

1-1-2017

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Recommended Citation

Thavornwattanayong, Wiwat and Sribundit, Namfon (2017) "Effects of family pharmacy intervention on clinical outcomes in primary care settings in Thailand," *The Thai Journal of Pharmaceutical Sciences*: Vol. 41: Iss. 1, Article 7.

Available at: <https://digital.car.chula.ac.th/tjps/vol41/iss1/7>

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Effects of family pharmacy intervention on clinical outcomes in primary care settings in Thailand

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Received: Aug 04, 2016

Accepted: Dec 29, 2016

Published: Jan 07, 2017

Keywords:

Clinical outcomes, family pharmacist, family pharmacy intervention, primary care

ABSTRACT

Background: Despite that pharmaceutical care has positive effect on improving patients' health, current data illustrate slight increasing of uncontrolled diabetes and uncontrolled hypertension among the Thai elderly. Family pharmacists applied more effective communication, partnership, and medication assessments to achieve effective outcomes. **Objectives:** To explore the effectiveness of family pharmacist intervention (FPI) comparing with the usual care in Thailand for diabetes patients with poor glycemic controlled and uncontrolled hypertensive patients in primary care setting. **Methodology:** Quasi-experimental study by recruiting eight primary health settings randomly assigned either the usual care group (four groups and each group had forty patients) and FPI group (four groups and each group had forty patients) from January to July 2015. In FPI, the intervention emphasized on active communication and partnership using idea, feeling, function, and expectation technique, background, affect, trouble, and handle technique, and medication assessment that concentrated on drug-related problems, drug-related suffering, and drug system problems. Both groups received monthly follow-ups visited and measured outcomes on the 3rd and 6th months. Paired-sample *t*-test or Independent *t*-test was used for comparative parameters such as blood pressure levels, fasting plasma glucose (FBS), and hemoglobin A1c (HbA1c) levels. **Results:** Eighty patients were recruited and followed up for 6 months. At baseline, demographic, disease characteristics, blood pressure levels, and glucose parameters were similar between the groups. After 6 months, systolic blood pressure (SBP) had significantly decreased in both groups ($P < 0.0001$ and < 0.0001 , respectively) and similar to FBS levels ($P = 0.033$ and 0.042 consecutively). However, overall parameters such as SBP, diastolic blood pressure, FBS, and HbA1c levels in FPI group significantly decreased more than the usual care group ($P = 0.002$, 0.006 , 0.033 , and 0.042 , respectively). **Conclusion:** FPI affirmed the reduction of blood pressure and blood glucose and demonstrated more effectiveness compared to the usual care in Thailand.

INTRODUCTION

Patient-centered care is related to the success of disease management, especially in cases of chronic diseases [1].

A patient's adherence does not only depend on effective health education given by health-care practitioners but also depend on the patient's perspective regarding his/her ideas, feelings, knowledge, and experiences and those of family members and friends. There is evidence of the benefit of patient-centered care [2,3], showing that it can increase compliance or adherence to treatment and lead to better health-related outcomes.

Family pharmacists [4] are increasingly considered to be a part of a health-care team and they attentively take care of

patients in primary settings, while implementing a patient-centered approach to the pharmaceutical care process. A family pharmacist practices six components of patient-centered care.

First of all, patient's sickness and illness experiences are explored. Sickness is explored in terms of pathophysiology by interviewing patients, physical examinations, and laboratory tests. As illness experience is defined as patient's ideas (I), feelings (F) about being ill, the impact of the health problem on daily functioning (F), and expectations (E) of what should be done about the health problem, the idea, feeling, function, and expectation (IFFE) can be explored by motivational interviewing [5]. Second, family pharmacists assess a patient as an overall dimension for the mutual understanding of physiological, psychological, and socioeconomic aspects. The

third component is finding common ground and then making an agreement between the patient and family pharmacist. The fourth component is related to the cooperation of health promotion and prevention in pharmaceutical care. The enhancement of the relationship between family pharmacist and the patient is the fifth component. The last component is the realistic practice within the specific contexts of patient, family, and community.

