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Randomized controlled trial of a family-oriented self-management program to improve self-efficacy, glycemic control and quality of life among Thai individuals with Type 2 diabetes

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A B S T R A C T

Aims: We evaluated a theoretically-derived family-oriented intervention aimed to improve self-efficacy, self-management, glycemic control and quality of life in individuals living with Type 2 diabetes in Thailand.

Methods: In a single-blinded randomized controlled trial, 140 volunteer individuals with Type 2 diabetes, recruited from a diabetes clinic in rural Thailand, were randomly allocated to intervention and control arms. Those in the intervention arm received routine care plus a family-oriented program that included education classes, group discussions, a home visit, and a telephone follow-up while the control arm only received routine care. Improvement in outcomes over time (baseline, Week 3, and Week 13 following intervention) was evaluated using Generalized Estimating Equations multivariable analyses.

Results: Except for age, no between-group significant differences were observed in all other baseline characteristics. Diabetes self-efficacy, self-management, and quality of life improved in the intervention arm but no improvement was observed in the controls. In the risk-adjusted multivariable models, compared to the controls, the intervention arm had significantly better self-efficacy, self-management, outcome expectations, and diabetes knowledge ($p < 0.001$, in each). Participation in the intervention increased the diabetes self-management score by 14.3 points ($\beta = 14.3$, (95% CI 10.7–17.9), $p < 0.001$). Self-management was better in leaner patients and in females. No between-group differences were seen in quality of life or glycemic control, however, in the risk-adjusted multivariable models, higher self-management scores were associated with significantly

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decreased HbA1c levels ($p < 0.001$) and improved patient quality of life ($p < 0.05$) (irrespective of group membership).

Conclusions: Our family-oriented program improved patients' self-efficacy and self-management, which in turn could decrease HbA1c levels.

1. Introduction

Diabetes mellitus is a growing chronic metabolic disorder that can lead to serious complications affecting individuals worldwide. In 2009 an estimated 7.5% of Thai adults (25 years or older) were living with diabetes [1]. In 2010, this condition was ranked among the leading causes of death among Thai individuals, with diabetes mellitus being the second leading cause of death in females [2]. This study focuses on Type 2 diabetes mellitus (T2DM), the predominant form of diabetes in Thailand.

While medical, nursing, and social services provide essential support for individuals living with a chronic condition [3], these services are often costly and limited in community settings in both developed and developing countries [4,5]. As a result of poor access to health services, people living in rural settings often have shorter lives and higher levels of illness and complication than those living in cities [6]. Although such community health practices, if in place, provide invaluable support to patients with a chronic illness, they cannot provide the continuous follow-up required to fully meet patients' needs [7]. These professional services may also have a debatable impact on individuals' quality of life or improvement of other medical outcomes [8].

The scarcity of resources to support patients living in rural communities resulted in the recognition of the key roles that family members can have in the care of the chronically ill. Consequently, in the past decade, self-management health programs have progressively included family members [9]. Numerous studies have shown health care strategies involving family members can improve self-efficacy, knowledge about the condition, and self-care skills in individuals with a chronic condition such as T2DM [10–13]. A systematic review and meta-analysis of 52 randomized controlled trials found how such programs can improve patients' perceived physical and mental health [12]; while another narrative systematic review discussed how these interventions could enhance glycemic control in individuals with T2DM [14].

However, the beneficial effects of family-oriented health care programs on patients' health outcomes have not been consistent [14,15]. Some studies have shown how these programs could improve patients' self-efficacy and overall management of their diabetes [10,11], while another found that such interventions did not improve self-management nor glycemic control [15].

Furthermore, such family-oriented interventions are more likely to be conducted on individuals with Type 1 diabetes and less likely to involve adult patients with T2DM. Hence, a family-oriented program that will involve adult patients together with their family members to improve diabetes self-management and self-efficacy is necessary. These family-oriented health care programs, and especially those relating to the management of diabetes, are highly relevant in Thai society in which family members have a fundamental role to assist other family members with illnesses such as T2DM.

Self-efficacy represents the confidence to carry out a particular behavior in order to accomplish a specific goal [16,17]. There are two basic elements of self-efficacy: efficacy expectations (self-efficacy) and outcome expectations [18]. Self-efficacy develops confidence in an individual's ability to perform behaviors and to overcome barriers to achieving that goal. An outcome expectation is a person's belief that they will attain a positive health outcome resulting from specific behavior [18]. Diabetes self-management is defined as the ability of individuals with diabetes to manage their blood glucose levels, maintain personal hygiene, consume an appropriate diet, comply with medications, and sustain an acceptable level of physical activity [19].

Self-efficacy is broadly acknowledged to be a useful predictor of enhanced self-management [20]. An individual who has greater perceived efficacy will attempt to achieve a specific goal even in the face of barriers [16]. Various studies have found that T2DM educational programs based on self-efficacy theory can enhance self-management [17,21] and can delay the onset of complications arising from the condition [22].

1.1. *Diabetes self-management in Thailand*

The Diabetes Association of Thailand has defined the Clinical Practice Guidelines for persons with diabetes [23]. According to the Guidelines, all newly diagnosed cases should be provided with diabetes education and self-care support delivered by health care providers in groups or individually. Specific content and strategies (assessment, goal setting, planning, implementation, and evaluation) are outlined [23]. Although these Guidelines are informative, a high proportion of individuals with T2DM are unable to achieve glycaemic control (30% of men; 41% of women) [1].

Several diabetes self-management programs have been found to be effective in improving knowledge, self-care activities, glycaemic control, and quality of life for Thai individuals with T2DM [22,24,25]. Examples of Thai self-management practices include timely intake of medications, healthy eating, care of skin and feet, and engaging in regular physical exercise. Although the results are positive, diabetes self-management education has not as yet been standardized and a multidisciplinary team approach is not widely utilized [26] within Thai communities.

