

**Research Article****The effects of patient – centered pharmaceutical care intervention among uncontrolled hypertensive patients in communities**

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**Abstract**

This randomized control trial aimed to evaluate the effects of the patient-centered pharmaceutical care (PCPC) intervention among the uncontrolled hypertensive patients. The participants were uncontrolled hypertensive patients, selected from four health-promoting hospitals in Muang Phayao district, Phayao province, Thailand. Eligible patients were recruited and randomly assigned, by the hospital, to either PCPC (n = 36) or usual care (UC) group (n = 33). The PCPC group was provided with three PCPC interventions at home and one telemonitoring by a clinical pharmacist. Primary outcomes were systolic (SBP) and diastolic blood pressure (DBP). Secondary outcomes were patients' knowledge; self-care behaviors; medication adherence and quality of life (QOL). The outcomes were measured at baseline, sixth and twelfth week of the study. At the first evaluation, the results indicated that knowledge and self-care behaviors in the PCPC group were significantly higher than those of the UC group. At the end of the study, the SBP of PCPC group was lower than that of the UC group significantly. According to the PCPC group, patients' knowledge and self-care behaviors were improved significantly compared to the UC group. Medication adherence and QOL were not significantly differences. In conclusion, the PCPC intervention was an effective intervention for uncontrol hypertensive patients and it improved patients' SBP, knowledge and self-care behaviors.

**Keywords:** Hypertension, Patient – Centered care, Pharmaceutical care, Pharmacist

## Introduction

Despite advances in pharmacological treatment, hypertension is a common chronic medical condition and confers the major attributable risk to cardiovascular diseases and death. In Thailand, hypertension is non-communicable disease that has the highest prevalence rate [1]. Blood pressure (BP) control in patients on antihypertensive medication has been evaluated as unsatisfactory in the United States, Canada, and other European countries [2]. While medications are unarguably the most important therapy for hypertension, behavioral strategies have long been recommended as adjunctive therapies [3,4]. Specifically, an educational approach designed to help patients incorporate commonly accepted lifestyle changes. It has also been proposed that there should be an increasing patient participation in hypertension care.

The patient-centered care is used to describe tailoring treatment to patient needs, setting patient goals based on patient preference, and increasing the humanness of care [5-6]. The main principle makes healthcare providers understand their patient's morbidity, disease, and illness in other forms, such as fears and concerns, which will make healthcare providers collect data from their patients directly, solve a health problem and make good and long-lasting relationships with their patients and relatives [7]. The previous studies showed the effectiveness of patient-centered care in increasing medication adherence [8,9], supporting self-management, and improved quality of life [10].

The application of patient-centered care in pharmacy practice among uncontrolled hypertensive patients indicated that patient-centered care improved the BP control and medication adherence [9]. However, in Thailand,

there is a lack of evidence in showing the effects of the application of patient-centered care intervention among patients with uncontrolled hypertension.

This study applied the concept of patient-centered care into pharmacy practice. The PCPC interventions were set up for uncontrolled hypertensive patients. The objective of the study was to evaluate the effects of PCPC intervention among the uncontrolled hypertensive patients on BP, patients' knowledge, self-care behaviors, medication adherence, and quality of life as compared with the usual care group.

## Materials and Methods

### Study design and setting

The study was a randomized control trial, conducted in uncontrolled hypertensive patients. We recruited the first four sub-district health promoting hospitals in Muang Phayao district, Phayao province, Thailand, which had the highest number of uncontrolled hypertensive patients, according to data from the database of the Ministry of Health. To compare the intervention and usual care, two of the hospitals were randomly assigned to the PCPC interventions and two of them were in the UC group. Eligible patients were screened by the hospital and assigned to either group. Patients provided written informed consent to participate. Patients were assured of their right to refuse consent without it affecting their receipt of any community or health services. The study was approved by the Human Research Ethical Committee of the University of Phayao (No.2/019/59).

