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Research article

Clinical outcomes and economic evaluation of patient-centered care system versus routine-service system for patients with type 2 diabetes in Thailand

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ABSTRACT

Introduction: Patient-centered care in diabetes is another approach for outcome improvement, yet the supporting economic and clinical evidence remains limited in Thailand.

Objectives: This study compared health outcomes and cost-utility of implementing Patient-Centered Care Systems (PCCS) in a primary care setting vs. the Routine Service System (RSS) in a hospital setting.

Methods: The economic evaluation was performed using a randomized controlled study design. The participants aged ≥18 were enrolled from Phimai City in Nakhon Ratchasima Province, Thailand from June 2022 to February 2023. Totally, 309 well-controlled patients with initial care in a hospital were referred to receive the PCCS at the primary care setting or remained receiving the RSS in the hospital. Outcomes of different approaches such as fasting blood sugar, Hemoglobin A1c (HbA1c), direct medical costs, direct nonmedical costs and utility were prospectively collected at months 0, 3 and 6. Fisher's exact test, *t*-test or Wilcoxon signed-rank test were used to analyze data, whichever was appropriate. An incremental cost-effectiveness ratio was calculated, and various sensitivity analyses were performed.

Results: The PCCS showed significantly reduced HbA1c ($p < 0.001$) and a greater number of patients with improved HbA1c ($p < 0.001$). The PCCS were a cost-saving strategy due to incurring lower total costs (60.15 vs. 73.42 USD) and gaining more quality-adjusted life-years (QALY) (0.340 vs. 0.330) compared with the RSS. With a ceiling ratio of 4,659 USD/QALY, the PCCS had a 94.6 % probability of being cost-effective.

Conclusion: This finding indicated that the PCCS in a primary care setting was a cost-saving strategy by lowering cost, providing a higher quality of life and improving glycemic control compared with the RSS in a hospital setting. However, generalizing the findings in a country as a whole, the economic evaluation of PCCS and RSS should be conducted among different levels of hospitals from all regions in Thailand.

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1. Introduction

Type 2 diabetes (T2D) is one of the increasingly prevalent noncommunicable diseases (NCDs) worldwide [1]. The International Diabetes Federation has estimated that 537 million people (20–79 years) worldwide have diabetes, with the majority living in low and middle income countries and estimated deaths of 6.7 million each year. This number is predicted to rise to 643 million by 2030 and 783 million by 2045 [2]. In Thailand, the 6th National Health Examination Survey conducted from 2019 to 2020, reported a 9.5 % prevalence of diabetes among Thais over 15 years of age. Of those, 26.3 % of treated patients with diabetes were uncontrolled, and diabetes remains a leading cause of death in Thailand [3].

Diabetes is recognized as an NCD related to lifestyle [1]. The goals and therapeutic choices of diabetes management can be person-centered, aiming at treating symptomatic hyperglycemia, reducing the risk of long-term complications and maintaining general health, well-being and quality of life in a holistic context [1,4,5].

A patient-centered behavioral or social approach produces a long-lasting impact on effective disease management. Patient-centered care (PCC) has been recognized as a desirable attribute of healthcare since the late 1980s. Patient-centeredness combines several perspectives, like a bio-psycho-social perspective, meaning focusing on patients and honoring their preferences as a holistic being rather than adopting a biomedical perspective focusing on the disease [6]. PCC is an important factor in the self-management of T2D and is associated with improved health outcomes such as quality of life and self-care behaviors in this population [7]. In their consensus report, the American Diabetes Association, also advocated PCC to enhance patient engagement in self-care activities for T2D self-management [8]. Related studies conducted around the globe such as in Saudi Arabia, the Netherlands, China, India, Iran, Turkey and among African Americans, showed the effectiveness of PCC in improving glycemic control and self-care behaviors among adults with T2D [9–15]. The findings from the systematic review and meta-analysis of 20 randomized controlled trials provided evidence supporting the effectiveness of patient-centered, self-management care interventions [16]. In addition to clinical effectiveness, the findings from an economic study of PCCS in the Netherlands reported the cost-effectiveness of PCCS for patients with T2D who had 8.5 % baseline Hemoglobin A1c (HbA1c) [10].

In Thailand, public hospitals are paramount for the Nation's health care safety. The Ministry of Public Health reported a steadily increased trend of patients with NCDs receiving care in public hospitals over the last few years [17]. Patients visiting overcrowded public hospitals create difficulties for healthcare personnel in providing qualified health services [18]. Therefore, a primary care cluster policy was established in 2016. This policy governs the use of the Family Practice Model, employing a person-centered approach. This approach encourages the family physician and interdisciplinary team to understand how patients interpret their illnesses, to establish the relationship between illness and organic pathology, and to ensure customers' centeredness in decision-making related to or impacting them [19–22].