In Thailand, nurses play a major role in providing diabetes education for individuals with T2DM; however nurses cannot meet the demand, with only 35% of primary care units offering a diabetes education service delivered by nurses [27]. Thai culture has strong kinship and family ties with family members providing physical, mental and economic support to people with diabetes. In particular, family support has been found to influence the ability of the individual to self-manage their diabetes [28]. The assistance provided included helping the individual by preparing healthy food, prompting medication and exercise activities, and facilitating access to health professionals [28].

Most family-carers in Thai society are informal carers who are family members supporting their parents, siblings or spouses. These informal carers may have limited understanding of the health conditions their relative is experiencing. Several researchers have found family-oriented interventions are associated with glycemic control and better health outcomes for individuals with T2DM and their carers [12,15]. To our knowledge, a family-oriented educational program targeting individuals with T2DM has never been conducted in Thailand.

This prospective single-blinded randomized controlled clinical trial is the first study to compare diabetes self-efficacy, self-management, diabetes knowledge, glycemic control, and quality of life among adults (35 years or older) with T2DM, randomized to receive a family-oriented self-management program together with routine health care, with those randomized to receive only routine care. We hypothesize that the study intervention would be effective in enhancing better health outcomes among Thai individuals living with T2DM.

2. Materials and methods

Ethical approval for the study was obtained from the Human Research Ethics Committees of the Australian Catholic University, Approval Number 2014-222Q, and Suratthani Public Health Office in Thailand, Document Number ST0032.009/4824. The trial was registered in the Australian New Zealand Clinical Trials Registry, registration number ACTRN12615001249549.

2.1. *Design, population and setting*

A single-blinded randomized controlled trial with follow up assessments was conducted to evaluate a family-oriented intervention aimed to improve diabetes self-management in individuals living with Type 2 diabetes mellitus in Thailand. The setting was the diabetes clinic at Thachang Hospital where there was no existing structured diabetes education program prior to this study. Individual diabetes education is provided for newly diagnosed cases during their first visit. The program is unstructured with no theoretical foundation.

The target population consisted of adults diagnosed with T2DM who attended for follow up care at the diabetes outpatient clinic. A notice board announcement about the research project invited patients to participate in this study. Potential study participants were people diagnosed with T2DM for 6 months or more who met the following inclusion criteria: (1) aged 35 years or older and living in the Thachang District, Thailand; (2) having a fasting plasma glucose level of more than 140 mg% recorded during two follow-up visits at least a month apart; (3) an ability to communicate, read and write the Thai language; (4) willingness to receive home visits; (5) access to a telephone; and (6) having a family member living with them. Those with diabetes-related severe complications, or with comorbidities that hindered their participation in the trial, or those being treated with insulin were excluded from this trial.

Discontinuation criteria included those who developed severe complications during the program (e.g. retinopathy, stroke, hypertension, or acidosis) or those who subsequently required treatment with insulin. The inclusion criteria for the family member included: (1) living in the same residence with the patient, (2) being a spouse, child, grandchild, sibling, or friend, and (3) aged 18 years or older.

Prior to commencement, the participants were verbally informed that they would be randomly allocated to an intervention or control group. The study Participant Information Sheet also disclosed this random allocation to the participants. Participants were enrolled by a registered nurse at the diabetes clinic. All patients, who met the study criteria and were willing to participate, provided written consent and were then randomly allocated (ratio of 1:1) to the intervention or control arm. An opaque envelope was prepared from a computer-generated sequence of random numbers to facilitate the allocation. The study researchers were blinded to the preparation of these envelopes. The methods have been discussed in detail elsewhere [29].

2.2. *Sample size calculation*

The sample size was estimated based on a known effect size (effect size = 0.58) from the primary outcome of the diabetes self-management score (Mean difference = 8.35, SD = 14.28) [30]. The level of significance was set at = 0.05 (probability of type 1 error) and a power of 0.90 (1- probability of Type 2 error), resulting in 50 participants in each group. We anticipated that approximately 40% of the participants would be lost to follow-up thus resulting in a required sample of 70 individuals per group (i.e., 140 in total).

2.3. *Intervention program*

The family-oriented self-management intervention program was designed based on self-efficacy theory [16]. As outlined in the study methods reported elsewhere [29], four information sources—performance accomplishment, vicarious experience, verbal persuasion, and physiological information—were used based on social cognitive theory which enhanced self-efficacy. Goal setting was demonstrated and then participants established their own goals and designed their personal action plans. Participants learned and practiced specialized skills—meal planning, physical activities, problem solving diabetes-related complications—enhancing competence (*performance accomplishment*). Individuals who performed appropriate behaviors were promoted as 'models of successes' to other participants encouraging *vicarious experience*. Verbal persuasion was used to encourage participants to expand their skills and activities as they began making lifestyle changes.

The program consisted of three education sessions delivered at baseline, Week 5, and Week 9. The education sessions were provided in a group of approximately 8–12 dyads (individual and family member) per group and the facilitator of the education session (NW) was a Thai National and a registered nurse. At the beginning of each two-hour session, participants received a Diabetes Information Workbook which was developed for this study. During the first hour of the education session the facilitator actively engaged participants with the information topics and self-help worksheets provided in the Workbook. The second hour allowed participants to discuss the topics presented earlier.

The Diabetes Information Workbooks (1–3) included self-help worksheets and were developed in English and then translated into Thai. The content of the Workbooks was guided by The Clinical Practice Guidelines for Diabetes [23], clinical guidelines from the National Institute for Health and Care Excellence [31], National Evidence Based Guideline for Patient Education in Type 2 Diabetes from the National Health and Medical Research Council Australia [32] and self-efficacy theory [18]. The Workbooks were reviewed by a panel of 2 diabetes self-management experts in Australia and then verified for content and cultural validity by a panel of 3 experts in Thailand. The Workbooks have been tested for readability and comprehensibility by 3 patient and carer dyads, who reported that the resources were helpful in gaining knowledge as well as self-management ability.

