ผลการบริบาลทางเภสัชกรรมร่วมกับการให้ความรู้ด้านอาหารให้สอดคล้องตามวิถีอีสาน ในผู้ป่วยเบาหวานชนิดที่ 2
Effects of Pharmaceutical Care with food Education According to Isan Life Style in Patients with Type 2 Diabetes Mellitus

นิพนธ์ต้นฉบับ

Original Article

พวงเพชร เพชรโทน[1,2*], ปาริโมก เกิดจันทึก[3] และ สายทิพย์ สุทธิรักษา[3]

[1] นิสิตหลักสูตรเภสัชศาสตรมหาบัณฑิต สาขาเภสัชกรรมคลินิก คณะเภสัชศาสตร์
[2] ฝ่ายเภสัชกรรม รพ.สหัสขันธ์ อ.สหัสขันธ์ จ.กาฬสินธุ์ 46140
[3] สาขาวิชาเภสัชกรรมคลินิก คณะเภสัชศาสตร์
[1,3] มหาวิทยาลัยมหาสารคาม อ.กันทรวิชัย จ.มหาสารคาม 44150
*** Corresponding author:** phettone@gmail.com

วารสารไทยเภสัชศาสตร์และวิทยาการสุขภาพ2564;16(2):120-129.

Phuangphet Phettone[1,2*], Parimoke Kerdchantuk[3], and Saithip Suttiruksa[3]

[1] Student in Master's of Pharmacy program (Clinical Pharmacy), Faculty of Pharmacy
[2] Pharmacy Department, Sahasakhan Hospital, Sahasakhan, Kanlasin, 46140, Thailand
[3] Department of Clinical Pharmacy, Faculty of Pharmacy
[1,3] Mahasaraham University, Kantarawichai, Mahasarakham, 44150, Thailand
*** Corresponding author:** phettone@gmail.com

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บทคัดย่อ

วัตถุประสงค์: เพื่อศึกษาผลการบริบาลทางเภสัชกรรมร่วมกับการให้ความรู้ด้านอาหารตามวิถีอีสาน (กลุ่มทดลอง) เทียบกับการดูแลตามปกติ (กลุ่มควบคุม) ในผู้ป่วยเบาหวานชนิดที่ 2 ต่อค่า HbA1c ความรู้เกี่ยวกับโรคเบาหวานและอาหารตามวิถีอีสาน ความร่วมมือในการรับประทานอาหาร การรับประทานยา และการออกกำลังกาย อัตราการครอบครองยา และเจตคติต่อโรคเบาหวาน **วิธีการศึกษา:** การวิจัยเชิงทดลองแบบสุ่มและมีกลุ่มควบคุม ทำในคนไข้ที่คลินิกผู้ป่วยนอกโรคเบาหวาน โรงพยาบาลสหัสขันธ์ จ.กาฬสินธุ์ จำนวน 88 และ 87 คน ตามลำดับ การทดลองนาน 3 เดือน เปรียบเทียบผลลัพธ์ก่อนและหลังการทดลอง และระหว่างกลุ่ม **ผลการศึกษา:** เมื่อสิ้นสุดการศึกษา พบว่ากลุ่มทดลองมีค่า HbA1c ลดลงจากก่อนทดลอง และน้อยกว่ากลุ่มควบคุมอย่างมีนัยสำคัญ (*P*-value < 0.001 ทั้งคู่) โดยสามารถลดค่า HbA1c ให้น้อยกว่า 7.0% ได้ถึงร้อยละ 40.2 ในขณะที่กลุ่มควบคุมพบเป็นร้อยละ 0 กลุ่มทดลองมีความรู้เกี่ยวกับโรคเบาหวานและอาหารตามวิถีอีสาน ความร่วมมือในการรับประทานอาหารและการรับประทานยา อัตราการครอบครองยา และเจตคติ (ยกเว้นการออกกำลังกาย) ที่สิ้นสุดการศึกษาดีกว่าก่อนการศึกษา (*P*-value < 0.05) ส่วนเมื่อสิ้นสุดการศึกษากลุ่มทดลองมีผลลัพธ์ดังกล่าวดีกว่ากลุ่มควบคุม (*P*-value < 0.05 สำหรับทั้งหมด) **สรุป:** การบริบาลทางเภสัชกรรมร่วมกับการให้ความรู้ด้านอาหารตามวิถีอีสานทำให้ระดับ HbA1c และผลลัพธ์ทางคลินิกต่าง ๆ ดีขึ้นอย่างมีนัยสำคัญทางสถิติ ควรส่งเสริมให้มีบริการที่นำวิถีท้องถิ่นเข้ามาร่วมปรับเปลี่ยนพฤติกรรมคนไข้เบาหวานให้กว้างขวางมากขึ้น

คำสำคัญ: การบริบาลทางเภสัชกรรม, อาหารอีสาน. เบาหวานชนิดที่ 2

Abstract

Objective: To examine effects of pharmaceutical care with food education according to Isan Life style (test group) in patients with type 2 diabetes on HbA1c level compard with the usual care. Other outcomes included knowledge about diabetes and Isan food, compliances to diet, medications, and exercise, medication possession ratio and attitude toward diabetes. **Method:** In this randomized controlle trial, patients at the type 2 diabetes clinic of Sahatsakhan Hospital, Khalasin province were randomized to test group (n = 88) or control group (n = 87). The intervention took about 3 months. Within-group and between-group comparisons were conducted. **Results**: At the study end, HbA1c in the test group was lower than baseline and than that of the control group (*P*-value < 0.001 for both). A 40.2% and 0% of patients in the test and control groups, respectively reached the HbA1c of < 7.0%. When compared with baseline, test group had scores of diabetes, diet compliance, medication compliance, medication possession ratio and attitude (except exercise compliamce) improved significantly at the end of the study (*P*-value < 0.05). All of such outcomes were significantly better in the test group than the control group (*P*-value < 0.05 for all). **Conclusion:** Pharmaceutical care with food education according to Isan Life style improved HcA1c levels and other clinical outcomes significantly. More local lifestyle should be incorporated into lifestyle modification for diabetic patients.

