the theme of family support it was shown that family members are facilitators in both developing and developed countries including Iran[74], Finland[84], and Germany.[63] Most of the barriers came from developing countries such as Oman and Bangladesh. In Asia there remains a lack of healthcare providers of HSS[66,80] along with poor accessibility to diabetes services of HSS.[75] There are still barriers for individual care, such as self-management and lifestyle behavior in both developing countries (Oman) and developed countries (USA and Japan).[62,66,79] Developing countries (Iran) and developed countries (USA, Canada, and UK) have difficulty in communication between patients and healthcare providers in the PPI theme.[65,70,74,78] Continuity of care and referral systems may also be barriers in both developed and developing countries, such as lack of

team cooperation in Canada,[65] and difficulty in managing continuity of care in Oman[66] and Australia.[82] Thus, the aforementioned message of each theme from this review could be the basis for the initial setting of diabetes care in countries without effective systems for diabetes care, especially developing countries.

The results from previous qualitative reviews showed several barriers for diabetes management. Rushforth et al. (2016) showed the barriers only from the providers' perspective to achieve effective diabetes management in primary care, including limited time and resources for clinicians, lack of confidence in knowledge of guidelines and skills, initiating and facilitating patient behavior change, frustrations over patient compliance, and anxieties about treatment intensification.[19] In this review barriers were found in the HSS theme such as providers' lack of time.[63–67,82] Providers also required more Continuing Professional Education (CPE) in the ICP theme.[63–66,68,69,72,78,82] Handelsman et al. (2011) discussed clinical inertia as a barrier to diabetes care due to multiple treatment guidelines, algorithms and goals recommended by different organizations and societies.[7] This review has confirmed clinical inertia due to new guidelines that frustrated healthcare providers[68,69] in the theme of PS. Sohal et al. (2015) reported barriers to diabetes management including lack of understanding about diabetes management and facilitating factors including trusting care providers, appropriate exercise and dietary advice, and family involvement.[5]

This review mentions understanding about self-management in the SM theme. Some patients had good understanding, but didn't follow good management guidelines due to their personal context.[62,66,69,71,83] This review also supports family involvement for better diabetes care.[63,71,73,74,76,82,84] However, in the FI theme, this review also shows that family can be a barrier.[71] It is important that both patients and their family members know how to manage diabetes. Franklin et al. (2017) studied patients' and healthcare professionals' perceptions of interaction to better understand the context in which interactions shape self-management and opportunities for collaborative goal-setting.[18] In the SM theme, this review also shows that collaborative goal setting is a key to better diabetes care.[62,66,68,71,76,79,81,83]

This review mentioned the difficulty of access to care in the HSS theme.[66,72,80] Jones and Crowe (2017) studied factors impacting diabetes management among minorities including treatment accessibility and acceptability, and cultural roles within families.[22] Park et al. (2015) revealed that East Asian immigrants showed struggles with multi-contextual barriers, a lack of consensus on cultural strategies, and language barriers.[21] These reviews were excluded from our research because they focused on minorities whereas our research focused on general perspectives which can be implemented in wide areas. However, there are similarities among the perspectives of Asian immigrants and the patients in our study such as cultural beliefs and attitudes which can be barriers to diabetes care[66,69] in the SM theme and language barriers[66,68,74,80] in the PPI theme.

McSharry et al. (2016) stated that medication-taking for Type 2 diabetes is a unique adherence context, which requires the development of condition-specific interventions. The present findings indicate patients understand the need for medications but adjust dosage and timing in their daily lives.[20] This review showed the theme of medication adherence which corresponded with McSharry's (2016) study in terms of unique adherence contexts. Some studies in this review showed medication adherence is dependent on patients' personal context[73,74] in the SM theme.