In Thailand, the role of the family pharmacy is currently widespread due to the policy of the National Health Security Office [6,7] which integrates family pharmacy services into the primary healthcare system. The provision of a family pharmacy service in a primary care setting has been developed by the Society of Family Pharmacists, Thailand (SOFT) and the Thai Community Pharmacy Society. These professional organizations have encouraged hospital pharmacists and community pharmacists to extend their pharmaceutical services to the area of family and community health care. To provide a certain service, six components of patient centered care should be employed concurrently with the family pharmacy interventions (FPI) as covered by the IFFE and BATH (Background, Affect, Trouble and Handle) techniques [4,5]. These actions aim to explore drug-related problems (DRP: an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes) [12], drug-related suffering (DRS: an event or circumstance involving drug therapy that actually or potentially interferes with the patient's mental health) [13], and drug system problems (DSP: a problem involving a drug system that actually or potentially interferes with the patient's access to the drug for health therapy) [13] of each individual patient. FPIs not only emphasize the aspect of curing, but also account for the caring and healing [4,7,14,15] of individuals. FPI also leads to partnership [4, 10, 11] and understanding of the patients through a healing relationship [14-15], and trust [16,17]. The consequences are the achievement of superior health outcomes [18,19].

No pharmacist's intervention in Thailand focuses on exploring the patient's experience, collaborating to achieve trust and a healing relationship [20-23]. Their interventions usually involve patient education, prescription assistance, medication management (monitoring of drug therapy, medication review and assessment of medication complications), and life-style modifications. There has only been one study examining family pharmacy services in a Thai setting: Sakthong, et al. [24] conducted qualitative interviews with patients with hypertension, hyperlipidemia and diabetes. Unfortunately, this previous study did not cover any aspects of the patient's clinical outcome.

Since it would seem that no pharmacist's intervention in Thailand focuses on the patient's experience or tries to form a healing relationship with the aim of achieving improved clinical outcomes, and since there doesn't appear to be any study of the effectiveness of such a system [20-24], this study aims to fill this apparent gap by exploring the effectiveness of FPI in Thailand compared with usual practice for diabetic patients with poor glycemic control, and for uncontrolled hypertensive patients in a primary care setting. In addition, this study attempts to find out just how effective the IFFE and BATH techniques are, in terms of improving clinical outcomes.

METHODOLOGY

Design

This quasi-experimental study compared FPI using a patient-centered approach versus usual care. This study was approved by the Institutional Review Board of the Faculty of Pharmacy, Silpakorn University, Thailand (The approval number was 20/2557).

Study Setting

Of 31 District Health Promotion and Prevention Centers in Muang district of Nakhon Pathom province, Thailand, eight eligible centers met the requirements of (1) being willing to participate, (2) having health checks monthly, and (3) having a health-care team (including doctor, pharmacist, nurse and others) working on the health check day were randomly assigned to either the usual care groups or the FPI groups from January to July 2015. Each group was covered by four centers, and there were forty patients in each group. Forty patients received care from family pharmacists who employed a patient-centered approach. The other forty patients in the other group received usual care.

Patients and Randomization

To calculate the desired sample size [16] of this study, a power was 80% with a 5% margin of error. Mean difference and standard deviation values of 8.3 and 20, respectively, from Leung *et al.* [17] were used. The appropriate sample size was calculated to be 36 in each group, so it was determined that a sample of 40 for each group was required, allowing for 10% attrition.

The inclusion criteria for the 80 patients (10 patients per center were needed) were elderly patients aged 60 years or more with uncontrolled blood pressure (systolic blood pressure [SBP] >150 mmHg or diastolic blood pressure [DBP] >90 mmHg) or patients with Type 2 diabetes with fasting plasma glucose (FBS) >130 mg/dl in the last 3 months before the baseline assessment. The eligible patients did not have other chronic diseases or life-threatening conditions. The exclusion criteria were a eGRF (estimated Glomerular Filtration Rate) lower than 60 ml/min/1.73 m² and patients who had changed their medication regimen from the baseline regimen for any reason.