Keywords: pharmaceutical care, Isan diet, type 2 diabetes mellitus

Editorial note
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Introduction

Lifestyle modification is crucial for glycemic control in diabetes patients. However, most diet modification is usually not tailored to local diet culture; hence, a failure or difficulties in glycemic control. There is an urgent need to implement food education incorporating local culture into lifestyle modification intervention for a better glycemic control.

Diabetes mellitus is a chronic non-communicable disease that requires constant treatment throughout the patient's life. Without proper treatment, complications may occur in various organs.[1] In addition, diabetes is a disease that has a high cost of treatment which could result in burdens to patients and their families or caregivers.[2] The International Diabetes Federation conducted a study and found the occurrence of micro- and macro-vascular complications.[1] It is associated with an increase in HbA1c levels. Controlling blood sugar levels to the target can reduce the incidence of complications and mortality. HbA1c reduction can reduce the risk of complications.[1,3] Therefore, the Ministry of Public Health service system has

developed a service plan to support and solve diabetes problems by requiring blood sugar control to have a target HbA1c of no more than 7.0%.[4]

Sahatsakhan Hospital is a community hospital with thirty of hospital beds. It is in the northeast or Isan region of Thailand. Based on data as of 1 October 2018, there were a total of 2,511 patients diagnosed with type 2 diabetes, with 309 patients (12.3%) with HbA1c level not higher than 7.0 percent but the other 87.7% has HbA1c level greater than 7.0%. An interview on diabetic patients at Sahatsakhan Hospital revealed that the patients tried to change eating glutinous rice or sticky rice which is the preferred carbohydrate in Isan diet to jasmine rice or white rice (unpublished data). Jasmine rice is recommended for the diabetic patients because it has a glycemic index lower than sticky rice. Some patients could practice consuming jasmine rice but certain portion of them experienced hypoglycemia. Suffering from trembling and sweating at night, the patient corrected the condition by drinking syrup to relieve the symptoms. These patients had HbA1c higher than 7.0%. Some patients reported that eating white rice did not make them full or satisfied. Therefor they still ate glutinous rice without limiting the amount of rice in each meal. When the patients changed their diet, they could become tired of the food so they drank syrup and energy drinks, and ate more frequently. Many patients liked to eat sweet fruits with glutinous rice to increase their appetite.

It has been well known that eating habit has an effect on blood sugar control. In the study of Chongcharoen and others in 2008, a self-care promotion model to control blood sugar levels of type 2 diabetic patients was examined.[5] It was found that diabetic patients had poor eating behaviors regarding type and quantity of food. For patients with occupations that could interfere with meal time, irregular administration of medications with respect to meals could happen. This medication noncompliance could hinder glycemic control.[5] When socializing with friends and/or family members, diabetic and non-diabetic individuals shared the same foods, either those highly in fat and sugar or not. Various studies found that Thai diabetic patients thought that food control is complicate, impractical and boring.[6,7]

Pender suggested that eating habits are a complex behavior related to both internal and external factors.[8] It is an integration of the way of life of individuals and families. External factors that are obstacles in controlling food may include occupation, socialization, family meal culture, and non-cooperation of family members. For example, drivers could sometimes face irregular meal times. In socialization, foods high in fat and sugar are usually inevitable. In a given family, all members usually share the same food, not specially prepared for diabetic family member(s). Family members could also inappropriately encourage diabetic member(s) to have regular foods shared with other members. For internal factors affecting diet control behavior, diabetic individuals could view diet control as complicate, bring and impractical. In addition, poor dental health could worsen the consumption of food rich in fiber.

In the study by Lerman and others, consuming proper diet of diabetic patients was the result of cognitive process, habits and personality such as addiction, taste, self-control, and lack of correct knowledge and understanding.[9] Albarran and others found that family dietary culture focused on the preference of family members rather than the glycemic control of their diabetic members.[10] Therefore, family affects diet control of diabetic patients.

Foods with low glycemic index are preferable for diabetic patients. Regional foods in the Thai northeast or Isan region are mostly with low glycemic index, except for glutinous or sticky rice. As a staple food in Isan area, difficulties in glycemic control among diabetic patients in Isan persist.

Eating is endemic and has an effect on disease control. For example, Mediterranean diet is based on the eating traditions of Greeks, south Italians, and Spaniards.[11,12] The principal aspects of this diet include proportionally high consumption of olive oil, legumes, unrefined cereals, fruits[13], and vegetables, moderate to high consumption of fish, moderate consumption of dairy products (mostly as cheese and yogurt), moderate wine consumption, and low consumption of non-fish meat products. Olive oil has been studied as a potential health factor for reducing all-cause mortality and the risk of chronic diseases. The Mediterranean diet is associated with a reduction in all-cause mortality[14], an probably lower risk of heart disease and early death.[15,16] The American Heart Association and American Diabetes Association recommend the Mediterranean diet as a healthy dietary pattern that may reduce the risk of cardiovascular diseases and type 2 diabetes, respectively.[17,18] The work of Rees and others concluded that the Mediterranean diet, low glycemic diet, low carb diet, high protein food could effectively reduce the occurrence of cardiovascular disease and diabetes.[16]

In terms of healthy eating plans, Dietary Approaches to Stop Hypertension or DASH diet has been widely recommended the most widely a well-balanced approach to eating for the general public. The American Heart Association considers the DASH diet "specific and well-documented across age, sex and ethnically diverse groups.[17] The other diets recommended by the US Dietary Guidelines include the Mediterranean diet and vegetarian diet.

