Original Article

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Effectiveness of a Patient-Family-Shared Care Program on Delaying the Progression of Chronic Kidney Disease in Uncontrolled Type 2 Diabetic Patients: A Quasi-Experimental Study

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Abstract:

Objective: This study aimed to examine the effectiveness of a patient-family-shared care program in delaying the progression of chronic kidney disease (PFS-DCKD-P) in uncontrolled type 2 diabetic patients within Phrae province, Thailand.

Material and Methods: In this quasi-experimental research, twenty-three patient-family member dyads in the intervention group completed the 16-week PFS-DCKD-P; while twenty-two patient-family member dyads of the control group received a regular program. Outcomes included: patients' shared care, family members' shared care and the clinical outcomes, which were chronic kidney disease clinical indexes (CKDC-Indexes). Differences were compared within the groups before and after participating in the program as well as differences between groups after participating in the program. Descriptive statistics, paired t-test, and independent t-test statistics were used for data analysis.

Results: The patients' shared care of a decision-making component and a reciprocity component, systolic blood pressure (SBP), and blood sugar (BS) after program participation were higher than before in the intervention group (p-value<0.05). When compared between groups, the SBP of the intervention group was lower than the control group (p-value<0.05). There were no statistical differences of patients' and family members' shared care mean scores between the two groups. However, family members' shared care of the communication component was increased in the intervention group (p-value<0.05).

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Conclusion: The PFS-DCKD-P showed no explicit effectiveness on improving shared care for both patients and family members, nor for CKDC-Indexes. Further studies should optimize each program activity and encourage more consistent participation from family members.

Keywords: delaying progression of CKD, shared care program, Type 2 diabetes

Introduction

Type 2 diabetes mellitus (T2DM) is a major public health problem in many countries[1,2]. The prevalence of T2DM prevalence in Thailand was 6.9% in 2008-2009[3], 8.9% in 2014[4], and 12.4% in 2019-2020[3]. T2DM causes both macrovascular complications; including coronary disease, stroke, peripheral neuropathy, and microvascular complications; such as diabetic retinopathy, diabetic foot, and chronic kidney disease (CKD)[5,6].

CKD is defined as abnormalities in kidney structure or function persisting for more than 3 months, e.g., glomerular filtration rate (GFR) <60 mL/min/1.73 m^2 or albuminuria ≥30 mg per day[7,8]. CKD usually shows no symptoms until it is advanced[9] and impacts both the patients' physical quality of life; including physical functioning, pain, vitality, and mental quality of life, which can include depression and anxiety[10]. In addition, CKD patients often progress to end-stage kidney disease (ESKD). They typically need renal replacement therapy, which affects many aspects of their lives. Unfortunately, many poor ESKD patients often die before receiving this therapy[9].

Managing T2DM is significant in the prevention of long-term complications; such as CKD. There are several ways to improve T2DM patients' quality of life;[11] including patient-based interventions[12,13] and family-based interventions[14,15]. Usually, these interventions are specific to either the patients or families; however, a combination of both patient and family interventions or shared care, also called patient-family-based interventions, are limited.

Theoretically, shared care is an interpersonal interaction system composed of communication, decision-making, and reciprocity that patients and family caregivers use to exchange social support[16]. Social support refers to the giving and the interchange of emotional, informational, and/or instrumental resources in response to perceiving another's needs[17]. Shared care has 3 components: 1) Communication, used to exchange advice, information, and emotional support about his or her illness experience or situations between members of a care dyad; 2) Decision-making, a patient's capacity to seek information and be involved in decisions about his or her care. The caregiver's understanding of the situation is very important in making patient treatment decisions; 3) Reciprocity, characterized as partnership and empathy within care dyads[16].

Patient-family-shared care interventions in previous studies explained co-practice of communication, decision-making, and reciprocity between patients and family members. Ideally, patients are self-aware and practice good behaviors to control their symptoms or complications. Family members participate by exchanging information with patients, leading to decision-making in some situations; additionally, they also help patients both in the physical and emotional aspects[16-19]. Patient-family-shared care interventions have been utilized for patients with pressure sores[18], heart failure[17], continuous ambulatory peritoneal dialysis[19], and chronic cardiac problems[16]. Their study findings show that this type of intervention improved the outcomes of patients[16-19]. Outcomes from those studies[16-19] mainly improved shared-care scores between patients and family dyads, however, previous studies regarding shared care in CKD are limited. One study of CKD individuals with CAPD[19] indicated outcome improvements, including increased shared care scores, exit site infections, and serum albumin levels. Previous studies regarding shared-care interventions mostly improved outcomes among individuals with other diseases. However, to our knowledge, there has as of yet been a study on delaying the progression of CKD in uncontrolled T2DM individuals to improve outcomes; including, shared-care scores, serum creatinine (SCr), estimated glomerular filtration rate (eGFR), blood pressure (SBP and DBP), and blood sugar (BS) in people with CKD. As a result, there is a lack of information as to how such a program could improve T2DM individuals' care planning.

The purpose of this research was to examine the effectiveness of a patient-family-shared care program on delaying the progression of CKD in uncontrolled T2DM patients. The outcomes of interest were: patients' shared care scores, patients' chronic kidney disease clinical indexes, and shared care scores of family members that care for these patients. The outcomes of the intervention group before and after participating in this program, and between the intervention and control groups before and after participating in this program were compared. It was hypothesized that patients and family members whom participated in the PFS-DCKD-P would have improved patients' shared care scores, patients' CKDC-Indexes, and family members' shared care scores.

Material and Methods

Study design and setting

This quasi-experimental study consisted of an intervention and a control group taking pre-post tests to determine the effectiveness of the patient-family-shared care program. The tests were taken, and biological measures were collected in weeks 0 and 16. The outcomes included SCr, eGFR, blood pressure (BP), including SBP and DBP, and blood sugar (BS) levels. The research was conducted in Phrae province, at two sub-district health-promoting hospitals (SHPHs). The patients under the responsibility of these two SHPHs were recruited and enrolled into either the intervention group or control group. The first and second SHPHs were located 8 and 5 kilometers away from the city; respectively: both SHPHs were 3 kilometers apart.