To recruit the patients, we visited the 8 eligible centers on the date that patients had their monthly health checks (normally the health check date was not on the same day in any given month). A "First Come First Served" system was used for normal health checks in each center, so we recruited patients who met the criteria in the queue and assigned an Arabic numeral to each patient. Every third eligible patient received information about the purpose of the study and was invited to participate, and then patients indicating an interest in participation were asked to provide written informed consent.

Intervention

Usual care

Forty patients in the usual care group met the physician and pharmacist at every visit. Pharmacists prescribed medication

as per their scope of practice to achieve treatment targets. Approximately 5 min was spent with each patient.

FPI

On each visit, each patient normally had a physical examination and laboratory test. After that, a family pharmacist interviewed each patient regarding the six components of patient-centered care, emphasizing active communication and partnership using IFFE and BATH techniques and medication assessments covering DRPs, DRS, and DSPs.

The family pharmacist explored both the disease and illness. The IFFE were assessed for the understanding of each patient as a whole person, and then the common ground for solving DRPs, DRSs, or DSPs was set. Patients were informed about health promotion or disease prevention, such as lifestyle modifications, nutrition, and exercise. Effective listening, questioning, and communication with empathic response were used throughout the interview. The family pharmacist and patient relationship was enhanced at every visit. All patients' data were documented, and appointments for the follow-up were arranged for all patients. The patient-centered care processes of the family pharmacists usually took a lot of time - much more than that for the usual care. Each family pharmacy process took approximately 15 min per visit.

Patients in both groups received follow-up visits every month.

Outcome measures and follow-up

Baseline data on age, gender, concomitant illnesses, FBS, HbA1c, and blood pressure were collected from medical records in the primary health centers. The primary clinical outcomes of the present study were SBP, DBP, FBS, and HbA1c. After baseline measurement, all primary outcomes were measured after 3 and 6 months of the treatment.

Data Analysis

For continuous variables, two-sample *t*-test or Mann-Whitney *U*-test was used for the comparison of baseline characteristics of patients between the FPI group and usual care group. The Chi-square test was used for categorical variables.

To compare the effectiveness of the family pharmacy program, the primary outcome of each follow-up period was compared with the baseline results using paired-sample *t*-test or Wilcoxon signed-rank test, which compared the primary outcome between the two groups using independent *t*-test or Wilcoxon Mann-Whitney *U*-test. Statistical Package for the Social Science (SPSS) version 11.0 was used to analyze the data.

An "Intention-to-treat" and "Last observation carried-forward" approach was employed for the loss of follow-up patients.

RESULTS

Eighty patients were recruited from January to July 2015 and followed up for 6 months. The mean age of the patients was 68.7 years and 77.5% were female. Most of them had both uncontrolled diabetes and hypertension (72%). The patients

were equally divided into two groups to receive intervention from family pharmacist and usual care. The demographic and disease characteristics at baseline were similar (Table 1).

The primary endpoints were assessed after the third and the 6th months.

Table 2 shows an inter-group analysis of the results and demonstrates significant differences in mean SBP ($P = 0.002$) and DBP ($P = 0.006$) at study end with patients receiving FPI achieving optimally lower values of SBP and DBP compared to usual care. These differences remained significant when assessed by baseline analysis ($P < 0.0001$) (Tables 3 and 4).

Table 5 shows that the mean FBS (175.38% and 176.93%) and hemoglobin A1c (HbA1c) levels (8.48% and 8.50%) for the two groups were similar at the baseline. After 6 months, the overall mean FBS and HbA1c values had decreased significantly more in the FPI group than the usual care group ($P = 0.033$ and 0.042 , respectively) and they were significantly different when assessed using baseline analysis ($P < 0.0001$) (Table 6).

In the usual care group, the data also show a significant decrease in SBP and FBS when evaluated using baseline analysis (Tables 3 and 6) but in the end, the levels are still higher than those of the FPI group.