Like other parts of the world, foods in Thailand are different from region to region. For each given region, there are foods that are and are not suitable for diabetic patients. In promoting proper diets for diabetic patients, integrating local foods into the dietary lifestyle modification is more sustainable than introducing recommended foods alien to the local patients. The critical point is to promote more healthy local foods, and demote those unhealthy ones. Diabetic patients registered at Sahatsakhan Hospital are patients with cultural traditions of the Isan or northeastern region. Pharmaceutical care has been implemented in these diabetic patient for quite sometimes, with poor to moderate improvement in glycemic control. Therefore, a more elaborate lifestyle modification specific to Isan diets together with pharmaceutical care could allow more successful and sustainable therapeutic compliance and ultimately glycemic control.

The objective of this study was to investigate the glycemic control effect of pharmaceutical care with food education according to Isan lifestyle, or the experimental intervention, in patients with type 2 diabetes registered at the outpatient diabetic clinic of Sahatsakhan Hospital. Specifically, we compared HbA1c levels between patients receiving the experimental intervention (test group) and those receiving only usual care (control group), at the end of the study. In addition, within each of the two groups, we compared HbA1c levels at baseline and at the end of the study. Hypothetically, there was no difference in HbA1c levels between the two groups at the end of the study and no change of HbA1c levels within each group. In addition, we also examined other outcomes including knowledge about diabetes and Isan food, compliances to diet, medications, and exercise, medication possession ratio and attitude toward diabetes, with the same comparisons and hypotheses as those of HbA1c.

Methods

In this prospective randomized controlled trial, study population was patients with type 2 diabetes mellitus registered at the Outpatient Diabetic Clinic of Sahatsakhan Hospital. Inclusion criteria were as follows. They had to have been diagnosed with type 2 diabetes for 3 months or more. Their HbA1c, taken within less than a month before randomization, had to be more than 7.0%. They took at least one medication for diabetes. They had to be conscious and without psychological disorders, able to use medications by themselves, able to read and write, and willing to participate. We excluded patients who were functionally dependent, with fragility, with dementia, at high risk of severe hypoglycemia, with severe symptoms until hospitalized, or referred to other hospital for continuous diabetes care.

Sample size was estimated based on the effect of pharmaceutical care obtained from the study of Wishah and others.[19] With a type I error of 5% and a power of 80%, 56 participants per group were needed. To compensate for an attrition rate of 30%, 73 participants per group were required. A total of 175 prospective participants were selected by simple random sampling. After randomization, 87 and 88 participants were assigned to control and test groups, respectively.

Research instruments

Research instruments consisted of data collection form and questionnaires and the experimental intervention. The patient data collection form and questionnaire on the patients' knowledge and compliance were developed by the researchers. The patient data collection form include gender, age, weight, height, BMI, universal health coverage, marital status, education level, occupation, smoking, drinking, income, HbA1c, medication, comorbidity, duration of comorbidity, duration of diabetes mellitus.

The questionnaire contained 5 sections as follows. In section 1, 10 items asked about diabetes knowledge with a response format of "correct," "incorrect" or "do not know." For each given item with true statement, one point was awarded for "correct" answer; while one point was rewarded for "incorrect" answer for any given item with false statement. A score of zero point was given otherwise. In the second section, 10 items assessed dietary compliance. For each healthy item, the answer could be 1 for "doing that every day," and zero for "doing that 3 – 4 days a week" and "not doing

that at all." For each non-healthy item, one point was rewarded for "not doing that at all" and zero points otherwise. In section 3, five questions assessed exercise compliance. In section 4, six items assessed the participant's medication compliance. Scoring for sections 3 and 4 was similar to that of section 2. In section 5, ten items evaluating the attitude toward diabetes (the disease, its treatment and self-care). The response was classified as "disagree," "neither disagree nor agree," and "agree."

Medication possession ratio (MPR) was defined as the proportion of drug use of patients as prescribed by the doctor. MPR was assessed by based on both oral and injectable drugs. DRPs were assessed as guided by the concept of pharmaceutical care.[20]

Content of the data collection form and questionnaires was validated by three physicians and a high validity was found with an Index of Item Objective Congruence (IOC) of 1 for all questions. To further test for content validity of the questionnaire especially relevancy and clarity, Item Content Validity (I-CVIs) and Content Validity for Scale (S-CVI) (I-CVIs) were determined. To obtain the I-CVIs, the number of experts judging the item as relevant or clear (rating 3 or 4) was divided by the total number of the experts. Each of all questionnaire items had I-CVI of at least 0.8 which is the cut-off criterion of acceptable content validity. For internal consistency reliability, the questionnaire was assessed in 20 patients comparable to the prospective participants from the out-patient department. The questionnaire was found to have an acceptable internal consistency reliability with a Cronbach's alpha coefficient of 0.72.

Data collection prodedure

Data collection using questionnaire and interviews were cinducted at first visit and at the end of the study. Participants were tested for FPG level at every visit at the diabetes clinic. HbA1c levels and other clinical outcomes (diabetes knowledge, dietary compliance, exercise compliance, medication compliance, medication possession ratio, and attitudes) were assessed at the start and at the end of the 90 days intervention.

Experimental intervention and procedure

Participants with HbA1c over 7.0 percent were randomized into either the test or control group. Patients in the control group received the service as usual at the diabetes clinic of Sahatsakhan Hospital. In usual care at the clinic, after registration, the patient was directed to blood test, and history taking by nurse. After meeting with the physician, treatment plan was made and new visit was scheduled. Medications were dispensed with advice as necessary by the pharmacist. In addition to the usual care, patients in the test group also received pharmaceutical care together with food education in accordance with Isan lifestyle.