Participants

The two SHPHs with T2DM patients having registered for treatment consisted of 446 and 709 patients, respectively[20]. The desired sample size was calculated from Sarin's study[21] using the G*power program. A desired power of 80% at a 5% significant level, with an effect size of 0.50 was set. After compensating for a 20% dropout rate, a minimum sample size of 42 participants per group was required. The participants were recruited as follows:

First, a purposive sampling of one district was performed. Second, two SHPHs were purposively selected as they had adequate non-communicable disease management policies, population numbers in the targeted range, and good coordination between public health personnel within the research area, samples, and researchers. Third, a random sampling of individuals was performed from all T2DM individuals registered at the two SHPHs. Those were assigned into the intervention group and control group.

Inclusion criteria for participants were: 1) aged between 35-75 years, 2) had HbA_1C greater than 7%, 3) were in CKD stage 2 and stage 3b 4) had the ability to communicate in Thai language, 5) had the ability to use a telephone or Line application, and 6) had the willingness to participate in the program. The exclusion criteria were: 1) Being admitted into a hospital, 2) being unable to help oneself, 3) experienced medical complications during participation in the program, such as kidney infection, kidney failure stage 4-5, heart failure, stroke, and/or coronary artery disease.

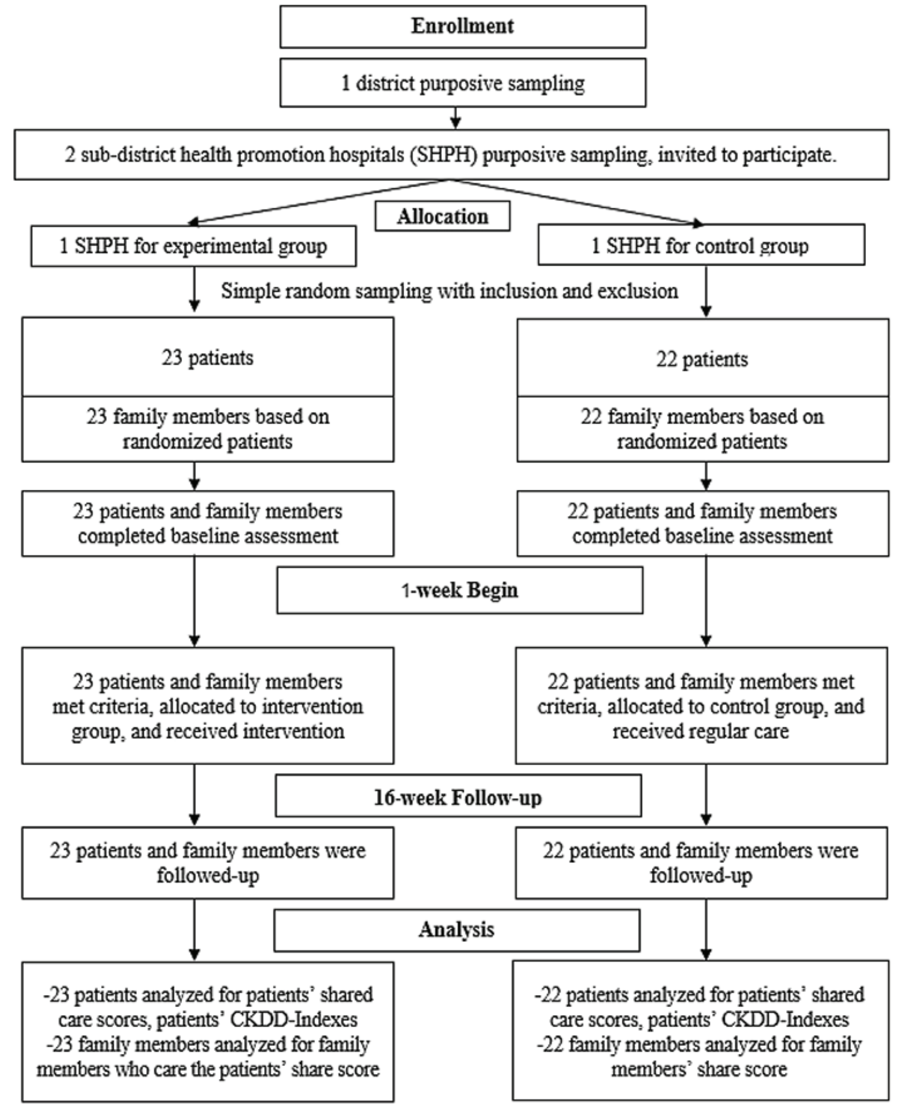

Figure 1 The CONSORT flow diagram on the development of the quasi-experimental study

The inclusion criteria for family members were: 1) be the primary family members caring for T2DM individuals, 2) be able to communicate in the Thai language, 3) be able to use a telephone or Line application, 4) be willing to participate in the program. The exclusion criterion was: being unable to participate in the program activities more than 2 times. Figure 1. shows the CONSORT flow diagram on the development of the quasi-experimental study[22].

Research instrument

The Patient-Family-Shared-Care Program on Delaying the Progression of CKD (PFS-DCKD-P) developed by researchers, combined nursing service activities through the practice of nurses supporting the shared care of individuals and family members. It utilized the role of the individuals and family members through the practice of themselves and Sebern's shared care concepts[23] for the program's scope. The contents and activities of the program were contributed by the nurse researchers. The program consisted of five activities with a duration of 16 weeks. Activities were spaced 4 weeks apart from each other as follows: In week 1, two 1.30-hour activities were carried out, encompassing health education on diabetes mellitus and CKD, patient care best practices, and group activities for sharing shared care experiences among individuals and family members. In week 4, a 30-to 60-minute follow-up at the individuals home was performed. In week 8, a 3-hour face-to-face disease review and knowledge practice, that included: group activities for finding information that had both positive and negative impacts on their practice, stimulating decision-making on the choice of practice, an action plan for problem-solving, and participation practice, were intervened. In week 12, a second follow-up at the individuals home was managed. In week 16, consistent implementation of participation plans between the patients and family members was performed.

Data collection instruments

1. The participant personal questionnaires, including: 1) The Patient Personal Questionnaire (PPQ), comprising of demographic information, including age, gender, marital status, education, occupation, average monthly income, T2DM onset, T2DM treatment duration, comorbidity, and risks for kidney disease. 2) The Family Member Personal Questionnaire (FPQ) was used to gather six demographic data akin to the PPQ. Furthermore, it encompassed the history of illness, number of family members, relationship with the patient, and time of patient care.