However, the overall result in the end indicated that the participants in this study did not achieve the optimal goals of blood glucose level (<130 mg%) or HbA1c level (<7.0 mg%) in the FPI group, while the FBS and HbA1c values decreased more than those of the usual care group.

DISCUSSION AND CONCLUSION

The results of the primary clinical outcomes (blood pressure level and blood glucose level) in this study demonstrated significant improvements for patients in both groups, with all mean values being reduced in the FPI group more than in the usual care group. Overall, the results revealed that the FPI program was more effective than that of the usual care group. The findings were consistent with previous reviews showing that pharmacist-led care or involvement in a team-based care program using a pharmaceutical care approach improves patient health outcomes including blood pressure and FBS control [18-23], and it was interesting that the study found significant differences between the two groups. An attempt to understand the underlying mechanisms by which the FPI achieved superior outcomes in this study may suggest that this is a result of applying the IFFE and BATH techniques and medication assessment (DRPs, DRSs, and DSPs) to the patient-centered approach processes, which led to enhancements, more understanding of the patients, and a strengthening of the patient-centered care [3,24-27]. This was achieved through a healing relationship [14,15], trust [18,19], and an enhancement of the collaboration of care between patients and pharmacists [32]. Those are the consequences of achieving superior health outcomes [33,34].

This study revealed that after 6 months, groups of patients demonstrated a slight improvement but still had poor glycemic control [35] (FBS >130 mg%, and HbA1c >7.0 mg%), since to achieve these therapeutic goals needs a longer time,

Table 1: Patients' baseline demographic characteristics

Characteristics	Family pharmacy (n=40)	Usual care (n=40)	P-value
Gender			
Male (%)	17.5	27.5	0.43
Female (%)	82.5	72.5	
Age (years)	69.22±5.12	68.18±5.52	0.38
Concomitant illness			
Diabetes mellitus (%)	20	30	0.06
Hypertension and diabetes mellitus (%)	80	70	
SBP (mmHg)	154.22±10.15	155.42±11.37	0.620
DBP (mmHg)	83.28±7.88	82.50±9.46	0.692
FBS (mg%)	176.93±39.7	175.38±33.72	0.84
HbA1c (mg%)	8.48±1.03	8.50±0.82	0.93
Duration of hypertension or diabetes (years)	8.82±5.28	9.40±7.50	0.23

SBP: Systolic blood pressure, DBP: Diastolic blood pressure, FBS: Fasting plasma glucose, HbA1c: Hemoglobin A1c

Table 2: Comparison between groups for SBP and DBP at baseline and 3- and 6-month follow-ups

Parameters	Baseline			3 months			6 months		
	Mean±SD		*P-value	Mean±SD		*P-value	Mean±SD		*P-value
	Family pharmacy (n=40)	Usual care (n=40)		Family pharmacy (n=40)	Usual care (n=40)		Family pharmacy (n=40)	Usual care (n=40)	
SBP (mmHg)	154.22±10.16	155.43±11.37	0.620	145.80±15.11	149.15±15.30	0.328	139.00±11.32	147.68±12.64	0.002
DBP (mmHg)	83.28±7.88	82.50±9.46	0.692	82.25±10.87	81.93±9.98	0.890	77.83±7.11	83.53±10.74	0.006

*Independent t-test. SBP: Systolic blood pressure, DBP: Diastolic blood pressure, SD: Standard deviation

Table 3: Comparison within groups for SBP at baseline and 3- and 6-month follow-ups

Intervention	Baseline	3 months versus baseline		6 months versus baseline	
	Mean±SD	Mean±SD	**P-value	Mean±SD	**P-value
Family pharmacy (n=40)	154.22±10.16	145.80±15.11	<0.000	139.00±11.32	<0.0001
Usual care (n=40)	155.43±11.37	149.15±15.30	0.001	147.68±12.64	<0.0001

**Paired-sample t-test. SBP: Systolic blood pressure, SD: Standard deviation

Table 4: Comparison within groups for DBP at baseline and 3- and 6-month follow-ups