In the test group, the pharmacist reviewed the patient's information from the electronic medical record database to assess DRPs. In the first visit of this new intervention, the patient was interviewed by the pharmacist. The patient's general information was obtained, medication possession ratio, medication compliance and DRPs were determined. The patient's diabetes knowledge, dietary compliance, attitude toward diabetes, and diabetes related quality of life were assessed. The following activities were also performed at the first, second and third visits which were held at the beginning of the study, the end of the first month, and the end of the second month, respectively. Pharmaceutical care was used to build self-care skills and identify, solve and prevent DRPs. These interventions were conducted by the pharmacist planning all activities with the patient for about 15 minutes in each visit. The patient was given self-care booklet concerning Isan lifestyle with additional information tailored to individual patient. At the end of the third month, all outcomes were assessed including medication possession ratio, medication compliance, diabetes knowledge, dietary compliance according to Isan lifestyle, and attitude toward diabetes.

Patients in the test group received pharmaceutical care with food education according to Isan lifestyle for patients with type 2 diabetes. Based on the intervention, participants were given knowledge about the disease, medications, and medication administration in accordance with the patient lifestyle by using posters and self-care guide. DRPs of the participants were identified and solved. Any problems in drug administration were corrected by pharmacists. The pharmacist introduced the experimental intervention which was the Isan dishes menu according to the Isan lifestyle and self-care skills to the participant. Self-care skills consisted of the following 5 steps.

In the first step, the pharmacist evaluated the participant's current health behaviors, identified DRPs, and determined medication possession ratio, medication compliance, diabetes knowledge, attitudes and dietary compliance before the

intervention. In the second step, the pharmacist provided information about diabetes and worked with the participant to solve the existing DRPs. In setting individual patient's glycemic control target, the pharmacist interpreted the patient's blood sugar levels to convince the patient to participate in setting and achieving the goal. In the third step, the patient was asked to demonstrate how they administered their medications so the pharmacist could help correct errors, if any.

In the fourth step, pharmacist helped the patient schedule medications to be consistent with their Isan dietary lifestyle as follows. At the Buddhist temple, the patient should take their before-meal oral and injection medications when monks start their breakfast. When working outside for example rice filed or plantations, for those who start their work in the early morning, they should not take medications before, but after the morning work break by taking the medications before breakfast as prescribed. In cooking, when the patient is starting to cook the last dish, the patient should take medications. This is because Isan people like to eat right after cooking. These various scheduled medication administrations are designed to fit various lifestyle activities for individual patients.

In the fifth step, the pharmacist provided knowledge about diet to control blood sugar suitable for Isan lifestyle. First, the idea of the patient and family members having meal together was conserved. This could alleviate the stress on the patient about having meal with different dishes and probably separately from family members. Usually sticky or glutinous rice is pooled in the family's large sticky rice basket for everyone to share. With no control, diabetic patients could fall into the old habit of having sticky rice with portion similar to what they took before. Patients in the test group and their family members were guided to allow a smaller portion of sticky rice for the patient. To be more practical, they were guided to put the portion of sticky rice for the patient in a personal small rice basket. In addition, based on the amount per serving of carbohydrate, 6 small molded lumps of sticky rice was considered one serving (Figure 1). For patients who did not eat sticky rice, serving portion of starchy rice (e.g., plain rice, rice noodle, potato, and pumpkin) was also taught for the patients and their family members (Figure 2). Since usually no side dishes are taken with sticky rice, patients able to control blood sugar could have determined serving portion of fruits (Figure 3). Leaning materials included daily medication demonstration sheet, daily injection demonstration, patient education poster and self-care booklet according to Isan lifestyle.

While participants in the test group received care as mentioned above, participants in the control group received the usual care provided by the diabetes clinic.

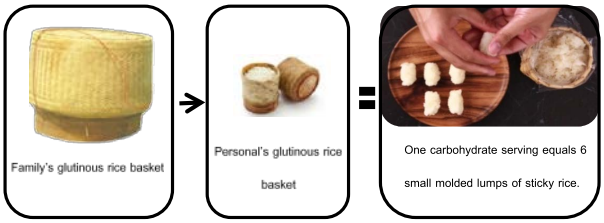

Figure 1 Serving portion of sticky rice.[21]

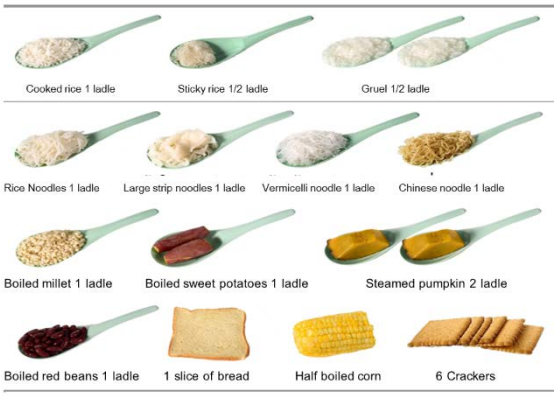

Figure 2 Serving portion of starchy rice.[21]

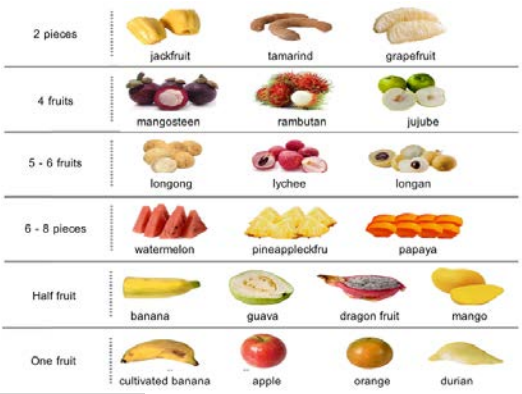

Figure 3 Serving portion of fruits for diabetic patients.[21]

This study was approved by Mahasarakham University Ethics Committee for Research Involving Human Subjects (Approval number: 105/2562). All participants were given information about voluntary nature of the study. Participants could withdraw from the study at any time. Once written

informed consent was obtained, participants were randomized into study groups.