The teaching program contained a range of relevant topics including blood sugar monitoring, diet, foot hygiene, physical activity, and coping with diabetes-related complications. The first education session (Workbook 1) focused on general diabetes knowledge such as the meaning, types, signs and symptoms, complications, coping with diabetes-related complications, and blood sugar monitoring. At Week 5, the second education session (Workbook 2) focused on the diabetic diet. The last education session (Workbook 3) provided at week 9 focused on physical activities and foot care.

Study participants were asked to record all their daily activities including their newly learned health care practices in a Daily Diary. It was recorded by participants or carers and discussed in the next session. Compliance with the program and review of any potential problems were evaluated during a home visit at Week 3 and a telephone follow-up call at Week 7 (Fig. 1).

The intervention group received routine care and participated in the study program. In contrast, the controls received standard routine care from clinical staff which included blood sugar testing, medical and nursing physical examinations, and medication follow-up.

2.4. *Instruments and data collection*

Demographics and study outcomes were similarly collected from all participants in intervention and control arms. Baseline demographic data reported by the participants included: marital status, occupation, monthly household income and education. Baseline demographic data extracted from patients' records included: age, sex, body mass index, duration of diabetes, comorbidities, diabetes-related complications, systolic and diastolic blood pressures, fasting blood sugar and glycosylated hemoglobin (HbA1c).

2.5. *Primary and secondary outcomes*

Diabetes self-management was the primary outcome and was measured by the Summary of Diabetes Self-Care Activities Scale (SDSCA) [33]. The secondary outcomes included: diabetes self-efficacy measured by the Diabetes Management Self-Efficacy Scale (DMSES) [34] and the Perceived Therapeutic Efficacy Scale (PTES) [35]. Quality of life was measured using the Thai version of 12-item Short-Form Health Survey (SF-12) including both physical and mental components [36] and diabetes knowledge was measured using the Diabetes Knowledge Questionnaire [37]. All scales were self-administered, while HbA1c was extracted from the patients' health records. The SDSCA, DMSES, and SF-12 were previously translated into Thai language versions with demonstrated reliability and validity in Thai samples [25,38,39]. The PTES and DKQ were translated into Thai language versions using the forward and backward translation technique and were validated by experts in Thailand.

The SDSCA (Thai) contained 20 items and measured self-care activities in the last 7 days [25]. Internal consistency for the SDSCA has been previously reported with reliability of 0.89 [25]. The DMSES (Thai), with 20 items, measured confidence in diabetes self-management ability [38], and responses ranged from 1 (definitely not) to 5 (yes definitely). The DMSES (Thai) has established internal consistency ($\alpha = 0.95$) [38]. The PTES contained 10 items and measured confidence in outcome expectation (1 = definitely not to 5 = yes definitely). The PTES has demonstrated internal consistency ($\alpha = 0.94$) [35]. The DKQ, with 24 items, measured diabetes knowledge with three possible responses: "yes", "no", or "I don't know" (scored as incorrect). A test key was used to score responses as either correct or incorrect. The DKQ has indicated internal consistency ($\alpha = 0.78$) [37]. The SF-12 (Thai), with 12 items, had scores from 0 to 100 points, with higher scores reflecting better quality of life. The internal consistency of the Thai version of SF-12 is good with $\alpha = 0.83$ [39]. All outcome measures were collected for both study groups over the 3 study time points (baseline, Week 5, and Week 13) except for the HbA1c which was collected from the patients' health records at baseline and Week 13. The time points selected reflect when the patient was expected to have increased knowledge or show change in behavior relative to the delivery of information within the sessions.

After the study was completed, participants in the control arm were provided with the study intervention Workbooks. Study participants and research assistants involved in data collection were blinded to trial arm allocation.

2.6. *Data analysis*

We used descriptive statistics (e.g., Pearson Chi square, Mann-Whitney test) to summarize patient characteristics at baseline. The Shapiro Wilk test was used to assess the normality of continuous variables. Continuous outcome measures were compared between the intervention and control arms using

