

THE EFFECTS OF INTEGRATED LAUGHTER, MILD PHYSICAL ACTIVITY AND DIETARY SELF-CONTROL ON BLOOD PRESSURE AND SERUM LIPID PROFILE AMONG HYPERTENSIVE PATIENTS IN COMMUNITY-BASED CARE, PATHUM THANI, THAILAND

Luckwirun Chotisiri¹, Tabtip Trongsakul², Khemika Yamarat^{1,*},
Surasak Taneepanichskul¹

¹ College of Public Health Sciences, Chulalongkorn University, Bangkok, 10330, Thailand

² Bueng Kham Phroi Health Promoting Hospital, Lamlukka, Pathum Thani, 12150, Thailand

ABSTRACT:

Background: There is considerable interest in non-pharmacological therapy in community-based treatment of hypertensive patients. The objective of this study was to evaluate the effects of integrated laughter, mild physical activity and dietary self-control (ILMPAD Program) on blood pressure and serum lipid profile among hypertensive patients in community-based care, Pathum Thani province, Thailand.

Methods: A randomized control study design was applied to two groups. Hypertensive patients were recruited to participate in the ILMPAD program at the clinic. All participants were assigned to the intervention and the control group by simple random allocation, matching on sex-and age-specific groups. A 3 month of ILMPAD program consisted of a 10 minute giving knowledge, a 40 minute exercise training and a 10 minute individual record of dietary intake, exercise, stress and relaxing. The activity of ILMPAD program was repeated every month at the clinic under the monthly physician's appointment until 3 successive months elapsed. The control group received only the usual care of health promoting hospital, including routine physicians' treatment. The primary expected outcomes were changes in blood pressure (BP) from baseline data 3 months after starting the ILMPAD program, compared between two groups. The secondary expected outcomes were changes in serum lipid levels (cholesterol, triglyceride, LDL and HDL) from baseline to 3 months after starting the ILMPAD program, compared between the two groups.

Results: Of 69 randomly allocated participants one group was exposed to the ILMPAD program (n=34) and one group functioned as control groups (n=35). Compared with the baseline data, there was no significant difference of blood pressure between the two groups ($p>0.05$). However, there were significant difference of cholesterol, LDL and HDL in the intervention group after received a 3 month of ILMPAD program ($p < 0.001$, < 0.001 , and < 0.05 , respectively).

Conclusions: ILMPAD program might be effective in lowering blood pressure and improving serum lipid among hypertensive patients in community-based care. However, larger and longer trial studies will be needed to evaluate this program.

Keywords: Blood pressure, Serum lipid, Hypertensive patients, Thailand

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INTRODUCTION

Hypertension is one major non-communicable disease in developing countries, the effects of high blood pressure is related to the relative risks of heart disease, kidney disease, stroke and other

complications [1]. Treatment of hypertension to control high blood pressure involves anti-hypertensive

* Correspondence to: Khemika Yamarat
E-mail: khemika.Y@Chula.ac.th

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drug use and lifestyle therapy. The recommendation to begin lifestyle therapy, such as having a healthful diet which includes reducing salt and sodium, being physically active, smoking cessation and limited alcohol consumption could reduce the risk of developing complications due to high blood pressure [2]. Thus, there is considerable interest in treating hypertensive patients with lifestyle therapy in combination with anti-hypertensive drugs. Various studies suggest the efficacy of mind-body intervention can control blood pressure [3, 4]. Moreover, East Asian exercises such as Chinese martial art:- Tai Chi, Qi Gong and others are used as an alternative modality for lowering blood pressure [5-7]. Furthermore, mirthful laughter can contribute the lower risk of cardiovascular disease (CVD) and fewer myocardial infarction (MI) reoccurrence. Moreover, laughter has been reviewed that is manifested both physically and psychologically [8, 9]. In addition, based on Bandura's self-efficacy theory, that self-efficacy motivates participation in physical activity, which suggests potential use of these measures in other contexts [10]. Therefore, the author combined a set of approaches by using laughter technique [11], with Chinese exercise namely "Jinkangkong" which is popular in Nonthaburi [12], giving short talks about blood pressure, and individual checklist for dietary intake. Pilot study the results showed laughter technique in combination with Jinkangkong exercise was effective in lowering systolic blood pressure after 8 weeks among old patients with mild hypertension. However, the effects of integrated laughter and mild physical activity, plus with dietary self-control (ILMPAD program) is still unknown, we hypothesized that ILMPAD program would show significant improvement in blood pressure control and serum lipid (cholesterol, triglyceride; TG, low-density lipoprotein; LDL and high-density lipoprotein; HDL). Therefore, the objective of the present study was to evaluate the effects of ILMPAD program on blood pressure and serum lipid among hypertensive patients in community-based care at Pathum Thani, Thailand.