### Participants and randomization

The participants were uncontrolled hypertensive patients domiciled in their cluster with an accessible medical history in sub-district health

promoting hospital database. Inclusion criteria were:

(1) age > 20 years old; (2) have uncontrolled hypertension defined as BP > 140/90 mmHg on at least 2 consecutive visits; (3) take at least one antihypertensive medication; (4) did not have any home care visit within 3 months. However, patients who had characteristic compatibility with at least one of the following exclusion criteria (1) had hypertensive crisis, cardiovascular diseases, kidney disease, psychiatric disorders, or immune deficiency disorders; (2) had severely impaired hearing or speech or could not communicate in Thai; (3) pregnancy; (4) patients who cannot help themselves or disabilities were excluded from our study.

A statistical program was used to perform the calculations. Sample size calculation set up a statistical significance level which was 0.05 and power was 80. The mean difference of systolic blood pressure in the previous study of patient-centered care [11] was applied to the program. The mean difference was 14.12 mmHg (mean SBP among intervention and control groups were 13.73 and 0.38 mmHg, respectively). We increased 30% of the sample size to prevent the loss to follow up, finally the sample size was 72 patients. Computer-generated restrict randomization was then done in a one- to- one ratio, using stratified sampling to ensure balance within clusters. Then there were 36 patients in each group and 18 participants for each hospital.

### **PCPC intervention**

The PCPC group was received three PCPC interventions at home and one telemonitoring by a clinical pharmacist. The PCPC interventions were developed applying patient-centered care approach. The interventions were given to participants at the first visit and the next third and fourth of following week. The

telemonitoring was conducted at the twelfth following week of the study. Each visit undertook 30 – 60 minutes. The home intervention provided individual health education and medication therapy management. The contents of individual health education were hypertension-related knowledge including meaning of blood pressure and interpretation, hypertension prevention, self-care practices, healthy diet, regular physical excise, alcohol drink and cigarette smoking cessation and treatment. The goals of medication therapy management were educated the patients regarding their medications, increased adherence to medication therapy and identified and prevented medication complications related to medication therapy. The medication therapy management services in this study were depended on the participants' drug related problems. Medication therapy management included four core elements: (1) comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events; (2) evaluating and monitoring the patient's response to therapy; (3) documenting the care delivered and communicating essential information to the patient's other primary care providers; and (4) providing information, support services, and resources designed to enhance patient adherence with his/her therapeutic regimens.

### **Usual care**

Control group participants were given usual-based pharmacist care within the primary care. The usual care was be given health education, preventive care, and treatment as needed, routinely by health care providers at the patients' registered health-promoting hospitals. The UC group did not receive any home visits and telemonitoring during the study timeframe.

### Outcomes and Measures

Primary and secondary outcomes were measured at the screening visit (baseline), and follow-up visits at home (week 6 and 12) by an independent researcher. The primary outcomes were SBP and DBP. Blood pressure was measured by trained pharmacy students using an electronic blood pressure meter Omron® HEM- 7203 throughout the study. The sitting was measured twice at 1-minute intervals and once after the patient had remained seated for 5 minutes. The secondary outcomes were percentage of participants with normalized blood pressure after the PCPC intervention, patients' knowledge on hypertension; self-care behaviors; medication adherence and QOL.

The percentage of participants with normalized blood pressure or control hypertensive patients was defined as percentage of patients who have blood pressure below or equal 140/90 mmHg. The validated questionnaires were used to evaluate the patients' knowledge on hypertension; self-care behaviors; medication adherence and QOL. This questionnaire was adapted from related studies [11-14] and tested for content validity by 3 experts. A final draft questionnaire was undertaken in a pilot study in 40 hypertensive patients. Cronbach's alpha reliability was 0.981.

Hypertension related knowledge was scored based on participants' responses to ten dichotomous questions (correct answer =1; wrong answer =0). The hypertension related knowledge score was ranged from 0 – 10. Self-care behaviors assessment consisting of 15 questions rates on a Likert-type scale of 0 to 2 with 0=never, 1=sometimes, and 2=always. The medication adherence questionnaire adapted from Morisky

Medication Adherence Scale (MMAS) [13], consisted with 6 items with a scoring of "Yes" (0) and "No" (1), total scores range from 0 to 6. Patients' quality of life was measured using the Euro-Qual-5D (EQ-5D-5L) [14], a standardized measure of health comprising four physical health dimensions and one emotional dimension, with five possible answers for each dimension (1=no problem, 2=slight problems, 3=moderate problems, 4=severe problems, and 5= unable/extreme problems).