2. The patient shared care instrument-3 (PSCI-3), which was originally developed by Sebern[23] and then translated and modified to the Thai version by Pairojkittraku et al[19]. It is a self-administered questionnaire used to assess patient-related shared care, and includes 19 items with a rating scale (1=completely disagree; 6=completely agree), for 3 components of shared care: communication, decision-making, and reciprocity. There is no overall score for the PSCI-3; instead, the individual, separate scores for each of the 3 factors are calculated from the average scores for all questions related to a specific component. For communication, there are 5 questions with a score of 5-30 points. For decision-making, there are 6 questions with a score of 6-36 points. For reciprocity, there are 8 questions with a score of 8-48 points. The communication and decision-making components have all positive questions. However, for the reciprocity aspect, all questions are negative; thus, scores must be reversed before analyzing[23]. The PSCI-3 was validated on T2DM Thai individuals. The reliability of communication, decision-making, and reciprocity components were 0.80, 0.67 and 0.73, respectively; and overall it was 0.76.

3. The Family Member Shared Care Instrument-3 (FSCI-3). originally developed by Sebern[23] was translated to the Thai version by Pairojkittraku et al[19]. It is a self-administered questionnaire used to assess family-member related shared care. The FSCI-3 has a 19-item rating scale (1=completely disagree; 6=completely agree), for 3 factors of shared care: communication, decision-making, and reciprocity. The PSCI-3 and the FSCI-3 are worded slightly different[23]. The FCSI-3 uses the same scoring criteria as the PSCI-3. The FSCI-3 was validated on Thai family members, with the reliability of communication, decision-making, and reciprocity factors being 0.94, 0.75 and 0.89, respectively; overall it was 0.76.

4. The CKD Clinical Indexes (CKDC-Indexes) were developed according to the outcomes of the study: serum creatinine (SCr) of the patients was drawn for testing at a provincial hospital's laboratory, with clear testing guidelines. eGFR of the samples were calculated and reported by the Phare Hospital Laboratory Department. They were calculated by entering SCr, gender, and the patients' age into the chronic kidney disease epidemiology collaboration equation (CKD-EPI). Blood pressure (BP) of the patients; including systolic blood pressure (SBP) and diastolic blood pressure (DBP), were measured using the sphygmomanometers of the SHPHs, with annual calibration. The blood sugar (BS) of the patients were obtained from fingertips after 8 hours of fasting at the SHPHs. The BS test has been used to monitor the patients' blood glucose levels in remote settings[24].

Data collection procedure

Outcomes: The primary outcome was the shared care scores, the PSCI-3 and FSCI-3 scores, for assessing the programs' effectiveness. The secondary outcome was the CKDC-Indexes.

The experimental group: During the first week, the nurse researchers convened with T2DM individuals and family members of the experimental group in a meeting room at SHPH. Participants were administered pre-test questionnaires, including PPQ, FPQ, PSCI-3, and FSCI-3, and their CKDC-Indexes were evaluated. After completing the questionnaires, the PFS-DCKD-P was carried out as follows: *In week 1*, the nurse researchers conducted educational and group activities sessions that lasted 1.30 hours each, led by the head of the nurse researchers. During the educational session, the participants received health education concerning diabetes mellitus, CKD, and best practices for patient care. In the group activity sessions, the patients and family members were divided into 4 groups, sharing information on shared care experiences within their dyads and groups. *In week 4*, the nurse researchers conducted a 30- to 60-minute follow-up as a home visit. The participants were assessed on their shared care experiences regarding food preparation and consumption, exercise, medication use, avoidance of alcohol/tobacco, and goal achievement. Furthermore, they received information and support tailored to their individual needs and problems. *In week 8*, the nurse researchers facilitated face-to-face reviews of diseases and knowledge practice as well as group activity sessions: each lasting 1.30 hours and led by the head of the nurse researchers. The participants were assessed on their knowledge of diseases and practice, with content as that of the first week. In the group activities session, the dyads were divided into four groups and engaged in decision-making, problem-solving, and practice participation, based on information with both positive and negative impacts on their practice.

In week 12, the nurse researchers performed the second follow-up home visit for evaluating the patients' shared care practice; in the same manner as *week 4*. The participants also received tailored information. *In week 13 to week 15*, the participants employed consistent implementation of participation plans between the dyads. In week 16, the researchers summarized the overall participation in the program, asked participants to complete post-test questionnaires, assessed individuals' CKDC-Indexes, and acknowledged all participants for participating in the program.

The control group: The nurse researchers met the control group's participants, both patients and family members in a meeting room at the SHPH, during the first week on the scheduled date. The participants were given the PPQ, FPQ, PSCI-3, and FSCI-3 pre-test questionnaires to complete, and their CKDC-Indexes were assessed by the nurse researchers. The participants received the usual care from assistant researchers; including health education on diabetic self-care and complication prevention, from weeks 1-15. *In week 16*, the nurse researchers administered post-test questionnaires and assessed the T2DM individuals' CKDC-Indexes, followed by a 3-hour intensive health education session, and expressed gratitude to all subjects for their involvement in the study.

Statistical analysis

Descriptive statistics were utilized to describe participants' characteristics. The chi-square test and the independent t-test were used to compare the differences between the intervention and control groups. The paired *t*–test was used to compare the differences of mean scores within the groups before and after participating in the program. The independent *t*–test was used to compare the differences of mean scores between the intervention and the comparison group after participating in the program. The level of statistical significance was a p–value<0.05.

Ethical considerations

The ethics of this study were approved by the Human Research Committee of Phrae Provincial Public Health Office (IRB: COE No.1/2565).

Results

Participants characteristics

In this study, a total of 90 participants were recruited, from two SHPHs. Participants included 23 individuals and 23 family members in the intervention group and 22 individuals and family members in the control group. Only education levels and occupation type of patients differed between both groups at baseline (p–value<0.05) (Table 1). For family members, only the mean duration of patient care was different between both groups at baseline (p–value<0.05) (Table 2).