MATERIALS AND METHODS

This study was conducted at the representative of health promoting hospital namely "Bueng Kham Phroi" where located in Bueng Kham Phroi sub-district, Lamlukka district, Pathum Thani, this hospital was purposive selected from 12 places which are organized by Lamlukka community hospital, under Pathum Thani Provincial hospital and the Ministry of Public Health (MOPH), respectively. Each of health promoting hospitals can

provide healthcare services up to 200 outpatients a day [13].

Participants, by matching age and sex, were randomly assigned into two groups. The sample size was calculated based on a previous study [14]. The sample size required in each group in the current study was 17 cases per group with 80% power at the 5% significant level. To compensate for a 30 % dropout rate, patients might have uncontrolled blood pressure with higher 160/100 mmHg for twice months under physician's appointment, changing for pharmacological treatment, and/or physician's appointment over than 3 months interval (if have) and individual reasons included with age period with death. However, patients who lived in the same family and/or neighborhood with the inclusion criteria, the researcher might consider to fill in those arms equally. Finally, the overall sample size was 69 cases.

The inclusion criteria were specified as follow: both men and women, age range from 50 to 80 years, diagnosed of hypertension for at least 1 year, taking antihypertensive drug(s), with a blood pressure not exceeding 160/100 mmHg and regular once a month attending at the hypertension clinic included those who were ex-smoker more than 1 year, drinking alcohol < 2 unit in men; <1 unit in women. However, patients were excluded in case of age younger than 50-year and/or age older than 80-year, suffering from other complications such as having serum glycemic higher than 126 mg% with and/or diabetes medication or coexistence of hypertension with diabetes, renal failure, hearing impairment and vision problem/retinopathy, disability/limiting movement, current smoker or ex-smoker less than 1 years, drinking alcohol > 2 unit in men; > 1 unit in women. Furthermore, those could not speak/read Thai language, and communicable diseases such as TB, HIV were excluded. After participants signed consent, physical fitness test for Thais elderly from Division of Physical Activity Health, Department of Health, the Ministry of Public Health was screened to ensure that participants fit enough to perform an exercise by themselves. All participants were tested the readiness of physical fitness (flexibility, balance and agility) by physical technician from Lamlukka community hospital. Moreover, five items of stress assessment, the online version from the Department of Mental Health, Ministry of Public Health, Thailand was used to 1) evaluate participant's opinions and feelings during a prior of 2 weeks and 2) exclude in case of stress may cause high blood pressure. The full score of 8-15 showed high to severe stress, the score of 0-4 and 5-7 showed mild to moderate stress that was acceptable score of stress