According to this review, there were several barriers in diabetes management which require further improvement such as referral systems, continuity of care, and improved self-management by patients. Those aspects were consistent with previous qualitative reviews as mentioned above in terms of barriers. This review also found interesting points in healthcare providers' competency which requires more attention from healthcare systems to improve diabetes care. In addition to the barriers, there were some supportive factors such as community

linkage, family involvement, and providers' support. This review found several studies[63,71,73,74,76,82,84] which revealed that family members of diabetes patients were the most supportive persons for their care. This suggests that the new diabetes management strategies should also focus on family members and community support. Our suggestion for approaching families is to implement home care in order to create mutual understanding of proper diabetes management.

Limitations

This study may not have used all related articles due to limited ability to retrieve all resources, limiting accessibility to about 45.5%. This study also excluded intervention studies such as program and technology interventions. Publication bias is a factor in this study as only published articles were selected. In an effort to eliminate selection bias, two researchers worked independently to retrieve and choose articles in accordance with the CASP criteria. This study might not be applicable to specific groups of diabetes patients (e.g. travelling patients, patients with disabilities, and events such as Ramadan).

Conclusion

In conclusion, this review found nine themes from both diabetic patients and health care providers to improve health outcomes. In-depth information showed facilitating factors in some themes such as community involvement, team cooperation, providers' support and family involvement. There were also numerous barriers in the themes that involved perspectives of diabetes management. Hence, addressing

these barriers may be deemed useful in improving diabetes care. This is basic information for diabetes care development in order to achieve better patient outcomes and better health care systems for continuous quality improvement (CQI).

Practical implications

Effective diabetes management is a key to success in achieving treatment goals for diabetic patients. Perspectives from both patients and healthcare providers can be one indicator that reflects the quality of diabetes management or services. This study can be used in establishing interdisciplinary teams. Community engagement and good services must be developed for a better system design to achieve treatment goals.

Acknowledgement

Appendix 1. Search term strategy for perspectives from providers and patients to diabetes management

Databases	Combination Search Terms	Number of first record after checking duplicated
Web of Science		15
	• Diabetes Management (AND) Patient needs	
	• Diabetes Management (AND) Patient perceptions	
	• Diabetes Management (AND) Patient opinions	
	• Diabetes Management (AND) Patient perspectives	
	• Diabetes Management (AND) Provider needs	
	• Diabetes Management (AND) Provider perceptions	
	• Diabetes Management (AND) Provider opinions	
	• Diabetes Management (AND) Providers perspectives	

CINAHL   56

- Diabetes Management (AND) Patient needs
- Diabetes Management (AND) Patient perceptions
- Diabetes Management (AND) Patient opinions
- Diabetes Management (AND) Patient perspectives
- Diabetes Management (AND) Provider needs
- Diabetes Management (AND) Provider perceptions
- Diabetes Management (AND) Provider opinions
- Diabetes Management (AND) Providers perspectives

PubMed   1343

- Diabetes Management (AND) Patient needs
- Diabetes Management (AND) Patient perceptions
- Diabetes Management (AND) Patient opinions
- Diabetes Management (AND) Patient perspectives
- Diabetes Management (AND) Provider needs
- Diabetes Management (AND) Provider perceptions
- Diabetes Management (AND) Provider opinions
- Diabetes Management (AND) Providers perspectives

Science Direct   567

- Diabetes Management (AND) Patient needs
- Diabetes Management (AND) Patient perceptions
- Diabetes Management (AND) Patient opinions
- Diabetes Management (AND) Patient perspectives
- Diabetes Management (AND) Provider needs
- Diabetes Management (AND) Provider perceptions
- Diabetes Management (AND) Provider opinions
- Diabetes Management (AND) Providers perspectives