Table 1 Baseline characteristics of Type 2 diabetes mellitus (T2DM) individuals (n=45)

Characteristics	Intervention group (n=23)		Control group (n=22)		p–value
	n	(%)	n	(%)	
Age (years)					
50–59	4	(17.39)	1	(4.50)	0.190[b]
60–69	14	(60.87)	13	(59.10)	
70–79	5	(21.74)	8	(36.40)	
Mean (S.D.)	65.48	(6.15)	67.82	(4.56)	
Gender					
Male	9	(39.10)	3	(13.60)	0.291[b]
Female	14	(60.90)	19	(86.40)	
Marital status					
Single	2	(8.70)	1	(4.55)	0.444[b]
Married	16	(69.56)	12	(54.55)	
Widowed/divorced	5	(21.74)	9	(40.90)	
Education					
Primary school	18	(78.30)	20	(90.90)	0.008[b]
Secondary school	5	(21.70)	2	(9.10)	
Occupation					
Not working/unemployed	9	(39.10)	5	(22.70)	0.017[b]
Day laborer/works for hire	2	(8.70)	8	(36.40)	
Shopman	6	(26.10)	2	(9.10)	
Agriculturist	6	(26.10)	3	(13.60)	
Other:	0	(0.00)	4	(18.20)	
–Basketry	0	(0.00)	2	(9.10)	
–Housewife	0	(0.00)	1	(4.55)	
–Wood carver	0	(0.00)	1	(4.55)	
Average monthly income (Thai Baht)	22[c]		15[c]		
600–3,600	12	(54.55)	6	(40.00)	0.219[b]
3,601–6,600	7	(31.80)	6	(40.00)	
6,601–9,600	1	(4.55)	1	(6.70)	
9,601–12,600	2	(9.10)	2	(13.30)	
Mean (S.D.)	4,000.00 (3,056.30)		3,363.64 (2137.32)		

Table 1 (continued)

Characteristics	Intervention group (n=23)		Control group (n=22)		p-value
	n	(%)	n	(%)	
T2DM onset (years)					
1-5	4	(17.40)	5	(22.70)	0.711[b]
6-10	8	(34.70)	3	(13.60)	
11-15	7	(30.40)	4	(18.20)	
16-20	2	(8.70)	8	(36.40)	
21-25	1	(4.40)	2	(9.10)	
26-30	0	(0.00)	0	(0.00)	
31-35	0	(0.00)	0	(0.00)	
36-40	1	(4.40)	0	(0.00)	
Mean (S.D.)	12.30 (7.51)		13.32 (7.36)		
T2DM treatment duration (years)					
1-5	4	(17.40)	5	(22.70)	0.711[b]
6-10	8	(34.70)	3	(13.60)	
11-15	7	(30.40)	4	(18.20)	
16-20	2	(8.70)	8	(36.40)	
21-25	1	(4.40)	2	(9.10)	
26-30	0	(0.00)	0	(0.00)	
31-35	0	(0.00)	0	(0.00)	
36-40	1	(4.40)	0	(0.00)	
Mean (S.D.)	12.17 (7.69)		13.27 (7.43)		
Comorbidity					
No	0	(0.00)	5	(22.70)	
Yes: (answer more than 1 item.)	23	(100.00)	17	(77.30)	
-Hypertension	20	(87.00)	16	(72.70)	
-Heart disease	0	(0.00)	1	(4.50)	
-Lipidemia	20	(87.00)	13	(59.10)	
-Gout	1	(4.30)	0	(0.00)	
-Other;	0	(0.00)	3	(13.60)	
-Herniated disc	0	(0.00)	1	(4.53)	
-Scoliosis	0	(0.00)	1	(4.53)	
-Cystic kidney disease	0	(0.00)	1	(4.53)	
Risk for kidney disease					
No	17	(73.90)	19	(86.40)	0.294[b]
Yes:	6	(26.10)	3	(13.60)	
-A family has history of kidney disease	1	(4.30)	1	(4.50)	
-Take analgesic continuously for a long time.	3	(13.00)	2	(9.10)	
-history of illnesses with urinary tract disease; kidney stones, enlarged prostate, and nephritis	2	(8.70)	0	(0.00)	

*p-value<0.05, [a] Comparison means difference by using independent *t*-test, [b] Comparison group variables by using chi-square test, [c] There were missing data, T2DM=Type 2 diabetes mellitu, S.D.=standard deviation

Table 2 Baseline characteristics of family members caring for type 2 diabetes mellitus individuals (n=45)

Characteristics	Intervention group (n=23)		Control group (n=22)		p-value
	n	(%)	n	(%)	
Age (years)					
14-24	4	(17.40)	1	(4.60)	0.637[b]
25-34	1	(4.40)	1	(4.60)	
35-44	2	(8.70)	3	(13.60)	
45-54	6	(26.10)	3	(13.60)	
55-64	5	(21.70)	4	(18.20)	
65-74	5	(21.70)	10	(45.40)	
Mean (S.D.)	49.00	(18.57)	57.86	(15.97)	
Gender					
Male	9	(39.10)	7	(31.80)	0.421[b]
Female	14	(60.90)	15	(68.20)	
Marital status					
Single	6	(26.10)	3	(13.60)	0.655[b]
Married	17	(73.90)	17	(77.30)	
Widowed/divorced	0	(0.00)	2	(9.10)	
Education					
Did not attend school	2	(8.70)	0	(0.00)	0.122[b]
Primary school	8	(34.80)	9	(40.90)	
Secondary school	8	(34.80)	6	(27.30)	
Associate degree	2	(8.70)	3	(13.60)	
Bachelor's degree	3	(13.00)	4	(18.20)	
Job/occupation					
Not working/unemployed	2	(8.70)	4	(18.20)	0.720[b]
Day laborer/works for hire	6	(26.10)	8	(36.30)	
Government/state enterprise employees	0	(0.00)	1	(4.50)	
Retailer	6	(26.10)	4	(18.20)	
Agriculturist	5	(21.70)	2	(9.10)	
Other;	4	(17.40)	3	(13.60)	
-Self-employed	1	(4.35)	1	(4.55)	
-Student/attends college	3	(13.05)	0	(0.00)	
-Seamstress	0	(0.00)	2	(9.10)	
Average monthly income (Thai Baht)					
0–3,500	11	(47.83)	10	(45.50)	0.186[b]
3,501–7,000	7	(30.43)	7	(31.80)	
7,001–10,500	2	(8.70)	1	(4.50)	
10,501–14,000	0	(0.00)	2	(9.10)	
14,001–17,500	3	(13.04)	2	(9.10)	
Mean (S.D.)	5,254.55)	(4,905.95	5,386.36	(4,868.78)	
History of illness					
No	12	(52.20)	10	(45.50)	1.000[b]
Yes: (answer more than 1 item)	11	(47.80)	12	(54.50)	
-Hypertension	6	(26.10)	9	(40.90)	
-Hypertension	2	(8.70)	4	(18.20)	
-T2DM	4	(17.40)	4	(18.20)	
-Gout	0	(0.00)	1	(4.50)	
-Other:	4	(17.40)	1	(4.50)	
-Hyperthyroidism	1	(4.35)	0	(0.00)	