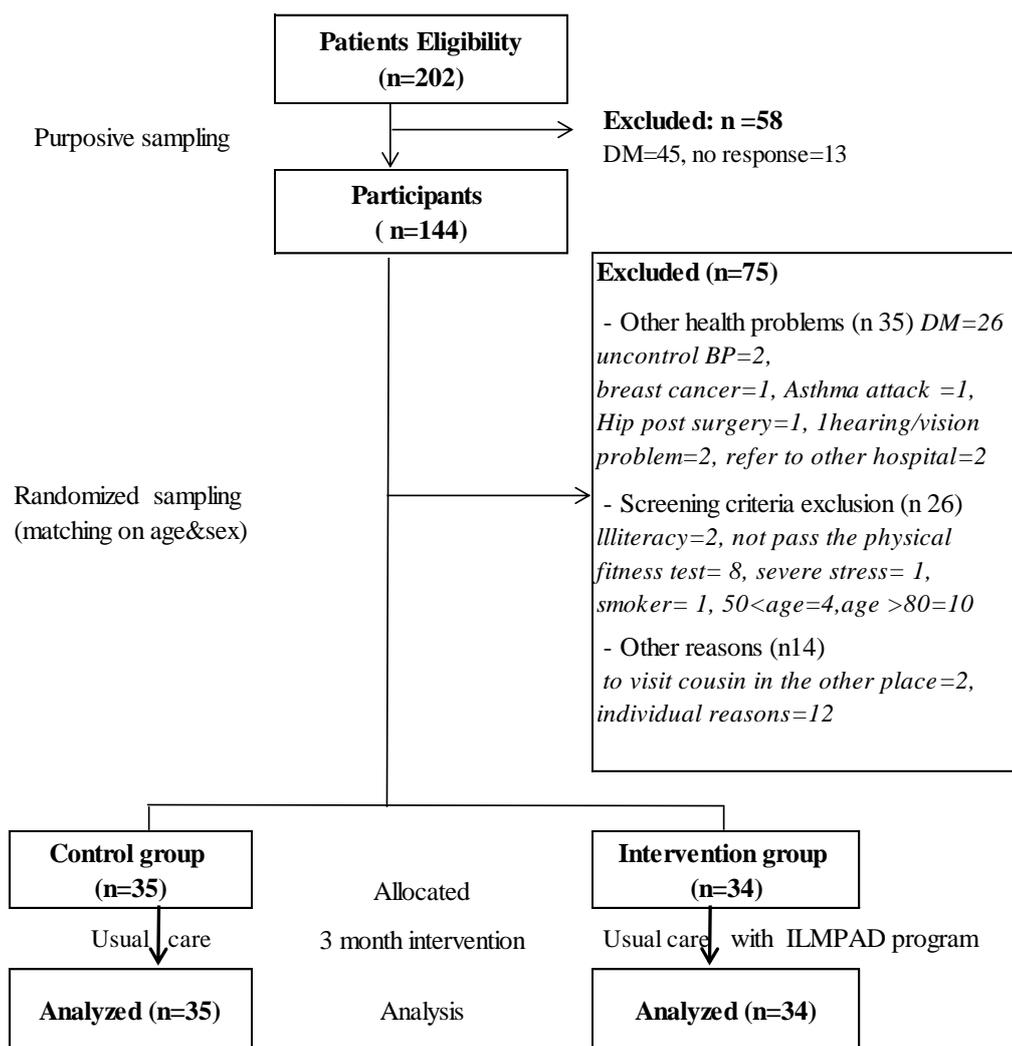


Figure 1 Study population of hypertensive patients

assessment through the program. On the other hand, high to severe stress score of 8-9 and 10-15 were excluded.

The recruitment began in January 2015 and was completed in May 2015. As illustrated in Figure 1, from 202 chronic out-patients, 58 participants did not meet inclusion criteria. Of the 144 participants were eligible for screening, 75 cases were excluded after recruitment due to health problems, other chronic condition (n=35), screening criteria exclusion (n=26) and other reasons (n=14). The remaining sixty nine patients were enrolled as participants, randomly allocated to the ILMPAD program (n=34) and the control group (n=35).

Participants in the intervention group were measured for 1) routine hypertensive measurements (body weight: BW, body mass index: BMI, waist circumferences: WC and blood pressure: BP), 2) ILMPAD program intervention 3) individual

counseling from physician 4) collecting antihypertensive medication from the pharmacist and 5) arranging the next month appointment. The description of ILMPAD program consisted of laughter plus with mild physical activity and dietary self-control based on the concept of lifestyle modification which suggest for all patients with hypertension consuming healthy food, being physically active, quit smoking and reduced alcohol consumption [2, 15] Therefore, the major components of ILMPAD program included: 1) giving a 10 minute short talk on hypertension knowledge, 2) individual checking for a 10 minute in terms of dietary intake, exercise stress and relaxing and 3) a 40 minute group exercise training (laughter plus with mild physical activity that we called “Jinkangkong exercise”). ILMPAD program was repeated at hypertension clinic of Bueng Kham Phroi health promoting hospital in monthly,

Table 1 Session of ILMPAD Program

Month	Session	Group education (10min)	Group exercise training (40 min)	Individual checklist (10 min)
I		1. Introduction to the program 2. Blood pressure reading	1. Introduction to physical activity 2. Exercise practice - Warm up: Laughter - Main exercise: Jinkangkong - Cooling down: deep breathing	20 item- Checking - Dietary intake - Exercise - Stress & relaxing
Month I interval	<u>At home-individual visit I</u> (20 min): To remind participants follow program			
II		Short talk about 1. Eating plan: High fiber, low fat, low salt, low sodium 2. Exercise: getting for 150 minutes a week 3. Assess your stress	Repeated of exercise training as month 1 st	20 item- Checking - Dietary intake - Exercise - Stress & relaxing
Month II interval	<u>At home-individual visit II</u> (20 min): To foster participants follow program			
III		Short talk about complications due to high blood pressure (stroke, heart disease, kidney disease)	Repeated of exercise training as month 1 st	20 item- Checking - Dietary intake - Exercise - Stress & relaxing