Total   1981

Appendix 2. Summary of 38 excluded studies

N.	Author, Year (Cited Reference)	Author Comments	CASP Score
1	Ali Habiba I,2010 (55)	Not meet inclusion criteria due to other perspectives. This study is a perspective of women at risk for T2DM not T2DM patients.	9
2	Barbara S, 2012 (53)	Not meet inclusion criteria due to special patients of Maltese immigrants	9
3	Cassimatis M, 2014 (25)	Not meet inclusion criteria due to being an intervention study in technology	8
4	Furler J, 2008 (28)	Not meet inclusion criteria due to being an intervention study in coaching	9
5	Mathew R, 2012 (29)	Not meet inclusion criteria due to being an intervention study in education program	9
6	Moser A, 2008 (30)	Not meet inclusion criteria due to being an intervention study in nurse-led and shared-care program	9
7	Odgers-Jewell K, 2017 (31)	Not meet inclusion criteria due to being an intervention study in group-based education program.	9
8	Pooley Colin G, 2008 (59)	Not clear objective according to CASP criteria.	Did not pass the screening
9	Smith C, 2016 (32)	Not meet inclusion criteria due to being an intervention study in group education program.	8
10	Sturt J, 2006 (33)	Not meet inclusion criteria due to being an intervention study in self-management education program.	9
11	Wermeling M, 2014 (34)	Not meet inclusion criteria due to being an intervention study in lifestyle counseling and weight management program. And this study did not pass CASP screening criteria.	Did not pass because it was not enough reason in introduction
12	Almansour HA, 2017 (54)	Not meet inclusion due to studying in a special event as Ramadan	8
13	Andrews SM, 2017 (26)	Not meet inclusion criteria due to being an intervention study in telemedicine.	9
14	Berenguera A, 2016 (35)	Not meet inclusion criteria due to being an intervention study in a person-centered intervention.	9
15	Beverly EA, 2010 (36)	Not meet inclusion criteria due to being an intervention study in spousal support program	8
16	Burridge Letitia H, 2015 (37)	Not meet inclusion criteria due to being an intervention study in GP-led integrated diabetes care program	9
17	Chapman A, 2016 (38)	Not meet inclusion criteria due to being an intervention study in psychological care program	9
18	Concha JB, 2016 (39)	Not pass CASP and cross-cultural skill intervention	Did not pass CASP because it was irrelevant introduction
19	Cotugno JD, 2015 (58)	Not passed CASP screening criteria due to no statement on gaps of study, no evidence for an objective.	Did not pass CASP
20	Gillani SW, 2017 (52)	Not meet inclusion criteria due to special patients as ethnic groups with physical disability	8
21	Gucciardi E, 2013 (40)	Not meet inclusion criteria due to being an intervention study in self-monitoring of blood glucose program and special patients as black Caribbean and South Asian Canadians	9
22	Hu J, 2013 (57)	Not meet inclusion criteria due to special patients as Hispanic immigrants and include family members' perspective which is not DM patients	9
23	Halperin IJ, 2018 (41)	Not meet inclusion criteria due to being an intervention study in diabetes care across the institute of medicine's six domains of quality program	7
24	Lawton J, 2009 (42)	Not meet inclusion criteria due to being an intervention study in practice-based diabetes care program	7
25	Malpass A, 2009 (43)	not meet inclusion criteria due to physical activity, dietary intervention program	9
26	Ogunrinu T, 2017 (44)	Not meet inclusion due to being an intervention study in health education program	9
27	Neesha R. Patel, 2016 (51)	Not meet inclusion criteria due to special patients and event as British south Asians on holiday	7
28	Peel E, 2004 (45)	Not meet inclusion due to being an intervention study in blood glucose self-monitoring program	8
29	Peytremann-Bridevaux I, 2012 (9)	Not meet inclusion due to being an intervention study in Regional Diabetes Program	9
30	Ralston JD, 2004 (46)	Not passed CASP screening criteria and being an intervention study in diabetes support program	Did not pass because it was not enough information of introduction
31	Richardson BS, 2015 (47)	Not meet inclusion due to being an intervention study in community health worker model program	9
32	Ritholz MD, 2014 (60)	Not pass CASP screening criteria as it is unclear evidence for the objective.	Did not pass the screening
33	Samuel-Hodge CD, 2013 (56)	Not meet inclusion due to a perspective of family members not DM patients	9
34	Sunaert P, 2011 (48)	Not meet inclusion due to being an intervention study in education program	8
35	Mathiesen AS, 2017 (27)	Not meet inclusion due to being an intervention study in digital	9
36	Pilkington FB, 2011 (61)	Not meet CASP screening criteria, as it does not provide relevant introduction to the aim of the study.	Did not pass the screening
37	Yamakawa M, 2008 (49)	Not meet inclusion due to being an intervention study in health education, competency and empowerment program	9
38	Fort MP, 2013 (50)	Not pass CASP screening criteria and primary healthcare and community support model program	Did not pass because it was complicated introduction