Data analysis

Data were presented with descriptive statistics including frequency with percentage and mean with standard deviation. Comparisons of means of continuous variables between the two groups were conducted using independent t test, or Mann-Whitney U test if not normally distributed. For within-group comparisons, paired t test or Wilcoxon signed rank test, if sata not normally distributed, was used. For categorical variables, Chi-squared test or Fisher's exact test was used to compare differences between the two groups, as appropriate. A type I error (α) of 5% was set as a significance level (*P*-value < 0.05). Statistical analysis was performed using STATA software version 14.

Results

Of a total of 175 participants (88 and 87 in the control and test groups, respectively), the majority of them were women, under the Universal Coverage payment scheme, married, with primary school education, in agriculture, not smoking, having alcohol at least once in their life, with a monthly income of 5,000 baht or less no differences between the two groups (Table 1). Participants in the control and test groups were also comparable according to age (50.3 and 50.3 years) and body mass index (BMI) (26.4 and 26.3 kg/m^2) (Table 1). Their mean BMIs in both groups indicated overweight.

The average HbA1c levels were high and comparable between the two groups (8.9% and 9.0% for the control and test groups, respectively) (Table 2). They were diagnosed with DM for 5.9 and 4.9 years, respectively, and the majority were with DM for 5 – 10 years (75.0% and 70.1%, respectively). Most of them were treated with glipizide and metformin (83.0% and 83.9%, respectively). Most had comorbidity (81.8% and 83.9%), mainly hypertension and hyperlipidemia.

HbA1c level in the test group at the end of the study (7.5%) improved (or decreased) significantly from baseline (9.0%) (*P*-value < 0.001); while no change was found in the control group. At the end of the study, HbA1c level in the test group was significantly lower than that of the control group (7.5% and 8.9%, respectively, *P*-value < 0.001). A total of 40.2% of participants in the test group could achieve HbA1c of less than 7%; while none in the test group did.

Table 1 Participant's demographic characteristics (N = 175).

Characteristics	Control group (n, %) (N = 88)	Test group (n, %) (N = 87)	*P*-value
Gender: female	74 (84.1)	74 (85.1)	0.860[a]
Age (mean ± SD)	50.3 ± 6.2	50.3 ± 6.3	1.000[b]
Weight (kg) (mean ± SD)	63.7 ± 5.4	63.6 ± 5.7	0.998[b]
Height (cm) (mean ± SD)	155.4 ± 4.6	155.6 ± 4.2	0.858[b]
BMI (kg/m^2) (mean ± SD)	26.4 ± 2.2	26.3 ± 2.1	0.460[b]
Health care payment			0.978[a]
Universal Coverage Scheme	78 (88.6)	77 (88.5)	
Civil Servant Medical Benefit Scheme	10 (11.4)	10 (11.5)	
Marital status			0.999[a]
Single	9 (10.2)	9 (10.3)	
Married	72 (81.8)	71 (81.6)	
Widowed/divorced/separated	7 (8.0)	7 (8.0)	
Education level			0.973[a]
Primary school	62 (70.5)	60 (69.0)	
Junior high school	19 (21.6)	19 (21.8)	
High school	5 (5.7)	5 (5.7)	
Associate degree	0	0	
Bachelor's degree	2 (2.3)	3 (3.4)	
Postgraduate	0	0	
Occupation			0.988[a]
Not working	10 (11.4)	10 (11.5)	
Small trading business	10 (11.4)	11 (12.6)	
Self-employed	15 (17.0)	15 (17.2)	
Agriculture	51 (58.0)	48 (55.2)	
Government employee	2 (2.3)	3 (3.4)	
Smoking			0.414[a]
Yes	4 (4.5)	2 (2.3)	
No	84 (95.5)	85 (97.7)	
Drinking alcohol			0.109[a]
Yes	74 (84.1)	80 (92.0)	
No	14 (15.9)	7 (8.0)	
Income (Bath)			0.924[a]
≤ 5,000	67 (76.1)	62 (71.3)	
5,001 – 10,000	21 (23.9)	20 (23.0)	
10,001 – 15,000	0	0	
15,001 – 20,000	0	0	
20,001 – 25,000	0	0	
≥ 25,001	0	5 (5.7)	

[a] Chi-squared test, [b] Independent t test.

Table 2 Participant's clinical characteristics (N = 175).

Characteristics	Control group (n, %) (N = 88)	Test group (n, %) (N = 87)	*P*-value
HbA1c (%) (mean ± SD)	8.9 ± 0.9	9.0 ± 1.1	0.398[a]
Diabetic drugs			0.865[b]
Glipizide + Metformin	73 (83.0)	73 (83.9)	
Insulin + Metformin	15 (17.0)	14 (16.1)	
Comorbidity			0.714[b]
No	16 (18.2)	14 (16.1)	
Yes	72 (81.8)	73 (83.9)	
Hypertension	75 (85.2)	70 (80.5)	0.429[c]
Hyperlipidemia	75 (85.2)	70 (80.5)	0.429[c]
Duration of comorbidity (yrs)			
Hypertension			0.775[c]
< 5	55 (62.5)	61 (70.1)	
5 – 10	33 (37.5)	26 (29.9)	
Hyperlipidemia			N/A
< 5	88 (100.0)	87 (100.0)	
5 – 10	0	0	
Duration of DM (yrs) (mean ± SD)	5.9 ± 1.7	4.9 ± 1.4	0.469[b]
< 5 years	22 (25.0)	26 (29.9)	
5 – 10 years	66 (75.0)	61 (70.1)	

[a] Independent t test, [b] Chi-Square test, [c] Fisher's Exact Test, N/A = statistical analysis not applicable.