Table 2 (Continued)

Characteristics	Intervention group (n=23)		Control group (n=22)		p-value
	n	(%)	n	(%)	
-Laryngeal cancer	1	(4.35)	0	(0.00)	
-Migraine	1	(4.35)	0	(0.00)	
-Asthma	1	(4.35)	0	(0.00)	
-Allergic rhinitis	0	(0.00)	1	(4.50)	
Number of family members					
1-5	17	(73.90)	17	(77.30)	0.294[b]
6-10	6	(26.10)	5	(22.70)	
Mean (S.D.)	4.83	(1.67)	3.86	(1.70)	
Relationship with patient					
Father/mother	2	(8.70)	3	(13.60)	0.217[b]
Spouse	9	(39.10)	8	(36.40)	
Son/daughter	4	(17.40)	4	(18.20)	
Relatives	2	(8.70)	4	(18.20)	
Other;	6	(26.10)	3	(13.60)	
-Younger sister	1	(4.35)	2	(9.07)	
-Grandchild	5	(21.75)	1	(4.53)	
Time of patient care (years)	22[c]				
1-5	10	(45.50)	6	(27.30)	0.803[b]
6-10	7	(31.80)	5	(22.70)	
11-15	4	(18.20)	3	(13.60)	
16-20	1	(4.50)	6	(27.30)	
21 25	0	(0.00)	2	(9.10)	
Mean (S.D.)	7.77	(4.94)	12.05	(7.51)	

*p-value<0.05, S.D.=standard deviation

2. Comparison of the PSCI-3 mean scores of individuals in the intervention group before and after participating in the program, and between the intervention and the control groups after participating in the program.

The PSCI-3 mean scores of the individuals in the intervention group before and after participating in the program showed no differences in the three shared care components (p-value>0.05). The PSCI-3 mean scores were also considered for each item of the individuals after participating in the program. The mean score of the decision-making item that said: “When I am sick, I do as much as I can for myself,” and the mean score of the reciprocity item that said: “I listen to my family member/companion,” were statistically, significantly increased after participating in the program compared to before (p-value=0.030 and p-value=0.031, respectively). However, the PSCI-3 mean scores of the intervention and the control groups after participating in the program showed no statistical difference in the shared care components of communication, decision-making, and reciprocity (p-value>0.05) (Table 3).

3. Comparison of the CKDC-Indexes mean scores of individuals in the intervention group and the control group before and after participating in the program, and between the intervention and the control groups after participating in the program.

When examining the CKDC-Indexes of individuals in the intervention group, SBP and BS decreased after participating in the program compared to before participating

Table 3 Patient shared care instrument–3 (PSCI–3) mean scores of the intervention and the control groups before and after participating in the program (n=23), and PSCI–3 mean scores of the intervention group and the control group after participating in the program (n=45)

Items of PSCI–3	Intervention group (n=23)			Control group (n=22)			After participating the program		
	Before	After	p–value	Before	After	p–value	Intervention group (n=23)	Control group (n=22)	p–value
Communication, Mean (S.D.)	**20.41 (6.01)**	**21.55 (8.04)**	**0.476**	**19.41 (5.23)**	**19.32 (6.40)**	**0.944**	**21.55 (8.04)**	**19.32 (6.40)**	**0.315**
1. There is no one to talk with about how I am feeling.	4.48 (1.62)	4.22 (1.88)	0.582	4.32 (1.67)	4.14 (1.70)	0.401	4.22 (1.88)	4.14 (1.70)	0.880
2. I don’t like to bother my family member/ companion by telling him/her I am feeling sick.	4.55 (1.44)	4.36 (1.81)	0.657	4.05 (1.53)	4.00 (1.75)	0.916	4.36 (1.81)	4.00 (1.75)	0.502
3. I never ask my family member/companion for advice about my health problems.	4.05 (2.06)	4.45 (1.68)	0.323	4.36 (1.50)	4.18 (1.37)	0.669	4.45 (1.68)	4.18 (1.37)	0.558
4. My family member/companion doesn’t like to tell me when s/he is feeling sick.	4.30 (1.74)	4.39 (1.67)	0.814	3.81 (1.83)	3.86 (1.28)	0.923	4.39 (1.67)	3.86 (1.28)	0.243
5. My family member/companion doesn’t like to worry me when s/he is feeling sick.	3.04 (1.55)	3.78 (1.98)	0.115	2.82 (1.53)	3.14 (1.42)	0.425	3.78 (1.98)	3.14 (1.42)	0.217
Decision–making, Mean (S.D.)	**29.05 (5.05)**	**28.70 (4.94)**	**0.817**	24.38 (4.96)	**29.19 (4.26)**	0.001	**28.70 (4.94)**	**29.19 (4.26)**	**0.735**
6. When there is something wrong with my family member, s/he gets as much information as s/he can about the cause of the problem.	4.74 (1.14)	4.57 (1.65)	0.643	4.90 (1.38)	4.48 (1.33)	0.176	4.39 (1.44)	4.48 (1.33)	0.840
7. When there is something wrong with my family member; s/he does what s/he can relieve the symptoms.	5.00 (1.17)	4.65 (1.40)	0.357	5.09 (0.81)	4.86 (1.39)	0.528	4.65 (1.40)	4.86 (1.39)	0.614
8. If my family member is not feeling well, then s/he decides whether s/he ought to stay home or go out.	5.14 (0.77)	4.73 (1.35)	0.242	5.00 (1.11)	4.86 (1.08)	0.665	4.73 (1.35)	4.86 (1.08)	0.714
9. When my family member is not feeling well, then s/he decides when to call the doctor or nurse.	5.14 (0.79)	4.71 (1.62)	0.310	4.55 (1.44)	5.18 (0.50)	0.059	4.71 (1.62)	5.18 (0.50)	0.203
10. My family member talks to the doctor or nurse about his/ her symptoms and the causes of his/her illness.	4.78 (0.85)	5.17 (0.83)	0.059	4.86 (1.21)	4.95 (0.72)	0.747	5.17 (0.83)	4.95 (0.72)	0.352
11. When my family member is sick, s/he does as much as s/he can for her/himself.	4.48 (1.38)	5.26 (0.86)	0.030*	5.14 (1.04)	5.09 (0.87)	0.883	5.26 (0.86)	5.09 (0.87)	0.514
Reciprocity, Mean (S.D.)	**37.24 (5.27)**	**39.29 (5.56)**	**0.249**	**37.95 (4.96)**	**29.19 (4.26)**	**<0.001**	**28.70 (4.94)**	**29.19 (4.26)**	**0.735**
12. I listen to my family member/companion.	4.52 (1.24)	5.13 (0.63)	0.031*	4.95 (1.38)	5.32 (0.57)	0.268	5.13 (0.63)	5.32 (0.57)	0.298
13. We have a partnership.	4.78 (1.31)	5.22 (0.85)	0.195	5.05 (0.81)	5.41 (0.50)	0.189	5.22 (0.85)	5.41 (0.50)	0.365

