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Research Paper

Effectiveness of a family-based program for post-stroke patients and families: A cluster randomized controlled trial

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ABSTRACT

Objective: To examine the effectiveness of a family-based program for post-stroke patients and their families.

Methods: A cluster randomized controlled trial design was used. Participants were randomly selected in the experimental group (3 districts) and the comparison group (3 districts), with 62 families recruited. Sixty-two persons with new stroke and families (family caregivers and family members) who met the inclusion criteria were assigned to two groups, 31 in each group. Using the Neuman System Model as a framework, we implemented the stressors assessment and family-based intervention into the program. Participants in the comparison group received usual care, and those in the experimental group underwent a stressors assessment and received the family-based program. Measurement of functional status, depression, and complications in post-stroke patients and family function in family caregivers and family members, as well as caregiver burden and caregiver stress in family caregivers, were assessed at baseline, 4 weeks, and 12 weeks after enrollment. Data analysis included descriptive statistics, the chi-square test, Bonferroni test, and repeated measures analysis of variance.

Results: After participating in a 12-week family-based program, post-stroke patients in the experimental group showed statistically significant improvements in their functional status and decreased depression compared to the comparison group ($P < 0.05$). The family function of the experimental group was significantly improved, and caregivers' burden and stress were decreased compared to the comparison group ($P < 0.05$). Three patients in the experimental group and seven in the comparison group experienced complications.

Conclusions: The study findings suggest that the present family-based program improved family function in family caregivers and family members and decreased caregiver burden and stress in family caregivers. The program also improved functional status and reduced depression in post-stroke patients. It is suggested the duration of the program be extended to assess its sustainable effectiveness.

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What is known?

- Stroke is a major public health issue worldwide and a leading cause of long-term disability.
- Existing intervention programs mostly involve only family caregivers but do not focus on the family as a unit.

What is new?

- We assessed five variables, including physiological, psychological, sociocultural, developmental, and spiritual, that affect the health outcome of stroke patients and family function, caregiver stress, and caregiver burden.
- We implemented a family-based program based on the Neuman Systems Model to improve patient outcomes and family outcomes in patients with stroke.

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1. Introduction

Stroke is a serious global public health problem and one of the main causes of death. An estimated 11.8% of all deaths and long-term disability occur in developed and developing countries owing to stroke [1–3]. However, developing countries lack sufficient information, resources, policies, and structures to bear the burden of stroke [4]. In Thailand, stroke is the second leading cause of death, and mortality has increased from 47.8 per 100,000 population in 2017 to 55.5 in 2021 [5]. Although medical technology and public health advances can help reduce stroke mortality, stroke survivors typically still experience disabilities. Therefore, early recovery among patients with stroke is crucial, especially during the first 3–6 months (the “golden period”), when the aim is to improve patients’ physical, mental, and performance abilities in daily activities; reduce disability; and prevent complications [6].

Family functioning is an important part of protection after stroke because families play an important role in the recovery of patients with stroke [7]. Family members are the first to adopt the role of caregiver immediately following a stroke [8]. Family members, especially direct family members, can support the primary caregiver through direct or indirect supervision in other activities by helping them with medical appointments; providing caregiving; assisting them with housework; and offering transportation [8,9]. A family caregiver refers to an unpaid family member, spouse, child, friend, or neighbor who provides care for a person with chronic disease who needs assistance in managing tasks, including bathing, dressing, and taking medicine [10]. However, family caregivers must often take on their new role suddenly, which results in changes in the pattern of family function [11,12]. During this period, a family caregiver may face new problems in caring for post-stroke patients related to a lack of knowledge and skill in providing care, such as regarding medication management, food preparation, complication prevention, stroke recurrence, and the availability of community resources [13]. Moreover, caring for patients with stroke for long periods results in becoming isolated from society, lacking a personal life, and having less time to care for one’s own physical health (e.g., dealing with back pain caused by lifting stroke patients). The family may also have to face other life uncertainties and loss of family income. These factors can increase the stress on caregivers and families [14].

Previous studies have found that recovery programs for post-stroke patients during the transitional phase from hospital to home are not well grounded [15–18]. Most intervention programs developed by researchers focus on increasing the knowledge and developing the skills of family caregivers, such as by providing information, skills training [15,16,19], and home visits. This includes using technology to develop caregiver skills, such as via telephone visits [20]. These studies have used theories and concepts such as the Transitional Care Model [15,16,21], Orem’s Self Care Deficit Nursing Theory [22], Bandura’s self-efficacy theory [23], the Chronic Care Model [24], and information-motivation-behavioral skills theory [19]. The limitations of the programs presented in previous studies may be owing to their focus on the individual level (e.g., family caregivers) rather than the family system, which includes the whole family as a unit. Few intervention studies have assessed family variables that may affect outcomes or measured family functioning in the acute stroke period [25,26].