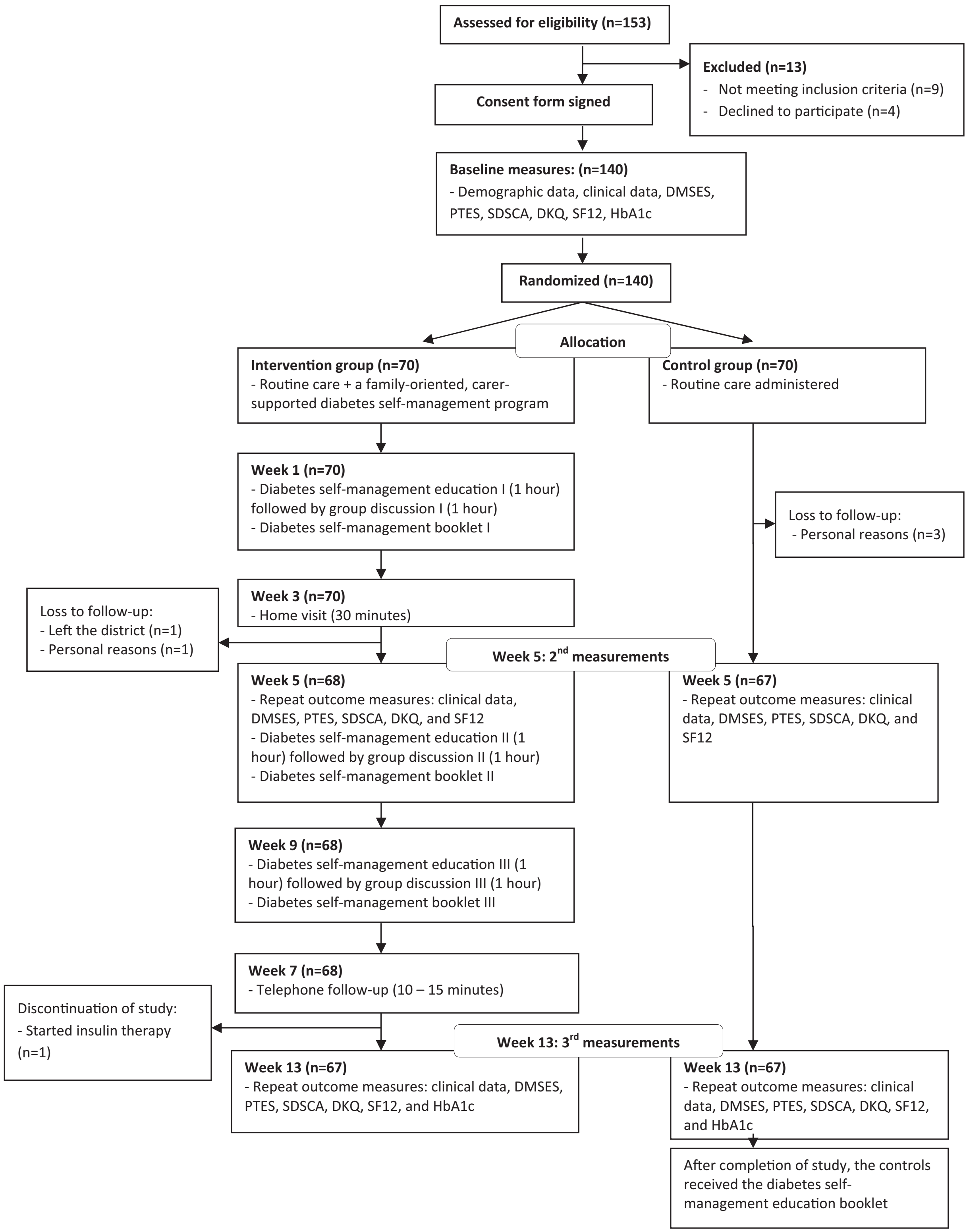

Fig. 1 – Flow diagram of individuals with T2DM participating in the study. Abbreviations: DMSES (Diabetes Management Self-Efficacy Scale), PTES (Perceived Therapeutic Efficacy Scale), SDSCA (Summary of Diabetes Self-Care Activities), SF12 (12-item Short Form Health Survey), DKQ (Diabetes Knowledge Questionnaire), HbA1c (Haemoglobin A1c).

the Mann-Whitney test, and the Friedman test was used to assess within-group differences in the repeated measures of the study outcomes.

Multivariable Generalized Estimating Equations (G.E.E.) regressions were used to model each of the study outcomes while accounting for correlated data within the repeated measures study design. The intervention and control arms were compared in adjusted models. The adjusted models compared both arms over time while accounting for age, sex, body mass index, education, occupation, income, duration of illness, diabetes-related complications, comorbidities, blood pressure, and baseline measures of self-management, self-efficacy, knowledge, hemoglobin A1C, and mental and physical quality of life. Both per-protocol and intention-to-treat (ITT) analyses were conducted. The ITT method included all study participants (those who withdrew or completed the study) based on the initial treatment assignment and not on the treatment eventually received. Statistical significance was set at a p value of $\leqslant$0.05 (two sided). All analyses were conducted using IBM SPSS software, version 22.

2.7. Quality assurance

Study measures were collected by three research assistants who were trained to collect data from patients and medical records. All data extracted from medical records were checked and validated by the study's lead author (NW).

3. Results

A total number of 153 individuals expressed willingness to take part in this study and were assessed for eligibility. Nine individuals did not meet the inclusion criteria and four refused to participate. After signing the informed consent, the remaining 140 participants were randomized to the intervention or control arms with 70 participants in each. Three individuals from each study arm discontinued the study (total 6 patients, 4.3%) with reasons described in supplemental Fig. S1. None of the participants reported any complications or any harms relating to the intervention during the study program.

At baseline, except for age, no significant differences in baseline characteristics were observed between the intervention and control arms. Patients allocated to the intervention group were significantly older (mean age in years 61.3 (SD 11.6)) than the controls (mean age 55.5 (SD 10.50)), $p = 0.003$ (Table 1).

Within-group comparisons showed diabetes self-efficacy, self-management, quality of life and diabetes knowledge improved over time in the intervention group (p value < 0.05, in each outcome) with no change observed in HbA1c levels (p value = 0.3). In contrast, no significant differences were found in diabetes self-efficacy, self-management, and quality of life over time in the control group. Moreover, a significant rise in HbA1c (indicating a deterioration) was detected in the controls (increase from mean score 6.3 (SD 1.5) to 7.3 (SD 1.4), $p = 0.01$). However, diabetes knowledge improved over time in the control group ($p < 0.001$) (Table 2).

At baseline, except for outcome expectations measured by PTES, no significant differences were observed between the intervention and control groups in all study outcomes. Between-group comparisons at Week 5 and Week 13 showed

Table 1 – Baseline characteristics of individuals randomized to either the intervention or control arm.

Patient characteristics	Intervention N = 70	Control N = 70	P*
Age (years), mean (SD)	61.3 (11.6)	55.5 (10.5)	0.003
Female (%)	75.7	70.0	0.4
Married (%)	80.0	80.0	1.0
Occupation (%)			
Not working	45.7	25.7	
Manual work	38.6	52.9	
Office work	15.7	21.4	0.051
Income per month (Thai Baht)† (%)			
10,000 or less	28.6	22.9	
10,001–20,000	41.4	31.4	
20,001 or more	30.0	45.7	0.2
Education (%)			
Primary or no education	80.0	65.7	
Secondary or higher	20.0	34.3	0.06
Comorbidity (%)	81.4	80.0	0.8
Taking one hypoglycaemic agent (%)	24.3	27.1	0.7
Taking two or more hypoglycaemic agents (%)	75.7	68.6	0.3
Diabetes-related complication	18.6	11.4	0.2
Haemoglobin A1C (HbA1C), mean (SD)	7.0 (2.0)	6.3 (1.5)	0.1
Less than 7% (%)	51.4	67.1	
7% and above (%)	48.6	32.9	0.06
Body mass index (Kg/m^2), mean (SD)	26.0 (4.4)	27.5 (5.2)	0.051
Duration of disease (years), mean (SD)	6.0 (4.7)	5.4 (4.3)	0.6
Fasting blood sugar (mg/dl), mean (SD)	179.0 (35.4)	171.6 (31.2)	0.2
Systolic blood pressure (mmHg), mean (SD)	133.69 (12.8)	136.1 (12.8)	0.2
Diastolic blood pressure (mmHg), mean (SD)	75.3 (10.0)	76.5 (11.8)	0.7