Table 3 (continued)

Items of PSCI–3	Intervention group (n=23)			Control group (n=22)			After participating the program		
	Before	After	p–value	Before	After	p–value	Intervention group (n=23)	Control group (n=22)	p–value
14. I would feel bad if my family member / companion did not tell me about symptoms that are bothering him/her.	3.33 (1.83)	3.95 (1.56)	0.323	3.86 (1.11)	4.57 (1.36)	0.139	3.95 (1.56)	4.57 (1.36)	0.179
15. When my family member/companion tells me about something hurts; I help him/her evaluate it further.	4.39 (1.27)	4.83 (1.19)	0.153	4.55 (1.44)	4.95 (0.77)	0.095	4.83 (1.19)	4.95 (0.77)	0.673
16. If we try something that doesn't help, then we try something else.	4.78 (0.74)	4.87 (1.10)	0.724	4.50 (1.21)	5.09 (0.75)	0.020	5.04 (0.77)	5.09 (0.75)	0.835
17. If one of us is ill, then we figure out how we should treat the illness together.	5.09 (1.00)	5.30 (1.06)	0.468	4.95 (1.04)	5.23 (0.69)	0.342	5.30 (1.06)	5.23 (0.69)	0.775
18. We go to see the doctor together, so we know what is going on.	5.22 (0.90)	5.00 (1.04)	0.328	4.86 (4.96)	5.32 (0.57)	0.106	5.00 (1.04)	5.32 (0.57)	0.214
19. If my family member's nurse or doctor tells me what the problem is, and what I should do, then I can do what they tell me to do.	5.30 (1.02)	5.30 (1.11)	1.000	5.32 (1.38)	5.27 (0.63)	0.840	5.30 (1.11)	5.27 (0.63)	0.907

*p–value<0.05, S.D.=standard deviation

in the program (p-value=0.022 and p-value=0.001, respectively). However, the eGFR, SCr, and DBP before and after participating in the program were not different (p-value>0.05). After participating in the program, the SBP of individuals in the intervention group was significantly decreased compared to the control group (p-value<0.001). However, eGFR, SCr, DBP and BS of individuals in the intervention and the control groups after participating in the program were not different (p-value>0.05). Results for the control group showed that eGFR decreased significantly in week 16 compared with that in week 0 (p-value<0.05). (Table 4).

4. Comparison of the FSCI-3 mean scores of family members in the intervention group before and after participating in the program, and between the intervention and the control groups after participating in the program.

For the intervention group, the family members' mean shared care scores were not different before and after participating in the program for the components of communication, decision-making, and reciprocity (p-value>0.05). In addition, after participating in the program, there was no difference in the family members' mean shared care scores for the intervention and the control group for the components of communication, decision-making, and reciprocity (p-value>0.05). When considering specific components, the mean score for one of the communication items: "My family member/companion doesn't like to worry me when s/he is feeling sick," was statistically significantly higher in the intervention group compared to the control group (p-value=0.020) (Table 5).

Discussion

The PFS-DCKD-P was developed to evaluate its effects of individuals' shared care score, individuals' CKDC-Indexes, and family members' shared care scores among patients-family member dyads with T2DM. Various PFS-DCKD-P components were based on Sebern's shared care concepts[23].

The mean scores of the patients' 3-component shared care for the intervention group before and after participating in the program, and between the intervention and the control group after participating in the program

Table 4 Chronic Kidney Disease Clinical Indexes (CKDC-Indexes) of the intervention group (n=23), and the control group (n=22) before and after participating in the program, and between the intervention and the control groups after participating in the program

CKDC-Indexes, Mean (S.D)	Intervention group (n=23)			Control group (n=22)			After participating the program		
	Before	After	p-value	Before	After	p-value	Intervention group (n=23)	Control group (n=22)	p-value
eGFR	62.73 (14.63)	65.08 (15.65)	0.206	74.63 (14.01)	68.06 (15.75)	0.001*	65.08 (14.63)	68.06 (15.75)	0.528
SCr	1.09 (0.26)	1.05 (0.28)	0.247	0.87 (0.19)	0.96 (0.26)	0.146	1.06 (0.28)	0.96 (0.26)	0.215
BS	149.95 (30.67)	123.50 (25.63)	0.001*	137.65 (34.45)	143.85 (43.39)	0.001*	123.50 (25.63)	142.00 (42.01)	0.085
SBP	138.17 (22.23)	126.43 (10.90)	0.022*	129.77 (12.12)	140.27 (12.04)	0.333	126.43 (10.90)	140.27 (12.04)	0.001*
DBP	74.04 (10.30)	77.74 (8.46)	0.226	75.00 (6.88)	77.67 (6.64)	0.004*	74.04 (10.30)	77.74 (8.46)	0.975

*p-value<0.05, eGFR= estimated glomerular filtration rate, SCr =serum creatinine; BS=blood sugar, SBP=systolic blood pressure, DBP=diastolic blood pressure