A family-based intervention program is defined as involving one or more individuals consisting of relatives, family members, family caregivers, and parents or legal caregivers cohabiting under the same roof [27]. They may or may not be related by blood or law, and care takes place at home or in a community setting with no reimbursement [28]. The program combines activities to build family support with health education to increase physical activity and

emotional support, love, warmth, and family relationships. Consequently, family assessments will help with understanding the structure, function, and role of the family in caring for patients with stroke. These can also help with controlling symptoms and preventing complications or the recurrence of stroke. The Neuman System Model is the most effective model to provide holistic care to patients. This model assessed the stressors that affect human beings [29]. Accordingly, in this study, we assessed the stressors in post-stroke patients and families and applied the family-based program to reduce stress and help the post-stroke patients to move toward recovery and happy family function.

2. Participants and methods

2.1. Study design and setting

A cluster randomized controlled trial was conducted from October 2021 to June 2022 in six districts in Chai Nat, a province in Central Thailand. The recruitment process was conducted in two steps. Six districts were selected to avoid contamination and then allocated to the experimental group (3 districts) and the comparison group (3 districts) using cluster randomization. The researcher recruited patients with new stroke, their family caregivers, and family members in the six districts. Inclusion criteria included patients with new stroke who were discharged within one month from a provincial hospital and had a family caregiver and family member living in the same house. If the participants met the inclusion criteria, they were invited to enroll in the program and sign the consent form. The trial was registered on Thai Clinical Trials (TCTR20211004002). The study is reported according to the CONSORT guidelines for reporting cluster randomized trials [30]. The study flow diagram is shown in Fig. 1.

2.2. Participants

The study participants comprised post-stroke patients and their family caregivers and family members. The inclusion criteria for post-stroke patients were as follows: first-time having an ischemic stroke with moderate to severe disability, according to the Modified Rankin Scale (score = 4), discharged from the hospital within one month of admission, and no complications related to stroke (i.e., pneumonia, urinary tract infection [UTI], pressure sores, and joint stiffness). The inclusion criteria for family caregivers were as follows: primary caregivers taking care of post-stroke patients with no financial compensation and living in the same house with the patient for at least one month. The inclusion criteria for family members were as follows: having a relationship with the post-stroke patient, providing assistance to the family caregivers, and living in the same house as the patient for at least one month. The sample data were obtained from the medical records at provincial hospital Thailand.

The sample size was calculated using G* Power software. A significance level of 0.05, a power level of 0.80, and an effect size 0.80 were set. This effect size was obtained from a previous study of a post-stroke care program for family caregivers and its impact on stroke survivors’ functional, clinical, and psychosocial outcomes [19]. The results of the program suggested a sample size in each group of 26. Considering a 20% attrition rate in a similar study [31], a total of 31 families were recruited, including post-stroke patients, family caregivers, and family members.