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.sapharm.2019.09.001.

References

1. Cho NH, Shaw JE, Karuranga S, et al. IDF Diabetes Atlas: global estimates of diabetes prevalence for 2017 and projections for 2045. *Diabetes Res Clin Pract.* 2018;138:271–281.
2. Rhodes P, Nocon A, Wright J. Specialist diabetes clinics in primary care: the views of GPs about the impact on quality of care. *Qual Prim Care.* 2003;11:265–270.
3. Cooper JG, Claudi T, Jenum AK, et al. Quality of care for patients with type 2 diabetes in primary care in Norway is improving. *Diabetes Care.* 2009;32(1):81.
4. Segal L, Leach MJ, May E, et al. Regional primary care team to deliver best-practice diabetes care: a needs-driven health workforce model reflecting a biopsychosocial construct of health. *Diabetes Care.* 2013;36(7):1898–1907.
5. Sohal T, Sohal P, King-Shier KM, et al. Barriers and facilitators for type-2 diabetes management in south Asians: a systematic review. *PLoS One.* 2015;10(9):e0136202https://doi.org/10.1371/journal.pone.0136202.
6. Khan H, Lasker SS, Chowdhury TA. Exploring reasons for very poor glycaemic control in patients with Type 2 diabetes. *Primary care diabetes.* 2011;5(4):251–255.
7. Handelsman Y, Jellinger PS. Overcoming obstacles in risk factor management in type 2 diabetes mellitus. *J Clin Hypertens.* 2011;13(8):613–620.
8. Piatt GA, Orchard TJ, Emerson S, et al. Translating the chronic care model into the community. *Diabetes Care.* 2006;29(4):811.
9. Peytremann-Bridevaux I, Lauvergeon S, Mettler D, et al. Diabetes: opinions, needs and proposed solutions of Swiss patients and healthcare professionals: a qualitative study. *Diabetes Res Clin Pract.* 2012;97(2):242–250.
10. Lewis CP, Newell JN. Patients' perspectives of care for type 2 diabetes in Bangladesh –a qualitative study. *BMC Public Health.* 2014;14(1):737.
11. Strickland PAO, Hudson SV, Piasecki A, et al. Features of the Chronic Care Model (CCM) associated with behavioral counseling and diabetes care in community primary care. *J Am Board Fam Med.* 2010;23:295–2305.
12. Stellefson M, Dipnarine K, Stopka C. The chronic care model and diabetes management in US primary care settings: a systematic review. *Prev Chronic Dis.* 2013;10:E26.
13. Frei A, Senn O, Chmiel C, et al. Implementation of the chronic care model in small medical practices improves cardiovascular risk but not glycemic control. *Diabetes Care.* 2014;37(4):1039.
14. Profili F, Francesconi P, Gini R, et al. Impact of chronic care model on diabetes care in tuscany: a controlled before-after study. *Eur J Public Health.* 2016;27(1):8–13.
15. Kong J-X, Zhu L, Wang H-M, et al. Effectiveness of the chronic care model in type 2 diabetes management in a community health service center in China: a group randomized experimental study. *Journal of Diabetes Research.* 2019;2019:12.
16. Baptista DR, Wiens A, Pontarolo R, et al. The chronic care model for type 2 diabetes: a systematic review. *Diabetol Metab Syndrome.* 2016;8(1):7.
17. Bongaerts BWC, Müssig K, Wens J, et al. Effectiveness of chronic care models for the management of type 2 diabetes mellitus in Europe: a systematic review and meta-analysis. *BMJ open.* 2017;7(3):e013076.
18. Franklin M, Lewis S, Willis K, et al. Patients' and healthcare professionals' perceptions of self-management support interactions: systematic review and qualitative synthesis. *Chronic Illness.* 2018;14:79–103. https://doi.org/10.1177/1742395317710082.
19. Rushforth B, McCrorie C, Glidewell L, et al. Barriers to effective management of type 2 diabetes in primary care: qualitative systematic review. *Br J Gen Pract.* 2016;66(643):e114–e127.