Phimai Hospital is located in the Nakhon Ratchasima Province in northeast Thailand. The hospital has implemented a PCC policy since 2019. Due to the imbalance between healthcare personnel and the number of registered patients with NCDs at Phimai Hospital, diabetes was chosen as a pilot project. In general practice, when patients with T2D have blood sugar levels well controlled, they will be referred to receive routine care in primary care settings. The family physician and interdisciplinary team implement the pilot project of a PCC approach in the primary care setting. After one year of implementation, the number of patients with T2D achieved the HbA1C target of <7 % increased from 7.51 % in 2019 to 25.12 % in 2020 [23]. Although the benefit of a PCC policy has been well established from our pilot project, the limited healthcare resources, such as human resources and funding, make expanding this approach challenging for all patients with T2D and other NCDs.

2. Aim

This study aimed to compare healthcare provision for patients with T2D in two settings: the PCCS in a primary care setting and the RSS in a hospital setting regarding health outcomes and cost-utility analysis.

3. Method

3.1. Study setting

The economic evaluation was performed using a randomized controlled study design to compare the costs and outcomes of treating patients with T2D in two different settings: the PCCS in a primary care setting and the RSS in a hospital setting. Phimai Hospital is classified at the secondary care level and serves as the headquarters of 19 primary care settings. The PCCS was conducted at nine randomly chosen primary care settings, while the RSS was performed at the Phimai Hospital.

3.2. Population and sample

About 6040 patients with T2D registered to receive treatment under the Phimai Hospital system. Of those, 1474 were well-controlled and referred to receive routine care at primary care settings close to their homes, while 4566 patients with T2D remained at Phimai Hospital for treatment. The referral system from hospital to primary care settings depends on antidiabetic treatment, fasting blood sugar (FBS), HbA1c level and patient's comorbidities.

In this study, patients with T2D having clinical status suitable for referral to receive care in a primary care setting were enrolled. The inclusion criteria were patients with T2D currently on oral antidiabetic drugs, FBS less than 200 mg/dl, HbA1c less than 9 % and registered in the hospital for over one year. Patients were excluded when they presented the following criteria: stage 4–5 chronic kidney disease, cardiovascular diseases, diabetic wounds or involuntary participation in research.

The sample size was calculated using the two independent groups' formula of two mean comparisons. The value of a variable in the formula was obtained from a related study in Thailand [24].

$$n = \frac{2\,\sigma^2 \left(Z_{\alpha/2} + Z_\beta\right)^2}{\left(\mu_1 - \mu_2\right)^2}$$

where $Z\alpha/2$ is the critical value of the normal distribution at $\alpha/2$, e.g., for a confidence level of 95 %, α is 0.05, and when the critical value is 1.96, $Z\beta$ is the critical value of the normal distribution at β, e.g., for a power of 80 %, β is 0.2, and the critical value is 0.84, $\sigma2$ is the population variance ($\sigma2$ is 1.58), and μ is the mean difference ($\mu1$ is -0.348, $\mu2$ is 0.076). The overall sample size totaled 280 people. Moreover, a 10 % follow-up loss rate was estimated. Therefore, 310 patients with T2D (155 per group) were enrolled and allocated to receive treatment in a hospital or primary care setting.

3.3. Study design and patient allocation

The randomized controlled study design with cluster sampling was used in this study. In the first step, the subdistricts were randomized in two groups (PCCS and RSS) based on their location, leading to five subdistricts for each group. Next, patients with T2D attending Phimai Hospital and lived in those subdistricts were recruited using quota sampling. This means that the proportion of recruited patients depended on the number of patients with T2D attending Phimai Hospital from such a county. A total of 155 patients with diabetes were enrolled in each intervention group. Then we used stratified random sampling based on the level of HbA1c ($\leq$8 % and $>$8 %) to ensure an equal number of controlled and uncontrolled diabetes patients in both groups.

Once patients were enrolled, they were provided consent forms during a visit to the diabetes clinic in the hospital setting. Only those providing written informed consent were included in the study. Of all 19 primary care settings, nine settings were randomly selected. Patients willing to receive treatment at these nine primary care settings were defined as the PCCS in a primary care setting or intervention group. Patients receiving the RSS at the hospital were defined as the control group.

3.4. Intervention group

In the primary care setting, the family physician and interdisciplinary team employed the integrated care system using three face-to-face sessions at initiation, the third month, and the sixth month. In each session, the six interconnecting components of PCC for diagnosis and treatment were applied as 1) building close relationships between patients and interdisciplinary team members and 2) exploring, assessing and analyzing the situation. These included the nature of diabetes (symptoms of hypoglycemia or hyperglycemia, complications and their management), other concomitant diseases, illness with IFFE questions (patient's ideas, feelings, expectations and functions), drug compliance, eating and exercise behavior, 3) emphasizing patient's life, family history and psychological and social behaviors, 4) setting and agreeing to the achievable goals of FBS and HbA1c levels between patients and interdisciplinary team, (5) attending both nutrition and exercise education with a nutritionist when FBS was over 140 mg/dl, or HbA1c was over 7 % and (6) emphasizing self-care and self-records for food items as well as nutrition and exercise practice to incorporate them in their lifestyle.