### Statistical analysis

Descriptive statistics were used to describe demographic characteristics, expressed as frequency and percentage for categorical variables; mean  $\pm$  SD, for numerical variables. Chi-square test and Fisher's exact test was tested for categorical variables. Student's t – test and Wilcoxon rank - sum test was used for evaluating the effect of PCPC between intervention and control group in terms of numerical variables. The repeated measures ANOVA was analyzed to compare a significance of outcomes among intervention and control group. A statistical value of  $p < 0.05$  was taken as significant.

## Results

### Participants characteristics

The 69 participants were enrolled and completed the study: 36 were in the PCPC group while 33 were in the UC group. The baseline patient characteristics at the beginning of the study were shown in table 1. There was no substantive difference between the groups at baseline for demographic or medical data.

**Table 1** Participants' Baseline Characteristics

Characteristics	PCPC (n=36)	UC (n=33)	p-value
<b>Sex; n (%)</b>			
Female	15 (41.7)	21 (63.6)	0.068
Male	21 (58.3)	12 (36.4)	
<b>Age; mean (SD), years</b>	59.6 (8.1)	61.7 (11.6)	0.388
<b>Body weight; mean (SD), kg</b>	63.7 (11.8)	62.8 (12.5)	0.750
<b>Height; mean (SD), cm</b>	159.7 (7.8)	158.8 (8.9)	0.664
<b>BMI; mean (SD), kg/m<sup>2</sup></b>	24.9 (4.0)	24.8 (4.2)	0.895
<b>Co-morbidities; n (%)</b>			
Diabetes	4 (11.1)	8 (24.2)	0.151
Dyslipidemia	12 (33.3)	8 (24.2)	0.406
<b>Blood pressure; mean (SD), mmHg</b>			
SBP	151.75 (20.14)	147.52 (25.36)	0.443
DBP	93.25 (16.94)	86.42 (16.94)	0.094
<b>Antihypertensive drugs; n (%)</b>			
BBs	13 (36.1)	10 (30.3)	0.609
CCBs	24 (66.7)	17 (51.5)	0.200
Diuretics	2 (5.6)	1 (3.0)	1.00
ACEIs	15 (41.7)	13 (39.4)	0.848
ARBs	9 (25.0)	16 (48.5)	0.043
Others	1 (2.8)	4 (12.1)	0.186
<b>Number of Antihypertensive Drugs per Patient;</b>			
n (%)			
1	16 (44.4)	13 (39.4)	0.677
2	14 (38.9)	14 (42.4)	
3	5 (13.9)	3 (9.1)	
4	1 (2.8)	3 (9.1)	
<b>Knowledge; mean (SD)</b>	7.81 (1.51)	6.82 (1.83)	0.017
<b>Self- care behavior; mean (SD)</b>	1.32 (0.28)	1.25 (0.29)	0.278
<b>Medication Adherence; mean (SD)</b>	4.86 (1.36)	5.06 (1.46)	0.558
<b>Quality of life; mean (SD)</b>	0.92 (0.12)	0.95 (0.07)	0.306
<b>Quality of life Scale; mean (SD)</b>	86.11 (10.29)	80.76 (17.46)	0.131

SD, Standard deviation; BMI, Body mass index; SBP, Systolic blood pressure; DBP, Diastolic blood pressure; BBs, Beta blockers; CCBs, Calcium channel blockers; ACEIs, Angiotensin-converting enzyme inhibitors; ARBs, Angiotensin II receptor blocker

### Primary outcomes:

The results of SBP and DBP were shown in table 2. As regards SBP in week 6, the result showed that the mean SBP of PCPC and UC group were  $141.78 \pm 19.57$  and  $149.39 \pm 23.34$  mmHg, respectively. There was no statistically significant difference between the groups ( $p = 0.15$ ). Nevertheless, the SBP in the PCPC group slightly decreased from baseline statistically significant ( $p < 0.001$ ) while the UC group did not. Similarly, DBP was not statistically significant between PCPC and UC groups (mean  $\pm$  SD;  $84.11 \pm 12.92$  vs  $82.85 \pm 12.38$  mmHg, respectively;  $p = 0.69$ ). DBP was significantly lower from baseline in PCPC group ( $p = 0.001$ ).