20. McSharry J, McGowan L, Farmer AJ, et al. Perceptions and experiences of taking oral medications for the treatment of Type 2 diabetes mellitus: a systematic review and meta-synthesis of qualitative studies. *Diabet Med.* 2016;33(10):1330–1338.
21. Park C, Nam S, Whittemore R. Incorporating cultural perspectives into diabetes self-management programs for East Asian immigrants: a mixed-study review. *J Immigr Minority Health.* 2016;18(2):454–467.
22. Jones V, Crowe M. How people from ethnic minorities describe their experiences of managing type-2 diabetes mellitus: a qualitative meta-synthesis. *Int J Nurs Stud.* 2017;76(Supplement C):78–91.
23. (CASP) CASP. *10 Questions to Help You Make Sense of Qualitative Research.* Oxford: CASP; 2006. [cited 2018 08 May]. Available from:. https://hhs.hud.ac.uk/lqsu/Useful/critap/Qualitative%20Research%20Checklist/CASP-Qualitative Research-Checklist-31.05.13.pdf.
24. Zaza S, Wright-De Agüero LK, Briss PA, et al. Data collection instrument and procedure for systematic reviews in the guide to community preventive services11The names and affiliations of the Task Force members are listed. *Am J Prev Med.* 2000;18(1, Supplement):44–74 on page v of this supplement and at http://www.thecommunityguide.org.
25. Cassimatis M, Kavanagh DJ, Smith AC. Perceived needs for supported self-management of type 2 diabetes: a qualitative investigation of the potential for a web-based intervention. *Aust Psychol.* 2014;49(2):75–85.
26. Andrews SM, Sperber NR, Gierisch JM, et al. Patient perceptions of a comprehensive telemedicine intervention to address persistent poorly controlled diabetes. *Patient Prefer Adherence.* 2017;11:469–478.
27. Mathiesen AS, Thomsen T, Jensen T, et al. The influence of diabetes distress on digital interventions for diabetes management in vulnerable people with type 2 diabetes: a qualitative study of patient perspectives. *Journal of Clinical & Translational Endocrinology.* 2017;9:41–47.
28. Furler J, Walker C, Blackberry I, et al. The emotional context of self-management in chronic illness: a qualitative study of the role of health professional support in the self-management of type 2 diabetes. *BMC Health Serv Res.* 2008;8:214.
29. Mathew R, Gucciardi E, De Melo M, et al. Self-management experiences among men and women with type 2 diabetes mellitus: a qualitative analysis. *BMC Fam Pract.* 2012;13(1):122.
30. Moser A, van der Bruggen H, Widdershoven G, et al. Self-management of type 2 diabetes mellitus: a qualitative investigation from the perspective of participants in a nurse-led, shared-care programme in The Netherlands. *BMC Public Health.* 2008;8:91.
31. Odgers-Jewell K, Isenring EA, Thomas R, et al. Group participants' experiences of a patient directed group-based education program for the management of type 2 diabetes mellitus. *PLoS One.* 2017;12(5):e0177688.
32. Smith C, McNaughton DA, Meyer S. Client perceptions of group education in the management of type 2 diabetes mellitus in South Australia. *Aust J Prim Health.* 2016;22(4):360–367.
33. Sturt J, Hearnshaw H, Barlow J, et al. Supporting a curriculum for delivering Type 2 diabetes patient self-management education: a patient-needs assessment. *Prim Health Care Res Dev.* 2006;6(4) 291–9.
34. Wermeling M, Thiele-Manjali U, Koschack J, et al. Type 2 diabetes patients' perspectives on lifestyle counselling and weight management in general practice: a qualitative study. *BMC Fam Pract.* 2014;15:97.
35. Berenguera A, Molló-Inesta À, Mata-Rases M, et al. Understanding the physical, social, and emotional experiences of people with uncontrolled Type 2 diabetes: a qualitative study. *Patient Prefer Adherence.* 2016;10:2323–2332.