Table 3 HbA1c levels before and after the experiment (N = 175).

	HbA1c (%) (mean ± SD)		*P*-value*
	Control group (N = 88)	Test group (N = 87)	
Before	8.9 ± 0.9	9.0 ± 1.1	*NS*
After	8.9 ± 0.9	7.5 ± 0.7	*< 0.001*
P-value†	*0.781*	*< 0.001*	

HbA1c level category	N (%)			
	Before		After	
	Control group	Test group	Control group	Test group
6.0 – 7.0%	0	0	0	35 (40.2)
7.1 – 8.0%	17 (19.3)	21 (24.1)	23 (26.1)	37 (42.5)
8.1 – 9.0%	44 (50.0)	48 (55.2)	31 (35.3)	13 (14.9)
9.1 – 10.0%	15 (17.0)	8 (9.2)	11 (12.5)	2 (2.3)
10.1 – 11.0%	8 (9.1)	8 (9.2)	20 (22.7)	0
11.1 – 12.0%	4 (4.5)	2 (2.3)	3 (3.4)	0
P-value$	*0.398*		*< 0.001*	

* Independent t test for between-group comparisons. † Paired t test for within-group comparisons. $ Chi-squared test.

At baseline, most mean scores including those of diabetes knowledge, dietary compliance, exercise compliance, medication compliance, and attitude toward diabetes were not different between the two groups. On the other hand, medication possession ratio was significantly higher in the control group than the test group (65.0% and 62.7%, respectively, *P*-value = 0.020). **At the end of the study**, all mean scores were significantly higher in the test group than in the control group (*P*-value < 0.001 for all, except 0.041 for exercise compliance).

In terms of the **changes within each group**, in the **control group**, mean scores of diabetes knowledge and medication possession ratio significantly decreased (*P*-value = 0.006 and 0.016, respectively), and medication compliance significantly increased (*P*-value < 0.001). In the **test study**, most mean scores increased significantly (*P*-value < 0.001), except exercise compliance. In addition, none of patients in the control and test groups had the medication possession ratio of 80% or higher at baseline. However, at the end of the study, all patients in the test group had the medication possession ratio of 80% or higher, but those in the control groups did not.

Table 4 Mean scores of clinical, attitude and knowledge outcomes (N = 175).

	Mean score ± SD		*P*-value*
	Control group (N = 88)	Test group (N = 87)	
Diabetes knowledge			
Before	47.5 ± 8.7	53.9 ± 7.5	*0.327*
After	40.9 ± 8.7	94.8 ± 7.5	*< 0.001*
P-value†	*0.006*	*< 0.001*	
Dietary compliance			
Before	36.8 ± 10.8	34.7 ± 10.8	*0.065*
After	38.3 ± 14.2	94.7 ± 10.8	*< 0.001*
P-value†	*0.645*	*< 0.001*	
Exercise compliance			
Before	23.2 ± 7.6	23.7 ± 7.6	*0.066*
After	22.3 ± 6.4	24.6 ± 8.5	*0.041*
P-value†	*1.000*	*1.000*	
Medication compliance			
Before	36.8 ± 8.2	34.7 ± 8.2	*0.065*
After	38.3 ± 14.9	94.7 ± 10.8	*< 0.001*
P-value†	*< 0.001*	*< 0.001*	
Attitude toward diabetes			
Before	45.5 ± 6.9	44.1 ± 6.9	*0.073*
After	46.4 ± 9.1	88.0 ± 17.8	*< 0.001*
P-value†	*0.907*	*< 0.001*	
Medication possession ratio (raw score)			
Before	65.0 ± 7.3	62.7 ± 7.0	*0.020*
After	61.4 ± 5.8	97.3 ± 6.3	*< 0.001*
P-value†	*0.016*	*< 0.001*	
Medication possession ratio (categories)			
Before			
< 80%	88 (100.0%)	87 (100.0%)	
≥ 80%	0	0	
After			
< 80%	88 (100.0%)	0	
≥ 80%	0	87 (100.0%)	

* Independent t test for between-group comparisons. † Paired t test for within-group comparisons.

Discussions and Conclusion

In this study, all demographic characteristics between the two groups were not different. However, their overweight or obesity (BMI 25 - 29.90 kg/m^2) could contribute to poor glycemic control. This was consistent with the study of Salam and Siddiqui (2013)[22] where they found that patients with normal BMI were more likely to be able to control their blood sugar since obese people tend to eat foods that are high in calories and low in fiber.

This pharmaceutical care with food education according to Isan lifestyle resulted in better glycemic control and diabetes knowledge; while the usual care did not. It has been shown that diabetes knowledge could affect dietary compliance and glycemic control as measured by HbA1c. A study in Pathum Thani, a province in central Thailand, in 2011 showed that diabetes knowledge and attitude towards self-care could predict 26.3% of the variance of self-care behavior of diabetic patients.[23] Another study in Thailand in 2007 also showed that diet control was inversely related with blood sugar levels with statistical significance (r = -0.158, *P*-value < 0.05).[24] These two studies confirmed that patients with diabetes who have good diabetes knowledge will reach the treatment's glycemic control goal by learning and modifying their health care behavior.