Intervention	Baseline	3 months versus baseline		6 months versus baseline	
	Mean±SD	Mean±SD	**P-value	Mean±SD	**P-value
Family pharmacy (n=40)	83.28±7.88	82.25±10.87	0.393	77.80±7.11	<0.0001
Usual care (n=40)	82.50±9.46	81.93±9.98	0.518	83.53±10.74	0.354

**Paired-sample t-test. DBP: Diastolic blood pressure, SD: Standard deviation

Table 5: Comparison within groups for FBS and A1c at baseline and 3- and 6-month follow-ups

Parameters	Baseline			3 months			6 months		
	Mean±SD		**P-value	Mean±SD		**P-value	Mean±SD		**P-value
	Family pharmacy (n=32)	Usual care (n=28)		Family pharmacy (n=32)	Usual care (n=28)		Family pharmacy (n=32)	Usual care (n=28)	
FBS	175.38±33.72	176.93±39.71	0.870	157.28±44.62	162.14±40.31	0.661	144.38±25.78	160.36±30.73	0.033
HbA1c	8.48±1.03	8.50±0.82	0.927				7.81±1.02	8.3±0.78	0.042

**Paired-sample t-test. FBS: Fasting plasma glucose, SD: Standard deviation, HbA1c: Hemoglobin A1c

Table 6: Comparison between groups for FBS at baseline and 3- and 6-month follow-ups

Intervention	Baseline	3 months versus baseline		6 months versus baseline	
	Mean±SD	Mean±SD	**P-value	Mean±SD	**P-value
Family pharmacy (n=32)	175.38±33.72	157.28±44.62	0.033	144.38±25.78	<0.0001
Usual care (n=28)	176.93±39.71	162.14±40.31	0.051	160.36±30.73	0.002

**Paired-sample *t*-test. FBS: Fasting plasma glucose, SD: Standard deviation

which is common in clinical practice; however, the American Diabetes Association, the American College of Cardiology, and the American Heart Association [36] recommend that elderly patients are treated best with higher target HbA1c levels [35]. Furthermore, all these findings support the American Geriatric Society's (AGS) guidelines for diabetes mellitus management in the elderly [37]. Thus, based on these findings, we decided to design the treatment focusing on individual patients and made agreements depending on the patients' expectations rather than achieving clinically objective parameters in 6 months, so we found blood pressure and blood glucose decreased step by step in this study.

Relating to a trend toward better clinical parameters, particularly in the FPI group, each 1% drop in HbA1c level is associated with a significant reduction in the risk of diabetes-related death (21%), myocardial infarction (14%), and microvascular complications (37%) [38]. Thus, reduced FBS and HbA1c values are considered to be important even though they did not achieve their optimal values.

The findings were consistent with previous reviews showing that pharmacist-led care or involvement in a team-based care program using a pharmaceutical care approach improves patient health outcomes [37,38]. Moreover it has proved that FPI, an intervention which involves exploring the patient's experience, may result in positive effects, enhance pharmaceutical care, and reveal greater effectiveness compared to the usual care system. Adopting this intervention could lead to major patient and public health benefits, so pharmacists should be encouraged to find time in their work routines to explore their patients' psychosocial characteristics.

With respect to limitations, our follow-up period was relatively short (6 months). The reason for this short period was because this study was a new pilot intervention for Thailand and pharmacists had expressed concerns over it, so we were allowed to do our experiment with our intervention approach for 6 months only, after which time all the patients were sent back to the usual care process. Thus, a longer follow-up is suggested for future studies.

The findings suggest that the idea feeling function and expectation of patients and the subsequent background of illness may result in positive effects, so pharmacists should be encouraged to find time in their work routines to explore their patients' psychosocial characteristics. The study also demonstrated that FPI accelerated the reduction of blood pressure and blood glucose levels and revealed greater effectiveness compared to the usual care system. Adopting this intervention could lead to major patient and public health benefits.

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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