3.5. Control group

The control group received standard care in the diabetes clinic in Phimai Hospital according to the routine practice in Thailand. Physicians follow the available treatment guidelines to diagnose, provide treatment and follow up on disease progression every three months. Pharmacists are responsible for dispensing and counseling to ensure patients understand medication use. In the case of FBS over 200 mg/dl or HbA1c over 8 %, patients received nutrition and exercise education from a nutritionist.

3.6. Data collection

Patients with T2D meeting the eligibility criteria were included in the study. After patients were willing to participate and signed a written informed consent form, they were interviewed face-to-face while waiting to see a physician. Data were collected at baseline (month 0) and months 3 and 6. Data collection forms consisted of four parts: 1) patient characteristics, 2) clinical outcomes, 3) quality of life and utility and 4) costs. All questions took around 15 min to complete. Patient characteristics including sex, age, marital status, education, occupation, health insurance, duration of diabetes and comorbidities were collected at month 0. Clinical outcomes such as 1) FBS were retrieved from patients' electronic health records in months 0, 3 and 6, and 2) HbA1c was collected in months 0 and 6.

Quality of life and utility data were collected using the EQ-5D-5L (Thai Version) [25] in months 0, 3 and 6. The EQ-5D-5L contains five items divided in five domains: mobility, self-care, daily activities, pain/discomfort and anxiety/depression. All five items can be rated from no to severe problems. The total score ranged from -0.33 to 1.00, with a lower score reflecting lower health status.

Because the perspective of the study was society, direct medical costs and direct nonmedical costs were analyzed. Direct medical costs included medication costs, diagnosis tests, outpatient visits, inpatient visits, labor costs and transport from hospital to primary care settings. Direct medical costs were collected from patients' electronic health records in months 0, 3 and 6. Direct nonmedical costs included expenses incurred by patients for transport, food, nonmedical equipment, costs of informal care, other medicine to control diabetes and accommodation while seeking healthcare (self-reported). Direct nonmedical costs were directly collected from patients at the follow-up visit in month 3. All costs were reported in 2023 and were converted from THB to the USD using an exchange rate of 34.342 THB per USD as of April 17, 2023 [26]. All details for data collection are shown in Fig. 1.

4. Economic analyses

4.1. Base-case analysis

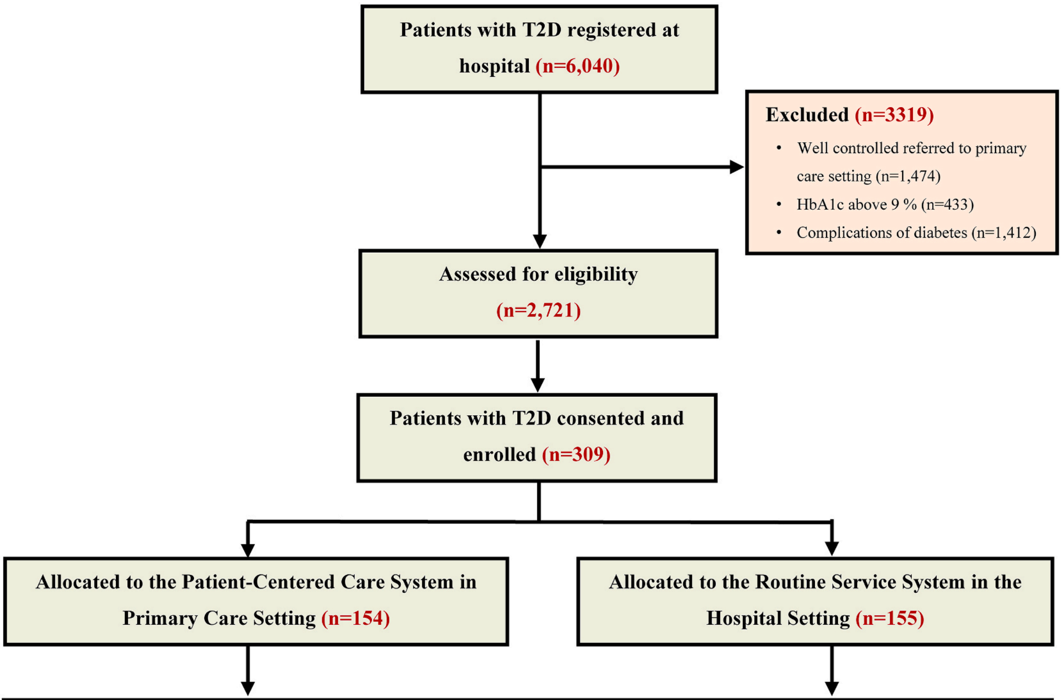
In a comparison with T2D treatment between the PCCS and the RSS, we estimated the incremental cost-effectiveness ratios (ICERs) by considering the parameters of costs and clinical effectiveness. Clinical effectiveness was quality-adjusted life-years (QALYs), which is the product of life year and utility. ICER was the difference in total costs divided by the difference in total effectiveness. The ICER was calculated using the equation below [27].