In our present study, patients receiving food education according to Isan lifestyle had better diet compliance, glycemic control, attitude toward diabetes, medication possession ratio and medication compliance than the control group. These findings were consistent with the study of Pongprapaphan revealing that behavior was complicate with factors that

influence both patients and environment, such as family, society, and friends.[25] In terms of diet, a study by Lerman and others (2004)[9] found that only 58% of diabetes patients ate appropriate diet. The result could be influenced by thinking process, behaviors and personality, such as addiction to food flavors, misunderstanding to self-control, career, socializing, and eating out at any ceremonies offering foods unsuitable for diabetic patients. For most families, a limited number of dishes could force all family members to have the same diet; dishes catered to diabetic family members are less or even impossible.[25]

In our study, pharmaceutical care with food education according to Isan lifestyle could empower the patient in their diet control. Before the experiment, since diet control was complicate, diabetic patients had hard time controlling their blood sugar. In order to achieve a glycemic control based on the target before the appointed doctor visit, the patient usually skips meals and took only 1 – 2 meals per day for a few days before the visit. In addition, some patients change from glutinous rice to plain rice. Since Isan patients do not like plain rice, they usually eat less plain rice; hence less carbohydrate consumed and eventually blood sugar too low. When experiencing hypoglycemia, they take sweets, syrup or carbonated beverages to alleviate the symptoms.

Occupation could affect glycemic control. In this study, most participants were agriculturists of which some of their meals could not be on time. As a result, medications scheduled with regard to meals could be taken irregularly.[25] In addition to occupation, patients with older age could forget taking medications and those with limited diabetes knowledge could not comply with diet suitable for glycemic control.[9]

The intervention in our study could improve medication compliance as shown by the medication possession ratio. While none of the patients receiving usual care achieved a possession ratio of at least 80% either at baseline or at the end of the study; all patients receiving the Isan diet based lifestyle modification had improved from completely not achieving the 80% possession ratio cut-off value at baseline, to a complete achievement of the possession ratio in all patients at the end of the study. This complete possession ratio could result in a better glycemic control in the test group as reflected by HbA1c levels at the end of the study. At baseline, none of the patients had HbA1c levels lower than 7.00; 40.2% of them achieved the target of less than 7.00 at the end of the study.

Any non-compliance to medications, diet and exercise compliance probably could not be detected in the usual doctor visit, nurse screening, and pharmacy dispensing, unless any abnormalities, problems or poor glycemic control were detected any points of care which could prompt the healthcare provider's attention. All causes of such problems could then be identified, solved and prevented through consultation or certain intervention. These problems could include wrong drug administration, poor glycemic control, non-compliance to medications, diet and exercise, inadequate fasting time of less than 8 hours for blood test, and skipping meals or reducing carbohydrate a few days before doctor visit to achieve a low fasting plasma sugar (FPG). Since FPG level is labile and cannot represent glycemic control. While FPG level can be manipulated by short-term diet modification, HbA1C level needs at least 2 to 3 months of regular diet modification to see a full effect.

Pharmaceutical care with food education according to Isan lifestyle could add value of pharmacists in addition to the solvation of drug-related problems.[26] Pharmacists could help the patient identify non-compliance to medications, diet and exercise, identify more convenient drug administration time and method, and plan diet modifications suitable to the patient's dietary and work lifestyle. The patient could have better diet for glycemic control and at the same time do not alienate themselves from their family members and vice versa. Such diet modification could be easily practiced and more likely to sustain.

Knowledge about diabetes self-care and diet modification could be delivered to the patient by the pharmaceutical care with food education according to Isan lifestyle. At every visit, patients, especially those with poor glycemic control were reviewed and assessed for all of their information, findings, knowledge and understanding. In consultation, their diabetic health status and preference were used in improving the patient's long-term knowledge[27] and understanding, and ultimately compliance.

The guidelines for treating diabetes have emphasized providing knowledge about self-care of patients as the center of treatment.[28] Treatment compliance is associated with improved treatment outcomes.[29] Educating and creating skills for self-care of diabetes, helping and supporting to take care of oneself is important to achieve the goal of treatment and reduce the occurrence of both acute and chronic complications. Educating diabetes and building skills for self-

care should consider the needs and the attitude of patient to succeed in taking care of diabetes. Providing pharmaceutical care with food education according to Isan lifestyle is in line with the way of life of the patient can increase sustainable compliance in disease control.

Our study had certain limitations. At every visit, the interview by the pharmacist took about 15 minutes which could sometimes worry the patient about their order to see the doctor. Shorter interview session should be developed for more practical consultation. Since many patients with poor glycemic control could be candidate for improving dietary modifications, more pharmacists should be available for this 15-minute long consultation. In our study, with one pharmacist worked with the patient, the overall patient care process was delayed. A more private place should be used so the consultation is not distracted by the surrounding.

All aspects of lifestyle should be modified to achieve the best possible glycemic control. Since exercise compliance was still low after the pharmaceutical care with food education according to Isan lifestyle, exercise motivation in accordance with to their lifestyle should also be incorporated. In addition, optimal BMI in diabetes patient could result in a lower risk of cardiovascular diseases and coronary heart disease.[30] To be more comprehensive, diabetic foot care should also be included in the consultation. Finally, duration of the intervention and follow-up should be longer to examine the long-term and sustainable effects of the intervention.