3 months continually. Furthermore, Participants were encouraged to do activities via program individually at home visiting with researcher and healthcare staff of health promoting hospital for 2 times. Two weeks later after ILMPAD program intervention started at clinic of the first month, the first home visit was followed after 2 weeks to remind participants in the intervention program. The second time was repeated in month 2nd and month 3rd interval in order to ensure that those had followed through the program intervention which are shown in Table 1.

The usual care for the control group consisted of 1) monthly physician's appointment, 2) routine hypertensive measurements (body weight: BW, body mass index: BMI, waist circumferences: WC and blood pressure: BP, 3) individual counseling from the doctor, 4) collecting antihypertensive drugs from the pharmacist and 5) arranging the next appointment.

Measurement procedures were done in both groups of participants received all routine care at Bueng Kam Phroi Health Promoting Hospital. Participants did not know if they were in the intervention or the control group, the single-blind technique was used to separate groups for different appointment schedules at the clinic. Standard services at clinic in health promoting hospital was available on every Tuesday-office timetable of each month. Therefore, participants in the intervention group were set up at the second week of the month while participants in the control group were

scheduled on the third and fourth week of the month, respectively. Before and after the ILMPAD program intervention, all participants examined for physical assessment, measurement of body weight: BW, body mass index: BMI and waist circumferences: WC. Blood pressure was measured in a sitting position at least on two different occasions which followed the JNC7 guideline. For serum blood test, all participants were asked to fast from food, beverages, tea, coffee, and smoking for at least 12 hours before drawing blood. Serum blood testing involved collecting 5 ml of blood between 6.00 and 8.00 A.M. Other parameters were completed regularly before the ILMPAD program started. All clinical measurement was monitored by a team of multi-professional health staff under Lamukka community hospital in Pathum Thani, Thailand.

The results obtained were statistically analyzed using SPSS statistical package version 16.0. The independent t-test and the Chi-square test were used to evaluate statistical differences between the control and ILMPAD groups. The dependent t-test was used to analyze the differences between baseline and at month 3rd. All analysis used a 95% confident interval (CI) and the level of significance for all the statistical tests was set at p-value less than 0.05.

ETHICAL CONSIDERATION

This study was reviewed by the Ethics Review Committee for Research Involving Human Research Subjects, Health Sciences Group from

Table 2 Baseline characteristics (N=69)

Variables	ILMPAD group (n=34)		Control group (n=35)		p-value
	n	(%)	n	(%)	
Sex: women	25	(73.5)	25	(74.4)	0.85
Marital status: married	20	(58.8)	25	(71.4)	0.40
Education: elementary school	24	(70.5)	28	(77.1)	0.06
Occupation: housekeeper/unemployed/retirement	29	(85.3)	25	(71.4)	0.22
Non-smoker	26	(76.5)	24	(68.6)	0.50
Non-alcohol drinker	26	(76.5)	25	(71.4)	0.76
Family history of hypertension: unknown	20	(58.8)	22	(62.9)	0.93
	Mean	(SD)	Mean	(SD)	
Age (years)	66.2	(6.2)	66.7	(6.7)	0.75
Body Mass Index: BMI (kg/ m ²)	24.9	(3.2)	24.6	(3.5)	0.73
Waist circumferences: WC (cm)	88.0	(8.1)	85.8	(8.5)	0.28
Duration of hypertension (years)	9.2	(3.8)	8.9	(3.0)	0.68
Duration of taking Medication (years)	8.9	(3.3)	8.2	(3.0)	0.41

Table 3 Clinical outcome variables (N=69)