* Continuous variables were compared between the intervention and control arms using the non-parametric Mann-Whitney test, whereas proportions were compared using Chi-square tests. Statistical significance was determined if p value $\leqslant$0.05.
† Exchange rate: 1 USD = 32.78 THB at 31/01/2015.

Table 2 – Within group comparisons by study health outcomes over time: baseline, Week 5, and Week 13.

Patient health outcomes	Intervention				Control			
	Baseline	Week 5	Week 13	P*	Baseline	Week 5	Week 13	P*
Diabetes self-efficacy								
DMSES, mean (SD)	55.6 (12.0)	69.8 (11.9)	76.0 (9.4)	<0.001	58.7 (11.4)	58.2 (11.7)	60.7 (13.1)	0.7
PTES, mean (SD)	32.4 (6.1)	37.9 (4.7)	40.8 (4.0)	<0.001	34.8 (6.1)	33.7 (6.0)	35.3 (6.3)	0.4
Self-management								
SDSCA, mean (SD)	80.9 (15.9)	96.5 (12.7)	102.8 (12.1)	<0.001	80.5 (13.4)	80.2 (14.7)	80.4 (18.1)	0.7
Quality of life								
PCS, mean (SD)	46.7 (6.6)	50.0 (5.5)	49.9 (6.9)	0.04	48.2 (5.6)	49.2 (5.5)	49.4 (5.6)	0.7
MCS, mean (SD)	54.1 (8.6)	56.0 (7.7)	58.4 (7.2)	0.03	54.3 (7.8)	54.3 (7.3)	54.7 (6.5)	0.9
Diabetes knowledge								
DKQ, mean (SD)	10.7 (3.3)	17.1 (3.5)	16.5 (3.1)	<0.001	10.6 (3.1)	11.7 (3.3)	13.2 (3.0)	<0.001
Glycaemic control								
HbA1c, mean (SD)	7.0 (2.0)	–	7.0 (1.2)	0.3	6.3 (1.5)	–	7.3 (1.4)	0.01

Abbreviations: DMSES (Diabetes Management Self-Efficacy Scale), PTES (Perceived Therapeutic Efficacy Scale), SDSCA (Summary of Diabetes Self Care Activities), PCS (Physical Component Summary), MCS (Mental Component Summary), DKQ (Diabetes Knowledge Questionnaire), HbA1c (Haemoglobin A1c).

* Within group comparisons were analyzed using the non-parametric Friedman test. Statistical significance was determined at p value $\leqslant 0.05$.

that diabetes self-efficacy, self-management, and knowledge were better in the intervention arm compared to that in the controls ($p < 0.001$, in each outcome at each study point). However, no between-group differences were seen in HbA1c levels or physical component of quality of life, but at Week 13 the intervention arm scored higher than the controls in the mental component of quality of life (Table 3).

Using Generalized Estimating Equations, seven separate multivariable models were constructed for each of the study outcomes while adjusting for baseline variables as shown in Table 4. In the adjusted models, compared to the controls, the intervention arm had significantly better self-management, self-efficacy, outcome expectations, and diabetes knowledge ($p < 0.001$, in each of the outcomes). Participation in the study program increased the diabetes self-management score by 14.3 points ($\beta = 14.3$, Wald 95% CI 10.7–17.9, $p < 0.001$), the self-efficacy score by 10.8 points ($\beta = 10.8$, Wald 95% CI 8.3–13.2, $p < 0.001$), the outcome expectations score by 3.0 points ($\beta = 3.0$, Wald 95% CI 1.9–4.1, $p < 0.001$), and the diabetes knowledge score by 3.3 points ($\beta = 3.3$, Wald 95% CI 2.5–4.2, $p < 0.001$). Better self-management significantly increased self-efficacy ($p < 0.001$), both physical ($p = 0.03$) and mental ($p = 0.002$) components of quality of life, knowledge ($p = 0.02$), and significantly improved glycemic control by decreasing HbA1c levels ($p = 0.002$). The higher the baseline diabetes self-efficacy, the better was the self-management ($\beta = 0.4$, Wald 95% CI 0.2–0.6, $p < 0.001$), and the better the outcome expectations ($\beta = 0.2$, Wald 95% CI 0.2–0.3, $p < 0.001$) (Table 4).

Compared to males, females had higher self-management scores ($\beta = 5.3$, Wald 95% CI 1.4–9.1, $p = 0.007$). A one point increase in body mass index decreased diabetes self-management by 0.5 points ($\beta = -0.5$, Wald 95% CI -0.9 to -0.2, $p = 0.006$), outcome expectations by 0.1 points ($\beta = -0.1$, Wald 95% CI -0.3 to -0.0, $p = 0.02$), and also decreased physical health by 0.2 points ($\beta = -0.2$, Wald 95% CI -0.3 to -0.0, $p = 0.01$). There was no association between age and all study outcomes, except in physical health which significantly decreased as the patient aged ($\beta = -0.2$, Wald 95% CI -0.3 to -0.1, $p < 0.001$). Self-management decreased as HbA1c levels increased. One point increase in taking one hypoglycemic agent decreased outcome expectation by 4.7 points ($\beta = -4.7$, Wald 95% CI -8.5 to -0.9, $p = 0.02$), diabetes knowledge by 1.9 points ($\beta = -1.9$, Wald 95% CI -3.1 to -0.8, $p = 0.001$) and one point increase in taking two or more hypoglycemic agents decreased diabetes knowledge by 2.2 points ($\beta = -2.2$, Wald 95% CI -3.3 to -1.1, $p = 0.001$).