2.3. Procedure

2.3.1. Interventions for the experimental group

The family-based program was developed based on the Neuman

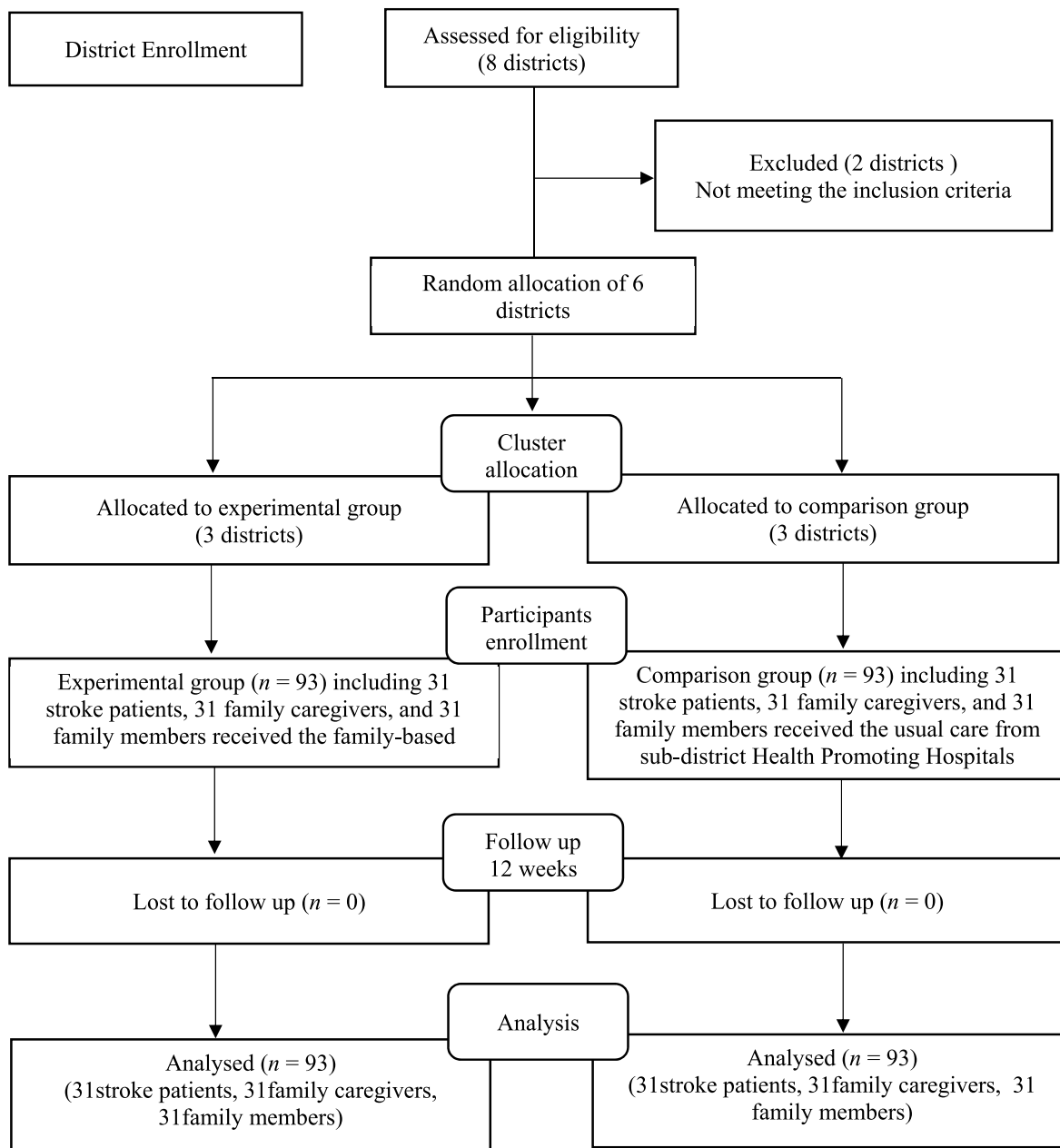


Fig. 1. The CONSORT flow diagram.

Systems Model [32]. Before conducting the intervention, in-depth interviews and focus group interviews were conducted to assess the needs or problems of post-stroke patients, family caregivers, and family members. The findings showed that stroke caused post-stroke patients and family physiological, psychological, sociocultural, developmental, and spiritual effects. Most patients with stroke felt stress and hopelessness owing to disability from stroke. Family caregivers and family members needed education regarding care for stroke patients as well as having free time and privacy and obtaining both physiological and psychological assistance. The family-based program was developed based on the findings of the qualitative interviews together with a systematic review and meta-analysis. The program comprised activities over a 10-week period that were led by the researcher. The intervention was provided to post-stroke patients, family caregivers, and family members at the participant’s home because patients with stroke were discharged

from the hospital at different times. This program adopted various strategies such as family supportive therapy, stress management, time management, empowerment, home visits, and telephone visits, as shown in Table 1.

2.3.2. Usual care for the comparison group

The comparison group received usual care from the Sub-District Health Promoting Hospital. A community nurse conducted a home visit at least once a month within the first month after discharge. Community nurses administered care to post-stroke patients and families, including assessing problems in post-stroke patients and their families and providing care as required. After the first home visit, the community nurse would determine whether additional home visits were needed based on the condition of the patients with stroke. Home visits were ended if the Barthel Index reached or exceeded 15 [21,33].

Table 1
Family-based program for post-stroke patients and families.

Schedule	Family-based program	
	For post-stroke patients	For families (family caregivers & family members)
Week 1	<p>Session 1: The researcher assessed the stressors and needs of stroke patients, including physiological, psychological, sociocultural, developmental, and spiritual variables, according to the Neuman Systems Model, in order to provide nursing care following the need or problem (15 min).</p> <p>Session 2: Stress management and emotional support (45 min). The researcher provided information about common psychosocial disturbances in post-stroke patients, such as depression and uncertainty about the future. Advice about coping strategies was also given, such as how to do deep breathing exercises and express anxiety, and psychological support was provided.</p>	<p>Session 1: Researcher assessed the stressors and needs of families, including physiological, psychological, sociocultural, developmental, and spiritual variables, according to the Neuman Systems Model in order to provide nursing care following the need or problem (15 min).</p> <p>Session 2: Family supportive therapy and counseling by psychiatric nurse consisted of 1) providing opportunities for caregivers and family members to talk about living with the patient, patient care, and express feelings of frustration or problems that arise after providing care for stroke patients at home, and 2) empowerment to continuing care (45 min).</p> <p>Session 3: Time management (30 min). The researcher gave advice to family caregivers and family members and organized a schedule for patient caretaking to reduce the caregiver burden and caregiver stress.</p>
Week 2	<p>Session 3: The researcher provided knowledge and practice as needed on the problem, such as speech therapy and active–passive exercises (90 min).</p>	<p>Session 4: The researcher provided knowledge and skills as needed on the problems experienced by participants (90 min). The education topics consisted of the following. 1) Causes, symptoms, and prevention of pressure sores, joint stiffness, and urinary tract infection. Additionally, the researcher gave wound care instructions, including equipment use. Participants then engaged in wound care practice. 2) Causes, symptoms, and prevention of aspiration pneumonia, including food preparation and feeding methods. 3) Swallowing exercises for dysphagia. 4) Active–passive exercises, including rehabilitation.</p>
Week 3	<p>Session 4: The researcher used empowerment to build hope in post-stroke patients (60 min).</p>	<p>Session 5: Social support (60 min) The researcher provided information about the importance of external resources and social support and equipment for patients with stroke, including coordinating with community leaders and health care services to provide equipment and social welfare, such as a fund to support patients with stroke and their caregivers.</p>
Week 4	<p>Session 5: Encourage the stroke patients to continue the program (60 min).</p>	<p>Session 6: Participants reviewed all topics and returned to demonstrate their knowledge and skills, as well as to ask questions regarding problems (60 min).</p>
Week 6,10	<p>Session 6: Telephone visits (15–20 min). The researcher assessed physiological, psychological, sociocultural, developmental, and spiritual stressors and needs in post-stroke patients and provided advice.</p>	<p>Session 7: Telephone visits (15–20 min). The researcher assessed physiological, psychological, sociocultural, developmental, and spiritual stressors and needs in family caregivers and family members and provided advice.</p>
Week 8	<p>Session 7: Home visit (15–30 min). The researcher assessed patients' needs after the intervention, including having opportunities to share feelings, ask questions, express needs for support, and coordinate responsive actions.</p>	<p>Session 8: Home visit (15–30 min). The researcher assessed the needs of family caregivers and family members after the intervention, including having opportunities to share feelings, ask questions, express needs for support, and coordinate responsive actions.</p>