36. Beverly EA, Wray LA. The role of collective efficacy in exercise adherence: a qualitative study of spousal support and Type 2 diabetes management. *Health Educ Res.* 2010;25(2):211–223.
37. Burridge LH, Foster MM, Donald M, et al. Making sense of change: patients' views of diabetes and GP-led integrated diabetes care. *Health Expect.* 2015;19(1):74–86.
38. Chapman A, Yang H, Thomas SA, et al. Barriers and enablers to the delivery of psychological care in the management of patients with type 2 diabetes mellitus in China: a qualitative study using the theoretical domains framework. *BMC Health Serv Res.* 2016;16:106.
39. Concha JB, Mayer SD, Mezuk BR, et al. Diabetes causation beliefs among Spanish-speaking patients. *Diabetes Educat.* 2016;42(1):116–125.
40. Gucciardi E, Fortugno M, Senchuk A, et al. Self-monitoring of blood glucose in Black Caribbean and South Asian Canadians with non-insulin treated Type 2 diabetes mellitus: a qualitative study of patients' perspectives. *BMC Endocr Disord.* 2013;13(1):46.
41. Halperin IJ, Mukerji G, Maione M, et al. Adult patient perspectives on care for type 1 and type 2 diabetes across the institute of medicine's 6 domains of quality. *Can J Diabetes.* 2018;42(1):36–43.
42. Lawton J, Rankin D, Peel E, et al. Patients' perceptions and experiences of transitions in diabetes care: a longitudinal qualitative study. *Health Expect : an international journal of public participation in health care and health policy.* 2009;12(2):138–148.
43. Malpass A, Andrews R, Turner KM. Patients with Type 2 Diabetes experiences of making multiple lifestyle changes: a qualitative study. *Patient Educ Couns.* 2009;74(2):258–263.
44. Ogunrinu T, Gamboa-Maldonado T, Ngewa RN, et al. A qualitative study of health education experiences and self-management practices among patients with type 2 diabetes at Malamulo Adventist Hospital in Thyolo District, Malawi. *Malawi Med J.* 2017;29(2):118–123.
45. Peel E, Parry O, Douglas M, et al. Blood glucose self-monitoring in non-insulin-treated type 2 diabetes: a qualitative study of patients' perspectives. *Br J Gen Pract.* 2004;54(500):183–188.
46. Ralston JD, Revere D, Robins LS, et al. Patients' experience with a diabetes support programme based on an interactive electronic medical record: qualitative study. *BMJ Br Med J (Clin Res Ed).* 2004;328(7449):1159.
47. Richardson BS, Willig AL, Agne AA, et al. Diabetes connect: african American women's perceptions of the community health worker model for diabetes care. *J Community Health.* 2015;40(5):905–911.
48. Sunaert P, Vandekerckhove M, Bastiaens H, et al. Why do GPs hesitate to refer diabetes patients to a self-management education program: a qualitative study. *BMC Fam Pract.* 2011;12(1):94.
49. Yamakawa M, Makimoto K. Positive experiences of type 2 diabetes in Japanese patients: an exploratory qualitative study. *Int J Nurs Stud.* 2008;45(7):1032–1041.
50. Fort MP, Alvarado-Molina N, Peña L, et al. Barriers and facilitating factors for disease self-management: a qualitative analysis of perceptions of patients receiving care for type 2 diabetes and/or hypertension in San José, Costa Rica and Tuxtla Gutiérrez, Mexico. *BMC Fam Pract.* 2013;14:131.
51. Patel NR, Kennedy A, Blickem C, et al. "I'm managing my diabetes between two worlds": beliefs and experiences of diabetes management in British South Asians on holiday in the east—a qualitative study. *Journal of Diabetes Research.* 2016;2016:8 Article ID 5436174.
52. Gillani SW, Sulaiman SAS, Abdul MIM, et al. A qualitative study to explore the perception and behavior of patients towards diabetes management with physical disability. *Diabetol Metab Syndrome.* 2017;9:58.
53. Barbara S, Krass I. Self-management of type 2 diabetes by Maltese immigrants in