A significant improvement in the outcome measures was observed in all seven multivariable models as the program progressed from baseline to Week 5, and ended in Week 13 as shown in the 'visit' variable in Table 4.

Per-protocol analyses (on 134 individuals who have completed the three time points in data collection) produced similar results to those found in the intention to-treat analyses (on 140 study participants) (results not shown).

4. Discussion

We evaluated the effectiveness of a family-oriented self-management program in improving knowledge of diabetes, self-efficacy, self-management, quality of life and glycemic control in patients with T2DM. Using a randomized controlled

Table 3 – Between group comparisons by study health outcomes over time: baseline, Week 5, and Week 13.

Patient health outcomes	Baseline			Week 5			Week 13		
	Interv.	Control	P*	Interv.	Control	P*	Interv.	Control	P*
Diabetes self-efficacy									
DMSES, mean (SD)	55.6 (12.0)	58.7 (11.4)	0.2	69.8 (11.9)	58.2 (11.7)	<0.001	76.0 (9.4)	60.7 (13.1)	<0.001
PTES, mean (SD)	32.4 (6.1)	34.8 (6.1)	0.02	37.9 (4.7)	33.7 (6.0)	<0.001	40.8 (3.9)	35.3 (6.3)	<0.001
Self-management									
SDSCA, mean (SD)	80.9 (15.9)	80.5 (13.4)	0.9	96.5 (12.7)	80.2 (14.7)	<0.001	102.8 (12.1)	80.4 (18.1)	<0.001
Quality of life									
PCS, mean (SD)	46.7 (6.6)	48.2 (5.6)	0.1	50.0 (5.5)	49.2 (5.5)	0.2	49.9 (6.9)	49.4 (5.6)	0.2
MCS, mean (SD)	54.1 (8.6)	54.3 (7.8)	0.8	56.0 (7.7)	54.3 (7.3)	0.2	58.4 (7.2)	54.7 (6.5)	<0.001
Diabetes knowledge									
DKQ, mean (SD)	10.7 (3.3)	10.6 (3.1)	0.9	17.1 (3.5)	11.7 (3.3)	<0.001	16.5 (3.1)	13.2 (3.0)	<0.001
Glycaemic control									
HbA1c, mean (SD)	7.0 (2.0)	6.3 (1.5)	0.1	–	–	–	7.0 (1.2)	7.3 (1.4)	0.2

Abbreviations: DKQ (Diabetes Knowledge Questionnaire), DMSES (Diabetes Management Self-Efficacy Scale), HbA1c (Haemoglobin A1c), Interv (Intervention), PCS (Physical Component Summary), PTES (Perceived Therapeutic Efficacy Scale), SDSCA (Summary of Diabetes Self Care Activities), MCS (Mental Component Summary).

* Between-group comparisons were analyzed using the non-parametric Mann-Whitney test. Statistical significance was determined at p value $\leqslant 0.05$.

clinical trial we have found that a theoretically-derived, family-oriented educational program can significantly improve patients' self-efficacy, self-management, and diabetes knowledge.

4.1. *Family involvement*

This family-oriented approach was undertaken within a culture that has strong family and kinship ties as expressed in daily life and in interactions with family. Our findings are similar to Choi et al.'s work which demonstrated that family support was associated with improved self-care behaviors. However, unlike Choi et al.'s study we did not find any improvements in blood glucose control [40]. Another study has also found that family interventions improved self-efficacy, knowledge of diabetes, and diabetes self-management [10]. Family support is another resource assisting individuals with T2DM to improve their self-care activities [14,15] and these findings support the additional benefit achieved by including the family in the education program.

Family support is essential in the Thai society 'where the family has an important role in the provision of physical, mental and socio-economic support to people living with diabetes' (p.556) [28]. Despite religious differences, Asian countries are culturally similar in terms of the primary responsibility for the ill-health of members traditionally remaining with other family members living in the home [41]. The specific role that the family member provides to support an individual with diabetes has been reported as primarily food preparation and diet management (China [42], Japan [43], Korea [40], Taiwan [44], Thailand [45]), encouraging and monitoring exercise (China [42] Japan [43], Thailand [45]) and blood glucose monitoring and other self-care behaviors (China [42], Japan [43], Thailand [45]). This study contributes to existing knowledge on the role of the family members in diabetes care within Asian communities with clear similarities in the roles of family members presented in this study.

4.2. *Self-efficacy theory supporting self-management*

A theoretically derived diabetes education program based on self-efficacy theory, with the additional benefit of family support, has shown a direct improvement in self-efficacy for Thai patients and an increase in required behaviors for the long-term management of T2DM. The finding contributes to existing research showing that diabetes self-management interventions promote self-efficacy [46]. Other researchers have found that T2DM education programs based on self-efficacy theory were effective in improving self-management [17,20,47]. Our findings are similar to other studies using self-efficacy theory to structure diabetes education programs in Taiwan [17]. Yoo et al. also found that a self-efficacy-enhancing intervention can be beneficial for patients who set out to improve their self-management behavior and health status [47]. We propose that these studies all suggest that there are patient benefits in using self-efficacy theory to shape diabetes education programs for T2DM.

4.3. *Quality of life and glycemic control*

We found no associations between the family-oriented self-management intervention and better quality of life or

Table 4 – Prediction of individual patient outcomes over time by baseline variables: repeated measures generalized estimating equations in seven multivariable analyses* – intension to treat analyses (*n* = 140).