$$\mathrm{ICER} = \frac{\text{Total cost}_{\mathrm{PCCS}} - \text{Total cost}_{\mathrm{RSS}}}{\text{Effectiveness}_{\mathrm{PCCS}} - \text{Effectiveness}_{\mathrm{RSS}}}$$

4.2. Sensitivity analysis

A univariate sensitivity analysis was conducted to investigate parameter uncertainty. All variables such as costs and utilities varied within a specified range. If standard deviation or standard error was available, we used it as a range for one-way sensitivity analysis. When no such data were available, costs varied within the ±20 % range. The results are displayed as a tornado diagram.

In addition, probabilistic sensitivity analysis was performed. A Monte Carlo simulation was run one thousand times using Microsoft



Data collection		Time		
		Month 0	Month 3	Month 6
Health outcome	Hemoglobin A1c	/		/
	Fasting blood sugar	/	/	/
Humanistic outcome	Quality of life	/	/	/
	Utility	/	/	/
Cost	Direct medical costs	/	/	/
	Direct non-medical costs		/	

Fig. 1. Trial flow diagram.

Excel. The random sampling of the model parameters was based on data distribution. Beta distribution was appropriate for utility data because of the range of 0–1. The gamma distribution was appropriate for cost data owing to the positive values. The results are presented as a scatter plot on the cost-effectiveness plane and a cost-effectiveness acceptability curve.

4.3. Statistical analysis

We presented categorical variables as numbers (percentages) and continuous variables as means (standard deviations, SD). The continuous variables included age, duration of diabetes, HbA1c level, FBS, EQ-5D-5L score and costs. The categorical variables included sex, marital status, education, occupation, health insurance and comorbidities. Descriptive statistics were used to analyze patient demographics. Binary or categorical outcome measures were analyzed using Fisher's exact test, and continuous measures were analyzed using the *t*-test or a nonparametric equivalent (Wilcoxon signed-rank test). We determined statistical significance using a two-tailed P value of <0.05, and all statistical analyses were carried out using STATA, Version 14.0 (StataCorp LLC, TX, USA).

5. Results

5.1. Sociodemographic characteristics of patients with T2D

A total of 310 patients with T2D were enrolled in this study. One patient was excluded due to deaths from accidents; therefore, 309 patients remained for further analysis. Of those, 154 patients were in the PCCS group, while the remaining 155 were in the RSS group. The sociodemographic characteristics of patients are listed in Table 1. Almost all characteristics, except occupation, did not significantly differ between the PCCS and RSS groups. The mean age of all patients was 61.50 ± 10.65 years. Most patients were female, had a primary level of education, worked on a farm, had diabetes for less than five years, and used the Universal Health Coverage Scheme.

5.2. Health outcomes of patients with T2D

Table 2 represents the clinical characteristics of the participants. The average HbA1c and FBS at month 0 were 7.02 ± 0.99 % and 136.41 ± 22.85 mg/dl, respectively. Initially, the average HbA1c and FBS at month 0 of the RSS and the PCCS groups did not significantly differ (p = 0.968 and p = 0.411, respectively). The average change in FBS between months 3 and 0 was insignificant in either group (p = 0.326). However, the average change between months 6 and 0 for FBS and HbA1c significantly differed in the PCCS

Table 1
Sociodemographic characteristics of patients with type 2 diabetes.