2.4. Measurement

2.4.1. Demographic characteristics

The researcher developed a questionnaire to elicit information about participants' demographic characteristics, including age, sex, marital status, education level, underlying diseases, occupation, income, relationship with the patient, caregiver skills, effect of care, and hours of care.

2.4.2. Barthel Index

Functional status would be measured with Barthel index which developed by Mahoney & Barthel [34]. It is used to measure activities of daily living, including 1) feeding, 2) bathing, 3) grooming, 4) dressing, 5) bowel control, 6) bladder control, 7) toilet use, 8) transfers, 9) mobility, and 10) climbing stairs. The original Barthel Index used score 0, 5, 10, or 15 and categorizes five levels: very severe disability (0–20), severity disability (25–45), moderate (50–70), mildly (75–90), and 100 physical independent but not necessary normal or social independent. In 1994, Jitapunkul translated and modified the scoring Barthel Index into Thai version. The total score range is 0–20 and categorizes into four levels: 0–4 = total dependence; 5–8 = severe dependence; 9–11 = moderately severe dependence; and more than 12 = mild severe dependence [35]. The Cronbach's α coefficient was 0.94 [36].

2.4.3. Patient Health Questionnaire-9

The Patient Health Questionnaire-9 (PHQ-9) was translated into Thai language by Lortrakul et al. [37] and used to assess the severity of depression. It has nine questions based on the 9 Diagnostic and

Statistical Manual of Mental Disorders (DSM-IV) criteria for major depressive episode. Each item is scored 0 (not at all), 1 (a few days), 2 (more than half the days), or 3 (almost every day); the sum of all item scores is between 0 and 27. The score is divided into four levels: 5–9 is considered to indicate minimal symptoms, 10–14 is considered minor depression, 15–19 is considered moderately severe major depression, and more than 20 is considered severe major depression. The PHQ-9 was used to screen for depression among Thai stroke patients, and the Cronbach's α coefficient was 0.78 [38].

2.4.4. Post-stroke complications

This checklist was developed by the researcher to assess complications in patients with stroke. The checklist consisted of five items, including aspiration pneumonia, UTI, pressure sores, joint stiffness, and recurrent stroke. Aspiration pneumonia and UTIs were assessed according to the criteria of the Centers of Disease Control and Prevention [39]. Pressure sores were assessed using the criteria of the National Pressure Ulcer Advisory Panel [40]. Joint stiffness was assessed using the range of motion for each joint (e.g., wrist, elbow, hip, knee, ankle), measured using a goniometer. Recurrent stroke was determined by reviewing the medical records. All complications were measured using a dichotomous scale (yes/no). The researcher piloted the instrument with new stroke patients. The content validity index of the checklist was 0.80 and the Cronbach's α coefficient was 0.78.

2.4.5. Chulalongkorn Family Inventory

The Chulalongkorn Family Inventory (CFI) was adapted from

Family Assessment Device (FAD) [41], which was developed by Trangkasombat [42]. It is a self-report questionnaire in the Thai language to assess the family function. The CFI questionnaire comprises 36 items in the following seven domains: 1) problem-solving, 2) communication, 3) roles, 4) affective responsiveness, 5) affective involvement, 6) behavior control, and 7) general functioning. The CFI score, each with a score of 1–4. Higher scores reflect healthy functioning or better family functioning. A previous study reported that the reliability coefficient was 0.92 [43].

2.4.6. Burden Interview

The Burden Interview is a measure used to assess the burden on caregivers, which was developed by Zarit et al. [44]. Toonsiri, Sunsern, and Lawang (2011) translated the Burden Interview into a Thai version, which comprises 22 items, each with a score of 0–5. Higher scores denote a heavy caregiver load and reflect a heavy burden. The reliability tested by a caregiver of patients with chronic illness was 0.92 [45].