Table 5 Family members' shared care index–3 (FSCI–3) mean scores of the intervention group and the control group before and after participating in the program (n=23), and the FSCI–3 mean scores of the intervention group and the control group after participating in the program (n=45)

Items of FSCI–3	Intervention group (n=23)			Control group (n=22)			After participating the program		
	Before	After	p–value	Before	After	p–value	Intervention group (n=23)	Control group (n=22)	p–value
Communication, Mean (S.D.)	21.09 (6.28)	22.68 (6.79)	0.185	19.81 (5.40)	20.68 (6.10)	0.667	22.78 (6.65)	20.68 (6.10)	0.276
1. There is no one to talk with about how I am feeling.	3.96 (1.87)	4.48 (1.76)	0.162	4.68 (1.73)	4.32 (1.52)	0.364	4.48 (1.76)	4.32 (1.52)	0.746
2. I don't like to bother my family member / companion by telling him/her I am feeling sick.	3.87 (1.84)	4.57 (1.65)	0.096	4.05 (1.53)	4.64 (1.43)	0.169	4.57 (1.65)	4.64 (1.43)	0.878
3. I never ask my family member/companion for advice about my health problems.	4.32 (1.62)	4.77 (1.38)	0.267	4.36 (1.50)	4.50 (1.30)	0.734	4.78 (1.35)	4.50 (1.30)	0.478
4. My family member / companion doesn't like to tell me when s/he is feeling sick.	4.74 (1.32)	4.48 (1.44)	0.426	3.81 (1.83)	3.86 (1.49)	0.918	4.48 (1.44)	3.86 (1.49)	0.167
5. My family member/companion doesn't like to worry me when s/he is feeling sick.	3.91 (1.73)	4.48 (1.56)	0.183	3.18 (1.84)	3.36 (1.53)	0.676	4.48 (1.56)	3.36 (1.53)	0.020*
Decision–making, Mean (S.D.)	29.70 (4.85)	29.17 (6.65)	0.670	28.14 (6.05)	30.41 (3.23)	06.052	29.17 (6.65)	30.41 (3.23)	0.436
6. When there is something wrong with my family member, s/he gets as much information as s/he can about the cause of the problem.	4.83 (1.19)	4.57 (1.65)	0.503	4.32 (1.78)	4.68 (1.17)	3.054	4.57 (1.65)	4.68 (1.17)	0.786
7. When there is something wrong with my family member; s/he does what s/he can relieve the symptoms.	4.83 (1.15)	4.78 (1.45)	0.883	4.95 (1.09)	4.95 (1.09)	1.783	4.78 (1.45)	4.95 (1.09)	0.656
8. If my family member is not feeling well, then s/he decides whether s/he ought to stay home or go out.	4.96 (0.83)	4.83 (1.30)	0.672	4.45 (1.37)	5.18 (0.50)	1.171	4.83 (1.30)	5.18 (0.50)	0.237
9. When my family member is not feeling well, then s/he decides when to call the doctor or nurse.	5.00 (1.00)	5.00 (1.31)	1.000	4.77 (1.41)	5.18 (0.50)	1.090	5.00 (1.31)	5.18 (0.50)	0.547
10. My family member talks to the doctor or nurse about his/her symptoms and the causes of his/her illness.	4.96 (0.88)	4.83 (1.27)	0.503	4.82 (1.30)	5.14 (0.56)	1.090	4.83 (1.27)	5.14 (0.56)	0.298
11. When my family member is sick, s/he does as much as s/he can for her/himself.	5.13 (0.69)	5.17 (0.98)	0.840	4.91 (1.54)	5.27 (0.63)	1.371	5.17 (0.98)	5.27 (0.63)	0.692
Reciprocity, Mean (S.D.)	39.00 (4.91)	40.19 (7.03)	0.301	39.27 (7.46)	41.36 (4.69)	0.501	40.19 (7.03)	41.36 (4.69)	0.522
12. I listen to my family member/companion.	5.22 (0.60)	5.22 (0.90)	1.000	5.05 (1.25)	5.32 (0.65)	1.412	5.22 (0.90)	5.32 (0.65)	0.298
13. We have a partnership.	5.26 (0.81)	5.17 (1.03)	0.680	5.00 (1.48)	5.50 (0.51)	0.501	5.17 (1.03)	5.50 (0.51)	0.670
14. I would feel bad if my family member/companion did not tell me about symptoms that are bothering him/her.	3.55 (1.60)	4.32 (1.46)	0.053	3.73 (1.80)	4.50 (1.41)	1.296	4.32 (1.46)	4.50 (1.41)	0.189

Table 5 (continued)

Items of FSCI–3	Intervention group (n=23)			Control group (n=22)			After participating the program		
	Before	After	p–value	Before	After	p–value	Intervention group (n=23)	Control group (n=22)	p–value
15. When my family member/companion tells me about something hurts; I help him/her evaluate it further.	4.78 (1.20)	5.09 (1.00)	0.245	4.86 (0.94)	5.09 (0.81)	0.560	5.09 (1.00)	5.09 (0.81)	0.676
16. If we try something that doesn't help, then we try something else.	4.57 (1.08)	4.87 (1.10)	0.307	5.00 (1.07)	5.09 (0.75)	1.540	4.87 (1.10)	5.09 (0.75)	0.988
17. If one of us is ill, then we figure out how we should treat the illness together.	5.05 (0.95)	5.00 (1.11)	0.789	5.00 (1.16)	5.32 (0.65)	0.631	5.00 (1.11)	5.32 (0.65)	0.437
18. We go to see the doctor together, so we know what is going on.	4.59 (1.10)	5.05 (1.00)	0.076	5.18 (1.01)	5.18 (0.73)	0.715	5.05 (1.00)	5.18 (0.73)	0.253
19. If my family member's nurse or doctor tells me what the problem is, and what I should do, then I can do what they tell me to do.	5.41 (0.73)	5.27 (1.16)	0.561	5.45 (0.96)	5.36 (0.58)	6.052	5.27 (1.16)	5.36 (0.58)	0.608

*p–value<0.05, S.D.=standard deviation

were not statistically different. Patients were not dependent on family members for all daily activities; thus, they could independently do some activities and care for themselves without having to wait for family members or relatives to help them. These individuals demonstrated self-confidence and self-determination in their activities. Family members were also of the opinion that individuals had the ability to manage their daily activities and disease by themselves. Thus, family members trusted patients and did not care for them closely. This study's findings differ from the study of individuals with CKD with continuous ambulatory peritoneal dialysis (CAPD). In that study, the experimental group showed an increase in their shared care scores regarding communication, decision-making, and reciprocity factors at 4 and 8 weeks after participating in a shared care-promoting program[19].