Variables	Model 1 SDSCA β (Wald 95% CI), *p*	Model 2 DMSES β (Wald 95% CI), *p*	Model 3 PTES β (Wald 95% CI), *p*	Model 4 PCS β (Wald 95% CI), *p*	Model 5 MCS β (Wald 95% CI), *p*	Model 6 DKQ β (Wald 95% CI), *p*	Model 7 HbA1c β (Wald 95% CI), *p*
Intervention *vs* control	**14.3 (10.7, 17.9), <0.001**	**10.8 (8.3, 13.2), <0.001**	**3.0 (1.9, 4.1), <0.001**	0.8 (−0.6,2.2), 0.3	1.3 (−0.6, 3.2), 0.2	**3.3 (2.5, 4.2), <0.001**	0.3 (−0.2, 0.7), 0.3
Age	−0.1 (−0.2, 0.1), 0.6	−0.1 (−0.3, 0.0), 0.1	0.0 (−0.0, 0.1), 0.5	**−0.2 (−0.3, −0.1), <0.001**	0.0 (−0.1, 0.1), 0.9	−0.0 (−0.1, 0.0), 0.6	−0.0 (−0.0, 0.0), 0.1
Female sex	**5.3 (1.4, 9.1), 0.007**	−0.8 (−4.0, 2.4), 0.6	1.1 (−0.2, 2.4), 0.1	−0.5 (−2.0,1.0), 0.5	0.3 (−2.0, 2.6), 0.8	0.3 (−0.6, 1.2), 0.5	0.2 (−0.2, 0.7), 0.3
BMI	**−0.5 (−0.9, −0.2), 0.006**	−0.0 (−0.3, 0.3), 0.9	**−0.1 (−0.3, −0.0), 0.02**	**−0.2 (−0.3, −0.0), 0.01**	0.1 (−0.1, 0.3), 0.2	0.0 (−0.0, 0.1), 0.2	−0.0 (−0.1, 0.0), 0.4
Occupation†							
Manual	2.7 (−1.5,6.8), 0.2	2.8 (−0.3,5.9), 0.1	**1.5 (0.3, 2.8), 0.02**	−0.0 (−1.7, 1.7), 1.0	1.0 (−1.6, 3.5), 0.5	**1.0 (0.1, 1.8), 0.02**	0.1 (−0.5,0.7), 0.7
Office work	1.7 (−2.8,6.3), 0.4	0.3 (−3.0,3.6), 0.9	1.4 (−0.3,3.1), 0.1	−0.4 (−2.3, 1.5), 0.7	−1.5 (−5.0,1.6),0.3	0.8 (−0.3, 1.9), 0.1	−0.1 (−0.7,0.5), 0.8
SDSCA	–	**0.2 (0.1, 0.3), <0.001**	−0.0 (−0.0, 0.0), 0.6	**0.1 (0.0, 0.1), 0.03**	**0.1 (0.0, 0.2), 0.002**	**0.0 (0.0, 0.1), 0.02**	**−0.0 (−0.0, −0.0), 0.002**
DMSES	**0.4 (0.2, 0.6), <0.001**	–	**0.2 (0.2, 0.3), <0.001**	−0.0 (−0.1, 0.0), 0.3	**−0.2 (−0.3, −0.0), 0.02**	0.0 (−0.0, 0.1), 0.5	−0.0 (−0.0, 0.0), 0.9
PTES	**−0.4 (−0.7, −0.0), 0.04**	**0.6 (0.4, 0.8), <0.001**	–	−0.0 (−0.2, 0.1), 0.6	−0.0 (−0.3, 0.2), 0.8	−0.1 (−0.2, 0.0), 0.2	0.0 (−0.0, 0.1), 0.5
PCS	0.2 (−0.1, 0.5), 0.2	**−0.3 (−0.5, −0.1), 0.0**	0.0 (−0.1, 0.1), 0.9	–	−0.1 (−0.3, 0.1), 0.2	**−0.1 (−0.2, −0.0), 0.001**	0.0 (−0.0, 0.1), 0.3
MCS	0.2 (−0.1, 0.4), 0.1	−0.1 (−0.3, 0.0), 0.1	−0.0 (−0.1, 0.1), 0.7	−0.1 (−0.1, 0.0), 0.2	–	0.0 (−0.0, 0.1), 0.5	−0.0 (−0.1, 0.0), 0.2
DKQ	−0.1 (−0.7, 0.5), 0.7	−0.3 (−0.7, 0.2), 0.3	−0.0 (−0.2, 0.2), 0.7	−0.2 (−0.4, 0.1), 0.2	−0.0 (−0.4, 0.3), 0.8	–	−0.0 (−0.1, 0.0), 0.6
HbA1c	**−7.8 (−11.1, −4.6), <0.001**	−2.3 (−5.1, 0.5), 0.1	0.0 (−1.3, 1.3), 1.0	−0.7 (−2.2, 0.9), 0.4	0.2 (−1.9, 2.3), 0.9	−0.6 (−1.5, 0.3), 0.2	–
Visit‡	**0.8 (0.6, 1.1), <0.001**	**0.8 (0.6, 1.1), <0.001**	**0.3 (0.2, 0.4), <0.001**	**0.2 (0.1, 0.3), 0.002**	**0.2 (0.0, 0.3), 0.007**	**0.3 (0.3, 0.4), <0.001**	**0.0 (0.0, 0.1), 0.001**
Agents††							
Agent 1	−7.8 (−19.1, 3.5), 0.2	−7.8 (−20.6, 5.1), 0.2	**−4.7 (−8.5, −0.9), 0.02**	0.6 (−4.4, 5.7), 0.8	0.9 (−3.7, 5.6), 0.7	**−1.9 (−3.1, −0.8), 0.001**	0.6 (−0.7, 1.9),0.4
Agent 2	−8.9 (−20.1, 2.4), 0.1	−8.2 (−21.2, 4.8), 0.2	−3.2 (−7.0, 0.5), 0.09	−2.2 (−7.2, 2.8), 0.4	−0.4 (−5.2, 4.3), 0.9	**−2.2 (−3.3, −1.1), 0.001**	0.3 (−1.0, 1.6), 0.7

Abbreviations: Agent 1 (taking one hypoglycaemic agent), Agent 2 (taking two or more hypoglycaemic agents), BMI (Body Mass Index), DKQ (Diabetes Knowledge Questionnaire), DMSES (Diabetes Management Self-Efficacy Scale), HbA1c (Haemoglobin A1c), MCS (Mental Component Summary), PCS (Physical Component Summary), PTES (Perceived Therapeutic Efficacy Scale), SBP (systolic blood pressure), SDSCA (Summary of Diabetes Self Care Activities).