According to the results in week 12, the mean of SBP in PCPC group was  $132.39 \pm 21.43$  mmHg while that of the UC group was  $145.27 \pm 24.89$  mmHg. The SBP showed statistically a significant difference between either group ( $p = 0.02$ ). However, DBP showed no difference between PCPC and UC group ( $p = 0.51$ ). The mean of DBP was  $82.02 \pm 12.02$  and  $84.06 \pm 12.50$  mmHg in PCPC and UC group, respectively. In accordance with a within-group analysis, we found that both of the SBP and DBP in PCPC group were statistically significant from baseline ( $p < 0.001$ ;  $p < 0.001$ , respectively), this result was not demonstrated in UC group.

**Table 2** Primary Outcomes: Comparisons between PCPC and UC group

Outcomes	PCPC (n=36)	UC (n=33)	Mean difference	p-value
<b>SBP; mean (SD)</b>				
Baseline	151.75 (20.14)	147.52 (25.36)	4.23	0.443
Week 6	141.78 (19.57)*	149.39 (23.34)	-7.61	0.145
Week 12	132.39 (21.43)*, **	145.27 (24.89)	-12.88	0.024
<b>DBP; mean (SD)</b>				
Baseline	93.25 (16.94)	86.42 (16.94)	6.83	0.094
Week 6	84.11 (12.92)*	82.85 (13.38)	1.26	0.692
Week 12	82.08 (12.02)*, **	84.06 (12.50)	-1.98	0.505

SBP, Systolic blood pressure; DBP, Diastolic blood pressure; SD, Standard deviation

\*Statistically significant compared within group to baseline ( $p < 0.05$ ); \*\*Statistically significant compared within group to week 6 ( $p < 0.05$ )

### Secondary outcomes:

The patients' knowledge and self-care behaviors were pretty good at baseline and better in the next measurement, especially in the PCPC group. The result indicated that the patients'

knowledge and self-care behavior scores in PCPC group were statistically significantly higher than the UC group in both week 6 and 12 follow-ups (table 3). However, there were not statistically significance on medication adherence and QOL in the 6<sup>th</sup> and 12<sup>th</sup> follow up week.

**Table 3** Secondary Outcomes: Comparisons between PCPC and UC group

Outcomes	PCPC (n=36)	UC (n=33)	Mean difference	p-value
<b>Number of patients with well-control BP; n (%)</b>				
Baseline	0 (0)	0 (0)		
Week 6	16 (44.44)	11 (33.33)	5	0.345
Week 12	23 (63.89)	14 (42.42)	9	0.074
<b>Knowledge; mean (SD)</b>				
Baseline	7.81 (1.51)	6.82 (1.83)	0.99	0.017
Week 6	8.56 (1.13)*	6.97 (1.61)	1.58	<0.001
Week 12	9.06 (1.19)*, **	6.97 (1.60)	2.08	<0.001
<b>Self-care behavior; mean (SD)</b>				
Baseline	1.32 (0.28)	1.25 (0.29)	0.07	0.278
Week 6	1.39 (0.23)	1.25 (0.30)	0.14	0.030
Week 12	1.48 (0.20)	1.27 (0.31)	0.21	0.001
<b>Medication Adherence; mean (SD)</b>				
Baseline	4.86 (1.36)	5.06 (1.46)	-0.21	0.558
Week 6	5.39 (0.84)	5.06 (1.46)	0.33	0.262
Week 12	5.33 (0.99)	5.15 (1.48)	0.18	0.555
<b>Quality of life; mean (SD)</b>				
Baseline	0.92 (0.12)	0.95 (0.07)	-0.03	0.306
Week 6	0.94 (0.12)	0.95 (0.07)	-0.01	0.591
Week 12	0.94 (0.12)	0.95 (0.07)	-0.01	0.656
<b>Quality of life Scale; mean (SD)</b>				
Baseline	86.11 (10.29)	80.76 (17.46)	5.35	0.131
Week 6	86.11 (10.29)	81.67 (11.66)	4.44	0.134
Week 12	88.06 (9.12)	83.03 (15.76)	5.03	0.115