2.4.7. Caregiver Strain Index

The Caregiver Strain Index (CSI) is a questionnaire that assesses caregiver stress developed by Robinson [46] and translated into Thai version by Oupra [47]. The questionnaire comprises 13 items. Each of the following major domains—financial, physical, psychological, social, and personal—has at least one item. Each “yes” response receives one point, and each “no” response receives zero points. Scores of ≥ 7 indicate that the caregiver is stressed. The CSI was used to assess the level of strain experienced by caregivers of stroke patients, with a Cronbach's α coefficient of 0.80 [47].

2.5. Data collection

Data were collected over nine months, from October 2021 to June 2022. The researcher evaluated the outcomes for post-stroke patients and families (family caregivers and family members) at three time points: baseline, 4 weeks, and 12 weeks after enrollment [19,48]. The Barthel Index, PHQ-9, and complication checklist were used to measure individual outcomes (in post-stroke patients); the family level was assessed using the CFI, Burden Interview, and CSI to measure family function, caregiver burden, and caregiver stress. Participants who were unable to participate until the end of the program were not included in the final analysis.

2.6. Data analysis

We analyzed descriptive and inferential statistics using SPSS for Windows version 18.0 (SPSS Co., Ltd., Bangkok, Mahidol License). Baseline demographic characteristics were descriptive, and chi-square and Fisher's exact test were used to determine the difference between groups for the categorical variables. During the preliminary examination of all variables, we found that the data functional status, depression, and caregiver stress do not follow a normal distribution. Therefore, we used non-parametric methods to compare differences, such as Friedman test, Wilcoxon signed-rank test, and Mann–Whitney *U* test. The repeated measures ANOVA with post hoc analysis were used to test between and within group differences.

2.7. Ethical considerations

This study was approved by the institutional review boards of the Faculty of Public Health, Mahidol University (COA No. MUPH 2020–120) prior to data collection. The Chai Nat Provincial Public Health Office, District Public Health Office in Muang, Hanka, Manrom, Wat Sing, Noenkham, Nong-Mamong, Director of Chai Nat

Hospital, and Heads of the Sub-district Health Promoting Hospitals provided access to conduct the research. All participants signed written consent forms after being informed verbally and in writing about the study's objectives and benefits, the confidentiality of all data collected, and their ability to withdraw without hindering access to health care services.

3. Results

3.1. Participant characteristics

A total of 31 families (i.e., 31 post-stroke patients, 31 family caregivers, 31 family members) were in the experimental group and 31 families were in the comparison group. There were no dropouts during the intervention (see Fig. 1).

Post-stroke patients in the experimental and comparison groups had a mean age of 67.03 years ($SD = 12.41$) and 66.23 years ($SD = 12.51$), respectively. In both groups, most were men, married, and had an education level of primary school or lower. Two-thirds of both groups were unemployed. There were no significant differences in patients' characteristics across the two groups, as shown in Table 2–a.

The mean ages of the family caregivers in the experimental and comparison groups were similar: 54.16 years ($SD = 15.19$) and 51.35 years ($SD = 18.09$), respectively (see Table 2–b). In both groups, most family caregivers were women, married, had an education level of primary school, and were employed. In the experimental group, family caregivers were a husband or wife; in the comparison group, family caregivers were a husband, wife, son, or daughter. Most caregivers in both groups were caring for post-stroke patients around the clock. There were no significant differences in family caregiver characteristics between the groups.

Family members in the experimental group and comparison group had a mean age of 41.71 years ($SD = 14.55$) and 52.9 years ($SD = 16.58$), respectively. In both groups, most family members were women, a relative of the patient, married, and employed. However, the education level of family members in the experimental group was higher than that in the comparison group (Table 2–c). There was a statistically significant difference between groups in terms of the mean age and education of family members.

3.2. Comparison of outcome variables between groups at baseline

At baseline, there were no significant differences between the experimental and comparison groups, as shown in Table 3–a and 3–b.

3.3. Effects of family-based program in post-stroke patients

3.3.1. Functional status of post-stroke patients

There were no significant differences in the mean rank of functional status score at baseline. After 4 weeks and 12 weeks, the mean rank of functional status score in the experimental group was significantly higher than that in the comparison group ($P < 0.05$), as shown in Table 4.

3.3.2. Depression in post-stroke patients

There were no significant differences in the mean rank of depression score at baseline. After 4 weeks, the mean rank of depression score in the experimental group tended to be lower than that in the comparison group without statistical significance. Conversely, after 12 weeks, the score for depression in the experimental group was significantly lower than that in the comparison group ($P < 0.05$), as shown in Table 4.

Table 2a
Characteristics of post-stroke patients.