The mean score for the family members' 3-component shared care within the intervention group before and after participating in the program, and between the intervention and the control group after participating in the program were not statistically different. Besides the husband-and-wife caregiver relationship, other family members cared for the patients in this study; such as grandchildren (21.8%, intervention group), the son/daughter (18.2%, control group) and other relatives (18.2%, control group). According to the cultural context of the participants in this study, some family members were less senior than patients. Therefore, more junior family members may be afraid of offending their patients by strictly monitoring their behavior. In addition, some patient-family member dyads in the intervention and the control groups did not live together; however, their family members often visited or cared for the patients at different times of the day.

Interestingly, within the intervention group the mean score for patients' care component of the decision-making item: "When I am sick, I do as much as I can for myself", and the mean score for patients' component of the reciprocity item: "I listen to my family member/companion," were statistically higher after participating in the program than before participating in the program (p-value<0.05). Moreover, family members for the intervention group showed a higher mean score of the communication component: "My family member/companion doesn't like to worry me when s/he is feeling sick." compared to the control group after participating in the program (p-value<0.05). In addition, the intervention group showed that the CKDC-Indexes, mean SBP, and BS were decreased after participating in the program compared to before participating in the program (p-value<0.05). Furthermore, after participating in the program, the patients' mean SBP for the intervention group was lower than that of the control group (p-value<0.05). However, the results for the control group showed that eGFR decreased significantly in week 16. This might be due to the education program or routine program that can help individuals with diabetes modify their behavior. As a result, the eGFR in week 16 was lower than that in week 0 in the control group.

The activities of the PFS-DCKD-P during the 1st and 8th week included: educating and reviewing practical knowledge for patients and family members through working with nurses, activities of exchanging information/practice experience, shared care planning, solving practical problems, and implementing the plan through the practice of patients and family members. The 4th and 12th week included follow-up visits with patients. Nurses shared practices for shared care to delay CKD by encouraging both patients and family members to review symptoms as well as practice modifying their behaviors at home. These activities may not have resulted in changes in all components of participants' shared care; including communication, decision-making, and reciprocity; however, some items of these were found to have changed. In addition, these activities also provided education and reviewed knowledge of patients and family members. These activities helped patients to know and apply some practices that reduced their SBP and BS.

The PFS-DCKD-P revealed no effect on patients' shared care scores, patients' CKDC-Indexes, nor family members' shared care scores. Diverse possible reasons may account for these results. First, participation in the program activities of family members in the intervention group was not inconsistent and had a low rate. The participation rates of family members for the 1st through the 4th activities were 78.3%, 52.2%, 30.4% and 65.2%, respectively. Family members could not attend all sessions due to traveling to visit their children in other provinces, working, or attending school. Second, some parts of the research instruments including the PSCI-3 and FSCI-3, had lower reliability. Instruments for measuring patients' shared care scores and family members' shared care scores of Thai T2DM patients and family members were quite limited. Cross-cultural shared care tools might be less sensitive with Thai T2DM patient-family member dyads.

Third, the patients' personal factors may have affected their outcomes. A family history of kidney disease was found among 4.3% of patients in the intervention group and among 4.5% of patients in the control group; thus, genetic factors played an important role in disease acquisition for these patients. The time since the onset of patients' T2DM was 12.3 years (±7.51) in the intervention group and 13.3 years (±7.36) in the control group. Patients who have had T2DM for 15 years or more, along with hyperlipidemia, hypertension, and diabetic retinopathy, have an increased prevalence of advanced CKD[25]. The patients' mean age in the intervention group was 65.5 years (±6.15) and the control group was 67.8 years (±4.56). Increased age is associated with the greater incidence of diabetic nephropathy in patients with T2DM[26]. All patients of the intervention and the control groups had comorbidities combined with T2DM. The most common comorbidities in the intervention group patients were hypertension and dyslipidemia (87.0% for both conditions), whereas the most common comorbidity in the control group patients was hypertension (72.7%), followed by dyslipidemia (59.1 %). Kidney and blood pressure are related, kidney disease causes an increase in blood pressure, while hypertension accelerates the loss of kidney function and increases the rate of urinary albumin excretion[27]. Dyslipidemia is a major risk factor for the development and progression of diabetic nephropathy. In the study of the Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications (DCCT/EDIC) study, lower low-density lipoprotein cholesterol (LDL-C) and triglyceride (TG) levels were related to reduced risk for progression from moderate albuminuria to severe albuminuria or ESRD[28].

Finally, some family members bought store-brought, ready-to-eat meals for patients to eat. Since family members lacked time to cook and worked during the daytime, they bought processed or prepared foods for the T2DM individuals that they cared for. These foods were often very sweet, fatty, and salty. Hence, the patient's personal factors; including nutritional choices had a direct effect on patients' CKDC-Indexes.

Some limitations of this study were that the results from this intervention study may not be generalizable to other settings and populations. Moreover, during implementation of the program, some family members did not regularly participate in the activities. This reduction in participation likely affected the program's impact on their behavior and beliefs.

Some strengths of this study are that the PFS-DCKD-P developed a program using shared care concepts for Thai T2DM individuals and family members, for which they previously did not have access to. Additionally, the researchers were nurses whom ran all 5 activities of this program over 16 weeks by themselves. Moreover, the program activities were carried out through both the practice of nurses, and the practice of patients and family members.

Conclusion

This study revealed patients' shared care scores and family members' shared care scores were low in Thai T2DM individuals and family members. There was inadequate evidence that the PFS-DCKD-P, based on shared care concepts, made a difference for outcomes; including patients' shared care scores, CKDC-Indexes, and family members' shared care scores, for T2DM individuals and family members. Future studies should consider adjusting the project activity periods to have appropriate intervals and encourage greater participation from family members.

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Conflict of interest

The authors declare that they have no conflicts of interest.

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