

SELF-MANAGEMENT PROGRAM ON BLOOD PRESSURE CONTROL IN THAI HYPERTENSIVE PATIENTS AT RISK FOR STROKE : A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT: To determine the effects of self-management program on blood pressure control in hypertensive patients at risk for stroke, a randomized controlled trial design was conducted at the outpatient medicine clinic at Police General Hospital during July 2011 to February 2012 to evaluate the effectiveness of a self management program based on the Kanfer and Goelick-Buy (1991) self management model compared with usual care in improving blood pressure control. The participants were enrolled on criteria basis and computerized simple randomization into two groups and sealed envelope technique to divide equally to the experimental or the comparison groups (50/group). The intervention group attended four phases; problem assessment, need identification, preparation for self-management, practice for self-management, and evaluation self-management phases. The outcome of this study was blood pressure control which was measured at baseline and monthly over three months. Data were analyzed by Chi-square test. At three months the percentage of participants maintaining blood pressure control was significantly ($p = .001$) greater in the intervention group (36%, 95%CI = 0.22 to 0.50) compared with the control group (8%, 95%CI = 0.00 to 0.16). An effort to establish in large scale, long duration and sustainable self-management program is recommended.

Keywords: Self-management Program, Hypertensive Patients, Blood Pressure Control

INTRODUCTION

Hypertension (HTN) is a powerful risk factor that appears to promote the development of stroke directly. Over half of the hypertensive stroke cases in family medicine practice have either untreated or poorly controlled blood pressure (BP) [1]. As reported in the 2001 national health examination results [2], HTN prevalence in Thailand was found to concern 11 millions of the 50 million- Thais aged more than 15 years. The Ministry of Public Health [2] reported that it occurred 23.3% in men and 20.9% in women and estimated that 30.2% of population had inappropriate BP control. Moreover, the group of treated and controlled hypertensive patients had only 8.6% whereas the group of uncontrolled hypertensive patients had 15% [2] as high as those reported in developed countries.

Adequate treatment and control of HTN in individuals is associated with a significant reduction in strokes and cardiovascular events. It is estimated that effective treating blood pressure will result in a 36% reduction in the risk of stroke [3-5]. The Hypertension in the Very Elderly Trial (HYVET) involving 3,845 patients showed significant reduction in strokes and heart-related deaths

intreated patients compared to controls [5]. The sooner the diagnosis and management of HTN the lower the risk of cardiovascular disease.

The classification of people at risk for stroke of the Bureau of non-communicable disease, Department of Disease Control, Thai Ministry of Public Health [6] has three levels: 1) patient at high risk, 2) patient at moderate high risk, and 3) patient at very high risk. The hypertensive patients at risk for stroke in this study are in the first level: patient at high risk This level include people who have had 2 criteria for risk assessment, people who have had type 2 diabetes for more than 10 years and people with a family history of ischemic stroke, premature coronary heart disease or controllable diabetes. Previous studies showed that the reasons for poor BP control concern with health behaviors e.g., high sodium and caloric intake, alcohol consumption, overweight, stress and non-adherence to prescribed medical regimen [7, 8]. Non-adherence is linked to age, knowledge deficit, medication cost, complicated regimens, side effects, poor physician-patient communication and lack of social support [9]. The American Heart Association 2012 (AHA) [10] suggested that the primary goal of clinical management in BP control is to achieve the maximum reduction, in the long term, of total risk of cardiovascular morbidity and mortality. The goal

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of BP control or achieving BP based on JNC-7 guideline [11] is to keep systolic BP ≤ 140 mmHg and diastolic BP ≤ 90 mm Hg in general HTN, for diabetic or chronic kidney disease of BP less than 130/80 mm Hg.

Despite effective available treatment strategies, the lacks of adherence and persistence to medication regimen and lifestyle changes have contributed to inadequate BP control. It was found that more than 90 percent of patients who were treated with antihypertensive drug and at risk of stroke still had elevated BP [12]. Numerous interventions have been developed with the goal of improving in BP among patients with HTN. A Cochrane review included 38 randomized controlled trials (RCTs) of 58 various types of interventions (some tested in factorial trials) designed to improve patient BP in ambulatory settings [13]. The quality of the studies was generally low due to inadequate allocation concealment, lack of blinding of outcome assessors, loss to follow-up, and the small number of participants in trials. Moreover, educational strategy alone was largely ineffective in improving BP.