References

1. International Diabetes Federation. IDF 2017. (Accessed on Mar. 24, 2018, at http://idf.org/)
2. Ratasan C. Ramathibodi hospital diabetes outbreak and its impact on Thailand. 1st edition. Bangkok. Ramathibodi Hospital Publisher, 2014. (in Thai)
3. Aekplakorn W. Prevalence and management of diabetes and associated risk factors by regions of Thailand, Third National Health Examination Survey 2004. *Diabetes Care* 2007;30(8):2007-2012:
4. Office of the Permanent Secretary for Health. Office of Public Health Management Health Service System Development Plan (2018) - 2021. Bangkok. Ministry of Public Health, 2016: p.502. (in Thai)
5. Chongchareon W, Kahawong W, Apichato A, et al. A self-care promotion model for controlling blood sugar in type 2 diabetes. *Songklanagarind Med J* 2008;26(1):71-84. (in Thai)
6. Ketkan K. Health promotion behavior in the elderly with diabetes. Master of Nursing thesis (Adult Nursing). Bangkok. Graduate School, Mahidol University, 1998.
7. Phonploy W, Chuaprapaisil A, Chongcharoen W, Rattanachaiwong S. Self-care promotion for blood sugar control of non-insulin dependent diabetic patients. *J Songklanagarind Nurs* 1996;16(1):18-35. (in Thai)
8. Pender NJ. Health promotion in nursing practice (3rd ed.). Stanford, CT. Appleton & Lange, 1996.
9. Lerman I, Lozano L, Villa AR, et al. Psychosocial factors associated with poor diabetes self-care management in a specialized Center in Mexico City. *Biomed Pharmacother* 2004;58(10):566–570.
10. Albarran NB, Ballester MN, Morales GG, Ortega MI. Dietary behavior and type 2 diabetes care. *Patient Educ Couns* 2006;61(2):191-199.
11. Trichopoulou A, Martínez-González MA, Tong TY, et al. Definitions and potential health benefits of the Mediterranean diet: views from experts around the world." *BMC Med* 2014;12: article number 12. (doi: 10.1186/1741-7015-12-112)
12. Capatti A, Montanari M. Italian cuisine: A cultural history. New York. Columbia University Press, 2003: p.106.
13. Duarte A, Fernandes J, Bernardes JP, Miguel G. Citrus as a component of the Mediterranean diet. *J Spat Organizat Dyn* 2016;4(4):289-304.
14. Arnett DK, Blumenthal RS, Albert MA, et al. 2019 ACC/AHA Guideline on the primary prevention of cardiovascular disease. *Circulation* 2019; 140(11):596–646.
15. Dinu M, Pagliai G, Casini A, Sofi F. Mediterranean diet and multiple health outcomes: an umbrella review of meta-analyses of observational studies and randomised trials. *Eur J Clin Nutri* 2018;72:30-43.
16. Rees K, Takeda A, Martin N, et al. Mediterranean-style diet for the primary and secondary prevention of cardiovascular disease. *Cochrane Database Syst Rev* 2019;3(3):CD009825. (doi: 10.1002/14651858.CD009825.pub3)
17. Van Horn L, Carson JAS, Appel LJ, et al. Recommended dietary pattern to achieve adherence to the American Heart Association/American College of Cardiology (AHA/ACC) Guidelines: A scientific statement from the American Heart Association. *Circulation* 2016;134(22):505-529.
18. Evert AB, Dennison M, Gardner CD, et al. Nutrition therapy for adults with diabetes or prediabetes: A consensus report. *Diabetes Care* 2019; 42(5):731–754.
19. Wishah RA, Al-Khawaldeh OA, Albsoul AM. Impact of pharmaceutical care interventions on glycemic control and other health-related clinical outcomes in patients with type 2 diabetes: Randomized controlled trial. *Diabetes Metab Syndr* 2014;9(4):271-276.
20. Hepler CD, Strand LM. Opportunities and responsibilities in pharmaceutical care. *Am J Hosp Pharm* 1990;47(1):533-543.
21. Sammasut R. Exchanged food items. *Thai J Nutri Ther* 2004;15(1):33-45. (in Thai)
22. Salam MA, Siddiqui AF. Socio-demographic determinants of compliance among type 2 diabetic patients in Abha, Saudi Arabia. *J Clin Diagn Res* 2013;7(12):2810-2813.
23. Chiraphongsuwan A, Sawangphon P. Factors related to self-care behaviors of diabetic patients, Lat Lum Kaeo Hospital, Lat Lum Kaeo District, Pathum Thani Province. *J Pub Health Dev* 2011;9(2):130-142.
24. Siriwattanapornkul T, Oba N, Intarakamhang Na Ratchasima S. Factors related to blood glucose level among patients with diabetes mellitus type II. *J Nurs Sci Naresuan Univ* 2007;1(2):57-67. (in Thai)
25. Phongprapaphan P, Saenwiangchan S, Panya P. Development of a holistic health promotion model for diabetic patients. Bachelor of Nursing

Thesis. Bangkok. Department of Nursing, Faculty of Nursing. Graduate School, Bangkok Thonburi University, 2010. (in Thai)

26. Hanrin R. Classification of drug problems. *Thai J Pharm Pract* 2010;1(1):84-96. (in Thai)
27. Wisitchawut C. Human memory. Bangkok. Chuan Pim Printing House, 1977): pp.51-60. (in Thai)
28. The Endocrine Society of Thailand. Clinical Practice Guideline for Diabetes 2017. Bangkok/ Diabetes Association of Thailand In the Patronage of HRH Princess Maha Chakri Sirindhorn Siam Princess Royal, 2017. (in Thai)
29. WHO. First Global Ministerial Conference on Healthy Lifestyles and Noncommunicable Disease Control. Discussion paper. Prevention and control of NCDs: priorities for investment. World Health Organization, 2011.
30. National Institutes of Health. Your guide to lowering your blood pressure with DASH. 1st ed. Bethesda, MD. U.S. Department of Health and Human Services, National Institutes of Health National Heart, Lung, and Blood Institute, NIH Publication, 2006: p.64.