Sociodemographic characteristic	Total (n = 309)	PCCS (n = 154)	RSS (n = 155)	p-value
Sex, n (%)				
Female	239 (77.35)	116 (75.32)	123 (79.35)	0.418
Male	70 (22.65)	38 (24.68)	32 (20.65)	
Age, mean ± SD	61.50 ± 10.65	62.66 ± 10.60	60.34 ± 10.61	0.056
Education level, n (%)				
No education	13 (4.21)	8 (5.19)	5 (3.23)	0.805
Primary school	254 (82.20)	127 (82.47)	127 (81.94)	
High school	33 (10.68)	16 (10.39)	17 (10.97)	
Vocational certificate	5 (1.62)	2 (1.30)	3 (1.94)	
Bachelor's degree	4 (1.29)	1 (0.65)	3 (1.94)	
Occupation, n (%)				
Government/State Enterprise Officer	7 (2.27)	1 (0.65)	6 (3.87)	0.022
Private business	25 (8.09)	8 (5.19)	17 (10.97)	
Laborer	41 (13.27)	22 (14.19)	19 (12.26)	
Agriculturist	155 (50.16)	88 (57.14)	67 (43.23)	
Unemployed	81 (26.21)	35 (22.73)	46 (29.68)	
Healthcare scheme, n (%)				
UHCS	290 (93.85)	148 (96.10)	142 (91.61)	0.123
SSS	8 (2.59)	4 (2.60)	4 (2.58)	
CSMBS	11 (3.56)	2 (1.30)	9 (5.81)	
Duration of diabetes, n (%)				
<5 years	161 (52.10)	77 (50.0)	84 (54.19)	0.836
5–10 years	112 (36.24)	58 (37.66)	54 (34.84)	
>10 years	36 (11.65)	19 (12.34)	17 (10.97)	
Comorbidities, n (%)				
no	22 (7.12)	10 (6.49)	12 (7.74)	0.826
yes	287 (92.88)	144 (93.51)	143 (92.26)	
Hypertension	234 (75.73)	120 (77.92)	114 (73.55)	
Dyslipidemia	221 (71.52)	108 (70.13)	113 (72.99)	
Other comorbidities	33 (10.38)	14 (9.09)	19 (12.26)	

Abbreviations: PCCS, Patient-Centered Care System in Primary Care Setting; RSS, Routine Service System in Hospital Setting; UHCS, Universal Health Coverage Scheme; SSS, Social Security Scheme; CSMBS, Civil Servant Medical Benefit Scheme.

Table 2
Health outcomes of patients with type 2 diabetes.

Health outcome	Total (n = 309)	PCCS (n = 154)	RSS (n = 155)	P-value
FBS (mg/dl), mean ± SD				
Month 0	136.41 ± 22.85	136.34 ± 19.49	136.44 ± 25.78	0.968[a]
Month 3	135.72 ± 28.66	134.08 ± 25.10	137.31 ± 31.02	0.322[a]
Month 6	135.40 ± 29.75	130.69 ± 20.50	140.07 ± 36.17	0.005[a]
Change Mo 3 and Mo 0	−0.70 ± 29.56	−2.26 ± 26.88	0.86 ± 31.93	0.326 [b]
Change Mo 6 and Mo 0	−1.02 ± 30.38	−5.69 ± 22.14	3.63 ± 36.27	0.008 [b]
Change Mo 6 and Mo 3	−0.32 ± 31.58	−3.42 ± 24.75	2.76 ± 36.97	0.102 [b]
HbA1c (%), mean ± SD				
Month 0	7.02 ± 0.99	6.97 ± 0.96	7.06 ± 1.01	0.411[a]
Month 6	6.96 ± 1.19	6.62 ± 0.90	7.30 ± 1.34	<0.001[a]
Change Mo 6 and Mo 0	−0.06 ± 1.01	−0.36 ± 0.80	0.24 ± 1.11	<0.001 [b]
Number of patients with HbA1c improvement, n(%)	158 (51.13)	103 (66.88)	55 (35.48)	<0.001[c]
EQ-5D-5L, mean ± SD				
EQ VAS				
Month 0	73.16 ± 15.13	73.29 ± 14.86	73 ± 15.40	0.866[a]
Month 3	74.83 ± 14.74	75.92 ± 14.78	73.87 ± 14.72	0.223[a]
Month 6	76.31 ± 16.21	77.86 ± 17.24	74.77 ± 15.04	0.095[a]
EQ-5D-5L index				
Month 0	0.66 ± 0.18	0.64 ± 0.18	0.67 ± 0.14	0.087[a]
Month 3	0.67 ± 0.18	0.69 ± 0.20	0.66 ± 0.16	0.172[a]
Month 6	0.68 ± 0.20	0.70 ± 0.23	0.66 ± 0.17	0.037[a]
Change Mo 3 and Mo 0	0.02 ± 0.11	0.046 ± 0.12	−0.013 ± 0.10	<0.001[b]
Change Mo 6 and Mo 0	0.02 ± 0.14	0.06 ± 0.15	−0.015 ± 0.13	<0.001[b]
Change Mo 6 and Mo 3	0.01 ± 0.12	0.01 ± 0.15	−0.002 ± 0.10	0.026 [b]

a: Independent *t*-test, b: Wilcoxon signed-rank test, c: Fisher's exact test.
Abbreviations: Mo, month; PCCS, Patient-Centered Care System in Primary Care Setting; RSS, Routine Service System in Hospital Setting.

and RSS groups ($p = 0.008$ and $p < 0.001$, respectively). The mean changes were higher in the PCCS than in the RSS group. In addition, the PCCS group had a higher number of patients with improved HbA1c compared with the initial measurement (month 0) than those in the RSS group (103/154 vs. 55/155, $P < 0.001$).