Measures	ILMPAD group (n=34)		Control group (n=35)		Mean Diff.	95%CI		p-value
	Mean	(SD)	Mean	(SD)		Lower	Upper	
Blood Pressure(mmHg)								
Systolic BP	137	(13.5)	138.7	(9.7)	-1.7	-7.4	3.9	0.54
Diastolic BP	78.8	(9.8)	78.6	(11.1)	2.2	-4.8	5.3	0.93
Serum Lipid (mg/dl)								
Cholesterol	214.4	(36.2)	213.9	(29.4)	0.5	-15.4	16.3	0.96
Triglyceride	139.2	(63.1)	148.3	(72.2)	-9.1	-41.8	23.5	0.58
LDL	139.7	(34.6)	139.6	(28.7)	0.1	-15.3	15.4	0.99
HDL	47.2	(9.1)	44.9	(7.2)	2.4	-1.6	6.3	0.08

Chulalongkorn University (COA No.178/2557). Approval from director of the health promoting hospital was obtained for the use of medical records. Prior to participation, the purpose and procedures of the study were fully explained to participants and all participants provided written informed consent.

RESULTS

The baseline characteristics of 69 participants are shown in Table 2, thirty-four participants in the intervention group, the mean age was 66.2 year (± 6.2), most of participants were female, 58.8 % were married. Regarding education, 70.5 % had completed elementary school. In regarding to unemployed/housekeeping/retirement 85.3 %, non-smoker 76.5 % and non-alcohol drinker 76.5 %. The average of body mass index (BMI) was 24.9 \pm 3.2 kg/m², waist circumferences (WC) was 88.0 \pm 8.1 cm, duration of hypertension was 9.2 \pm 3.8 year and duration of taking antihypertensive agent was 8.9 \pm 3.3 year. Likewise, the general characteristic of 35 participants in the control group showed all variables similarly, the mean age was 66.7 year (± 6.7), 74.4% were female, 71.4 % married, 77.1%

completed the elementary school, 71.4% unemployed/housekeeping/retirement, 68.6% were non-smokers, 71.4 % were non-alcohol drinkers. The average of BMI was 24.6 \pm 3.5 kg/m², WC was 85.8 \pm 8.5 cm, duration of hypertension was 8.9 \pm 3.0 years with taking medication for 8.2 \pm 3.0 years. All variables were no statistically significant difference in general demographic characteristics and hypertension related characteristics.

In Table 3, the average of systolic and diastolic BP (SD) were 137(13.5), 78(9.8) mmHg. The average cholesterol, TG, LDL and HDL (SD) were 214(36.2), 139(63.1), 139.7(34.6) and 47.2(9.1) mg/dl, respectively. Similarly, the average of blood pressure and serum lipid in the control were not different significantly.

Comparison of outcome variables after a 3 month of ILMPAD intervention

In Table 4, changes in blood pressure and serum lipid from baseline through a 3 month of program between the ILMPAD group and the control group were present. The ILMPAD group showed significant differences in cholesterol, LDL and HDL ($p < 0.001$, 0.001, 0.05), respectively.

Table 4 Changes in blood pressure and serum lipid from baseline to a 3 month of ILMPAD Intervention (N=69)

Measures	Baseline mean (SD)	3 rd month mean (SD)	Mean differences	p-value
SBP (mmHg)				
Control group	138.7(9.7)	133.9(14.8)	-4.8	0.06
ILMPAD group	137.0(13.5)	136.6(15.2)	-0.4	0.86
DBP (mmHg)				
Control group	78.6(11.1)	76.8(10.1)	-1.8	0.39
ILMPAD group	78.8(9.8)	77.0(12.5)	-1.8	0.40
Chol (mg/dL)				
Control group	213.9(29.4)	205.3(37.5)	-8.6	0.24
ILMPAD group	214.4(36.2)	183.4(33.1)	-31	<0.001
TG(mg/dL)				
Control group	148.3(72.2)	129.7(50.8)	-18.6	0.07
ILMPAD group	139.2(63.1)	133.1(52.7)	-6.1	0.59
LDL (mg/dL)				
Control group	139.6 (28.7)	130.5(37.0)	-9.1	0.22
ILMPAD group	139.2(34.6)	113(25.5)	-26.2	<0.001
HDL (mg/dL)				
Control group	44,9(7.2)	51.1(18.5)	6.2	0.08
ILMPAD group	47.2(9.1)	53.8(11.4)	6.6	<0.05

SBP: systolic blood pressure, DBP: diastolic blood pressure, Chol: cholesterol, TG: triglyceride, LDL: low density lipoprotein, HDL: high density lipoprotein