Characteristics	Experimental group (n = 31)	Comparison group (n = 31)	χ^2/t	P
Age, years, Mean \pm SD	67.03 \pm 12.41	66.23 \pm 12.51	0.26	0.800
Sex			–	1.000
Male	18 (58.1)	18 (58.1)		
Female	13 (41.9)	13 (41.9)		
Marital status			–0.50	0.617
Married	16 (51.6)	18 (58.1)		
Single/widowed/divorced/separated	15 (48.4)	13 (41.9)		
Education level			0.48	0.490
Primary education and lower	27 (87.1)	25 (80.6)		
Secondary education and above	4 (12.9)	6 (19.4)		
Occupation			0.28	0.596
Employee	21 (67.7)	19 (61.3)		
Unemployed	10 (32.3)	12 (38.7)		
Alcohol consumption			–0.22	0.824
No	17 (54.8)	18 (58.1)		
Yes	–	2 (6.5)		
Ever	14 (45.2)	11 (35.4)		
Smoker (cigarette)			–0.43	0.672
No	17 (54.9)	16 (51.6)		
Yes	1 (3.2)	13 (41.9)		
Ever	13 (41.9)	2 (6.5)		

Note : Data are n (%) or Mean \pm SD.

Table 2b
Characteristics of family caregivers.

Characteristics	Experimental group (n = 31)	Comparison group (n = 31)	χ^2/t	P
Age, years, Mean \pm SD	54.16 \pm 15.19	51.35 \pm 18.09	0.66	0.511
Sex			0.34	0.562
Female	24 (77.4)	22 (71.0)		
Male	7 (22.6)	9 (29.0)		
Marital status			–	1.000
Married	20 (64.5)	20 (64.5)		
Single/widowed/divorced/separated	11 (35.5)	11 (35.5)		
Education level			–	1.000
Primary education and lower	16 (51.6)	16 (51.6)		
Secondary education and above	15 (48.4)	15 (48.4)		
Occupation			0.07	0.788
Employee	20 (64.5)	21 (67.7)		
Unemployed	11 (35.5)	10 (32.3)		
Relationship			–0.97	0.336
Husband/wife	13 (41.9)	10 (32.3)		
Son/daughter	12 (38.7)	10 (32.3)		
Relatives	4 (12.9)	8 (25.8)		
Father/mother	2 (6.5)	3 (9.6)		
Duration of care (h/day)			1.32	0.191
< 8	–	4 (12.9)		
8–12	6 (19.4)	7 (22.6)		
13–16	9 (29.0)	6 (19.3)		
17–23	3 (9.7)	4 (12.9)		
24	13 (41.9)	10 (32.3)		

Note : Data are n (%) or Mean \pm SD.

3.3.3. Complications in post-stroke patients

After 4 weeks, there was no significant difference in complications between the two groups ($P > 0.05$). Post-stroke patients in the experimental group did not develop any complications, while three in the comparison group developed complications (pressure sores and joint stiffness).

After 12 weeks, three post-stroke patients in the experimental group experienced complications (UTI, pressure sore at coccyx, and joint stiffness in shoulder), whereas seven patients in the comparison group experienced complications: one with UTI and shoulder stiffness, three with shoulder stiffness, two with wrist stiffness, and one with stiffness in the crook of the arm.

3.4. Effects of a family-based program on family caregivers

3.4.1. Family function in family caregivers

The mean scores of family function in the experimental group improved from baseline to 4 weeks and 12 weeks after enrollment, whereas in the comparison group, 4 weeks slightly decreased from baseline and slightly increased at 12 weeks. The two-way repeated measure ANOVA analysis indicated differences in the family function between and within the groups at three point times with statistical significance (Table 5).

3.4.2. Caregiver burden in family caregivers

The two-way repeated measures ANOVA analysis showed no significant differences in caregiver burden scores between the experimental and comparison groups ($F = 2.68, P = 0.107$).

Table 2c
Characteristics of family members.

Characteristics	Experimental group (n = 31)	Comparison group (n = 31)	χ^2/t	P
Age, years, Mean \pm SD	41.71 \pm 14.55	52.94 \pm 16.58	-2.83	0.006
Sex			0.65	0.421
Female	19 (61.3)	22 (71.0)		
Male	12 (38.7)	9 (29.0)		
Marital status			2.54	0.111
Married	17 (54.8)	23 (74.2)		
Single/widowed/divorced/separated	14 (45.2)	8 (25.8)		
Education level			15.08	<0.001
Primary education and lower	5 (16.1)	20 (64.5)		
Secondary education and above	26 (83.9)	11 (35.5)		
Occupation			0.34	0.562
Employee	24 (77.4)	22 (71.0)		
Unemployed	7 (22.6)	9 (29.0)		
Relationship			1.44	0.155
Relatives	15 (48.4)	15 (48.4)		
Son/daughter	14 (45.2)	8 (25.8)		
Husband/wife	1 (3.2)	6 (19.4)		
Father/mother	1 (3.2)	2 (6.4)		

Note : Data are n (%) or Mean \pm SD.

Table 3a
Comparison of outcome variables between groups at baseline by Mann-Whitney U test.

Variable	Experimental group (n = 31)		Comparison group (n = 31)		Z	P
	Mean rank	Sum of ranks	Mean rank	Sum of ranks		
Post-stroke patients						
Functional status	33.15	1027.50	29.85	925.50	-0.73	0.468
Depression	33.08	1025.50	29.90	927.50	-0.69	0.488
Family caregivers						
Caregiver stress	32.08	994.50	30.92	958.50	-0.26	0.798

Table 3b
Comparison of outcome variables between groups at baseline by independent t-test.