Australia: can community pharmacies play a supporting role? *Int J Pharm Pract.* 2012;21(5):305–313.

54. Almansour HA, Chaar B, Saini B. Pharmacists' perspectives about their role in care of patients with diabetes observing Ramadan. *Res Soc Adm Pharm.* 2017;13(1):109–122.

55. Ali HI, Baynouna LM, Bernsen RM. Barriers and facilitators of weight management: perspectives of Arab women at risk for type 2 diabetes. *Health Soc Care Community.* 2010;18(2):219–228.

56. Samuel-Hodge CD, Cene CW, Corsino L, et al. Family diabetes matters: a view from the other side. *J Gen Intern Med.* 2013;28(3):428–435.

57. Hu J, Amirehsani K, Wallace D, et al. Perceptions of barriers in managing diabetes: perspectives of Hispanic immigrant patients and family members. *Diabetes Educat.* 2013;39(4):494–503.

58. Cotugno JD, Ferguson M, Harden H, et al. "I wish they could be in my shoes": patients' insights into tertiary health care for type 2 diabetes mellitus. *Patient Prefer Adherence.* 2015;9:1647–1655.

59. Pooley CG, Gerrard C, Hollis S, et al. "Oh it"s a wonderful practice … you can talk to them': a qualitative study of patients' and health professionals' views on the management of type 2 diabetes. *Health Soc Care Community.* 2008;9(5):318–326.

60. Ritholz MD, Beverly EA, Brooks KM, et al. Barriers and facilitators to self-care communication during medical appointments in adults with type 2 diabetes. *Chronic Illness.* 2014;10(4):303–313.

61. Pilkington FB, Daiski I, Lines E, et al. Type 2 diabetes in vulnerable populations: community healthcare providers' perspectives on health service needs and policy implications. *Can J Diabetes.* 2011;35(5):503–511.

62. Beverly EA, Ritholz MD, Brooks KM, et al. A qualitative study of perceived responsibility and self-blame in type 2 diabetes: reflections of physicians and patients. *J Gen Intern Med.* 2012;27(9):1180–1187.

63. Goetz K, Szecsenyi J, Campbell S, et al. The importance of social support for people with type 2 diabetes – a qualitative study with general practitioners, practice nurses and patients. *GMS Psycho-Soc-Med.* 2012;9:Doc02.

64. Längst G, Seidling HM, Stützle M, et al. Factors associated with medication information in diabetes care: differences in perceptions between patients and health care professionals. *Patient Prefer Adherence.* 2015;9:1431–1441.

65. Brez S, Rowan M, Malcolm J, et al. Transition from specialist to primary diabetes care: a qualitative study of perspectives of primary care physicians. *BMC Fam Pract.* 2009;10:39.

66. Noor ANM, Al-Shafaee MA, Wahlström R, et al. Doctors' and nurses' views on patient care for type 2 diabetes: an interview study in primary health care in Oman. *Prim Health Care Res Dev.* 2013;14(3):258–269.