5.3. Utility of patients with T2D

The participants' utilities are represented in Table 2. The average EQ-5D-5L index and VAS scores at month 0 were 0.66 ± 0.18 and 73.16 ± 15.13, respectively. Initially, the average EQ-5D-5L index at month 0 of the RSS and the PCCS groups did not significantly differ ($p = 0.087$). However, the average change for the EQ-5D-5L index between months 3 and 0, months 6 and 0 and months 6 and 3 significantly differed in the PCCS and RSS groups. The mean changes were higher in the PCCS group than in the RSS group.

Table 3
Base-case result.

Cost and health outcome	PCCS (n = 154) Mean ± SD	RSS (n = 155) Mean ± SD
Cost, THB (USD)		
Direct medical costs		
Antidiabetic drugs	371.95 ± 286.97 (10.82 ± 8.35)	416.68 ± 311 (12.13 ± 9.05)
Diagnosis	929.1 ± 0 (27.04 ± 0)	929.1 ± 0 (27.04 ± 0)
Labor	564.90 ± 38.03 (16.44 ± 1.11)	462.92 ± 49.86 (13.47 ± 1.45)
Hospital travel cost	38.81 ± 0 (1.13 ± 0)	0
Subtotal	1904.76 ± 299.46 (55.43 ± 8.71)	1808.7 ± 338.19 (52.64 ± 9.84)
Direct nonmedical costs		
Patient's travel	15.68 ± 39.04 (0.46 ± 1.14)	198.04 ± 83.10 (5.76 ± 2.42)
Food	53.77 ± 78.22 (1.56 ± 2.28)	452.46 ± 435.87 (13.17 ± 12.68)
Informal care	16.25 ± 115.82 (0.47 ± 3.37)	51.65 ± 401.07 (1.50 ± 11.67)
Other out-of-pocket		
- SMBG	76.36 ± 482.13 (2.22 ± 0.065)	3.10 ± 38.56 (0.09 ± 1.12)
- Alternative treatment	0	8.71 ± 108.43 (0.25 ± 3.16)
Subtotal	162.07 ± 502.62 (4.72 ± 14.63)	713.92 ± 632.27 (20.78 ± 18.40)
Total cost	2067 ± 60.39 (60.15 ± 1.76)	2523 ± 73.71 (73.42 ± 2.15)
QALY	0.340 ± 0.096	0.330 ± 0.073
ICER	cost saving	

Total costs represent costs over the total 6-month study.
Abbreviations: PCCS, Patient-Centered Care System in Primary Care Setting; RSS, Routine Service System in Hospital Setting; THB, Thai baht; USD, US dollar; QALY, quality-adjusted life-years.

6. Economic results

6.1. Base-case results

Table 3 shows the base-case results. The PCCS group revealed a lower total cost than the RSS group (2067 vs. 2523 THB or 60.15 vs. 73.42 USD). However, the PCCS group gained more QALY than the RSS group (0.340 vs. 0.330 QALY). This indicated that the PCCS for patients with T2D was cost-saving.

6.2. Sensitivity analysis results

One-way sensitivity analysis showed that the cost of antidiabetic drugs of RSS, the utility of RSS at baseline and the cost of food of RSS were the top three influential parameters (Fig. 2).

Fig. 3A shows that almost 1000 iterations fell in the lower right quadrant on the cost-effectiveness plane, indicating that the PCCS in the primary care setting incurred lower costs and gained more QALYs compared with the RSS in the hospital setting. In addition, compared with the RSS in the hospital setting, the PCCS in the primary care setting had a higher chance of being cost-effective at all willingness-to-pay (WTP) levels (Fig. 3B).

7. Discussion

Diabetes is recognized as an NCD related to lifestyle. The goals and therapeutic choices of diabetes management can be person-centered, aiming at treating symptomatic hyperglycemia, reducing the risk of long term complications and maintaining general health, well-being and quality of life in a holistic context [1,5]. Although PCC can improve the quality of life [19–22], it might be associated with greater healthcare costs. Thus, the economic evaluation was performed using a randomized controlled study design to compare health outcomes and cost-utility of implementing the PCCS in a primary care setting vs the RSS in a hospital setting.