A literature review of experimental and quasi-experimental nursing research among hypertensive patients in Thailand [14] found that most of these studies were significant in changing patients' health behaviors, but not significant in improving BP. This might be due to limited follow-up period. Although many studies have conducted interventions integrating various method with the aim of achieving patients' good BP control, few studies have actually focused on the design, implementation and testing of interventions to improve adherence to self-management behaviors in hypertensive patients at risk for stroke.

One of the most widely accepted intervention is self-management program (SMP) known as the chronic disease SMP. This has been defined as the individual's ability to manage the symptoms, treatment, physical and psychosocial consequences and lifestyle changes inherent in living with a long term condition [15]. One study [16] found that self-management interventions decreased systolic BP by 5 mm Hg (effect size, -0.39 [CI, -0.51 to -0.28]) and decreased diastolic BP by 4.3 mm Hg (effect size, -0.51 [CI, -0.73 to -0.30]). SMP for HTN probably produce clinically important benefits. The elements of the programs most responsible for the observed benefits cannot be determined from existing data, and this inhibits specification of optimally effective or cost-effective programs [16].

Given the limited availability of studies on the effectiveness of SMP on hypertensive patients at

risk for stroke, this current research was conducted to support nursing research among hypertensive patients especially at risk for stroke, and to gain new knowledge that can be applied in nursing practice to improve control of patients' BP.

MATERIALS AND METHOD

Participants

A randomized controlled trial design with concealed allocation was conducted at the Bangkok Police General Hospital outpatient medicine clinic from July 2011 to February 2012. A hundred consecutive patients were prospectively included in this study, which was approved by The Research Ethics Committee of Police General Hospital.

All patients were 35 to 79 years of age diagnosed of essential primary HTN (based on the ICD10) and defined as a systolic BP of ranging 140 to 160 mm Hg and /or diastolic BP of ranging 90 to 100 mm Hg on any two clinic visits in the previous a year while taking antihypertensive medication. All patients were at high risk level for stroke assessed by the classification of people at risk for stroke [6]. Patients who had not completed all intervention sessions were dropped from the study.

The sample size was calculated based on a significance level of 0.01 and a power of 0.90 by using G* Power 3.1.3 [17]. Regarding the previous studied report, the average effect size (d) was 0.54 [18]. Therefore, the average correlation (r) was computed by using the equation [19]:

$$r = \frac{d}{\sqrt{d^2 + 4}}$$

The average correlation (r) translated from d (the effect size) which was the average effect sizes in the previous study. Substituting in the equation:

$$r = \frac{d}{\sqrt{0.54^2 + 4}} = 0.26$$

Utilizing an alpha of 0.01 and a power of 90% with the average correlation = 0.26, effect size = 0.2, k (number of repeated measures) = 4, and $\alpha = .05$, revealed that 88 patients were needed in both the experimental and comparison groups. A previous, similar study reported an attrition rate of 20% [20]; therefore, at least 106 patients were required. Initially, the researcher contacted patients meeting the inclusion criteria and 108 of them gave written, informed consent to be enrolled in the study. Prospectively, participants were equally allocated

into the intervention ($n = 54$) and comparison groups ($n = 54$) by using computerized simple randomization and sealed envelope technique. At the end 4 patients in each group (7.4%) were unable to participate throughout the whole study, the final samples consisted of 50 patients in each group.

Self-management Program

The self management program (SMP) based on the Kanfer and Goelick-Buy self-management model [21] was used, with appropriate methods and existing resources, to control BP. Self-management is the process of self-control and monitoring of change behavior on the basis of cognitive process and learning from past experience. The obtained information is then evaluated to make decision in response or to induce the desired behavior [21]. This program was composed of four phases that covered five sessions of implementation within twelve weeks. The first phase, 'problem assessment and need identification' offered a small group education session to set goal for promoting self-management in controlling HTN. The second phase, 'preparation for self management' offered two group education sessions to improve knowledge about HTN, Dietary Approach to Stop Hypertension (DASH) and exercise, stroke risk, enhance compliance with antihypertensive medication and self-management skills. The third phase, 'practice for self-management' involved an action and self regulation session using individualized telephone follow-up. The fourth phase, 'evaluation for self-management behaviors' involved the BP control evaluation and terminated the program. The participants in the control group completed the personal information, and their blood pressures were measured at baseline, the 1st, 2nd, and 3rd month after the intervention. Furthermore, they received the usual care during 3 months in the medical outpatient clinic and received the self-management booklet when they followed-up at the clinic after the program termination.