Table 5 Changes in blood pressure and serum lipid after ILMPAD program intervention between ILMPAD group and the control group (N=69)

Measures	ILMPAD (n=34)		Control (n=35)		Mean Diff.	95%CI		p-value
	Mean	(SD)	Mean	(SD)		Lower	Upper	
SBP(mmHg)	136.6	(15.2)	133.9	(14.8)	2.67	-4.53	9.87	0.46
DBP(mmHg)	77.0	(12.5)	76.8	(10.1)	0.17	-5.28	5.63	0.95
Cholesterol(mg/dL)	183.4	(33.1)	205.3	(37.5)	-21.99	-39.01	-4.97	0.01
Triglyceride(mg/dL)	133.1	(52.7)	129.7	(50.8)	3.43	-21.43	28.29	0.78
LDL(mg/dL)	113.8	(25.5)	130.5	(37.0)	-16.66	-31.97	-1.35	0.03
HDL(mg/dL)	53.8	(11.4)	51.1	(18.5)	2.65	-4.77	10.07	0.48

SBP: systolic blood pressure, DBP: diastolic blood pressure, Chol: cholesterol, TG: triglyceride, LDL: low density lipoprotein, HDL: high density lipoprotein

Changing of outcome variables between the intervention group and the control group

In Table 5, Changes in blood pressure and serum lipid between ILMPAD group and the control group after a 3 month of ILMPAD program intervention were present. The ILMPAD group also showed significantly different in cholesterol and LDL ($p < 0.05$). However, there was showed no significant difference in both systolic and diastolic blood pressure included the value of serum lipid; triglyceride and HDL ($p > 0.05$).

DISCUSSION

The hypothesis of the study was the ILMPAD program would show significant improvement in blood pressure and serum lipid (cholesterol, triglyceride; TG, LDL, and HDL). However, the result reported no significant improvement of blood pressure between two groups at $p > 0.05$, also there

was showed no significant difference before and after following a 3month of ILMPAD program intervention at $p > 0.05$.

The result finding showed unchanged both systolic and diastolic blood pressure in the intervention group may be in part explained due to the ageing process in both sex which supported by Taddei's study likewise Benetos's study [16, 17]. Moreover, ILMPAD program did not reveal differences before and after intervention also between two groups in this study that could explain that: 1) it was possible confounders of different taking medications in both groups although we equally allocated each participants that reported elsewhere 2) health mass media and others health information that we could not control in this study particular in the control group 3) Documented checklist in each month made participants who dislike had more stressful than the control group,

blood pressure therefore was measured it might read higher than the control group and 4) participants in the intervention group might not have followed the ILMPAD program sufficiently by themselves because of individual reasons and/or the social environment [18]. For example, the intervention period took place during the season of sweet fruit in Thailand (mango, durian, lambutan), annual Thai water festival in April which is very important for enjoying time with the family for cultural-religious celebrations including high energy food intake, sugary-beverage and alcohol consumption. These social environmental factors might have posed barriers to follow the program [19]. Improving blood pressure is not only depending on exercise, the literature also discussed the importance of the combination with other lifestyle modifications such as: control weight, sodium restriction, DASH diet, smoking cessation and moderation of alcohol consumption [2]. Findings in this study showed significant changes in cholesterol, LDL and HDL levels in the ILMPAD intervention group compared with the control group. This may indicate beneficial effects of the ILMPAD intervention on improving cholesterol LDL and HDL levels. Other studies indicated that health education led to lowering cholesterol, LDL levels and regular exercising increased HDL [20, 21]

CONCLUSION

Results from this study noted that the ILMPAD program might be effective in lowering blood pressure and improve serum lipid among hypertensive patients in community. However, larger and longer trail studies are needed to evaluate the efficacy of this program in clinical practice.

LIMITATION AND RECOMMENDATION

The design of this study does not allow for generalization to hypertensive patients who are under treatment in other health care facilities in Thailand. This study period included the national water festival during April which may have affected compliance in home care among participants which then could have impacted study findings. Future studies should carefully consider the seasonal calendar in planning research implementation. During the intervention period, monthly interval of home visit after meeting at clinic can directly provide individual support to patients enrolled in the program by offering individual tailored health education and counseling. Therefore, at home visits would be useful in improving behavior change among hypertensive patients.

CONFLICT OF INTERESTS

The authors report no conflicts of interest in this work.

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