Several different terms have been used to define the same scope of holistic care for patients with T2D. For example, the term "PCCS" is defined as a purposefully designed holistic care intervention providing information and skills needed for effective disease self-management based on patients' preferences to achieve optimum glycemic control by improving self-care behaviors in addition to the medication [28]. Another term, "Information-Motivation and Behavioral skill model (IMB)," is defined as a brief health promotion counseling affecting behavior changes, information and knowledge about behavior, the individual's motivation to perform the behavior and the behavioral skills necessary to perform the behavior [13]. Another term, "educational and behavioral interventions," supplements medical management and helps individuals with diabetes modify risk factors for diabetes complications [29].

Regarding health outcomes, reduced HbA1c and the number of patients with improved HbA1c were significantly higher in the PCCS group than in the RSS group. It has been reported that the benefit of each 1 % reduction in the mean level of HbA1c is associated with a 14 % risk reduction of myocardial infarction, a 21 % reduction in all diabetes-related deaths, and a 37 and 43 % reduction in microvascular complications and amputation risks, respectively [1,30,31]. Our findings aligned with the results from other countries

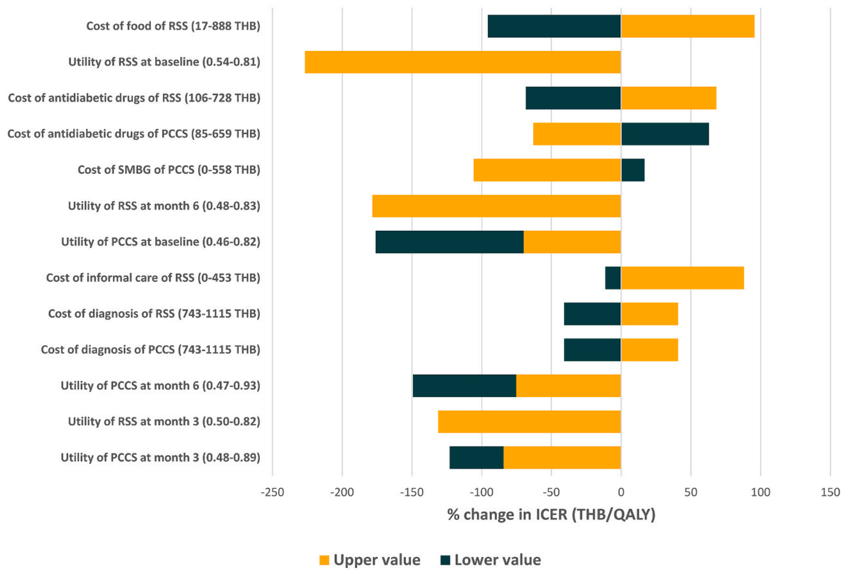


Fig. 2. Tornado diagram of the PCCS in Primary Care Setting compared with the RSS in Hospital Setting
Abbreviations: PCCS, Patient-Centered Care System in Primary Care Setting; RSS, Routine Service System in Hospital Setting; THB, Thai baht; QALY, quality-adjusted life-years.

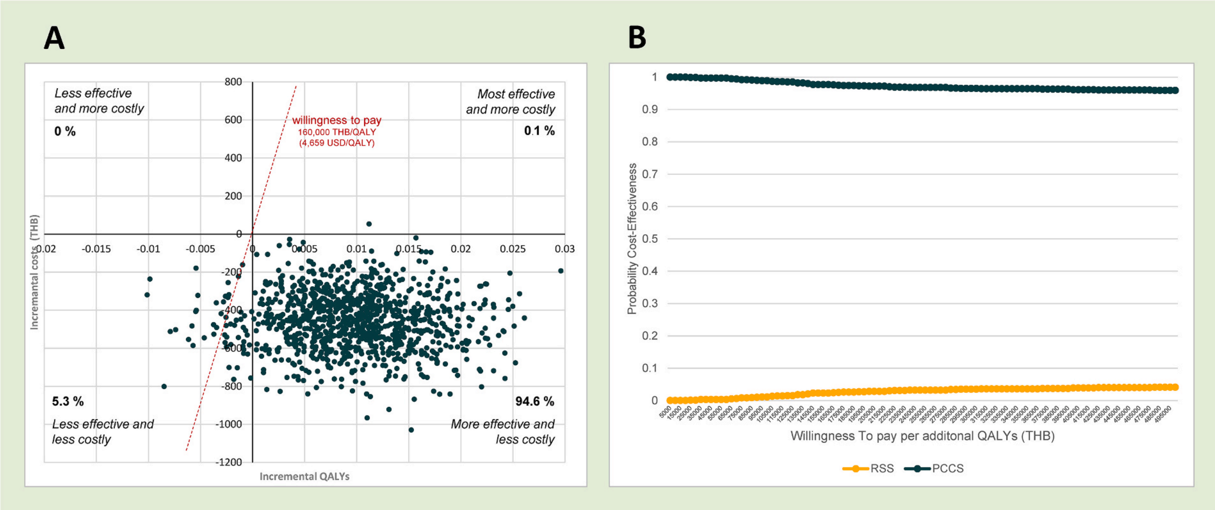


Fig. 3. A. Scatter plot of PCCS in Primary Care Setting compared with RSS in Hospital Setting among patients with Type 2 Diabetes on the cost-effectiveness plane; B. Cost-effectiveness acceptability curve (CEAC)
Abbreviations: PCCS, Patient-Centered Care System in Primary Care Setting; RSS, Routine Service System in Hospital Setting; THB, Thai baht; QALY, quality-adjusted life-years.