Data collection

The demographic data (age, gender, socioeconomic status, education) height, body weight, body mass index (BMI), pulse and BP were collected at the baseline. Participants' Medical history was obtained from participants' medical records available in the institution's clinic including duration of HTN and antihypertensive drug used. The BP readings were collected at baseline and at each month over three months after the intervention. BP readings were measured by an experienced and trained research assistant with automatic BPs monitor (Oscillometric)

calibrated cuff and the participant seated in a chair. These measurements were taken after the participant rested in the clinic waiting room and prior to the visit with the physician. If multiple BP measurements were recorded for any participant, the mean systolic blood BP and mean diastolic BP were used.

Data analysis

Descriptive statistics were used to summarize the patients' sociodemographic and medical characteristics. The comparability of the intervention and the control groups sociodemographic and medical characteristics at baseline was analyzed by using the percentage and Chi-square test. The Chi-square test was conducted to compare the proportion of participants achieving BP control in each arm of the study at baseline, the 1st, 2nd and 3rd month after the intervention. A 'P' value less than .05 was considered significant.

RESULTS

Participant characteristics

The participants were male 45%, and female 55%. The age ranged from 35 to 79 years with a mean of 59.6 y (SD = 9.66). Most of them were married 74%, completed the elementary school 41%. The income was mostly sufficient income (83%) (Table 1). Eighty percent of the participants (80%) had a BMI over 23 kg/m² [22]. Participants had been diagnosed with HTN for an average 1.6 (SD = 0.57) years with most taking two and three antihypertensive medications daily. Baseline personal and clinical characteristics between groups did not differ significantly except for the number of hypertensive drug used that was significantly different ($p = .02$) (Table 1).

Blood pressure control

At baseline, all participants (100%) in intervention and control groups had stage I HTN (i.e. systolic BP 140-159 or diastolic BP 90-99). At the 1st month of follow-up, most (92%) of participants in the intervention group had Pre-HTN (i.e. systolic BP 120-139 or diastolic BP 80-89) followed by 6% with normal BP (i.e. systolic BP ≤ 120 and diastolic BP < 80). In the control group, most of participants had stage I HTN (86%) followed by normal BP (6%). At the 2nd month of follow-up, most (68%) of participants in the intervention group had the stage I HTN and 30% had Pre-HTN. In the control group, most of participants (68%) had stage I HTN followed by the stage II HTN (24%) (i.e. systolic BP ≤ 160 or diastolic BP ≥ 100). At the 3rd month of follow up, most (68%) of participants' in the

Table 1 Participant characteristics at baseline (n=100)

Characteristics	Control group (n=50)		Intervention group (n=50)		χ^2	df	p-value
	n	%	n	%			
Age (years)					2.98	3	.40
35 – 49	7	14.0	7	14.0			
50 – 59	11	22.0	17	34.0			
60 – 69	22	44.0	21	42.0			
70 – 79	10	20.0	5	10.0			
Range = 60-69, M = 59.6, SD = 9.6							
Gender					.04	1	.84
Female	27	54.0	28	56.0			
Male	23	46.0	22	44.0			
Status					3.58	3	.51
Single	3	6.0	6	12.0			
Married	38	76.0	36	72.0			
Divorced	8	16.0	6	12.0			
Separated	1	2.0	2	4.0			
Education					2.36	4	.44
No literate	3	6.0	1	2.0			
Elementary	22	44.0	19	38.0			
Secondary	2	4.0	4	8.0			
Diploma	14	28.0	15	30.0			
Bachelor	9	18.0	2	4.0			
Income					3.47	1	.11
Insufficient	12	24.0	5	10.0			
Sufficient	38	76.0	45	90.0			
Range= 3,000-80,000 Baht, M=21,520.60, SD=14,308.91							
BMI (Body Mass Index) (kg/m ²)					0.25	5	.38
≤ 23	9	18.0	11	22.0			
>23	41	82.0	39	78.0			
Range= 17.2-42.7, M = 27.1, SD = 5.0							
Duration of HTN(years)					2.43	2	.31
1-5	24	48.0	19	38.0			
6-10	23	46.0	30	60.0			
> 10	3	6.0	1	2.0			
Number of drug used					8.44	2	.02
1 agent	5	10.0	17	34.0			
2 agents	22	44.0	17	34.0			
3 or more agents	23	46.0	16	32.0			