67. Kern DH, Mainous AG. Disease management for diabetes among family physicians and general internists: opportunism or planned care? *Fam Med.* 2001;33(8):621–625.

68. Raaijmakers LGM, Hamers FJM, Martens MK, et al. Perceived facilitators and barriers in diabetes care: a qualitative study among health care professionals in The Netherlands. *BMC Fam Pract.* 2013;14(1):114.

69. Brown JB, Harris SB, Webster-Bogaert S, et al. The role of patient, physician and systemic factors in the management of type 2 diabetes mellitus. *Fam Pract.* 2002;19(4):344–349.

70. Matthews SM, Peden AR, Rowles GD. Patient–provider communication: understanding diabetes management among adult females. *Patient Educ Couns.* 2009;76(1):31–37.

71. Carbone ET, Rosal MC, Torres MI, et al. Diabetes self-management: perspectives of Latino patients and their health care providers. *Patient Educ Couns.* 2007;66(2):202–210.

72. Dutton H, Rowan MS, Liddy C, et al. Patient perspectives on discharge from specialist type 2 diabetes care back to primary care: a qualitative study. *Can J Diabetes.* 2014;38(3):191–197.

73. Al-Qazaz HK, Hassali MA, Shafie AA, et al. Perception and knowledge of patients with type 2 diabetes in Malaysia about their disease and medication: a qualitative study Research in Social and Administrative. *Pharmacy.* 2011;7(2):180–191.

74. Karimi MH, Namdar AH, Jouybari L, et al. Facilitators and barriers of adaptation to diabetes: experiences of Iranian patients. *J Diabetes Metab Disord.* 2014;13(1):17.

75. Lewis CP, Newell JN. Patients' perspectives of care for type 2 diabetes in Bangladesh –a qualitative study. *BMC Public Health.* 2014;14(1):737.

76. Held RF, DePue J, Rosen R, et al. Patient and healthcare provider views of depressive symptoms and diabetes in American Samoa. *Cult Divers Ethn Minor Psychol.* 2010;16(4):461–467.

77. Lai WA, Chie W-C, Lew-Ting C-Y. How diabetic patients' ideas of illness course affect non-adherent behaviour: a qualitative study. *Br J Gen Pract.* 2007;57(537):296–302.

78. Alazri MH, Neal RD, Heywood P, et al. Patients' experiences of continuity in the care of type 2 diabetes: a focus group study in primary care. *Br J Gen Pract.* 2006;56(528):488–495.

79. Kato A, Fujimaki Y, Fujimori S, et al. A qualitative study on the impact of internalized stigma on type 2 diabetes self-management. *Patient Educ Couns.* 2016;99(7):12339.

80. Al-Azri M, Al-Azri H, Al-Hashmi F, et al. Factors affecting the quality of diabetic care in primary care settings in Oman: a qualitative study on patients' perspectives. *Sultan Qaboos University Medical Journal.* 2011;11(2):207–213.

81. Beverly EA, Wray LA, Chiu CJ, et al. Perceived challenges and priorities in co-morbidity management of older patients with Type 2 diabetes. *Diabet Med: a journal of the British Diabetic Association.* 2011;28(7):781–784.

82. Dhippayom T, Krass I. Supporting self-management of type 2 diabetes: is there a role for the community pharmacist? *Patient Prefer Adherence.* 2015;9:1085–1092.

83. Huang ES, Gorawara-Bhat R, Chin MH. Self-reported goals of older patients with type 2 diabetes mellitus. *J Am Geriatr Soc.* 2005;53(2):306–311.

84. Halkoaho A, Kangasniemi M, Niinimäki S, et al. Type 2 diabetes patients' perceptions about counselling elicited by interview: is it time for a more health-oriented approach? *Eur Diabetes Nurs.* 2014;11(1):13–18.

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