* Besides listed variables in table, each of the multivariable models was also adjusted for income, education, comorbidity, duration of illness, diabetes-related complications, blood pressure, none of which was statistically significant in any of the models.

† Occupation reference group was “Not working”.

†† Agents reference group was “not treated with hypoglycaemic agents”.

‡ Visit constituted of the three trial points in time: Baseline, Week 5, and Week 13.

improved glycemic control. No differences between the intervention and control arms were seen in both of these outcomes; however, in the risk-adjusted models, higher diabetes self-management scores significantly improved both physical and mental components of quality of life and also decreased HbA1c levels. Other studies have identified a poor relationship between reductions in HbA1C and improvements in self-efficacy and quality of life [48,49].

Further, a systematic review of diabetes self-management education, including 21 studies, found that the average baseline HbA1C before the intervention was 8.23% compared to our study baseline means of HbA1C of 6.3% (control) and 7% (intervention) [50], suggesting that, in this study, the sample was a group (intervention and control) with improved glycaemic control at baseline. In addition, the authors of this systematic review found a significant reduction in HbA1C of 0.44% points at 6 months, and 0.46% points at 12 months based on the pooled data [50]. In our study, the mean difference between the intervention and control arms found at 13 weeks was 0.30% in the HbA1C, (although not significant), suggesting that if the duration of this study had been extended to 6 or 12 months, (and sufficient sample was included) then similar differences may have been demonstrated. In addition, in our study the mean HbA1c in the intervention group remained stable after receiving the intervention, whereas, the mean HbA1c in the control group increased.

The Thai Clinical Practice Guidelines for diabetes promote a goal of an HbA1c of less than 7.0% (53 mmol/mol) [23] to minimize the risk of developing complications. Study participants were encouraged to achieve and maintain the goal of a HbA1c level of 7.0% (53 mmol/mol). In this sample, 65% (control) and 51% (intervention) of the sample had an HbA1C <7% at baseline. At Week 13, the mean HbA1C was 7.3% (control) and 7.0% (intervention) respectively. These samples on recruitment and at the end of the trial were mostly achieving this desired goal.

We also note that daily monitoring of blood glucose was not undertaken by participants in either the intervention or control groups due to the high cost of the equipment and consumables. Participants could however, access the nearest health center, if they felt unwell. Similarly, aspects of diet, physical exercise, and medication intake, which may affect HbA1C levels, were not monitored during the study.

4.4. *Other factors*

Similar to another report [51], we found obesity was an independent predictor of declining quality of life. In our study, higher BMI scores were also associated with lower self-efficacy scores and poorer self-management. The benefits of weight loss in improving glycemic control in individuals with T2DM are well documented [52]. Our study shows diabetes self-management is significantly better among females compared to their male counterparts. Females may have higher expectations to benefit from such health interventions [53], and, more than men may use social interactive resources such as support groups. Females may also better adhere to a healthy recommended diet which is less observed among men [54]. Further research into what factors encourage men to engage in self-management behavior and weight reduction is recommended.

No other sex differences were found in all other study outcomes. We found no associations between age and self-management, self-efficacy, mental health quality of life or glycemic control. Since older age was not associated with worse outcomes, our study reinforces the notion that self-management programs should not be restricted to any age group.

4.5. *Limitations*

As this study focused on self-efficacy and self-management abilities, standardization of the hypoglycemic agent dose was not undertaken. Nonetheless there was no significant difference in the numbers of hypoglycemic agents taken by participants in the control or intervention groups. No measures of the patients' diet or exercise units were taken and variation in these activities may have influenced the HbA1c. The study sample was sufficient to test the primary outcomes but was less able to test the small changes in HbA1c and possibly quality of life. This study was conducted in a community-based hospital within a rural setting and therefore may not be generalizable to urban settings. The sample necessarily excluded the most severe cases representing recruitment bias. Although the HbA1c data were collected at baseline and at week 13 (3 months and 1 week after initial baseline measurement), additional education was provided at week 9. Additional data were not collected 3 months (optimal period for HbA1c measurement) after this week 9 component of the intervention was delivered.

5. Conclusions

This family-oriented, diabetes education program, delivered by nurses, developed from self-efficacy theory and engaging family members in supportive care, has improved self-efficacy and self-care behaviors critical to reducing the complications associated with diabetes. Thai patients and their families may represent a unique population that has responded positively to this approach although studies in other samples are also supportive of these findings. This family-oriented diabetes education program can be easily administered by registered nurses, and may contribute to reduced burden on primary care services over the longer term. This approach conducted in a rural community hospital in Thailand, provides a model that could be translated into other rural communities. Engaging family support for individuals with T2DM has the potential to reduce the demands on diabetes educators and health services by providing additional support and potentially reducing complications.

Authors' contributions

NW, MC and PS led the initial conceptual development of the study. Subsequent study conception and design: NW, GM, MJ; Data collection: NW; Analysis of data: NW and GM; Interpretation of findings: NW, GM and MJ. All authors were involved in drafting the article and revising it critically for important intellectual content, and all authors approved the final version to be published.

Conflicts of interest

None.

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Appendix A. Supplementary material

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.diabres.2016.11.013.

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