Table 2 The percentage of participants classified by stage of HTN (n = 100)

Classification of HTN*	Baseline		1 st month		2 nd month		3 rd month	
	n	%	n	%	n	%	n	%
Control group (n=50)								
Normal	-	-	-	-	-	-	-	-
Pre-HTN*	-	-	3	6	4	8	6	12
Stage I	50	100	43	86	34	68	28	56
Stage II	-	-	4	8	12	24	16	32
Intervention group (n=50)								
Normal	-	-	3	6	1	2	2	4
Pre-HTN	-	-	46	92	15	30	34	68
Stage I	50	100	1	2	34	68	14	28
Stage II	-	-	-	-	-	-	-	-

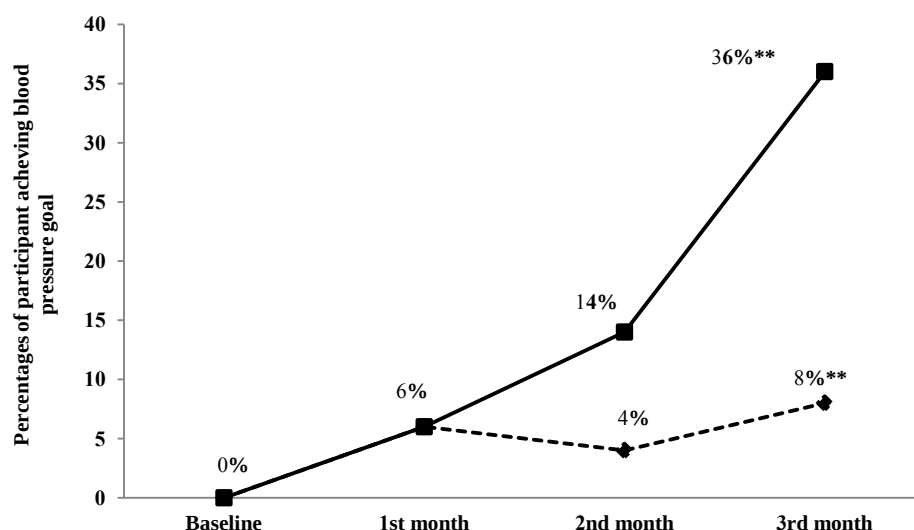
* **Note:** HTN: Hypertension

intervention group had Pre-HTN followed by stage I HTN (28%). In the control group 32% of participants had stage II HTN and 56% had stage I HTN, respectively. The participants' details of the stages of HTN are shown in Table 2. Regarding

achieving BP goal (Table 3), all participants in intervention and control groups had not achieved BP goal at baseline. At the 1st month of follow-up, participants in both groups had achieved BP goal (6%). At the 2nd and the 3rd month, participants in

Table 3 The proportion of participants in control of BP (n = 100)

BP Control	Control group (n=50)		95% CI	Intervention group (n=50)		95% CI	χ^2	p-value
	n	%		n	%			
Baseline	0	0	0	0	0	0	-	-
The 1 st month	3	6	0.00 to 0.13	3	6	0.00 to 0.13	-	-
The 2 nd month	2	4	-0.02 to 0.10	7	14	0.04 to 0.24	3.05	.160
The 3 rd month	4	8	0.00 to 0.16	18	36	0.22 to 0.50	11.42	.001

**Figure 1** The present study showed effect of SMP on percentages of participants achieving blood pressure goal $\chi^2_{(1, N = 100)} = 11.42, p = .001$ ** compared to control group at the same time point.

the intervention group had achieved BP goal higher than in the control group (14% vs 4% and 36% vs 8%, respectively).