SD, Standard deviation

\*Statistically significant within group compared to baseline ( $p<0.05$ ); \*\*Statistically significant within group compared to week 6 ( $p<0.05$ )

## Discussions

This study provided evidence of positive benefits of a patient-centered care of the pharmacist in hypertensive patients. The results demonstrated a significant reduction of SBP in the PCPC group more than the UC group. The mean SBP diminished relatively to the baseline in the

PCPC and UC group at 19.36 and 2.25 mmHg ( $p = 0.024$ ), respectively. The prior 24-week follow-up study reported a reduction of SBP in patients receiving pharmaceutical care by 1.8 mmHg in the intervention group and 1.8 mmHg in the control group [15]. Regarding DBP, the PCPC group diminished more than UC group. Although they

were not statistically significant in either group, but the DBP with lower than 90 mmHg was useful. The previous study showed that the rate of cardiovascular death was increased when DBP was above 90 mmHg [16]. SBP is more valuable in predicting the risk of cardiovascular disease than DBP [17,18]. The percentage of patients with well-controlled blood pressure at week 12, was not statistically different between both groups (PCPC group 63.89% vs UC group 42.42%,  $p=0.074$ ). These findings showed similarly to the previous study [19], the results presented there were 53% well-control in the intervention group and 47% in the control group and no significant differences were noted in this regard between groups.

The PCPC intervention reported here resulted in improvement in hypertension related knowledge and self-care behaviors which is a likely reason for better BP control. This increase in participants' level of self-management is in line with previous findings, which show that patient education program can be used to increase patients' knowledge and result in better understanding and management of disease [20-21]. At baseline, the knowledge level of PCPC group was higher than UC group ( $p=0.017$ ). Finding from the comparison of before and after knowledge scores in PCPC group revealed the significant higher knowledge level.

The present study indicated that there was no statistically significant difference in medication adherence between the PCPC group and UC group. It must be acknowledged that some studies reported statistically significant improvement in therapeutic outcomes (SBP, DBP, percentage of patients with controlled BP at the end of the study) with no significance in medication adherence [9, 23-25]. In the current study, the baseline medication adherence was high [13], pharmacist

intervention was not likely to find a statistically significant improvement in this outcome [25,26].

Hypertensive patients are often reported to experience a considerable reduction in QOL compared with normotension [27,28]. Our study showed that the PCPC group had a better quality of life after completion of the intervention, like the prior study, a pharmacist's intervention was shown to improve QOL [29] despite, there were no statistical difference between the PCPC group and UC group. QOL is extremely difficult to measure impartially, as it depends on many pre-existing and irreversible factors such as socio-economic status, intelligence, personality, and the nature and duration of the disease [30]. This may be one of the many reasons why QOL in our study participants was not statistically different.

Several limitations were mentioned. First, patients and the pharmacist could not be blinded about the intervention they revived because of the nature of the study. Secondly, the effect of pharmacist intervention was evaluated within a follow-up period of only three months, which is shorter compared to previous studies, hence, further studies should consider a longer period of at least 6– 12 months. Lastly, this study was conducted in a primary public hospital with a selective sample of hypertensive patients from a remote area of Thailand. The generalizability may be limited.

## Conclusions

This study concludes that patient-centered pharmaceutical care intervention in uncontrolled hypertensive patients significantly reduced systolic blood pressure. It was also found that there was a statistically significant increase in knowledge about BP and self-care behaviors compared to the control group over a 12-week period.

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