Variable	Experimental group (n = 31)	Comparison group (n = 31)	t	P
Family caregivers				
family function	104.58 \pm 11.45	102.12 \pm 11.97	0.82	0.413
Caregiver burden	34.48 \pm 13.52	35.77 \pm 11.79	-0.40	0.690
Family members				
Family function	103.23 \pm 7.97	103.32 \pm 13.34	-0.04	0.972

Note: Data are Mean \pm SD.

Table 4
Comparison of outcome variables for post-stroke patients between groups.

Variable	Experimental group (n = 31)		Comparison group (n = 31)		Z	P
	Mean rank	Sum of ranks	Mean rank	Sum of ranks		
Functional status						
Baseline	33.15	1,027.50	29.85	925.50	-0.73	0.468
After 4 weeks	36.56	1,133.50	26.44	819.50	-2.22	0.026
After 12 weeks	38.95	1,207.50	24.05	745.50	-3.28	0.001
Depression						
Baseline	33.08	1,025.50	29.90	927.50	-0.69	0.488
After 4 weeks	28.47	882.50	34.53	1,070.50	-1.33	0.183
After 12 weeks	23.73	735.50	39.27	1,217.50	-3.42	0.001

However, differences within each group over time were statistically significant ($F = 34.49$, $P < 0.001$), as shown in Table 5.

3.4.3. Caregiver stress in family caregivers

There were no significant differences in the mean rank scores for caregiver stress at baseline. In the experimental group at 12 weeks after enrollment, caregiver stress was significantly lower than that in the comparison group ($P < 0.001$), as shown in Table 6.

3.5. Effects of family-based program on family members

After completing the program, the mean scores of family function in family members in the experimental group improved from baseline to 4 weeks and 12 weeks after enrollment, whereas in the comparison group, week 4 slightly decreased from baseline and slightly increased at 12 weeks. The two-way repeated measure ANOVA indicated differences in the family function at three point

Table 5
Comparisons on outcome variables of family caregivers at three time points.

Variables	Group	Baseline (T1)	After 4 weeks (T2)	After 12 weeks (T3)	Group		Time		Group * Time	
					F	P	F	P	F	P
Family function	Experimental group (n = 31)	104.58 ± 11.45	110.23 ± 11.46	115.29 ± 11.39 ^a	7.46	0.008	17.33	<0.001	8.66	0.001
	Comparison group (n = 31)	102.13 ± 11.97	101.74 ± 11.07	104.06 ± 12.91						
Caregiver burden	Experimental group (n = 31)	34.48 ± 13.52	28.90 ± 11.95	21.45 ± 10.50 ^b	2.68	0.107	34.49	<0.001	2.77	0.082
	Comparison group (n = 31)	35.77 ± 11.79	33.61 ± 10.19	28.52 ± 12.20 ^b						

Note: Data are Mean ± SD.

^a T3 > T2 > T1.

^b T3 < T2 < T1.

Table 6
Comparison on mean rank of caregiver stress score between groups at three time points by Mann-Whitney U Test.

Time	Experimental group (n = 31)		Comparison group (n = 31)		Z	P
	Mean rank	Sum of ranks	Mean rank	Sum of ranks		
Baseline	32.08	994.50	30.92	958.50	-0.26	0.798
After 4 weeks	29.90	927.00	33.10	1026.00	-0.71	0.481
After 12 weeks	23.13	717.00	39.87	1236.00	-3.68	<0.001

times in both groups. The result showed that the scores of family function between the experimental group and the comparison group were significantly different ($F = 14.45, P < 0.001$). In addition, over time, the time-group interaction was statistically different ($F = 31.01, P < 0.001$); and there were interaction effects between the groups and time ($F = 13.40, P < 0.001$), as shown in Table 7.

4. Discussion

This study evaluated the effects of the family-based program on new post-stroke patients and families in Chai Nat province in Thailand. These results highlighted the role of families in helping these post-stroke patients to return to normal as possible. The results showed that post-stroke patients who participated in the family-based program effectively improved functional status and decreased depression and fewer complications than those who did not receive the family-based program. Also, the program improved the family function of family caregivers and family members and decreased the caregiver burden and caregiver stress in family caregivers. Possible reasons for the improvements are discussed below.

The family-based program provided opportunities for caregivers and family members to discuss their emotions and problems that arose while providing care to stroke patients at home. This process helped family caregivers clearly understand their feelings and release stress. This process helped family caregivers clearly understand their feelings and release their stress. Simultaneously, family members became aware of the problems in caring for them and the caregivers' burden. Family supportive therapy and stress management were provided, which can help with developing the problem-solving, communication, and conflict-resolution skills necessary for a well-functioning family. In this way, family caregivers and family members will be ready to deal with and

understand problems, learn to make decisions in solving problems, and effectively deal with problems that arise, resulting in improved family functioning. The present findings were in line with those of Clark, which revealed that counseling intervention could maintain family functioning and could in turn lead to improved functional and social patient outcomes [25]. Simultaneously, the family function of families after a stroke is associated with rehabilitation from the stroke. Therefore, good family function aids stroke patients' rehabilitation [49,50].