As shown in Figure 1, the change in the number of participants reaching the BP goal, as recommended by the JNC-7 [11] was also significantly greater in the intervention group at the 3rd month (36%) vs (8%); $\chi^2_{(1, N = 100)} = 11.42, p = .001$ compared with the control group.

DISCUSSION

Outcomes of the SMP showed that at three month follow-up 68% participants in the intervention group had pre-HTN followed by 28% with stage I HTN whereas 32% participants in the control group had stage II HTN and 56% stage I HTN. This means that overall the SMP was successful in reducing in systolic BP and diastolic BP and improving BP control. This study supported the evidence that a SMP could increase BP control in hypertensive patients at risk for stroke by using nursing strategies: skill training and facilitation through nurses providing patients with guidance to monitor progress and achieve agreed management goals. Consistent with the findings from Barlow et

al. [15] self-management interventions have a benefit effect on health outcomes of participants in the short term. Increase in self-efficacy was associated with three-month increase in health behavior change [23]. Initial intervention and follow-up should be early and often, incorporating the expectation of self-monitoring and deliberate follow-up [24]. Implementing an effective SMP by healthcare providers, remote patient encounters (telephone) and group setting within the current health care system remains an important challenge for improving HTN care.

Research findings revealed the SMP strength particularly when there is extensive implementation of goal setting for BP control and encouragement of patients to change their behaviors by using group discussion, self-management and reinforcement by a telephone call approach. Three methods are effective in promoting the health outcomes [25, 26]. In addition, the strengths in this study were random assignment among participants in both groups and use the assessment of people at risk for stroke as criteria for recruitment.

Regarding the difference of number of drug used in both groups might not be affected on blood pressure

control. At the baseline of the intervention researcher included all participants who had stage I HTN in both groups. From previous study [27] found that as in the Hypertension Optimum Treatment (HOT) almost 70% of patients required more than one drug to achieve a tighter control of blood pressure, and 24% received three drugs. In this study, most participants in the control group received 2 or 3 agents whereas participants in the intervention group received 1 to 3 agents. However, this study provided support for developing interventions to promote successful self-management among participants and improve quality of HTN management. Consistent with the findings of others on BP control [28], such teams foster communication between nurses and well-informed patients [29].

Therefore, the SMP was effective in providing the appropriate action for the participants with poor BP control. Moreover, this study monitored BP levels monthly and used telephone follow-up to improve the process of care and achieve BP control. Similarly, Bosworth et al. [30] conducted a behavioral intervention for hypertensive patients by telephone administered. Delivering an intervention by telephone may enhance the intervention's cost-effectiveness. Telephone interventions also provide an opportunity to reach more patients and these interventions may be more acceptable and convenient than in person interventions. Wongputtakham [31] conducted the effects of self-management on health behaviors and BP among hypertensive patients. The results revealed that BP of the hypertensive patients who received the self-management plan had significantly lower BP than those in the control group.

These findings suggest that the level of patient partnership in their clinical care is an important element in achieving BP control. Because hypertensive patients at risk for stroke are likely to need more special support to improve medication adherence and lifestyle changes. SMP with mutually planned activities between participants and health care providers, using a variety of techniques have been associated with a large net reduction in BP [13].

CONCLUSION

The findings of this study showed that a SMP promoted better systolic BP and higher BP control for Thai hypertensive patients at risk for stroke. SMP should be promoted in health care settings by incorporating them into the regular care. In addition, control of BP is crucial to delay clients'

progression to cardiovascular problems and stroke events, and even death.

With a broader perspective, interventions can be designed to focus on BP control and other activities to improve the quality of life of hypertensive patients at risk for stroke. Effective of BP control by using a SMP can also reduce the costs of medication use and promote an interactive process involving the clients as partner and coaching them to take ownership in managing their own health conditions [24]. This mode of care delivery, using self-management skill training and telephone follow-up is worth considering for other chronic disease management program and participants selected from several areas are needed for further studies.

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