[9–15], such as Saudi Arabia, the Netherlands, China, India, Iran, Turkey and among African Americans. In addition, the findings from the systematic review and meta-analysis of 20 randomized controlled trials supported the effectiveness of patient-centered, self--management care interventions in improving glycemic control and self-care behaviors among adults with T2D [16].

The duration of PCCS intervention showed some impact on HbA1c level. The findings from the systematic review and meta-analysis confirmed that the longer duration of PCCS interventions showed significantly reduced HbA1c compared with a shorter duration [16, 29]. This might be attributable to longer contact time between healthcare personnel and patients. However, performing interventions over a long period might cause fatigue for healthcare personnel.

Furthermore, the PCCS showed improved patient adherence to several better behavioral or medication treatments, for example, improved nutrition and fluid restriction for patients undergoing hemodialysis [32], the control of SBP for patients with uncontrolled hypertensive [33] and improved dyslipidemia management via risk prevention from healthy lifestyle [34]. This suggests that PCCS can also effectively improve disease management in other chronic diseases.

Additionally, this health economic evaluation provides the first evidence concerning the cost-effectiveness of the PCCS in a primary care setting compared with the RSS in a hospital setting in Thailand. The findings of this study indicated that the PCCS in a primary care setting had lower total cost while gaining more QALY than the RSS in a hospital setting for treating patients with T2D over six months. The cost savings of the PCCS alternative were clearly shown by the PSA result in which most iterations (94.6 %) fell on the lower right quadrant of the cost-effectiveness plane. At the WTP of 160,000 THB/QALY [35] (4659 USD/QALY), the PCCS in a primary care setting had a 98.5 % chance of constituting a cost-effective alternative. Showing evidence about the effectiveness of this approach will significantly contribute to the delivery of cost-effective management and decrease the considerable health and economic burden of diabetes as a major chronic disease in the Thai community.

The evidence for economic evaluation of the PCCS intervention in a primary setting for patients with T2D remains limited, making comparisons with the PCCS outcomes challenging. In the Netherlands, the study by Annabelle S. et al. [10] reported cost-effective, PCC for patients with T2D with a baseline HbA1c of 8.5 %; however, this approach was not cost-effective for those with a baseline HbA1c of 7.0 %. Patients in our study had a baseline HbA1c of 7.0 % and the findings showed the cost savings of the PCCS intervention. The discrepancy of the two studies may be explained by different treatment and care contexts, healthcare resources and costs to provide the intervention, the lifestyle of patients living in Western and Asian countries and WTP level to justify the cost-effective alternative.

7.1. Strengths and limitations

This study's randomized controlled trial design constituted a strength to prospectively collect individual patient data regarding costs, utility and clinical outcomes. It allowed us to perform within-trial cost-effectiveness studies based on real-world evidence of PCCS in diabetes care. All required data in each time point of measurement were completed.

The current study encountered several limitations. The follow-up period was only six months. This might not be sufficiently long to capture the long term outcomes of diabetes. Therefore, this study's estimated costs and outcomes did not represent the lifetime horizon as generally used in cost-effectiveness studies. Furthermore, the data collection was restricted to a single hospital. The local population and their lifestyles may not reflect the general Thai population. Consequently, the generalizability of our findings might be restricted to similar settings as in our study.

8. Conclusion

This study indicates that providing the PCCS in the primary care setting has positive effects, including sustaining glycemic control, improving the quality of life and reducing the costs of holistic care for well-controlled patients with T2D compared with providing the RSS in the hospital setting. Future studies regarding long term intervention, more hospital settings or providing the PCCS to other chronic diseases are required to confirm the benefit of the PCCS in Thailand.

Data availability statement

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Ethics approval

The protocol for the main trial was granted by the Research Ethics Committee Faculty of Pharmacy, Chiang Mai University (Cert. no. 007/2022/F, Study code 036/2564/บ May 30, 2022). All subjects provided written informed consent before participating.

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CRediT authorship contribution statement

Watanyoo Prayoonhong: Writing – original draft. **Wannakamol Sonsingh:** Writing – review & editing. **Unchalee Permsuwan:** Writing – review & editing.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:Unchalee Permsuwan reports article publishing charges was provided by Chiang Mai University Faculty of Pharmacy.

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