Further, family members participated in patient care, such as by helping the family caregiver with caring, doing housework, and offering transportation to medical appointments; this decreased the caregiving load of family caregivers, allowing them time to relax. Additionally, family caregivers can receive family support and external resources, reducing their workload and increasing the efficiency of caring for patients with stroke. These findings are consistent with prior studies revealing that supportive educational group intervention can reduce the burden of caregiving among family caregivers [51].

In the family-based program, education and skills training were provided as needed, and family caregivers could practice caring techniques until they felt confident. A booklet was distributed to family caregivers to help them recall what they had learned in the program. As a result, caregivers had decreased stress and care burden. These findings were in line with those findings of Wu et al. (2020), who reported that health education, information, and emotional support can decrease caregiver stress and improve the quality of life in post-stroke patients and families [52].

Additionally, the family-based program comprised home visits and telephone visits for patients with stroke, family caregivers, and family members to discuss their problems or needs. They received encouragement and reinforcement, which helped to motivate family caregivers in the practice of caregiving. These strategies also

Table 7
Comparison on family function of family member at three time points.

Group	Baseline (T1)	After 4 weeks (T2)	After 12 weeks (T3)	Group		Time		Group * Time	
				F	P	F	P	F	P
Experimental group (n = 31)	103.23 ± 7.97	110.23 ± 7.64	120.61 ± 8.20 ^a	14.45	<0.001	31.01	<0.001	13.40	<0.001
Comparison group (n = 31)	103.32 ± 13.34	102.42 ± 8.37	106.71 ± 11.17						

Note: Data are Mean ± SD. ^a T3 > T2 > T1.

helped them to feel reassured and confident in performing caring activities. These results were in accordance with those of earlier studies, suggesting that home visits might be incorporated into plans to ensure that family caregivers are skilled in patient care and to provide patients with social support [17,19].

Likewise, this study revealed that the family-based program improved the functional status of families and decreased depression and complications in post-stroke patients in the experimental group than in the comparison group. A previous study revealed that family caregivers had a very high level of stress owing to their lack of knowledge and skills and insufficient support from social resources [53]. The family-based program provided knowledge, skills training, family supportive therapy, and stress management, including home visits and telephone visits, to improve the caring capacity of family caregivers in making decisions and solving problems, which led to improved functional status and decreased depression among patients. The program also helped to decrease complications in patients with stroke. This finding reflects those of a study by Pitthayapong (2017), which revealed that improvement in the skills of family caregivers through health education, skills training, and home visits could improve activities of daily living in post-stroke patients [19]. Similarly, Dharma (2018) reported that education and skills training regarding stroke, adaptation, coping, and exercise improved functional capacity and quality of life [17].

Providing empowerment and receiving various types of social support from family caregivers and family members helped patients to become more hopeful and motivated to recover from their post-stroke condition, to want to take greater care of themselves without being dependent on caregivers, and to try to live their lives as normally as possible. A previous study found that approximately 88%–95% of post-stroke patients need support, especially during the first 3 months following discharge; family caregivers need support from family members and friends in the community to provide care [54]. Therefore, emotional support through counseling services for patients and caregivers can reduce stressful experiences in the care and management of patients with stroke [55].

Post-stroke complications in the experimental group was slightly lower than that in the comparison group. Research studies have revealed that complications in patients with stroke were found three months after discharge from the hospital [56]. The duration of the present intervention was 10 weeks, and the follow-up lasted for 12 weeks; thus, an extended follow-up period might be required.

5. Limitations

The study has strength in the randomized controlled trial and was implemented in new stroke patients in the golden period (3–6 months), which is the best time to assist stroke patients to relearn skills after brain damage and return to normal. The limitations of the study should be noted. First, although power analysis was conducted for sample size calculation with the ICC designated as nominal value 0.05, it might underpower with an estimated ICC assumption. Secondly, the small number of new cases of ischemic stroke in each month affected a long period of collecting data. Thirdly, the study period might be too short to evaluate a program's sustainability. Finally, participants were from 6 districts in one province in central Thailand, which could not refer to the general stroke population.

6. Conclusion

The family-based program effectively improved family function among family caregivers and family members and decreased the caregiver burden and stress among family caregivers. The program

also improved functional status and reduced depression in post-stroke patients. Therefore, this program can be used in the care of post-stroke patients in the community setting, especially those with moderate to severe disability. Further research should be conducted to assess the sustainability of the program's effectiveness.

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Data availability statement

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

CRedit authorship contribution statement

Saisunee Deepradit: Conceptualization, Methodology, Validation, Formal analysis, Investigation, Data curation, Writing - original draft, Writing - review & editing. **Arpaporn Powwattana:** Conceptualization, Methodology, Validation, Formal analysis, Investigation, Data curation, Writing - review & editing, Supervision, Project administration. **Sunee Lagampan:** Conceptualization, Methodology, Writing - original draft. **Weena Thiangtham:** Conceptualization, Methodology, Writing - original draft.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ijnss.2023.09.020>.

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